Good practice guidelines for psychological assessment and intervention for pain neuromodulation services

Psychologists in Pain Neuromodulation (PiPiN)

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Executive Summary

Neuromodulation for chronic neuropathic pain is an established and evidenced based treatment. A multidisciplinary assessment, including a psychological assessment, is recommended for all patients under consideration for surgery yet there are no existing guidelines to inform these assessments. Furthermore, access to psychological intervention prior to or after surgery can be variable.

This paper uses a core competency structure to provide a framework for psychologists working in pain neuromodulation services. It makes recommendations for good practice when conducting pre-operative assessments, planning pre- or post-surgical psychological intervention and considers some of the professional challenges for psychologists working in neuromodulation services.

Psychologists in Pain Neuromodulation (PiPiN) is a network of clinical psychologists working in UK neuromodulation services. The group meets regularly to discuss developments in the field of neuromodulation, psychological aspects of neuromodulation care and to share good practice.

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Section A: Evidence and Need for Recommendations

Introduction: Chronic Pain and Neuromodulation

Chronic pain is one of the leading causes of disability worldwide (GBD Disease and Injury Incidence and Prevalence Collaborators, 2017). In the UK, chronic pain is thought to affect 8 million adults and chronic back pain alone has been estimated to cost the UK economy in excess of £10 billion in a single year (British Pain Society, 2018). Although a variety of analgesic medications are available to help manage chronic pain, there are a number of patients for whom medication has little to no effect.

Neuromodulation through Spinal Cord Stimulation (SCS) was developed in the 1960's (Shealy et al 1967) as an alternative intervention for neuropathic pain. SCS is achieved by surgically implanting a small pacemaker-like device under the skin. Electrodes from this device are implanted into the epidural space (the space in the vertebral canal close to the spinal cord), and produce mild electrical currents intended to interrupt signals being sent to the brain which may contribute to a person's pain experience. SCS has since become an established and evidence based treatment, and has led to the development of a range of similar procedures including stimulation of the dorsal root (DRG stimulation), peripheral nerves (PNS) and occipital nerve (ONS).

Introduction: Psychological Factors in Neuromodulation

Since the early 1990s, a number of psychological and social factors have been suggested to have a possible impact on outcomes from neuromodulation. Early papers based on clinical opinion (e.g. Kid & North, 1993; Nelson, 1996) suggested that implantation should be avoided for patients who report unusual pain ratings, personality disorders, a history of abuse, alcohol/drug abuse, suicidal thinking, dysfunctional personality traits, faulty conception of pain or pain treatment, inadequate social support, unrealistic expectations and the inability to understand or manage the implantable device.

Some of these broad and wide ranging criteria have been subjected to further investigation, with a shift towards identifying factors that may be amenable to treatment or support needs, rather than identifying factors to be used as the basis for exclusion from treatment. In a similar vein, Doleys (2003) proposed a number of factors that could be positive indicators for SCS. Amongst other characteristics they suggested 'general psychological stability', 'moderate levels' of self-confidence and self-efficacy, realistic concerns regarding illness and proposed therapy, mild depression appropriate to the level of impairment and general optimism regarding outcome could be associated with better outcomes from surgery.

Yet the evidence base for the role of psychological factors in determining outcome from surgery remains relatively limited. Few well controlled studies have been conducted to investigate these issues, and there is significant variability in the measures used to capture factors such as mood. A systematic review of the impact of psychosocial variables on surgical outcomes, which included 21 studies of lumbar spine surgery and 4 studies of SCS surgery, concluded broadly that psychological variables were important predictors of SCS

outcomes, but the review was limited by the small number of SCS studies included (Celestin et al., 2009). Factors such as social support or substance misuse have not been investigated in detail in regard to SCS, thus clinicians are reliant on extrapolating from the broader chronic pain literature or the evidence base relating to other long term conditions.

In a more recent review (Fama et al., 2016) of nine studies, the presence of a 'psychological condition' on standardised mood screening scales made no difference to pain relief from neuromodulation.

North et al (1996) indicated patients with low anxiety but more frequent 'organic' symptoms were more likely to proceed to implant but overall the authors argued there was little evidence for selection on the basis of psychological testing. The small sample in this study, however, excluded anyone with significant co-morbidities (such as anxiety and depression) which may undermine the argument against psychological assessment as the patients most likely to have benefitted from this had been excluded.

Depression, poor sleep and low self-efficacy were shown to be associated with greater risk of SCS failure in a prospective study of 178 patients (Bendinger et al., 2015). Furthermore, in a smaller study of 40 patients with mixed back and leg pain there was evidence of better reported pain relief in patients with lower depression scale scores at preoperative assessment (Burchiel et al., 1995). In a sample of 137 consecutive patients, Paroli et al (2018) found psychological factors associated with a poor outcome following SCS included somatization, depression, anxiety and poor coping, drug addiction, and lack of social support. All three studies indicate an association between psychological factors and neuromodulation outcomes.

Whether depression may be associated with worse outcomes or may in fact improve following surgery remains unclear as highlighted by the review of Sparkes et al (2015). Several studies included in their review suggested depression was a contraindication, however, two of the papers found a significant improvement in depression following SCS surgery. A follow-up study conducted by the same group included 56 patients undergoing SCS implantation with follow up at 6 and 12 months post implantation. They found that depression and autonomous coping may impact the efficacy of SCS based on pain intensity and disability scores but also other factors such as age and duration of pain prior to implant could influence outcome.

Other studies have lent weight to the argument that mood may improve following surgery. For example, Falowski et al (2021) in a sample of 269 patients across 22 implant centres demonstrated significant improvements in low mood and anxiety with a reduction in pain catastrophisation and sensitisation following successful surgery. A similar finding was demonstrated in the systematic review of Fama et al (2016) that demonstrated improvements in depression scores at 12 months following surgery. This paper considers variations in treatment delivery including single disciplinary and multidisciplinary support alongside SCS.

Block et al (2017) considered the role of personality characteristics in predicting success from SCS in a sample of 414 patients recruited from a surgical clinic. Using the Minnesota

Multiphasic Personality Inventory-2-Restructured Form (MMPI-2-RF) they found the Demoralisation scales were associated with greater risk of relative worse outcome in terms of pain relief, post implant dissatisfaction and quality of life. Furthermore, the Emotional Dysfunction scale was associated with poorer functional ability, negative affect and greater dis-satisfaction following surgery. Using the MMPI-2-RF substance abuse scores, Block et al (2017) demonstrated more negative evaluation of the outcome of surgery in patients with higher substance misuse scale scores. Meanwhile, Olson et al.'s (1998) study of 40 patients suggested successful SCS was correlated with lower scores on the depression and mania scales of the MMPI.

Whilst negative thoughts associated with pain i.e. pain catastrophisation has been proposed to be relevant in predicting outcome, evidence in support of this remains limited. In a sample of 32 patients Lame et al. (2009) found that pain catastrophisation scores added little predictive power in their regression analysis.

Whether a patient is involved in litigation related to the injury associated with their chronic pain has been suggested to have a significant impact on outcome. In a meta-analysis of 129 studies including 20,498 patients, Harris et al (2005) identified that litigation was associated with poorer outcomes following surgery, a finding they held was "significant, clinically important and consistent" (p1644).

A limitation in the literature is that studies appear not to record outcome data further than 12 months post implantation. It would be of interest to follow patients over a longer period of time, both to fully determine the efficacy of SCS and its impact on quality of life in the longer term and also predictions of outcomes.

Overall, from the available literature, there appears to be an association between a number of psychological factors and outcome from neuromodulation. However, a clear understanding of how these associations should impact clinical decision making is lacking.

There is therefore a need to provide recommendations to guide clinicians considering referral for neuromodulation and also to promote best clinical practice for teams working within neuromodulation.

Traffic Light System to Guide Multidisciplinary Team (MDT) Decision Making

With limitations in the literature, it's important to hold on to the value of 'practice-based evidence' which integrates the best available evidence with the delivery of routine clinical practice (Holmqvist, Philips & Barkham, 2015). Therefore, PiPiN has proposed the following classifications for factors that may be identified during preoperative assessment. Several factors included below may not fall within the remit of the psychological assessment but instead would be captured by the broader MDT assessment. Those typically falling within the remit of the psychological assessment are indicated by asterisk although there is recognition that other members of the team may also have views on these factors. The focus of this guidance is of the role of practitioner psychologists working in pain neuromodulation. The guidance does not take a position on medical suitability for neuromodulation as this would fall outside of the scope of the practitioner psychologist.

Medical suitability assessments will fall under the responsibility of medical colleagues, such as anaesthetists, neurosurgeons and spinal surgeons.

	Factor
Red – contraindications (not currently suitable)	Unstable medical condition - An active condition currently undergoing investigation e.g. cancer
	Pain that is not neuropathic in nature
	High infection risk - Previous spinal infections or underlying active infections
	Waiting for other elective surgery
	High BMI - with no plan to bring BMI within target range
	Chronically high opioid use – >120mg morphine within 24 hours - unwilling or unable to engage with opioid reduction plan
	Use of illegal drugs - e.g. cannabis, cocaine, crack, heroin – unwilling or unable to engage with intervention to reduce or abstain
Amber – Cautions (considerations that may affect suitability and possible outcome of neuromodulation)	High BMI - Patient has engaged with plan to bring BMI within target range
	Chronically high opioid use – Patient is engaging with opiate reduction plan
	Use of illegal drugs – Patient engaged in treatment to reduce or abstain
	Untreated psychological distress (including PTSD, psychosis)* - Patient presents with significant psychological distress and has not accessed treatment / support - Significant emotional dysregulation, impulsivity/increased risk taking behaviours
	Suicidal ideation* - Patient presents with suicidal ideation + / - intent & plan - Absence of protective factors or engaging with treatment
	Health anxiety* - Patient presents with preoccupation with health *disproportionate* to the extent of their underlying condition or previous experiences of treatment for the underlying condition - Patient is not open to psychological formulation of their distress
	High physiological arousal* - May be trauma related
	Pain catastrophisation* - Patient has high score (i.e. clinical significance >30 on Pain Catastrophising Scale) on measure of pain catastrophising and not engaged in / willing to accept interventions
	Deteriorating neuro-behavioural / cognitive condition* - Progressive cognitive decline that may affect capacity to make the decision to consent or manage the system
	Compensation or litigation - Active litigation relating to the index event (Note this may affect progress in some patients, but there must be no assumption that this applies to all)
	Poor self-care / self-neglect*
	Multiple socio-economic stressors / Family crisis*
	Lack of social support/ social isolation* - impacting functional activities
	Unrealistic and/or passive expectations of outcome of neuromodulation
	Limited understanding of procedure
	Failure to engage with pain management / passive attendance / unable or unwilling to set realistic and meaningful goals
	Low activity/ Physical deconditioning
	Lack of consistency in reported pain and reported everyday functioning/Unusual pain rating
	Secondary gain from patient/others
Green – suitable for trial of neuromodulation	Active engagement in reduction of opioids or illegal drugs if required
	Appropriate management of psychological distress if required/stable mental health*
	Able to manage the technical demands of the equipment
	Realistic expectations of outcome of neuromodulation
	Clear understanding of procedure
	Clear understanding of pain neurophysiology
	Active self-management for pain

* Assessment would usually be the responsibility of the psychologist and can involve the views of other MDT professionals.

Current Clinical Guidance on Psychological Provision for Neuromodulation Services

Current guidance on the role of psychology within Neuromodulation services is limited. Whilst the NICE guidelines on spinal cord stimulation for chronic pain of neuropathic or ischaemic origin (2008) state that SCS should only be provided following assessment by a multidisciplinary team, it does not provide clarity regarding the professionals required to be involved in this process or what the assessment should cover.

More detail was provided by the British Pain Society (BPS) in 2009 in their recommendations for best clinical practice for SCS, in terms of the professionals who should be involved in a SCS MDT, as well as the content of the assessment. This document states that, "assessment by a psychologist is desirable to assess the patient's beliefs, expectations, and understanding of the treatment in relation to the condition." It emphasises the importance of discussing "pain management strategies, including activity pacing, both before and after the procedure."

The BPS (2009) recommend that patients with comorbid physical or mental illness be assessed in collaboration with relevant clinical teams and not be excluded from receiving neuromodulation on the basis of their complexity. In addition, they note that "cognitive impairment, communication problems, or learning difficulty resulting in failure to understand the therapy" are not contraindications for SCS, in the presence of support from an appropriate caregiver. Finally, this guidance recommends continuing postoperative input from the implant team inclusive of psychological support.

Current Practice within UK Neuromodulation Services

In light of the lack of standardised criteria for psychologists working in neuromodulation, one of PiPiN's aims was to map the current psychological provision within UK neuromodulation services. The mapping exercise was conducted using a short survey circulated to the PiPiN email distribution list in March 2020. By November 2020, twenty-five out of thirty centres responded to the survey. Nineteen confirmed that psychologists were routinely directly involved in clinical preoperative assessment, whilst six had ad-hoc or variable provision. Thirteen of the centres reported routinely including psychological input within their prehabilitation programmes for example via a SCS Pain Management Programme or one-to-one work-up.

With regard to postoperative psychological input the results were sparser. Nine centres reported routinely providing psychological follow up of patients after surgery, whilst others offered no routine follow up or had ad-hoc or variable provision. This data shows the significant variability across the UK, in terms of psychological input and wider aspects of the neuromodulation pathway. This means there is huge variability in patient experience and this is an area that warrants further attention.

Section B: Role of Psychologists in Neuromodulation Services

Assessment

As stated above, comprehensive pre-operative psychological assessment has been recommended as part of the multidisciplinary assessment required for patients under consideration for neuromodulation surgery (NICE, 2008; BPS, 2009). Crucially, the assessment must be part of the standard pathway for all patients.

In broad terms a psychological assessment should include a biopsychosocial clinical interview and be complemented by standardised assessment tools but as yet no framework has been developed to guide the approach to preoperative assessment for neuromodulation surgery. Below is an attempt to provide some guidance on a framework based on current clinic practice amongst PiPiN members.

Timing: The assessment should take place prior to any clinical intervention (e.g. trial implantation of the system). Where patients are being assessed sequentially rather than jointly by a multidisciplinary team, consideration should be given to the ordering of the assessments. For example, scheduling the psychological assessment after a specialist nurse or consultant assessment offers the opportunity to assess how much relevant procedural information the patient has retained. It should also allow enough time for the patient to access any additional intervention or support required prior to their procedure. Furthermore, services should be mindful of the fact that psychologists (or other professionals involved in the multi-disciplinary assessment) can be inadvertently perceived as gate-keepers of medical treatment. Services should be designed in such a way that enables patients to be assessed in a timely fashion by all the relevant members of the MDT without causing delay to trial or full implant.

Consent: There must be a clear explanation of the context of psychological assessment and how it will be used in the neuromodulation pathway. Clarification that the assessment is not something the patient must 'pass' but rather an opportunity to develop a holistic formulation that can be used to plan their treatment and hopefully increase the chance of them having a good outcome from surgery. Where a patient declines to undergo a psychological assessment there needs to be a clear process in place agreed within the clinical team as to how these situations are dealt with.

Content: a preoperative assessment is likely to cover a wide range of topics such as those set on the agenda below:

- Understanding of pain- beliefs and behaviours
- Impact if pain on function/quality of life/wellbeing
- Self-management/ coping strategies / social support
- Hopes and expectations
- Past pain related input
- Mental health- current and past
- Risk assessment

- Capacity to consent (assessment of cognitive function if required)

Format: The assessment should be undertaken directly with the individual, whether this is done in person or via a video link.

Use of Interpreters: In line with standard practice, it is recommended that professional interpreters are used to support communication when needed rather than family members or others who may accompany the patient. Additional time to prepare and conduct the assessment should be factored accordingly.

Standardised Questionnaires: In deciding which outcome measures to use, consideration should be given to the domains listed in the British Pain Society PMP Guidance (2021) and must be of appropriate validity and specificity. These domains include:

- Pain intensity and pain frequency
- Physical activity (including activities such as household chores)
- Emotional wellbeing
- Health related quality of life
- Satisfaction with social roles and activities
- Productivity (including work related activities both paid and unpaid)
- Participant's perception of treatment goal achievement
- Health-care utilisation
- Patient experience of the programme (both quantitative and qualitative)
- Process outcomes (monitoring concordance of the programme with best practice)

Additional measures selected on an individual basis may be required. Outcome evaluation should consider benchmarking changes against published minimally clinically important change values where possible.

To evaluate outcome of any intervention, repeat measures of those used at assessment (where this is applicable) should be administered at the commencement and completion of psychologically informed prehabilitation (e.g. an Spinal Cord Stimulator Pain Management Programme SCS PMP); at the completion of any trial of neuromodulation and at regular intervals during patient follow up.

Risk and Safeguarding: As part of all psychological assessment, it continues to be important to assess for levels of risk (i.e. risk to self from self-harm or suicide, risk to others, risk from others). Research has indicated an increased risk of suicide in both headache and musculoskeletal pain conditions (Hassett, Aquino & Ilgen, 2014; Trejo-Gabriel-Galan, Aicua-Rapún, Cubo-Delgado & Velasco-Bernal, 2017). This is considered important due to the levels of psychiatric comorbidity in chronic pain patients, particularly depression. Practitioners offering neuromodulation assessments in chronic pain should be aware that some conditions are associated with higher rates of suicide, such as cluster headaches which are commonly referred to as "suicide headaches" (Ji Lee et al., 2019).

These issues should be raised during assessment given that they can be an indicator of a depressive episode, which from previous research shows can reduce the predicted benefits felt from neuromodulation (see Psychological Factors in Neuromodulation section). Risk

should be managed in order to mitigate these effects, in addition to considering the priority of needs ahead of any surgery.

In assessing the level of current risk, practitioners should consider whether there are any previous or current incidents of self-harm or suicidality. For patients with cluster headaches, this can occur either during the pain attacks themselves (i.e. as a way to change the source of pain or to escape the pain all together) or between the attacks. Research indicates that suicide rates are higher within the attack itself (Lee et al., 2019) rather than between attacks. Patients may be able to express whether the suicidal ideation is a more active consideration in daily life, or a response in expression of the amount of pain they are faced with during the attack itself.

In assessing the level of future risk, practitioners should be aware of detecting suicidality when the patient considers their recovery period and any contingency plans if the neuromodulation device does not work. For example, whether they express any sense of despair if the device does not work, or a wish to end their life if there are no other medical options available.

Intervention

Psychological therapy or intervention may be required pre- or post- neuromodulation. Prehabilitation is at the frontier of interventions to optimise outcomes of surgical interventions. Prehabilitation has potential for improving pain related outcomes post-surgery and preventing pain related deterioration post-surgery. Systematic reviews of prehabilitation find interventions describing exercise and improving physical function, with measures focusing on pain, functional status, quality of life and satisfaction (e.g. Caliban et al 2016). There are examples of feasibility studies, protocols and interventions of prehabilitation which refer to a role of psychological factors or recognising a need for future research incorporating psychosocial targets, for example for lumbar fusion surgery (e.g. Lotzke et al 2016), breast cancer surgery (Brahmbhatt et al 2020) and knee and hip joint arthroplasty (Clode et al 2018). However, prehabilitation interventions specifically for psychological distress or integrating psychosocial factors in the treatment protocol are infrequent and there is an urgent need for research (Levett and Grimmett, 2019). An exception was reported by Sorel et al (2020) whose systematic review of perioperative interventions inclusive of psychological therapy targeting psychological distress in patients scheduled for total knee arthroplasty showed improved outcomes. There is scope for psychology-informed multimodal interventions in optimising outcomes, for example a systematic review and meta-analysis of current prehabilitation programmes for lumbar spine surgery patients finds a need to improve post-operative outcomes (Jansenn et al 2020) and a feasibility study of patient's experience of exercise based prehabilitation prior to breast cancer surgery reported participants recognised a need for psychological support to help with stress and emotion management to optimize health in the preoperative period (Brahmbhatt et al, 2020).

Also relevant to prehabilitation for pain related problems is the issue of chronic post-surgical pain as reported by Wylde, et al (2017). There are few systematic reviews of

interventions for chronic post-surgical pain. The authors found there was insufficient evidence to draw conclusions on effectiveness and interventions are predominantly pharmacological. The review found three studies addressing psychological factors: mindfulness-based stress reduction, mirror therapy for amputation and sensory discrimination training. They suggest more research on prehabilitation for this patient group is needed, recommending studies of multimodal interventions matched to pain characteristics.

The potential benefit of multimodal prehabilitation for patients referred for SCS is indicated by studies of psychological factors thought to impact on SCS outcomes. The factors reported in these studies of SCS outcomes include the following: psychological characteristics (e.g. Wolters et al 2013, Sparkes et al 2015 and Block et al 2017), psychosocial variables (e.g., Celestin et al 2009), psychoanalytic factors (Dumoulin et al 1996), family history of psychiatric illness (e.g., Sheldon et al 2020) and psychological risk factors (e.g. Block et al 2013). The few studies reporting psychology informed interdisciplinary interventions for people waiting for a SCS intervention have focused on pre-operative improvement and helping those people with suboptimal responses to initial treatment. A small scale study by Molloy et al (2006), combining cognitive behavioural therapy and spinal implantable devices found an association indicating potential outcome of reduced emotional distress and disability for those people with a suboptimal response to the initial treatment. McCracken et al (2015) found that people waiting for a SCS intervention seem to benefit at the pre-operative stage, from psychologically informed interdisciplinary treatment to improve functioning and quality of life without a reduction in their pain.

These findings suggest the potential for improved outcomes from prehabilitation among patients referred for SCS by offering evidence-based interventions for self-management of pain, integrating psychosocial interventions and coping skills to minimize and manage effects of pain in the context of their lives. There is a need for an evidence-base to describe how to combine these treatments, to determine how to optimise outcomes for the short term and whether there is a benefit to long term outcomes.

Prehabilitation Programme Content: From discussion within PiPiN, the following are common topics covered in neuromodulation prehabilitation:

- Pain neurophysiology- “Understanding pain”
- Psychoeducation and skills to address pain related fear avoidance and pain self-efficacy
- Identifying and dealing with psychosocial barriers to pain management techniques e.g. pacing/ activity management
- Psychological interventions for monitoring and managing mood
- Psychological and behavioural interventions to address reliance on medication or self-medication with alcohol
- Psychology based techniques to manage effects of context and environment
- Interventions and coping skills for surgery and acute pain including needle phobia, other phobias
- Planning for coping skills for those patients who have responded positively to psychological therapy for PTSD who are managing ongoing trauma symptoms

- Risk managing and mental health crisis planning
- Liaison with expert patient input and support
- Individual psychology sessions comprising: psychoeducation, dealing with psychosocial barriers to change, psychology based coping skills, psychological and behavioural interventions and mental health risk management, as appropriate.
- Dual psychology/physiotherapy sessions comprising: psychoeducation, understanding psychosocial barriers to pain management strategies and psychological and behavioural strategies for overcoming fear-avoidance and improving pain self-efficacy

People who undergo neuromodulation will likely continue to have chronic pain post-surgery. As such they are still subject to the psychological impact of living with a long-term health condition and may benefit from continued support beyond the trial and implantation phases.

Communication

Effective and efficient communication is crucial in healthcare settings to deliver patient-centred care. Practitioner psychologists specialising in neuromodulation can play a vital role in supporting and facilitating communication to benefit individuals with chronic pain and the collaborative interdisciplinary work within the MDT. Assessment, therapy, and communication skills as well as knowledge of psychological and cognitive theories, acquired in psychology training support the conveying of information. Crucially psychologists can also help individuals with chronic pain upskill to become independent communicators to navigate healthcare including their decision to proceed or decline neuromodulation treatment.

Informed consent: An important aim of good communication within a neuromodulation service should be to facilitate the patient in making an informed decision about the procedure to provide consent. Consent is founded in medical ethics and human rights law and is validated when given by patients who have the capacity to make decisions voluntarily and with information (www.nhs.uk, 2019). The basis of consent requires the neuromodulation MDT to explain the treatment and psychologists can contribute to this explanation in highlighting the patient's psycho-social context.

Time for communication: Within neuromodulation services, consideration must be given to the duration of appointment times, time for the conveying of information and psychological interventions to patients, time for supervision and team reflections, and regular meeting (in person or virtually) for team clinical discussions to formulate patient care plans. The provision of this clinical time within psychologists' job plans and good record keeping practice contributes to good neuromodulation MDT communications and patient-centred care.

Specialist psychologists providing psychological assessment and evaluation of individuals with chronic pain contribute significantly to clinical case formulation by integrating the biopsychosocial model as experienced by the patient. Communicating clinical case

formulation is an essential task within the MDT to support the team's collaborative aims towards the most appropriate treatment approach. Contributing information and understanding of patient's (and possibly their family/carer's) treatment aims and expectations of the neuromodulation device, conflicting feelings, concerns or worries around the procedure, their experience of previous pain treatments and interventions and how they coped with challenges can all build towards the MDT question; *is neuromodulation appropriate for this patient, or on balance will it cause biopsychosocial harm/distress?*

For effective case formulations to be openly discussed within the MDT, the appropriate time and space for meetings to discuss cases, needs to be planned and implemented regularly. Some useful points to consider:

- Does the neuromodulation MDT hold regular chaired team meetings?
- Is the remit of the meeting to discuss cases where psychologists can represent the patient's values, and offer case formulation and recommendations?
- Are MDT discussions including language used, considerate and respectful to patients and inclusive of social differences?
- What preparation can be done prior to sharing case formulations and how does language used need to be understood by all members of the MDT?
- How will MDT discussions and outcomes be communicated to the patient in a timely manner?
- Can supervision offer support towards case formulations and how to communicate these with the MDT?
- Is there a space to reflect on challenges that arise in MDT discussions?
- Are certain language used in the MDT discussions unhelpful if used with the patient and how can this be highlighted and supported to change?

Communication with patients: At various points of the patient journey within neuromodulation services, there can be opportunities for effective communications to represent the MDT approach and the biopsychosocial model. Careful consideration can be given at these various points by examining the methods and tools used to communicate information, sharing and clarifying team messages, involving administrative staff where appropriate, and evaluating patient feedback. Points to consider:

- Being mindful of language that might be distressing and or unhelpful within consultations and levels of comprehension (e.g. "the spinal cord stimulator is last treatment we can offer").
- Ensure information is clearly delivered and providing written information where appropriate.
- Making communication to patients clear and personalised in both written and verbal forms (e.g. using interpreters and translated documentation).
- Remember the impact of pain and medications on concentration and memory retention for patients.
- Ensuring patients and close family and or carers understand the neuromodulation treatment plan and the role of psychology.
- The conveying of information with regards to psychological assessment as part of neuromodulation assessment and or preparation.

- Explaining the importance of outcome measures as part of assessment, ongoing care, and service evaluations.
- Asking patients for feedback to engage them in the process.
- Checking patients' understanding at various points in their journey.

A systematic review of various interventions to improve patient comprehension of informed consent for medical procedures, found those with interactive elements such as teach-back and test-feedback, improved patient comprehension towards informed consent (Glaser et. al., 2020). Reviewing the literature, including studies such as the aforementioned and those reviewing cognitive learning styles and memory retention of information can shape how psychologists reflect on, plan and inform the MDT as to how communication can be made effective.

Identifying resources needed to facilitate methods of communication require discussions within the MDT and can include patient representatives, management and service leads. Collaboration with all the stakeholders involved provide opportunities for psychologists, with the MDT, to evaluate the various points of communication along the patient journey, methods utilised, clarification of messages including how and why psychology is part of and involved.

MDT working

Despite common aims of clinicians and patients, problematic communications can occur due to several reasons e.g., time pressures and busy clinics, differences in frames of reference about what information ought to be shared, incongruence in neuromodulation treatment aims and expectations, different professional ideologies, disagreements and distance between MDT members and patients, and sociolinguistic and social differences (Matthews, 1983).

Challenging communications can also include situations where there might be complex clinical decisions and ethical dilemmas. The impact of inter-professional hierarchical structures or rotating members of clinical teams can be obstacles to communication. Team decision making can be considered by neuromodulation psychologists e.g. using systemic and dynamic theories to formulate ways to improve communication. In managing complex patients, diffusion of responsibility due to confusion in clinical roles or unclear expectations of professional roles, can lead to undermining or disagreements, and or a "bystander effect" or reluctance to act (Latane and Darley, 1968; Fischer et al., 2011).

Ethically difficult situations can be a common experience of clinicians in healthcare setting (Jakobsen and Sørlie, 2016). Research studies have shown that clinicians describe ethical difficulties when feeling unable to fulfil patients' needs and expectations or when acting against their will (Grönlund et al., 2015; Rasoal et al., 2016). Whether MDT deliberations lead to differing options within the team or a decision the patient disagrees with, psychologists are well placed to offer support and insight to the MDT.

It is important to balance complex decision making based on risk, medical necessity, patient preference and recommended treatment (Bruns & Disorbio, 2018). Understanding the necessity of the medical procedure alongside discussions about biopsychological risks, grounded in patient preference, can help guide discussions within the multidisciplinary team with the aim of formulating a shared, clear plan for neuromodulation. The table below, from Bruns & Disobrio (2018), can be used alongside MDT assessment and is not designed to be used as a rigid decision making tool.

	Necessity of medical procedure			
Biopsychosocial Risk Level		**Elective, for reduction of subjective symptoms**	**Indicated, not urgent**	**Necessary**
	Low/Average Risk	Proceed with surgery as medically indicated after discussing available alternative treatments	Proceed with surgery as medically indicated	Proceed with surgery as medically indicated
	High Risk	Proceed with surgery only after exploring alternative treatments. Consider a referral to pain psychology.	Multidisciplinary risk reduction prior to surgery is recommended. Refer to pain psychology.	Proceed with surgery using multidisciplinary perioperative treatment. Referral to pain psychology
	Very High/Extreme Risk	Avoid surgery, explore alternative treatments. Intensive multi-disciplinary risk reduction prior to any surgery is strongly recommended. Refer for mental health treatment if severe biopsychosocial risk is present	Delay surgery if possible until patient is psychologically stable. Refer for mental health treatment if severe biopsychosocial risk is present	Proceed with surgery using intensive multidisciplinary perioperative treatment. Refer for pain psychology.

Table 2. Formulating with necessity of medical procedure and biopsychosocial risk levels Bruns and Disorbio (2018)

By facilitating discussion in this way, psychologists can add to the MDT's knowledge and understanding of their role within neuromodulation as one that supports the patient and the team. This can also make way for various methods used to elicit clinician reflections and communications such as Gibb's reflective cycle (Husebø et al., 2015), Schwartz rounds (Pepper et al., 2012; Flanagan et al., 2020) and reflective practice groups (Taylor, 2010).

Section C: Best Practice Guidelines

Recommendations for Best Practice in Providing Psychology Services in Neuromodulation

The framework below proposes minimum, good and best practice standards. The standards have been developed based on the available but limited evidence and expert consensus derived from discussion within PiPiN.

New Service Design/Business Case Development	
Minimum	Service design includes the appointment of a suitably qualified/experienced practitioner psychologist
Good	Consultation with a suitably qualified/experienced practitioner psychologist during business case development
Best	In-house suitably qualified/experienced practitioner psychologist involved in business case development

Assessment of Suitability for Neuromodulation	
Minimum	A suitably qualified/experienced practitioner psychologist provides consultation to an assessing multidisciplinary team and assessments for those screened as requiring it
Good	A suitably qualified/experienced practitioner psychologist provides direct assessment of all patients individually though separate from MDT environment
Best	A suitably qualified/experienced practitioner psychologist is integrated and forms part of the assessing MDT for all patients

Pre- Trial/Implant	
Minimum	A suitably qualified/experienced practitioner psychologist provides general/remote input with regards to broad pain management strategies prior to procedure e.g. in the form of literature Also makes recommendations where necessary for appropriate treatment by mental health services
Good	A suitably qualified/experienced practitioner psychologist provides structured input in the form of therapy sessions prior to procedure to include broader pain management strategies to meet expectations, mitigate catastrophisation, treat untreated common psychological comorbidity
Best	A suitably qualified/experienced practitioner psychologist form part of the development and delivery of a spinal cord specific pain management programme undertaken by the patient prior to procedure A suitably qualified/experienced practitioner psychologist provides highly specialised psychological therapy for a range of difficulties to mitigate risk of poor outcome (e.g. trauma informed therapy)

Post- Trial/Implant	
Minimum	A suitably qualified/experienced practitioner psychologist is available to provide consultation to a team for a patient who requires psychological consultation post-trial/implant
Good	A suitably qualified/experienced practitioner psychologist provides structured input in the form of therapy sessions following the procedure to reinforce broader pain management strategies to meet expectations, mitigate catastrophisation, treat untreated common psychological comorbidity
Best	A suitably qualified/experienced practitioner psychologist provides highly specialised psychological therapy for a range of difficulties to mitigate risk of poor outcome (e.g. trauma informed therapy)

A sample job description for a suitably qualified and experienced Practitioner Psychologist can be found in appendix 2.

Conclusion

It is hoped that these guidelines will provide new and experienced psychologists working within services providing neuromodulation for pain, with a consensus on what this role involves. It aims to support the development of new services and aid decision makers and commissioners on how best to establish neuromodulation services. It is not the final word on these matters and it is hoped that this document will be updated over time. Initial stakeholder engagement and consultation will be conducted prior to a final version being agreed, with the aim of publication in a relevant academic journal. PiPiN intend to review the document in 2028 and consider any necessary updates.

Finally, PiPiN welcome all psychologists working in the UK within chronic pain services which offer neuromodulation, services which receive referrals for patients with chronic pain being considered for neuromodulation or involved in research with neuromodulation, pain and psychology. If you are interested in joining, please contact Anna Graham (anna.graham@ggc.scot.nhs.uk), John O'Sullivan (john.o'sullivan8@nhs.net) or Toni Miles (toni.miles@esneft.nhs.uk).

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Appendix 1: UK Neuromodulation Centres Participating in PIPIN Guideline Development

UK Country	Region	Organisations Represented
England	London	Barts Health NHS Trust - St Bartholomew's Hospital
		Chelsea and Westminster Hospital NHS Foundation Trust
		Guy's and St Thomas' NHS Foundation Trust – St Thomas' Hospital
		St George's University Hospitals NHS Foundation
		University College London Hospitals NHS Foundation Trust – National Hospital for Neurology and Neurosurgery
	South East	Isle of Wight NHS Trust – St Mary's Hospital
		Kent Community Health NHS Foundation Trust
		Oxford University Hospitals NHS Foundation Trust
		The Royal National Orthopaedic Hospital NHS Trust
		University Hospital Southampton – Southampton General Hospital
	South West	North Bristol NHS Trust – Southmead Hospital
	East of England	Cambridge University Hospitals NHS Foundation Trust – Addenbrooke's Hospital
		East Suffolk and North Essex NHS Foundation Trust – Ipswich Hospital
		Norfolk and Norwich University Hospitals NHS Foundation Trust – Adelaide Health Centre

	North West	Northern Care Alliance NHS Foundation Trust – Salford Royal Hospital
		The Walton Centre NHS Foundation Trust
	Yorkshire and the Humber	Bradford Teaching Hospitals NHS Foundation Trust – St Luke's Hospital
		Hull University Teaching Hospitals NHS Trust – Castle Hill Hospital
		Leeds Teaching Hospitals NHS Trust – St. James's University Hospital
		Sheffield Teaching Hospitals NHS Foundation Trust – Northern General Hospital
		York and Scarborough Teaching Hospitals NHS Foundation Trust
	North East	South Tees Hospitals NHS Foundation Trust
Northern Ireland	Belfast	Belfast Health and Social Care Trust – Belfast City Hospital
	Antrim	Northern Health and Social Care Trust – Holywell Hospital
Scotland	Glasgow and Clyde	NHS Greater Glasgow and Clyde
Total		25

Appendix 2: Psychologist in Neuromodulation Job Description

TITLE:	Highly Specialist Psychologist in Pain Management and Neuromodulation
ACCOUNTABLE TO:	Head of Clinical Health Psychology Service
GRADE:	8b and above

Role Summary:

The Psychologist should work primarily within a Multi-disciplinary Pain Management Team, usually comprising Consultants in Pain medicine, Pain Specialist Physiotherapists, Pain Nurses and Occupational Therapists.

This will require a range of specialist skills and competencies in order to deliver highly specialist psychological assessment and intervention for clients with mental health needs in combination with pain management difficulties.

The Psychologist will undertake broad psychological formulations, individual and group-based psychological therapies underpinned by psychological theory.

Working closely with the multi-disciplinary team the Psychologist will also liaise with family, statutory, voluntary and independent sector agencies across a number of settings offering guidance, systemic interventions and consultation services.

Providing psychological input for the neuromodulation service within pain services requires additional specialist knowledge and skill, assessment skill, psychological consultancy advice and often complex MDT team work, at a senior level. This includes, in addition to assessment; patient advocacy, pathway planning,' within meeting' clinical case formulation from case presentation and offering psychological consultation, service development and planning for psychological input within the neuromodulation service.

Psychological input for neuromodulation includes: Conducting specialist assessment for patients suitability for an implantable device and elective procedures, considering their understanding of the process and expectations for likely outcomes, cognitive ability to manage the device and psychological resilience for managing uncertainties along the pathway. To also identify options available within the wider pain service to optimise management of the process and increase the efficacy of the clinical outcomes. For some Psychologists in Neuromodulation a combination of both outpatient and inpatient support may be required, depending on the Neuromodulation service remit.

The role requires highly specialist knowledge and skills of psychological interventions to both recommend and provide that can improve people's pain coping and Neuromodulation outcomes. The role also requires utilising highly developed research skills to either lead or

co-evaluate research projects and service audits as required to evaluate service delivery and take an active role in outcome evaluation and adding to the existing literature within the Neuromodulation specialism.
Qualification- Doctorate in Clinical Psychology (or equivalent)

1. Clinical

1.1 To provide highly specialist psychological assessment of pain management and coping, being able to differentially diagnose comorbid mental health conditions and/or formulate psychological coping responses that are contributing to and/or exacerbating pain coping and response to rehabilitation therapies. This includes providing a diagnostic assessment and consultation to individual patients and the wider MDT where appropriate, in a supportive and positive team environment.

1.2 To take a lead role in the psychological assessment, formulation and intervention/care of Pain Management patients with medical and social needs.

1.3 Provide recommendations for further action / treatment of patients referred for clinical psychology opinion as appropriate to patient need in discussion with individual patients and colleagues within the MDT, referring on to other agencies as required.

1.4 To provide highly specialist psychological assessment of referred patients, to determine immediate psychological treatment needs. This may include referral on to other specialist mental health services, primary care services, or community services. Assessments and formulations will be based on the use, interpretation, and the integration of complex data from self-report measures and clinical interview. These assessments may be part of a multidisciplinary assessment and include MDT handover and case discussion to support other disciplines and psychological assessment and decision making being optimised.

1.5 To develop appropriate discharge plans for clients at the end of specialist assessment and/or therapy as determined by treatment outcome and the conceptual framework of the clients' problems.

1.6 To act as a consultant and resource on psychological issues, within levels of competence, by establishing and monitoring therapeutic and assessment systems, staff training and support, and direct client work.

1.7 To undertake autonomous risk assessment and risk management for individual clients and to provide advice to other professionals within the service on the psychological aspects of risk assessment and risk management.

1.8 To communicate complex information in a sensitive and skilled manner, information pertaining to assessment, formulation and treatment plans of clients under his/her care and to monitor progress during the course of treatment both individually and within the teams/services. To manage agreed outcome data appropriately according to departmental policies.

2. Teaching, Training, and Supervision

2.1 To receive regular clinical professional supervision from a more senior and experienced psychology colleague within the field of pain psychology and specifically Neuromodulation and to locate this externally if there is not a suitable supervisor within the Trust.

2.2 To gain additional experience and skills relevant to the specialist neuromodulation service job (as agreed with the lead for psychology department or Directorate Head).

2.3 To maintain high standards of clinical competence by keeping updated on specialist literature, attending training days, conferences, and conducting evaluation.

2.4 To contribute to the peer MDT network and scientific understanding and/or literature, where appropriate, within the Pain Psychology and Neuromodulation specialist fields.

2.5 To contribute towards teaching of MDT staff where appropriate to capacity, and provide clinical consultation to medical staff.

2.6 To supervise more junior Qualified Clinical Psychologists within the Pain psychology and also Trainee Clinical Psychologists, if capacity enables such a placement.

3. Management, Recruitment, Policy and Service Development

3.1 To either lead or contribute to the development, evaluation and regular appraisal of the pain and Neuromodulation service operational policies and services, through professional research skills in service evaluation and audit.

4 Research and Service Evaluation

4.1 To ensure necessary caseload data is recorded and reviewed as required to support service evaluation and development needs.

4.2 To employ theoretical knowledge and evidence-based literature and research to support practice in both individual and team work, evaluation, and audit.

4.3 To take the initiative on projects related to quality, audit, and service development in line with the requirements of the individual teams/services and needs of the Trust.

4.4 To identify areas for the potential development of the services and either lead on service development opportunities or work with senior psychology colleagues.

5 Information Technology

5.1 To utilise information technology skills to update and maintain reporting and database information pertinent to client details and team/service performance.

5.2 To monitor and record CPD activities via computer-based packages, including staying up to date with required mandatory training in EPUT.

5.3 To employ general information processing skills to prepare reports, teaching materials, and professional correspondence.

6 GENERAL

6.1 To maintain the standards of service as set within the department and identify areas for improvement. These will be implemented after agreeing with the Head of the Clinical Health Psychology Service and the Head of Department.

6.2 To attend professional and management meetings for both the general Pain and psychology teams and also the Neuromodulation service where possible, to ensure that knowledge and skills are updated through developing a professional development plan, and to seek clinical guidance and supervision from either supervisor within the department or appropriate external supervisor if one is not available within the service given the specialism of both Chronic pain management and Neuromodulation.

6.3 To follow the British Psychological Society and HCPC code of conduct for Psychologists. Professional healthcare staff are responsible for complying with the standards set by their regulatory or professional bodies, Trust policies and relevant legislation. A breach of such standards may lead to action by NHS bodies independent of any taken by the regulatory or professional body concerned. It would be investigated fairly and appropriate steps taken to prevent a recurrence and address any wider causes.

6.4 To maintain and update required HCPC membership and professional registration.