

July 2020

Guidance on Resumption of Neuromodulation Services during the COVID-19 Recovery Phase

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Introduction

Coronavirus disease 2019 is caused by SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2). The virus is transmitted either through airborne droplets (e.g. coughing, sneezing or even respiration) or less commonly through direct contact (e.g. via contact with a surface, including medical equipment such as a pulse oximeter or nasal cannula, containing the virus). Based on the latest data, there appears to be little risk that brief contact with an asymptomatic carrier of the virus, such as that which occurs during a neuromodulation implant procedure, confers any appreciable risk of becoming infected. Early efforts geared towards social distancing to decrease the transmission of the virus is likely to be in place until definitive treatment or a vaccine is developed.

NHS hospitals were told to suspend all non-urgent elective surgery for at least three months from 15 April 2020 to help the services deal with the COVID-19 pandemic¹. This has significantly affected the patient population suffering from severe pain served by Neuromodulators in the UK. NSUKI produced practice recommendation on managing the neuromodulation devices during the pandemic².

The NHS is now entering a COVID-19 recovery phase, with some non-COVID services resuming. Planning for the recovery phase will depend on the ongoing impact of COVID-19 locally and the resources that are available. The demands on local capacity for neuromodulation work and restoration of services in this transitional phase will vary greatly across the United Kingdom. The situation will remain highly fluid as the emergence of new clusters of COVID-19 is monitored. The coronavirus pandemic has changed the way we have worked and will continue to change the way we offer services to improve patient care. In addition, there are new logistical challenges and evolving processes to ensure safe service delivery from patient's and staff perspectives.

A recent national survey performed by NSUKI of 300 patients awaiting implants, revealed deterioration in pain, mental health, and patient's ability to self-manage. Some patients reported increases in pain medication and reliance on support network. 92% of the patients showed a willingness to attend for COVID-19 testing, self-isolate prior to and after surgery and undergo the procedure as soon as possible.

This guidance is aimed at resumption of neuromodulation service including intrathecal drug delivery during the COVID-19 Recovery Phase.

If there is a second wave of COVID-19 pandemic then NSUKI's recommendations for the management of implanted neurostimulation & intrathecal drug delivery devices during the COVID-19 pandemic should be followed².

Factors to consider when resuming neuromodulation services

1. Local COVID-19 situation

It is likely that geographical variations in infection rates will occur. The decision to resume elective implant surgery should take into consideration the demand on healthcare resources including theatre access, staffing, personal protection equipment, and risk to staff and patients in your region.

2. Prioritising Procedures

- a. Category 2 & 3 patients: replacement of intrathecal pumps, replacement of internal pulse generators, revision procedures, treatment of cancer pain and intractable neuropathic pain for which evidence based SCS treatment is available should be prioritised³.
- b. When prioritising category 4 patients³, clinical needs as well as patient's own risk factors to acquiring COVID-19 infection⁶ should be taken into consideration.
- c. Interventions that do not fall within the categorisation should be assessed on an individual basis and a collaborative approach should be taken with other clinicians to guide prioritisation.
- d. It is important that the reasons for decision making in high risk cases are carefully documented, with at least two clinicians involved in the decision making process.

3. Reducing the risk to patients

- a. Non-invasive alternative treatments should be explored and discussed with the patients, before neuromodulation is considered.
- b. A robust MDT assessment as per NICE guidance TA159 on Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin should be undertaken prior to implant surgery⁴. This may be difficult due to social distancing guidelines and may not be feasible for all patients. Where possible telemedicine should be used to reduce face to face consultation.
- c. A screening trial is widely used to determine whether a patient should receive permanent SCS implant. The evidence for patient benefit and prognostic value of screening trials is limited⁵. In order to minimise patient visits to hospital, consider proceeding directly to a definitive procedure such as full implant with on table trial rather than first performing trial procedure. The risks and benefits of this should be discussed with the patient and documented.
- d. Services should follow local policy on the routine testing of patients for coronavirus and isolation prior to elective procedures and post-procedural isolation.
- e. Patients must understand their risks are greater if they are in an 'at risk', and 'very high risk' group of patients⁶.

- f. Use of local anaesthetic and conscious sedation may minimise risk of pulmonary complications as compared to general anaesthetic. Where feasible local anaesthesia and sedation should be used for implant surgery.
- g. The theatre turnaround time between the patients is going to be longer to allow social distancing for patients and staff, and the cleaning procedures after each case. Appropriate list planning process must be in place to avoid cancellations on the day of surgery and wasted visit to hospital for the patient with risk of exposure to COVID-19.
- h. Post-implant education should involve patient and their carer. It is essential to have a plan on programming in advance to reduce future face to face attendance.
- i. As far as possible, post-operative wound monitoring, activation of the therapy and any other troubleshooting should be performed via telemedicine.
- j. Attempts must be made to facilitate implant surgery to be carried out as a day case surgery.
- k. Troubleshooting videos and information should be developed.
- l. A routine face to face follow-up of patients implanted in the past should be avoided and should only be considered when troubleshooting could not be done via telemedicine.

4. Reducing risk to staff

- a. Patients having active symptoms of COVID-19 infection should have their procedure deferred unless there is an overriding clinical priority.
- b. Local protocols for appropriate PPE and social distancing should be followed.
- c. Where possible deep sedation or general anaesthesia requiring the potential need for airway support and subsequent aerosol generation should be avoided.
- d. Use of diathermy is an aerosol generating procedure, if possible, diathermy should be avoided or smoke evacuation for diathermy / other energy sources should be considered. If using diathermy even with smoke evacuation then local PPE guidance on aerosol generating procedures should be followed.
- e. Only minimum number of staff essential for surgery should be allowed in the operating theatres.

5. Reducing risk to industry partners

- a. Appropriate PPE as per local guidelines must be available.
- b. Social distancing protocols need to be maintained, except during actively imparting essential clinical care or monitoring.
- c. To minimise duration of stay in operating theatres, industry partners should only enter the theatre for the critical steps required during the procedure and should leave the theatre as soon as this is finished.
- d. Where possible remote programming and training of the patients to use devices should be undertaken.

- e. Post-implant programming visits should be kept to minimum.
- f. Where possible attendance of personnel from multiple companies during a single operating day should be avoided.
- g. Outpatient follow-ups should be very focused. The implanting team should have liaised with the patient and tried all attempts to troubleshoot via telemedicine. The implanting team should have a clear plan for face to face appointment and should communicate this clearly with industry partners before the appointment.

6. Consent

- a. It is recognised that face to face appointments to discuss the risks and benefits of treatment may not be in the best interests of patients and staff. However, it is important that the same principles of consent are followed, whether patients are spoken to on the telephone or by video call or in person.
- b. It is vital that patients understand the additional material risks of attending hospital and having surgery during the COVID-19 pandemic. This must be documented in the medical records.
- c. Written patient information on the additional risks of surgery during the COVID-19 pandemic should be available to patients to aid the consent process. You may already have one in your hospital or may wish to use information and consent for patients undergoing implant surgery during the coronavirus pandemic developed by NSUKI.
- d. The guidance in the General Medical Council (GMC) publication 'Consent: patients and doctors making decisions together' must be followed⁷.
- e. It is vital that the person discussing the risks of a procedure with the patient is not only familiar with the risks/benefits of the procedure but also remains current on the risks and mortality from COVID-19.

Reference:

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