



British Pain Society and Faculty of Pain Medicine of the Royal College of Anaesthetists

Standards of Good Practice for Spinal
Interventional Procedures in Pain Medicine

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THE BRITISH PAIN SOCIETY



FACULTY OF PAIN MEDICINE

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1 Introduction

This document describes the standards of good practice for pain specialists carrying out spinal interventional procedures in pain medicine as recommended by the British Pain Society (BPS) and the Faculty of Pain Medicine of the Royal College of Anaesthetists (FPMRCA). This document also defines the facilities required in order to safely carry out these procedures. This document however, does not serve as critical analyses of published evidence.

Interventional procedures are used widely to investigate and treat pain, caused by structures in and around the spine and other parts of the body. These procedures should not be undertaken in isolation and should include the support, guidance and decision making of an interdisciplinary team. Furthermore, these procedures should be undertaken in conjunction with rehabilitative interventions designed to reduce disability and enhance maximum improvement in quality of life.¹

The BPS and the FPMRCA recognise that clinicians from other medical disciplines perform spinal interventions. The FPMRCA however, only takes responsibility for the professional standards of Pain Medicine Specialists who hold FPMRCA or equivalent or are in recognised pain medicine training posts. These recommendations apply to both doctors in training, who perform interventional pain procedures under varying levels of supervision, and to established practitioners in non-training grades. The competencies expected of pain medicine doctors are defined in the Curriculum for a CCT in Anaesthetics (Certificate of Completion of Training) - Advanced Level Training (Annex E)².

2 Consent

It is important to work in partnership with your patients when performing pain interventions. Always discuss their condition and treatment options and likely outcomes with them. You must respect their right to make decisions about their care and that they have the required time to do this. This may include time to obtain further information (including a second opinion) and consult with others. Obtaining informed consent is a process of discussion and joint decision-making. You must be satisfied that you have informed consent before you provide any treatment. This will involve providing information to patients in a way that they can understand before asking for their consent. Always follow the guidance provided by the GMC (2008)³.

In deciding how much information to share with your patients you should take account of their wishes, religious beliefs (or none) and social and economic circumstances. The information you provide should be in proportion to the nature of their condition, the complexity of the proposed treatment and the seriousness of any potential side effects, complications or other risks. You may need to support your discussions by using written material, visual or other aids; any material used however, must be accurate and up-to-date. Furthermore, should you wish to use such material then this must be made available in an accessible format to the patient; factors such as age, ethnicity, cognitive/communication skills and capacity must be considered. Be aware of current recommendations about safeguarding vulnerable patients and follow the provisions of the 2005 Mental Capacity legislation⁴.

If you are the doctor providing treatment, it is your responsibility to discuss this with the patient. If this is not practical, you can delegate this responsibility to another doctor, provided you make sure the person to whom you delegate is suitably trained and qualified, has sufficient knowledge of the proposed treatment and understands the risks involved. They must understand and act in accordance with GMC guidance³. Some interventions may provide diagnostic information and this should be thoroughly explained to the patient and assessed by the physicians. Adequate time should be allowed for this to happen.

Adverse outcomes must be identified that may result from the proposed treatment including the potential outcome of taking no action. Risks will usually be side-effects/ complications or failure to achieve the desired aim. Patients must be informed about less serious complications if they are common and explain what the patient should do if they experience these. You must also inform patients if the treatment might result in a serious adverse outcome, even if the likelihood of this is minimal.

Written consent should be obtained but this is just the end point of the consent process. Use the patient's medical records or a consent form to record the key elements of your discussion with the patient. This should include the information you discussed, any specific requests made by the patient, any written, visual or other information given to the patient and the details of any decisions that were agreed.

3 Preparation and identification of patients

All hospital inpatients' must wear wristbands (identity bands) with accurate details that correctly identify them and match them to their care. All patient identification procedures must follow National guidelines^{5,6}. Allergies must be checked and noted according to local policy and practice.

The WHO safer surgery checklist must be used for all procedures to ensure appropriate checking of patient identity, site and nature of planned procedure, patient preparation, and readiness of equipment⁷.

When fluoroscopy is to be used in females of childbearing age, pregnancy status must be confirmed prior to the procedure according to National guidelines⁸.

Siting an intravenous cannula should be considered dependent upon hospital policy and practice. In patients where sedation is required, intravenous cannulation must occur. It is recommended to place an intravenous cannula for all techniques where a neuraxial spinal procedure is performed with local anaesthetic due to the small but life threatening risk of cardiovascular instability secondary to complications such as anaphylaxis, intrathecal and intravascular spread.

Patients receiving local anaesthesia should be fasted prior to the procedure according to local hospital policy and practice. If the patient is to have conscious sedation they must be fasted as for general anaesthesia according to local policy and practice^{9,10}.

4 Environment and facilities

Spinal interventions should be performed aseptically in an appropriate environment that adheres to local guidelines with regards to minimally invasive procedures. Infection prevention and control, monitoring, imaging and availability of assistance must all adhere to local policies and National guidelines. The clinical area should be of an adequate size in order to accommodate the staff and equipment necessary for safe minimally invasive procedure practice. The clinical area should have a fully equipped and staffed post anaesthesia care facility in close proximity. Resuscitation equipment, trained staff and facilities must be immediately available should this be required¹¹.

5 Anticoagulation

Particular care is needed in patients with disordered clotting either from medical problems or medication. The benefits and risks of the procedure should therefore be considered on an individual basis and, where needed, advice on withdrawal of anticoagulants should be sought from other clinicians involved in the patient's care such as supervising cardiologist, local haematology services and the patient's GP, where appropriate. This is important as abrupt withdrawal of anticoagulants may risk serious thrombotic episodes whereas the continued use carries an increased risk of bleeding¹²⁻¹⁵

6 Sedation and analgesia

It is recognised there is a wide variation in sedation practise ranging from no sedation at all to routine use. For most procedures sedation is not required as reassurance, presence of theatre staff and adequate local anaesthesia usually suffices. Anxious patients or those describing severe pain on injection may benefit from sedation.

In patients where sedation is required, intravenous cannulation must occur.

Feedback from the patient during the procedure should be obtained and sedation used should be light and short acting. There is no recommended absolute upper limit of sedative or analgesic as it is recognised that patients vary widely in their tolerance of sedatives and analgesics^{16,17}. Guidelines have been issued from the NPSA in response to excessive doses of drugs used for endoscopy in elderly patients¹⁸. These suggest a maximum of 5mg Midazolam and additional analgesic. It is recognised that intravenous alfentanil, fentanyl and morphine are commonly used during the course of procedures to provide analgesia alongside sedatives.

7 Assistance

Assistance should be available to ensure that the procedure can be carried safely and with enough support in case of emergency.

There are no specific guidelines or recommendations but the following should be considered:

Presence of Radiographer: It is legally applied and usual practice in the UK to have a radiographer in charge of the imaging system, though the practitioner may control and move the 'C-arm'.

Assistant to the practitioner: Skilled Assistance to the practitioner must be available for allowing the checking and drawing up of drugs in a safe and sterile manner.

Monitoring of the patient: This should be undertaken by a further attendant who does not have other responsibilities. This becomes more important for longer procedures where continuous observation and regular recording of vital signs is essential. It is recognised that in some (shorter) cases this may be the same assistant who initially helps the practitioner draw up the drugs.

Skill level: The assistant (s) should be skilled in Immediate Life Support (ILS) (Resuscitation Council UK). All assistance should come from appropriately trained nursing or theatre staff. The use of Health Care Assistants whose skill level, knowledge and training in resuscitation and drug therapy may be rudimentary are not considered adequate as the main form of assistance for the practitioner or for monitoring for the patient.

Other assistance: Extra help should be available to safely move the patient as required.

8 Fluoroscopy

Understanding the fluoroscopic anatomy of the spine is essential to safely perform diagnostic and therapeutic spinal interventions¹⁹. It is recommended that fluoroscopy (or ultrasound/CT guidance) is used for all spinal interventions.

For safe fluoroscopic assisted interventional procedures correct interpretation of key landmarks in AP, lateral and oblique views are important. A fluorolucent table is essential to perform fluoroscopic guided spinal interventions¹⁹. Relevant images should be stored in the patient's records or hospital radiology system for clinical and legal purposes according to local hospital guidance

A non-ionic water soluble contrast medium can be injected before injecting any medication at the target point to aid in excluding incorrect needle position. The contrast medium should be licenced for spinal (including intrathecal) injection. Iodine containing contrast agents should be used with caution in patients with altered renal function and large volumes should not be used in patients on metformin²⁰.

9 Infection control

The objectives of infection control in any establishment should include educating personnel about the principles of infection control and stressing individual responsibility for infection control, collaborating with the infection control unit in risk assessment, monitoring and investigating potential or actual related infections.

Infection-control recommendations should follow the NICE guideline - Prevention and control of Health care associated infection in primary and community care specifically (2012)²¹, the Health and Social care act (2008), Code of practice on the prevention and control of infections.

This guideline should also be used in conjunction with the relevant Infection control section of other guidelines by the Royal College of Anaesthetists and the British Pain Society.

This includes but not limited to:

- 1.** Standards for good practice for medial branch block injections and radiofrequency denervation for low back pain (2014)²²
- 2.** Spinal cord stimulation for the management of pain; recommendations for best practice (2009)²³
- 3.** Intrathecal Drug delivery for the management of Pain and Spasticity in adults; Recommendation for Best Clinical Practice (2008)²⁴
- 4.** Recommendations for good practice in the use of epidural injection for the management of pain of spinal origin in adults (2011)²⁵

Preoperative patient selection and preparation should involve the identification and treatment of all remote infections prior to interventional procedures.

There is little published evidence regarding the use of antibiotic prophylaxis for Spinal Cord Stimulation and Intrathecal Drug Delivery devices. However, infection of an SCS/ITDD system is a significant problem and, the consequences of infection may justify the use of antibiotic prophylaxis in most cases. This is not the case for spinal interventions without the need for implantation except for intradiscal procedures where the risk of discitis is well described. The risk of infection may be enhanced in diabetic and immunocompromised patients or as a result of systemic steroid therapy.

Meticulous aseptic technique is mandatory and this should include surgical scrub according to local policy, sterile gown, sterile gloves, facemask, skin preparation and sterile drapes around the injection site.

A sterile field should be used for opening the instruments/ kits associated with interventional procedures.

Patient hair should not be removed unless necessary to facilitate interventions. If hair is removed, it should be done immediately prior to surgery with the use of electric clippers.

Suitable skin preparation solutions include 0.5% chlorhexidine in alcohol or 10% povidone - iodine. If local guidelines exist for surgical skin preparation then they must be followed.

A wide area must be prepared and solutions must be allowed to dry before needle insertion. Particular care is required in skin preparation for caudal epidural injection because of the increased risk of skin contamination in this area.

When implantable devices are used operating rooms should meet standard recommendations for appropriate ventilation: positive pressure ventilation to adjacent areas with a minimum of 15 air changes per hour introduced at the ceiling with exhaust at the floor.

When peri-procedural imaging is anticipated the fluoroscopy or imaging unit should be draped within a sterile operative field at the start of the procedure.

The use of multi- dose vials for separate patients should not be practiced. Neither should contrast materials or other materials that can be contaminated by tissue fluids be shared among patients.

A dedicated contact person such as an infection control professional should be responsible for organisation of surveillance data, audit and dissemination of surveillance results.

10 Record keeping

Standards of record keeping should be audited in accordance with local clinical governance arrangements.

Records should include the following information:

- Clinical indication for injection
- Pain score (VAS, etc) at rest and activities of daily living before and after the procedure when diagnostic spinal interventions are preformed
- Date and time of procedure
- Type of procedure performed
- Name of clinician performing procedure (Printed and signed)
- Position of patient
- Sedation (if used), oxygen, monitoring
- Skin preparation
- Spinal level of injection
- Size of needle (gauge and active tip length)
- Radio-opaque contrast and dose if used
- Any difficulties encountered
- Injected drugs and doses
- Stimulation parameters, temperature, duration and the number of lesions when RF is used

- Appropriate images taken during the procedure to confirm the position of the needle and before and after injection a radio contrast dye if it is used. Relevant images should be stored in the patient's records or hospital radiology system for clinical and legal purposes according to local hospital guidance
- Post-procedure observations
- Aftercare instructions
- Follow up arrangements
- Contact details for patient and primary care team

11 Follow up and discharge planning

On the day of the procedure, patients' should be seen by a member of the treating team or a specifically assigned member of staff on admission and prior to discharge. The patient's limbs should be checked for numbness and/or weakness and the patient asked about urine retention or headache. Patients' should be ready for discharge one to three hours after the procedure. Usual medication can be resumed on the day of the procedure. If there is unexpected significant limb weakness, sensory loss or headache, an unplanned overnight admission may be necessary, with a review the following day before discharge.

If the procedure is complicated by inadvertent dural puncture then the patient may need a more prolonged admission and management in accordance with local guidance. Facilities for overnight stay should therefore be available.

After discharge, a reliable telephone contact number must be provided so that the patient can report any acute complication such as headache, fever, prolonged numbness/weakness or urinary retention. The day surgery unit, as part of the normal discharge procedure, should provide this.

Other healthcare providers (primary care team, emergency department or day care staff) who may be involved in the patient's care after the injection should know how to contact a member of the treating team or hospital staff by telephone in order to help make management decisions where necessary.

A letter, with a copy provided to the patient, should be sent to the patient's GP detailing the procedure and follow up arrangements. The letter should emphasise that fever, severe back pain or worsening neurological and/or urinary symptoms are potentially serious adverse events and that the patient should be monitored at primary care level for any such complications.

Emergency full spine MRI scanning must be available. Arrangements must be in place for urgent referral for neurosurgical or spinal surgical opinion.

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14 Conflicts of interest

This publication received no specific grants from any funding agency in the public, commercial, or not-for-profit sectors.

Drs K Simpson, G Baranidharan and S Gupta are editors of Oxford Specialist Handbook in Pain Medicine: Spinal Interventions in Pain Management, Oxford: Oxford University Press, 2012. The chapter: Applied anatomy and fluoroscopy for spinal interventions, pp 1-10 by S Gupta and K Dhandapani is referenced in this document.

Dr S Gupta has organised meetings sponsored by NeuroTherm Limited who market radiofrequency generators and disposables

Dr Vivek Mehta is the Principal Investigator of "A sham, controlled, randomised trial to investigate the effects of radiofrequency neurotomy using Simplicity III on patients with sacroiliac joint pain". This trial is being funded as an investigator initiated trial by Neurotherm Inc and is currently recruiting.



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