# Guidance on Competencies for Intrathecal Drug Delivery











Association for Palliative Medicine Of Great Britain and Ireland



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Intrathecal drug delivery (IDD) has been an option for the management of chronic pain since the 1980s. The discovery of opioid receptors in the central nervous system was the impetus to deliver opioids spinally to improve efficacy and minimise adverse effects. Several other drugs have been used since then with varying evidence and efficacy. Significant numbers of patients with cancer pain obtain inadequate analgesia from conventional medical management; a small percentage of this group may benefit from IDD. The most robust evidence for IDD is in the management of cancer pain. There is also evidence for the use of IDD in those with non-cancer pain; however NHS England will only commission IDD for cancer pain and spasticity. In addition there is substantial experience in the use of intrathecal baclofen for spasticity e.g. in patients with cerebral palsy and multiple sclerosis. IDD has been used successfully in adults and children.

Physicians involved in the provision of IDD need to be able to make a robust evaluation of the evidence for IDD including pros and cons of different techniques and drugs indicated in different situations. Outcomes are dependant on a variety of factors that may include physician and team expertise in selection, implantation, drug selection, drug titration and follow up. The way that different teams deliver IDD may vary; however each team must have a physician with competencies in selection of patients for therapy, IDD implantation and management of surgical complications, a pharmacist and drug preparation facility that can support IDD, an established and reliable on call system for detecting and managing complications, a case load that is sufficient to maintain team competencies, a programme of continuous professional development appropriate to IDD therapies and regular assessment and peer review of outcome data.

After care requires that emergency full spine MRI scanning must be available. Arrangements must be in place for urgent referral for neurosurgical or spinal surgical opinion.

IDD is delivered by a variety of different medical and surgical specialists and teams. Intrathecal drugs may be delivered by external or fully implantable/programmable systems. The general on call anaesthetist is most likely to be asked for advice about external systems; totally implanted devices need managing with advice and support from specialist teams.

The Faculty of Pain Medicine of the Royal College of Anaesthetists is concerned with the professional standards of pain medicine specialists, so this document focuses on the pain medicine specialist's contribution to IDD service provision.

The first level outlines the core knowledge, skills and attitudes for all anaesthetists specialising in pain medicine who may need to be involved with this therapy e.g. selecting patients who may be suitable for IDD, informing patients about the benefits and risks of IDD, making timely and appropriate referrals for IDD and emergency management of a patient who is receiving IDD. Whilst it is recognised that not all pain medicine specialists will be directly involved in providing an IDD service, all need to understand this therapy for eventualities such as the above. (Section A and Appendix A below).

The second level outlines the advanced knowledge, skills and attitudes required of pain medicine specialists who work in teams providing an IDD service. These competencies reflect those of the IDD module which is an option in the Special Interest Area (SIA) in Pain Medicine of the Royal College of Anaesthetists CCT Curriculum, which sets out competencies for trainees who elect to take a deeper interest in this area of pain medicine practice. (Section B and Appendix B below).

IDD is a multidisciplinary undertaking that requires medical, surgical and non-surgical skills. Pain medicine specialists will need a range of surgical skills depending on how members of the team in which they are working organise assessment, implantation and post-operative management of therapy. This creates a particular problem for anaesthetists in obtaining appropriate training because a basic standard of surgical expertise is mandatory for IDD to be carried out safely and for complications to be managed. More advanced skills are required if the pain physician performs the definitive implant procedure. However, all units that provide IDD must have formal links with neuro or spinal surgeons who can deal with complications such as coning or persistent CSF leakage. Any physician involved in implanting IDD must have skills in patient selection, device selection, implantation, intrathecal pharmacotherapy, pump maintenance and programming, detection and management of complications e.g. infection and neural compromise. There needs to be a well-defined process for the post-procedural monitoring and management of patients, which usually involves specialist nurses with additional training, a clear process to support patients with concerns and links with primary care regarding recognition of complications including under or overdose of intrathecal drugs. Patients and carers need to be educated about expected effects and complications of IDD.

Risks of failure to implement these guidelines

Patient Safety	Injury to patients, failure to adequately manage severe cancer- associated pain
Quality	Poor patient experience and clinical outcomes, complaints, impact on CGC rating
Infection Prevention	Increased risk of infection occurring or not being managed appropriately

Equipment	Incorrect or inadequate equipment procurement or equipment use
Workforce	Inadequate staff numbers, skill-mix and knowledge
Coordination of care between disciplines	Lack of coordination of care/support between disciplines for staff, leading to poor outcomes and patient experience
Service access	Lack of knowledge of referral and management pathways meaning poor access and outcome
Advanced care planning	Difficulties with pumps refills at end of life leading to poor outcomes and patient and family experience

## Guidelines

# A: Core competencies for practitioners in Pain Medicine

## Knowledge

- Knowledge of the science related to IDD;
- Knowledge of evidence-base for IDD in different pain conditions and spasticity including indications and contraindications for adults and children with cancer pain, non-cancer pain and neurological conditions;
- Knowledge of the pharmacology of intrathecal drugs;
- Understanding of practical aspects of using IDD devices and interactions with other devices and equipment;
- Understanding bio-psychosocial aspects of the patient's presentation that may influence outcome from IDD and that may need to be managed to support IDD;
- Knowledge of local referral pathways for patients being considered for IDD therapy;
- Understanding the need for timely referral for consideration of IDD therapy in selected patients with limited life expectancy.

## Attitudes and behaviours

- Effective communication with patients, families and carers;
- Effective communication with other healthcare professionals in primary and secondary care e.g. general practitioners, surgical specialties for assessment and treatment of urgent complications, neurologists, rehabilitation medicine physicians and/or paediatricians for patients with spasticity and communication with other specialist teams offering IDD therapy;
- Appreciation of appropriate skills mix for multidisciplinary pain management.

## Skills

- Assessment of pain and spasticity at a level commensurate with clinical practice and case mix;
- Ability to work in a multidisciplinary team;
- Ability to recognise complications and refer to other appropriate teams and specialists when needed.

# **Appendix A: Curriculum**

- 1. Basic sciences related to IDD including
- a. spinal cord anatomy/physiology
- b. potential mechanisms of action of spinally administered drugs and pharmacology of intrathecal drugs and excipients
- c. recommendations of the international poly-analgesic consensus group regarding intrathecal drug selection and administration infection control
- 2. Indications and contraindications for IDD and their evidence base
- a. in adults
- b. in children

- 3. Patient selection, screening and preparation for referral to a team that can deliver IDD including consideration of issues that may affect the provision of IDD:
- a. physical problems
- b. psychological issues
- c. social aspects
- d. balanced assessment of benefits and risks
- e. comprehensive understanding of alternatives to IDD
- f. the need for test dosing and the ability to either perform test dosing or refer to a team that can undertake and evaluate test dosing
- g. management of patient, family and carer expectations
- h. provision of rehabilitative support following IDD
- 4. Interactions of IDD systems with
- a. medical, electrical and/or magnetic equipment e.g. diathermy, physiotherapy equipment
- b. MRI scanners
- c. other implanted devices e.g. cardiac pacemakers
- 5. Follow up care to
- a. be competent to be involved in pump refilling and programming if this is appropriate; this requires sufficient ongoing practice to maintain competencies as serious adverse events can occur due to drug refill and/or programming errors
- b. recognise and manage symptoms including increased pain that may indicate the requirement for dose titration or drug switching
- c. recognise when further investigation may be needed either in relation to new symptoms, exacerbation of old symptoms or IDD device problems
- d. recognise, plan for and manage IDD pump replacements
- 6. Recognition of complications
- a. related to the patient
- b. related to the individual drug or drug combination
- c. related to the IDD device

## B: Competencies for practitioners in pain medicine who are involved in an IDD service

## Knowledge

- Knowledge of the science related to IDD;
- Knowledge of evidence-base for IDD in different pain and neurological conditions including indications and contraindications;
- Knowledge of contextual and practical considerations in assessment of patients with chronic pain and/or spasticity for IDD;
- Knowledge of the pharmacology of all classes of drugs that are used for IDD including the recommendations of the international poly-analgesic consensus group concerning the choice of drugs;
- Knowledge of contextual and practical considerations in provision of IDD and aftercare of patients with IDD;
- Understanding of practical aspects of using IDD devices including complex programming;
- Understanding IDD system interactions with other devices and equipment;
- Understanding bio-psychosocial aspects of pain that may influence outcome from IDD;
- Understanding the need for effective multidisciplinary working;
- Understanding of organisational aspects of provision of an IDD service;
- Understanding of funding arrangements for IDD therapy including funding of drug provision and revision surgery for catheter related problems or pump replacement.

## Attitudes and behaviours

- Effective communication with patients, families and carers;
- Effective communication with other healthcare professionals in primary and secondary care e.g. palliative care, surgical, paediatric and neurology teams, community neuro-rehabilitation and physiotherapy teams;

- Effective communication and liaison with support services e.g. pharmacy, radiology, microbiology;
- Appreciation of appropriate skills mix for multidisciplinary pain management;
- Ability to take effective leadership and liaison role in provision of IDD services;
- Ability and motivation to regularly monitor developments in IDD that is an evolving technique and the ability to respond to new information and changing recommendations for good practice;
- Commitment to audit the use of IDD and to modify clinical practice in the light of research and audit data.

#### Skills

- Accurate assessment of pain and spasticity;
- Ability to work in a multidisciplinary team;
- Ability to perform necessary practical procedures for safe, effective evidence-based practice including the surgical skills appropriate to IDD;
- Ability to assess the efficacy of IDD trials and select appropriate devices and techniques;
- Ability to refill and programme ITTD systems with sufficient case load and case mix to maintain competencies;
- Ability to recognise and manage complications and refer to other appropriate teams and specialists when needed;
- Radiographic interpretation of catheter and pump placement and the ability to use IT radiographic contrast via the pump when this facility exists.

## **Appendix B: Curriculum**

- 1. Basic sciences related to IDD including potential mechanisms of action of drugs
- a. spinal anatomy and fluoroscopic appearances during IDD
- b. effects of changes in the dynamics of CSF flow that can occur in patients with obstructive lesions e.g. after spinal cord trauma or malignancy
- c. pharmacology of spinal drugs and their delivery
- d. infection control
- 2. Indications and contraindications for IDD and their evidence base for pain and spasticity
- a. in adults
- b. in children
- 3. Patient selection, screening and preparation for therapy
- a. physical
- b. psychological
- c. social
- d. balanced assessment of benefits and risks
- e. comprehensive understanding of alternatives to IDD therapy
- f. management of patient, family and carer expectations
- g. delivering IDD as part of wider rehabilitative intervention
- 4. Interactions of IDD systems with
- a. medical, electrical and magnetic equipment e.g. diathermy, physiotherapy equipment
- b. MRI scanners
- c. other implanted devices e.g. cardiac pacemakers
- 5. Indications for trial of IDD and evaluation of trial outcomes
- 6. Indications for different IDD systems e.g. selection of fixed rate or totally programmable system; use of patient controlled intrathecal bolusing
- 7. Basic skills in
- a. patient positioning
- b. asepsis and infection control (hand hygiene, MRSA screening, antibiotic prophylaxis, surgical asepsis)
- c. familiarity with implanted IDD components

- d. techniques of accessing the intrathecal space
- e. fluoroscopic placement of spinal catheter
- f. primary surgical techniques including securing catheter, tunnelling, pocket formation and wound closure
- g. assessment of healing of wounds
- h. surgical skills needed for revision surgery
- 8. Programming and assessment of initial response to treatment
- 9. Follow up care including
- a. understanding IDD programming and diagnostics and the ability to demonstrate skills in these areas
- b. recognition and management of symptoms including increased pain that may indicate the requirement for reprogramming or revision of system
- c. recognition of when further investigation is needed either in relation to new symptoms, exacerbation of old symptoms or IDD device problems
- d. ability to recognise symptoms and signs of possible catheter granuloma
- e. recognition and management of IDD pump end-of-life
- 10. Recognition and management of complications
- a. related to the patient
- b. related to drugs
- c. related to the IDD device
- 11. Understanding of when to refer patients to other teams or specialists
- a. related to failure of IDD to provide adequate analgesia
- b. in the case of complications following IDD
- c. if new pain problems occurring after IDD
- 12. Audit should be supported by pain medicine specialists so that
- a. clinicians delivering IDD can collect data regarding indications for therapy, details of devices used, effectiveness of therapy and adverse events
- b. patients can be given unit specific outcome and complication data to inform their decision about whether to proceed with IDD
- 13. Pain medicine specialists delivering IDD therapy should be involved in
- a. defining appropriate protocols for continued support, surveillance and reprogramming of systems within their own service
- b. arranging formal collaboration with appropriate other local services e.g. surgeons, radiologists and microbiologists so that a seamless on call system is in place to deal with complications
- c. development of local and regional recommendations for good clinical practice in IDD based on best available evidence

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