

Short title: Responsibility for co-prescription of oral and intrathecal opioids

Introduction

The long-term intrathecal delivery of drugs is an established, evidence-based therapy for the management of refractory spasticity and cancer pain. The role of intrathecal therapy in chronic non-cancer pain is controversial and evidence for long term efficacy and safety is more limited.

The rationale is that drugs delivered directly to the site of action in the central nervous system, can achieve improved effect and fewer adverse effects, at only a small fraction of an equivalent systemic dose. (1,2,3,4) Where alternative routes of drug administration are available and tolerated, there are no firm grounds on which to expect that intrathecal administration would be associated with improved patient outcomes.

This modality of treatment is an invasive intervention, which is costly and labour-intensive, with potential for serious risks and complications: the balance of risk and benefit demands careful consideration.

Education of the patient increases their understanding of the potential benefits, risks and their responsibilities: the patient must be motivated to participate in the management plan, and consent to all aspects of the treatment. Discussion regarding the expectations for reduction in oral opioid with successful intrathecal treatment should occur, and the outcomes documented.

Both physician and patient should be aware of current data relating to safety and potential neurotoxicity of proposed intrathecal medications. (5,6,7)

Intrathecal opioid administration in patients with chronic non-cancer pain (CNCP)

Effective management of intrathecal opioid therapy requires rigorous appropriate patient selection- that should include comprehensive, multidisciplinary assessment of symptoms, disease, psychological and social factors, current and previous treatments and other treatment options.

Patients must have a clear sociopsychobiomedical formulation for their pain for which less-invasive modalities of management (including psychological and physical therapies) have failed.

The treating physician must be experienced with the therapy and device(s) to be utilised and must adhere to [PS11 \(PM\) Procedures in pain medicine clinical care standard](#). They should preferably have FPM Endorsement for Category 3 procedures.

This modality is optimally initiated, managed and supervised by appropriately trained and experienced specialist pain medicine physicians (SPMPs). However, it is recognised that other craft groups such as neurosurgeons, anaesthetists and palliative care physicians may develop appropriate skills in initiation, supervision, and management, and that some primary care physicians may develop skills in management of this modality.

Allocation and delegation of responsibility

The SPMP who is managing or supervising a patient with an implanted intrathecal analgesic infusion pump or port with attached ambulatory pump has the overall responsibility for all opioid prescriptions for that patient in a shared care model with primary care physicians (GP) and other specialists.

Other clinicians should not initiate or modify opioid therapy in these patients without discussion with the SPMP, including planning of reduction of oral opioids.

Where, by mutual agreement, the actual prescription for oral opioids has been delegated to another treating doctor, the SPMP retains responsibility for the appropriateness of the patient's opioid regimen in the context of an overall pain management program.

It is recognised that other pain conditions and any other acute medical or surgical problems that may arise should be managed according to clinical need. Necessary interventions may include regular and time-limited emergency oral or parenteral analgesic therapy. Timely communication with the responsible SPMP should then occur, once the acute problem has been stabilised.

Ongoing pain-related drug therapy, especially with opioid analgesics, should be discussed with and endorsed by the SPMP.

Real time prescription monitoring should be used, when available, before prescribing any opioid, by any route to a patient on intrathecal opioids.

Local regulatory permits should recognise the shared care context when oral and IT opioid formulations are co-prescribed.

References

1. Wallace M, Yaksh TL. Long-term spinal analgesic delivery: a review of the preclinical and clinical literature. *Reg An & Pain Med* 2000; 25(2): 117-57.
2. Deer TR, Pope JE, Hayek SM, Lamer TJ, Veizi IE, Erdek M, et al. The Polyanalgesic Consensus Conference (PACC): Recommendations for Intrathecal Drug Delivery: Guidance for Improving Safety and Mitigating Risks. *Neuromodulation : journal of the International Neuromodulation Society*. 2017;20(2):155-76.
3. Deer TR, Pope JE, Hayek SM, Bux A, Buchser E, Eldabe S, et al. The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines. *Neuromodulation : journal of the International Neuromodulation Society*. 2017;20(2):96-132.
4. Deer TR, Hayek SM, Pope JE, Lamer TJ, Hamza M, Grider JS, et al. The Polyanalgesic Consensus Conference (PACC): Recommendations for Trialing of Intrathecal Drug Delivery Infusion Therapy. *Neuromodulation : journal of the International Neuromodulation Society*. 2017;20(2):133-54.
5. Schultz DM, Orhurhu V, Khan F, Hagedorn JM, Abd-Elsayed A. Patient Satisfaction Following Intrathecal Targeted Drug Delivery for Benign Chronic Pain: Results of a Single-Center Survey Study. *Neuromodulation : journal of the International Neuromodulation Society*. 2020;23(7):1009-17.
6. Hatheway JA, Caraway D, David G, Gunnarsson C, Hinnenthal J, Ernst AR, et al. Systemic opioid elimination after implantation of an intrathecal drug delivery system significantly reduced health-care expenditures. *Neuromodulation : journal of the International Neuromodulation Society*. 2015;18(3):207-13; discussion 13.
7. Hamza M, Doleys D, Wells M, Weisbein J, Hoff J, Martin M, et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain medicine*. 2012;13(10):1304-13.

Faculty of Pain Medicine Professional Documents

POLICY – A document that formally states principle, plan and/or course of action that is prescriptive and mandatory.

STATEMENT – A document that describes where the college stands on a particular issue. This may include areas that lack clarity or where opinions vary. A statement is not prescriptive.

GUIDELINE – A document that offers advice on a particular subject, ideally based on best practice recommendations and information, available evidence and/or expert consensus. A guideline is not

This document has been prepared having regard to general circumstances, and it is the responsibility of the practitioner to have express regard to the particular circumstances of each case, and the application of this policy document in each case.

Professional documents are reviewed from time to time, and it is the responsibility of the practitioner to ensure that the practitioner has obtained the current version. Professional documents have been prepared having regard to the information available at the time of their preparation, and the practitioner should therefore have regard to any information, research or material which may have been published or become available subsequently.

Whilst the College and Faculty endeavours to ensure that documents are as current as possible at the time of their preparation, they take no responsibility for matters arising from changed circumstances or information or material which may have become available subsequently.

Promulgated: April 2023
Reviewed: November 2023
Date of current document: November 2023

© Copyright 2023 – Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists

*This work is copyright. Apart from any use as permitted under the Copyright Act 1968, no part may be reproduced by any process without prior written permission from ANZCA. Requests and inquiries concerning reproduction and rights should be addressed to the Chief Executive Officer, Australian and New Zealand College of Anaesthetists, 630 St Kilda Road, Melbourne, Victoria 3004, Australia. Email: ceoanzca@anzca.edu.au
Website: www.anzca.edu.au*