Journal of Pain Research

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ORIGINAL RESEARCH

Examining the Effects of Interventional Pain Management Staff Controlled Substance Agreement Education for Patients with Chronic Non-Cancer Intrathecal Drug Delivery Device Opioid Therapy: A Retrospective Review

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Background: Intrathecal drug delivery systems (IDDS) are effective tools for the management of chronic non-cancer pain, cancer-associated pain, and spasticity. Given the overall risks of opioid medications, it is imperative that IDDS opioid-infusion patients receive education regarding the risks versus benefits of their intrathecal opioid medications and that controlled substance agreements (CSAs) are utilized to both educate patients and hold them accountable for keeping IDDS programming visits, refill appointments, or other IDDS maintenance appointments.

Methods: A retrospective electronic medical record (EMR) review study was conducted at an interventional pain management practice, quantifying the number of non-cancer chronic pain IDDS opioid therapy patients with signed CSAs. An educational intervention was conducted to increase staff awareness regarding compliance with CSAs and the location of proper CSA documentation within the EMR. Follow-up EMR review and provider knowledge assessment surveys were deployed to assess the success of the intervention.

Results: Staff knowledge of CSAs increased from 14.3% (3/21) to 45.5% (10/22) following CSA education while their ability to locate CSAs within the EMR also increased from 38.1% (8/21) to 40.9% (9/22). Post-education intervention, rates of CSA documentation improved from 4.5% to 74.5%. Lastly, there was a 39.5% reduction in rescheduled IDDS appointments within the patient population studied.

Conclusion: The results of this study suggest potentially profound impacts that a simple education intervention can have on staff knowledge and compliance with CSA documentation for patients receiving IDDS opioid therapy for chronic non-cancer pain. Furthermore, implementation of CSAs for this patient population may be associated with a decrease in the number of missed, no-show, or rescheduled IDDS maintenance appointments, which have important patient safety implications. Further research is warranted to investigate the impact of CSA compliance on adverse patient outcomes and the potential cost-savings practices with required CSAs.

Keywords: controlled substance agreements, intrathecal drug delivery device, opioid therapy

Introduction

Intrathecal Drug Delivery Systems (IDDS) are currently utilized to deliver medications to the intrathecal space, effectively providing relief from chronic non-cancer pain, cancer-associated pain, or spasticity.[1] Chronic non-cancer pain conditions amenable to IDDS may include non-surgical low back pain, failed back surgery syndrome, phantom-limb

Received: 8 February 2025
Accepted: 18 May 2025
Published: 26 May 2025

pain or complex regional pain syndrome.[1] Spasticity is characterized by increased muscle tension/rigidity and associated with involuntary movement or contractures.[1] Intrathecal morphine administration for cancer pain in humans was first described in 1979 with the first usage of intrathecal pump implantation for cancer pain being described shortly thereafter in 1981.[2,3] In the 1990s, indications for IDDS usage expanded to include non-cancer painful conditions.[4] While published research has shown a dramatic decline of 54% in the use of IDDS for cancer-related pain between the years of 2014 to 2024, the Polyanalgesic Consensus Conference (PACC) continues to regularly update and publish guidelines for the management of both cancer and non-cancer pain with IDDS.[5–7]

IDDS can infuse a variety of medications, however, morphine, ziconotide, and baclofen remain the three medications approved by the Food and Drug Administration (FDA) for intrathecal use.[1] While many efforts have been made to implement formal controlled substance agreements (CSAs), amongst other measures, for those patients receiving *oral* opioid therapy for chronic pain and/or cancer-related pain to prevent opioid misuse, abuse, or diversion there is a paucity of research on the topic of CSAs for patients receiving opioid therapy via IDDS.

There are significant benefits to IDDS opioid therapy including improved pain, ability to avoid oral pain medications or analgesics, a reduction in opioid-related side effects, and more.[1] However, the risks of intrathecal opioids are also well-documented; drowsiness, hyperalgesia, respiratory depression, suppression of the hypothalamic-pituitary axis, nausea, vomiting, and pruritis amongst others.[1] Thus, it would seem reasonable for potential IDDS opioid therapy patients to receive pre-implant education on both the potential benefits and risks of IDDS opioid therapy as well as expectations regarding IDDS implants. These expectations may include, but are not limited to, compliance with scheduled return visits including those for pump refills, agreement to not consume oral opioids or other analgesics without the implanting provider's approval (given concerns for drug–drug interactions or opioid overdose), and reporting of adverse side effects from the therapy.

While it may seem excessive to establish CSAs for those patients receiving IDDS opioid therapy, there have been case-reports of patients penetrating the pump or catheter to gain access to medications.[8] Another case report highlights the possibility of respiratory failure following delayed intrathecal morphine pump refill.[9] In general, for issues of patient education, safety, and compliance, it makes logical sense to require CSAs prior to, or at the time of IDDS implant, and to review/update CSAs on an annual basis. Currently, no guidelines exist which recommend CSAs specifically for IDDS patients. Further, existing researching has shown conflicting results regarding the effectiveness of opioid treatment agreements or CSAs.[10,11] Despite this, multiple professional societies and organizations continue to support the use of CSAs for patients receiving opioid therapy, including the 2023 American Society of Interventional Pain Physicians (ASIPP) evidence-based consensus guidelines for the prescription of opioids for chronic non-cancer pain.[12]

This study sought to accomplish the following objectives:

1) To study the number of patients within an academic medical center interventional pain management practice receiving IDDS opioid therapy for chronic non-cancer pain and to determine whether these patients had an established CSA documented.
2) To assess the impact of an educational interventional on pain medicine staff knowledge on the importance of CSAs for IDDS patients and their knowledge of the documented CSA location within the electronic medical record (EMR).
3) To study any change in the number of non-cancer IDDS opioid therapy patients who no-showed, missed, or rescheduled pump follow-up or refill/maintenance appointments pre- and post- implementation of required signed CSA and associated patient education.

The study authors hypothesized that a department-wide CSA education intervention would increase staff awareness of the importance of CSAs for IDDS opioid therapy patients and result in improved staff and patient compliance with documented updated CSAs and, secondarily, a reduction in no-show, missed, or rescheduled IDDS-related appointments.

Methods

This retrospective review study was conducted between February and December of 2020 at the Mayo Clinic in Rochester, Minnesota and was deemed exempt from the site's Institutional Review Board (IRB) given the low-risk nature of EMR patient chart review and collection of internal staff survey data. No additional patient consent was required by the IRB as review of CSAs is often part of standard care for all patients receiving controlled substances. All patient data was de-identified using unique alphanumeric codes for tracking and the study was conducted in compliance with the Declaration of Helsinki.

Baseline Retrospective Electronic Medical Record Chart Review

Manual chart review of all current interventional pain medicine IDDS patients, using the institution's EMR system – EPIC was conducted to identify those receiving IDDS opioid therapy for treatment of chronic non-cancer pain. The review was completed by two registered nurses within the practice and an EPIC support specialist. The primary author of this study (CH) confirmed findings. The Inclusion criteria were adult patients with IDDS opioid therapy for chronic non-cancer pain. The exclusion criteria were patients under the age of 18 and those with IDDS infusing baclofen only or patients with IDDS opioid therapy for cancer-related pain. Cancer-pain IDDS patients were excluded from this initial study to minimize confounding variables as their care and/or pain is managed by multiple departments (ie, hematology, oncology, primary care, palliative care, and interventional pain medicine). Abstracted data included the following: documentation of a CSA contract between January 2019 and February 2020 and whether the CSA contract was signed by an internal pain medicine provider versus an outside department or clinician. We also abstracted the number of rescheduled pump maintenance (refill, rate adjustment, or other) or pump-associated follow-up appointments which included missed and no-show appointments as well as patient-initiated rescheduled appointments in the year of 2019.

Education Intervention

The primary intervention of this study was a single thirty-minute educational presentation provided to staff physicians, advanced practice providers, and nurses of the department at a March 2020 face-to-face department-wide monthly meeting. A staff physician and advanced practice provider conducted the educational presentation. The content included 1) why CSAs for IDDS opioid therapy patients are important and what the CSA agreement entails, 2) when CSAs for IDDS opioid therapy should be obtained (prior to or at the time of implant by implanting physician or advanced practice provider care team member and subsequently updated annually), and 3) where CSAs are located within the EMR.

The components of the CSA agreement were thoroughly reviewed, including, but not limited to, the importance of patients keeping their scheduled IDDS follow-up/maintenance appointments, the patient disclosure and approval of any oral opioid therapies by the IDDS implanting care team, and the right of the practice to request routine or random urine drug screens. The importance of CSAs for IDDS opioid therapy was explained by emphasizing the risks of opioid abuse, misuse, or diversion in addition to highlighting the possible ramifications of patients no-showing, missing, or rescheduling their IDDS follow-up/maintenance/refill appointments (ie, risks of opioid withdrawal, pump malfunction, wasted intrathecal medications). The department also discussed a protocol for patients who may not abide by the CSA policy. It was mutually agreed that any decisions of voiding a CSA for a non-cancer chronic pain IDDS opioid therapy patient would be at the discretion of the implanting provider and his/her associated care team, including the advanced practice provider and nursing staff. If this decision was made, the care team may choose to wean/discontinue the patient's IDDS opioid therapy. The educational content was delivered via PowerPoint, and a computer was utilized throughout the presentation to visually show staff how to navigate within the EMR to locate signed/documented CSAs.

Staff Knowledge Survey

A baseline and six-month post-intervention anonymous CSA knowledge assessment survey was sent to all pain medicine staff physicians, advanced practice providers, and nurses, involved in the care of IDDS patients, to assess the

effectiveness of the CSA education intervention. Trainees were excluded from survey distribution. The survey consisted of two questions: 1) My IDDS opioid therapy non-cancer chronic pain patients consistently have an updated CSA on file with this practice or another department/practice, and 2) I can find an updated CSA in the EPIC system for my intrathecal pump patients. Responders were able to answer if they agreed, disagreed or were uncertain for each of the two statements.

Results

Pre-CSA Department Education Intervention

22 patients were identified as currently receiving IDDS opioid therapy for chronic non-cancer pain. Following identification, the 22 patients' charts were reviewed for a signed CSA within the past 12 months. Of those 22 patients, 77.3% (n = 17) had no CSA on file, 4.5% (n = 1) had an updated CSA with the pain clinic, two had CSAs on file external to the pain clinic (eg, with their primary care provider), and 9.1% (n = 2) had outdated CSAs with the pain clinic (Figure 1). Next, each of the 22 IDDS opioid therapy patients with non-cancer chronic pain were chart reviewed for rescheduled appointments, including intrathecal pump refill appointments. In 2019, the 22 patients had a total of 43 rescheduled appointments.

The pain medicine staff baseline CSA knowledge assessment survey was deployed to 14 staff physicians, six advanced practice providers (APPs), and six registered nurses for a total of 26 clinical staff. 21 responses to the baseline CSA survey were obtained, resulting in a 80.8% survey response rate (21/26 staff responses) (Figure 2).

Post-CSA Department Education Intervention

At the conclusion of this study, 10.5% (n = 2) of the target patients requiring baseline or updated CSA for IDDS opioid therapy for chronic non-cancer pain were deceased, reducing the target patient population (those without a signed or updated CSA) from 19 to 17 total patients. Of those 17 patients, 76.5% (n = 13) had an updated CSA with the pain clinic post-educational intervention, 5.9% (n = 1) had an outdated CSA with the division, 11.7% (n = 2) had found an external provider for pump maintenance, and 5.9% (n = 1) was being treated out of state due to the COVID19 pandemic (Figure 3).

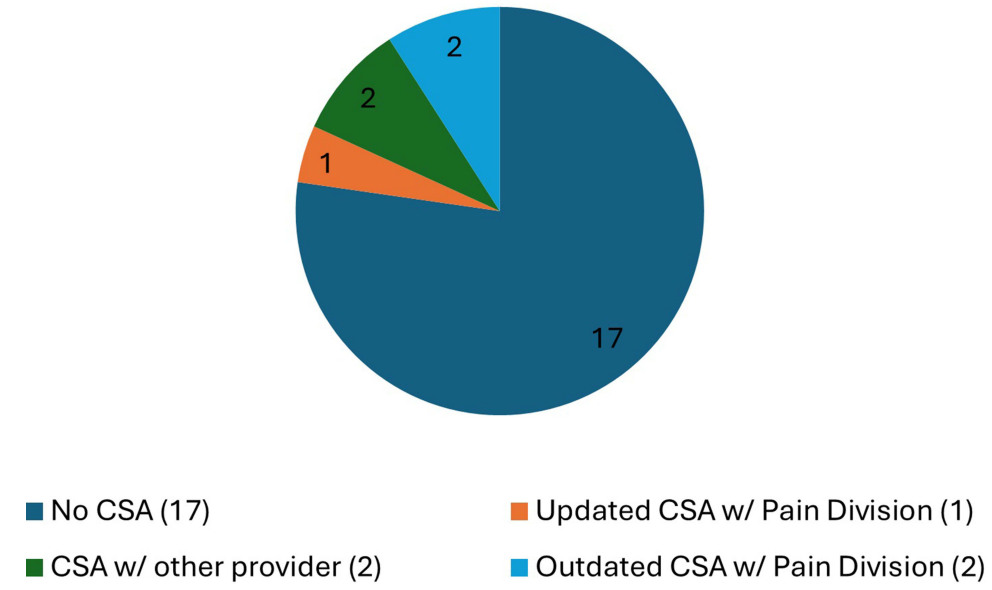

Figure 1 Pie chart showing the pre-education intervention number of CSAs for IDDS opioid therapy patients with chronic non-cancer pain. 17 patients with no CSA; 2 patients with CSAs outside of the pain division (ex. CSA with a primary care provider); 1 patient with an updated CSA within the pain division; 2 patients with outdated CSAs within the pain division. 22 patients total.

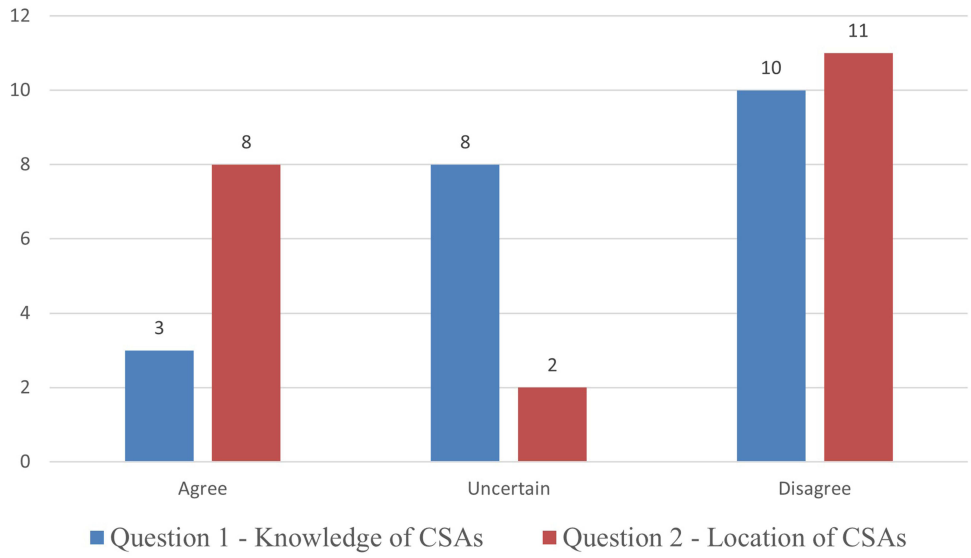

Figure 2 Bar graph depicting the baseline survey results for pain medicine staff. Staff answered the following two questions: 1) My IDDS opioid therapy non-cancer chronic pain patients consistently have an updated CSA on file with this practice or another department/practice, and 2) I can find an updated CSA in the EPIC system for my intrathecal pump patients.

The results indicated an improvement from a baseline 4.5% of patients with an updated CSA on file for IDDS opioid therapy for chronic non-cancer pain to 76.5% with an updated CSA. Furthermore, the number of missed, no-show, or rescheduled IDDS-related appointments for this patient population decreased from 43 in 2019 to 26 in 2020; a 39.5% decrease.

The results from the six-month post-education intervention follow-up staff CSA survey are illustrated in Figure 4. The response rate improved from 80.8% (21/26) to 84.6% (22/26). Regarding knowledge of CSAs for IDDS non-cancer chronic pain opioid patients, the number of staff agreeing with this statement increased from 14.3% (3/21) at baseline to 45.5% (10/22) at follow-up. Regarding staff knowledge of the location of CSAs within the EPIC EMR, the number of staff agreeing with this statement increased from 38.1% (8/21) at baseline to 40.9% (9/22) at follow-up.

Discussion

This study suggests that an educational intervention to bring staff awareness to the topic of CSAs for patients with IDDS opioid therapy for non-cancer chronic pain may 1) increase staff knowledge of and compliance with CSAs for patients with IDDS opioid therapy for non-cancer chronic pain, 2) increase staff awareness of the location of CSAs in the EMR, and 3) reduce the number of no-show, missed, or rescheduled IDDS-related appointments. While the benefits of staff awareness regarding the use of CSAs and the location of CSAs in the EMR are important, the benefit for pain practices in reducing rescheduled appointments is also significant. Rescheduled pain clinic appointments can result in delayed patient care, inefficient utilization of provider and staff time, reduced revenue, and more. Thus, any simple interventions which result in a reduction in missed, no-show, or rescheduled appointments are noteworthy.

In this study, the noticeable decrease (39.5%) in the number of cancelled, missed, no-show, or rescheduled pump-associated appointments for IDDS opioid therapy patients with non-cancer chronic pain, pre- and post- implementation of required signed CSA and CSA education, could be the result of several factors. For example, the COVID-19 shelter-in-place went into effect in March of 2020, which was around the time of study initiation. Therefore, clinic appointments were not as readily available to patients and pump patients may have been less likely to miss, no-show, or reschedule their appointments. On the other hand, following the staff CSA education intervention, it is possible that staff began to educate this patient population more thoroughly on the importance of keeping pump-associated clinic appointments, including the safety implications, thus resulting in the decrease in rescheduled appointments.

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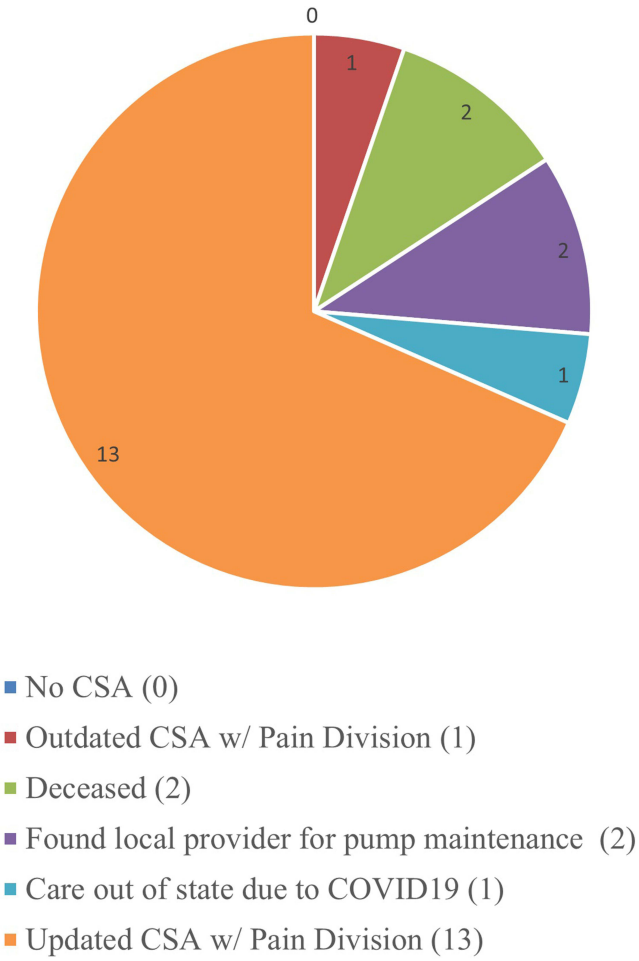

Figure 3 Pie chart showing post-intervention CSAs for IDDS opioid therapy patients with chronic non-cancer pain. 13 patients had an updated CSA with the pain division; 1 patient was receiving care out-of-state due to COVID-19; 2 patients had found local providers for pump maintenance and were no longer under the care of the pain division; 2 patients were deceased; 1 patient had an outdated CSA with the pain division; 0 patients had no CSA on file.

Given the well-known risks of IDDS opioid therapy, it is imperative that pain clinics utilizing this interventional treatment begin requiring CSAs. A baseline CSA should be obtained prior to or at the time of IDDS implant and updated on an annual basis. Patients should receive education on the components of the CSA including: 1) agreement to not take oral opioids unless prescribed/approved by the IDDS managing care team, 2) the agreement to not utilize illicit substances while receiving IDDS opioid therapy, 3) the importance of keeping follow-up IDDS-related clinic appointments (including intrathecal pump refills), and 4) agreement to inform the IDDS managing care team if any side effects should develop from the therapy. A clear discussion with the patient should be held about the risks of not abiding by the stipulations of the CSA including the possibility of weaning/discontinuation of the intrathecal opioid medications.

Strengths

Strengths of this study include the high response rates to the clinician and nursing baseline and follow-up surveys; 80.8% and 84.6%, respectively. Additional strengths include the ability to track all patients within the same EMR (EPIC) and the fact that no patients were lost to follow-up.

Limitations

Limitations of the study include failure to account for oral opioid therapies, the exclusion of IDDS opioid therapy for cancer-pain patient population, and the overall small number of total CSAs for the studied patient population within the study timeframe. However, given the success of this initial study, the study could be repeated with expansion to include

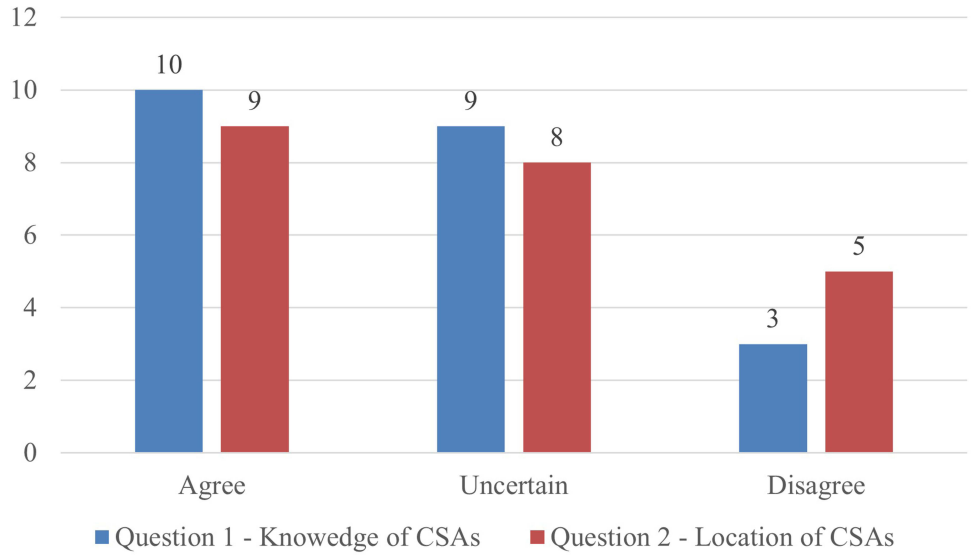

Figure 4 Bar graph depicting the post-education intervention staff CSA survey responses. Staff re-answered the following two questions: 1) My IDDS opioid therapy non-cancer chronic pain patients consistently have an updated CSA on file with this practice or another department/practice, and 2) I can find an updated CSA in the EPIC system for my intrathecal pump patients.

tracking of oral opioid consumption of IDDS chronic non-cancer pain opioid therapy patients as well as those receiving IDDS opioid therapy for cancer-related pain. Certainly, the most evident limitation of this study is that it did not include long-term follow-up data collection beyond six months, thereby presenting the risk of a "recency effect" of the educational intervention. Lastly, following the department-wide CSA education intervention, the number of staff agreeing with the importance/knowledge of CSAs increased by an n = 7 while the number of staff agreeing with their knowledge of the location of proper EMR CSA documentation only rose by n = 1. It would be helpful to replicate the study with a larger group of interventional pain staff members and more specifically track the roles/credentials (ie, physician, advanced practice provider, or nurse) of the survey responder.

Future Directions

Given the primary role of CSAs are for risk mitigation of high-risk medications and, thereby, patient safety, future iterations of this study should aim to track cost avoidance through improved safety outcomes (ie, avoidance of missed refills, adverse events, pain ratings, emergency department visits). Further, more clearly quantifying the impact of this study by tracking the quantity and type of any wasted intrathecal medications, due to missed, no-show, or rescheduled appointments is recommended. Future studies should also consider the duration of the effects of the educational intervention, which can be accomplished through longer-term follow-up data collection, as well as broadening the study patient population to include cancer patients.

Conclusions

This study has suggested that a simple educational intervention targeting staff who care for patients with IDDS opioid therapy for chronic non-cancer pain might improve staff CSA knowledge and compliance with CSA documentation. Further, staff CSA education interventions may result in a reduction in no-showed, missed, or rescheduled appointments for this patient population, thus improving pain practice efficiency, effectiveness and reducing overall costs.

Funding

No funding was received for any portion of the submitted work.

Disclosure

Chelsey Hoffmann, PA-C, MS, RD provides general consulting for Nalu Medical. Michael E Schatman is a senior medical advisor for Apurano Pharma. The authors report no other conflicts of interest in this work.

References

1. Shah N, Di Napoli R, Padalia D. Implantable intrathecal drug delivery system. StatPearls. 2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538237/. Accessed May 21, 2025.
2. Wang JK, Nauss LA, Thomas JE. Pain relief by intrathecally applied morphine in man. *Anesthesiology*. 1979;50(2):149–151. doi:10.1097/00000542-197902000-00013
3. Onofrio BM, Yaksh TL, Arnold PG. Continuous low-dose intrathecal morphine administration in the treatment of chronic pain of malignant origin. *Mayo Clin Proc*. 1981;56(8):516–520.
4. Winkelmüller M, Winkelmüller W. Long-term effects of continuous intrathecal opioid treatment in chronic pain of nonmalignant etiology. *J Neurosurg*. 1996;85(3):458–467. doi:10.3171/jns.1996.85.3.0458
5. Chung M, Kalia H, Schatman ME, Robinson CL. Current challenges and potential solutions for targeted drug delivery in cancer pain management. *J Pain Res*. 2025;18:467–469. doi:10.2147/JPR.S514833
6. Deer TR, Pope JE, Hayek SM, et al. The polyanalgesic consensus conference (PACC): recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation*. 2017;20(2):96–132. doi:10.1111/ner.12538
7. Deer TR, Hayek SM, Grider JS, et al. The polyanalgesic consensus conference (PACC): intrathecal drug delivery guidance on safety and therapy optimization when treating chronic noncancer pain. *Neuromodulation*. 2024;27(7):1107–1139. doi:10.1016/j.neurom.2024.03.003
8. Burton AW, Conroy B, Garcia E, Solanki D, Williams CG. Illicit substance abuse via an implanted intrathecal pump. *Anesthesiology*. 1998;89(5):1264–1267. doi:10.1097/00000542-199811000-00032
9. Ruan X, Couch JP, Liu H, Shah RV, Wang F, Chiravuri S. Respiratory failure following delayed intrathecal morphine pump refill: a valuable, but costly lesson. *Pain Physician*. 2010;13(4):337–341. doi:10.36076/ppj.2010/13/337
10. Starrels JL, Becker WC, Alford DP, Kapoor A, Williams AR, Turner BJ. Systematic review: treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. *Ann Intern Med*. 2010;152(11):712–720. doi:10.7326/0003-4819-152-11-201006010-00004
11. Cheatle MD, Savage SR. Informed consent in opioid therapy: a potential obligation and opportunity. *J Pain Symptom Manage*. 2012;44(1):105–116. doi:10.1016/j.jpainsymman.2011.06.015
12. Manchikanti L, Kaye AM, Knezevic NN, et al. Comprehensive, evidence-based, consensus guidelines for prescription of opioids for chronic non-cancer pain from the American society of interventional pain physicians (ASIPP). *Pain Physician*. 2023;26(7S):S7–S126.