CALIFORNIA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

GUIDELINES FOR THE DEVELOPMENT OF STANDARDIZED PROCEDURES AND POLICIES

FOR NURSES, NURSE PRACTITIONERS, AND PHYSICIAN ASSISTANTS

PERFORMING IMPLANTED INTRATHECAL DRUG PUMP REFILLS

CASIPP's mission is to promote the development and practice of safe, high-quality, cost-effective interventional pain medicine techniques for the diagnosis and treatment of pain and related disorders, and to ensure patient access to these interventions. In pursuit of this goal, CASIPP provides clinical guidance to assist members of the interventional pain community to develop their practice specific policies and procedures. One of the most advanced pain therapies implemented by interventional pain physicians is intrathecal infusion of analgesic medications via an implanted pump. These implantable drug delivery systems (IDDS) are among the most time consuming therapies as the pumps require ongoing maintenance, reprogramming, and refill on average every 30 and 90 days. To accommodate these frequent visits and support adequate access to this form of therapy, it is common for practices to enlist the assistance of nurses, nurse practitioners, and physician assistants to perform the refills and pump reprogramming. Importantly, these episodes of care require specific expertise, as adverse events have been reported with pump management and refills. Although adverse events during a pump refill are rare, programming errors, procedural errors, and medication administration errors can all lead to patient harm during the refill process. In addition it is crucial to the safety of patients that the provider performing the refill be trained and knowledgeable not only in the physical mechanics of the pump refill but also be aware of the potential complications associated with intrathecal therapy so as to be able to take appropriate actions when a complication is identified or suspected. A recent nationwide survey of nurses, NP's, and PA's revealed that there was no standardized training process and that they often lacked appropriate supervision and mentoring accompanied by an unexpected number of pocket fills.[1]

This variation in training and supervision is in part due to the wide discrepancies in scope of practice from one state to the next. In California, the Physician Assistant Board, the Nursing Board, and Medical Board have stipulated specific guidelines with regards to scope of practice of nurses, NP's and PA's. While the scope of practice is different for each profession, all require additional training, supervision, and standardized procedural guidance provided by a managing physician to engage in implanted intrathecal pump refills. This document serves as a set of recommended practice guidelines specifically for physicians wishing to engage nurses, NP's and PA's in the refill of intrathecal pumps. These recommendations are to be used in concordance with the guidelines set forth by the appropriate board (Medical Board, Nursing Board, and Physician Assistant Board).

The committee tasked with developing these guidelines consisted of physicians and nurses from both private and academic centers treating both pain and spasticity disorders with implanted intrathecal pumps. The fundamental principle of these guidelines is that implantable intrathecal drug delivery is an advanced medical therapy requiring specialty training, experience, and management by a licensed physician (MD/DO) whom we will refer to in the remainder of this document as the "physician pump

manager". The physician pump manager should be clinically competent (defined in California Code of Regulations (CCR) Section 1480(c) as "…to possess and exercise the degree of learning, skill, care and experience ordinarily possessed and exercised by a member of the appropriate discipline in clinical practice.") and completed the minimum training requirements and maintenance of proficiency as set forth in the 2017 Poly-Analgesic Consensus Conference (PACC) guidelines.[2] To enlist the assistance of nurses, NP's and PA's in the care and refill of intrathecal pumps for patients with IDDS, the physician pump managers should ensure adequate training and experience of the individual healthcare provider performing the refill procedure. The physician pump manager should also provide detailed procedures, protocols, and policies involving the care of patients with implantable pumps as well as provide appropriate resources (supplies and personnel) and supervision to perform the procedure such that the nurse, NP or PA can contribute to the care of patients with IDDS in a safe and appropriate fashion. When a practice enlists the services of an independent nursing agency to perform pump refills, the medical director of the agency should ensure that the nurse, nurse practitioner or PA fulfil the recommended training and experience outlined in this document. However, the outpatient physician pump manager for the patient should continue to provide supervision of the patient's care. All patients with an IDDS should have an appropriately trained physician pump manager to provide medical direction regardless of the clinical environment. In the event a patient is being cared for at a facility without a trained physician pump manager, the attending physician at the facility should seek consultation from the patient's outpatient physician pump manager.

Whereas the management of a patient with an intrathecal pump including pump refills is the practice of medicine, the California legislature provided a mechanism for exemption for nurses, NPs, and PAs by passing a series of laws that allows non-physicians to perform functions which would otherwise be considered the practice of medicine. The statutes that specifically applies to non-physicians performing activities that are otherwise considered the practice of medicine rely primarily on the development of standardized procedures. Standardized Procedures are authorized in the Business and Profession Code, Nursing Practice Act (NPA) Section 2725 and further clarified in California Code of Regulation (CCR 1480). The organized health care system including clinics, physician's offices, and hospitals must develop standardized procedures permitting registered nurses, nurse practitioners, and PAs to perform standardized procedure functions. A registered nurse, NP, PA may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedure and must provide the system with satisfactory evidence that the nurse, NP, or PA meets its experience, training, and/or education requirements to perform the functions.

Below is a template for a Standardized Procedure that CASIPP has developed for intrathecal pump refills that our members and interventional pain community can use to develop their practice specific procedures and policies.

Standardized Procedure Guidelines for Intrathecal Pump Refills

1: This Standardized Procedure Guideline for Intrathecal Pump Refills was prepared by a task force of the California Society of Interventional Pain Physicians consisting of members of the CASIPP board of directors, faculty members from several California Academic Medical Centers, and nurses trained and practicing intrathecal pump refills at both academic and private practice settings. These guidelines rely on academic, society, and manufacturer formal training programs as well as published peer reviewed clinical and scientific evidence, with input from the manufactures of the intrathecal pumps themselves. These Standardized Procedure guidelines will be updated at regular intervals as needed based on current clinical / scientific evidence or with changes in the manufacturing or operation of the pumps. This Standardized Procedure Guideline for Intrathecal Pump Refills is approved by the California Society of Interventional Pain Physicians Board of Directors (signatures and date below)

2: This standardized procedure for Intrathecal Pump Refills applies to nurses, NP's and PAs as in accordance with the criteria set forth below and within the scope of practice of the licensing board of the individual provider.

3: Requirements including education, training, and experience which are to be followed by registered nurses, NPs, and PAs prior to performing intrathecal pump refills via this standardized procedure functions are listed below. Prior to engaging in IDDS refills, the physician pump managers should ensure that the nurse, NP, or PA has appropriate malpractice coverage for performing a pump refill procedure. This should be confirmed with the individuals specific malpractice carrier. The physician pump manager should also ensure that the nurse, NP, or PA has also received comprehensive IDDS didactic training and can attest that the individual commands a firm knowledge and understanding of the topics listed below. Training can be accomplished by combining training from the physician pump manager, medical society training (North American Neuromodulation Society, CASIPP etc), manufacture instruction material (Medtronic, Flowonix, etc), and peer reviewed IDDS journal articles including the most recent Poly-Analgesic Consensus Conference guidelines on IDDS therapy.[34] Topics that all providers engaged in pump refills should be well versed in include:

A: Sterile technique

B: Risks and benefits of IDDS

C: Indications and Contraindications of all makes and models of devices the provider will refill

D: Pharmacodynamics and pharmacokinetics of approved and off-label IDDS medications.

E: Providers should also be able to recognize common IDDS complications and initiate emergency management protocols.

F: The refill provider should also receive training in the conditional MRI labeling requirements for each make and model of pump the provider is assigned to refill.

G: The provider should have access to and be trained on the manufactures recommended refill procedures for each make and model the provider is asked to refill.

4: Supervision:

A: A physician pump manager should directly observe the provider perform a minimum of 20 refills for each make and model of IDDS pump prior to performing refills without direct supervision.

B: A physician pump manager should observe and confirm competency in pre-procedure evaluation of pump patients for adverse events or complications of IDDS therapy.

C: The provider should also be assessed in appropriate sterile refill techniques including skin / pump site preparation, sterile drapes, and sterile acquisition and emptying of the pump reservoir.

D: The physician pump manager should also assess for appropriate pre-refill evaluation and identification of the medications to be injected into the pump, as well as competency with interrogation and reprogramming of the pump.

E: If an ultrasound is used to aid in the refill process, a physician pump manager should ensure appropriate training on the use of an ultrasound machine for use with intrathecal pump refills and directly observe the non-physician provider use of the ultrasound during the pump refill process for a minimum of 20 ultrasound guided refills.

H: To maintain proficiency, the provider should perform a minimum of 10 refills per make and model every year. If the number of refills drops to below 10 per year per each make and model, the provider should have direct supervision by a physician pump physician manager during the refill process.

I: After the initial certification of competency remote supervision is appropriate via phone, however, prior to making changes to the dosing program, the non-physician provider should first discuss and receive direction from the physician manager or physician designee.

J: Writing for refill prescriptions for identical medications should conform to professional board regulations. For example, writing for controlled substances for administration in pumps requires that physicians sign the prescription if a RN is performing the refill. PAs need to provide the name of the supervising physician on the script, and NPs should consult with physician pump manager prior to prescribing or refilling any controlled substances as stipulated by the California Nursing and Pharmacy boards. A valid DEA number is required for all providers providing prescriptions for controlled substances. Non-physician providers should also consult with the physician pump manager prior to changing daily dose, concentration, or composition of the intrathecal medications. The physician pump manager may authorize the non-physician provider to make small adjustments in dosage without being consulted provided the range of medication adjustment is stipulated in the practice specific standardized procedure.

K: A physician pump manager should conduct yearly evaluations of each non-physician provider to confirm provider has maintained competency and is knowledgeable about latest alerts and IDDS updates provided by the manufacturer and reported in the medical literature.

L: Physician pump managers should perform regular chart reviews and evaluate the patients once a year.

5: Specialized circumstances under which the non-physician provider is to immediately communicate with a patient's physician pump manager concerning the patient's care includes but is not limited to:

A: The presence of rash and/or skin breakdown over the pump site

B: Fluid collection around the pump

C: Significant tilting / rotation of the pump

D: The presence of bacteremia or localized infection

E: The presence of any alarms or pump residual volume discrepancies greater than 2 ml.

F: Any new neurological signs or symptoms that may be due to over or under infusion before, during, or after the pump refill

G: Any change in the neurological exam that would suggest the presence of a granuloma

G: Difficulty accessing the pump.

H: If the patient becomes unstable during the refill procedure the provider should call 911 for emergency transport to the nearest emergency room and alert the physician pump manger.

6: Resources non-physician providers should have available prior to performing IDDS refill:

A: The manufactures approved refill kit or appropriate sterile non-coring access needle and pump template

B: Supplies needed to perform a sterile procedure including aseptic skin prep solution, sterile drapes, sterile gloves, sterile syringes, syringe filter, and locking extension tubing, and if needed, local anesthetic should all be available prior to starting the refill procedure. Some physician pump managers might also require the use of barrier precautions including the use of a hat, mask, and/or gown.

C: Commercially available medications should be used when possible and compounded medications should be used only when obtained from a compounding pharmacy licensed by the state to provide sterile medication according to the standards set by United States Pharmacopeia (USP) chapter 797.[5]

D: In accordance with the ASHP Guidelines on Preventing Medication Errors and the PACC guidelines, an independent double check on dosing, infusion pump programming, and concentrations should be performed.[6,2]

E: An assistant such as an MA should be available to provide an extra set hands if needed for the procedure.

F: For programmable pumps, the manufacturer specific designated programmer should be available prior to the start of the refill procedure.

G: When a non-physician provider is unable to access a pump, the non-physician provider should have access to a physician pump manager to perform the pump refill prior to the low volume alarm being triggered.

H. The non-physician provider should be BLS certified and have access to an ACLS certified physician provider equipped with accessible resuscitation equipment in close proximity prior to the start of the refill procedure in the event of a pump pocket fill.

I. An appropriate intrathecal pump refill consent form reviewing the risks and benefits of the procedure including risks of using compounded medications should be available to the non-physician provider and used according to the frequency stipulated by the Standardized Procedure.

J. If the non-physician provider is administering controlled substances into the pump they should have access to CURES reports and urine medication compliance test results in accordance with the frequency recommended by the California State Medical Board.

K. An updated contact list for specific device representative assistance should be available for reference [eg. 1. Medtronic (SynchroMed II pump): (800) 707-0933 2. Flowonix (Prometra II pump): (844) 229-6729]. This list should be periodically updated.

7: The organized health care system, clinic, or hospital should maintain a record of non-physician providers authorized to perform intrathecal pump refills and which make and model of pumps they have been approved to refill.

8: Progress note and procedure note should be entered into the patient's chart after the refill procedure is completed.

9: This standardized procedure should be reviewed by the physician-pump managers in the organized health care system, clinic, or hospital every two years.

Detailed Refill Procedure:

A. **Initial Evaluation:** Assess patient's general medical condition and response to therapy. Assess site for any swelling, redness, drainage, tenderness, or rash. Discuss the need for dose titration along with any other medical concerns with supervising physician pump manager.

B. Set up

Gather materials and set up sterile field. Minimize traffic in the room and ensure adequate lighting

C. Patient Preparation

-When indicated for pediatric patients instruct family to place EMLA cream over pump reservoir and cover with plastic dressing 45 minutes prior to refill.

-Have patient lie on exam table such that the pump is easily palpated and accessible.

-Explain procedure to patient and family.

-Have patient or parent sign procedural consent form describing the risk and benefits of the procedure including the risks associated with the use of compounded medications, pump pocket fills, and infection. The consents should be filed in the patient's chart. The supervising physician pump manager should determine if the consents should be signed for each refill or at specified intervals as stipulated in the standardized procedure.

D. Procedure

INTERROGATE PUMP FOR CURRENT STATUS

-Turn on the manufactures programmer and interrogate the pump for the current infusion settings.

-Verify current pump settings, including reservoir volume, drug and concentration, dose, and alarm settings.

PERFORM REFILL

- Prep and drape skin above the pump in a sterile fashion.

-If medications are received in a commercially prepared vial, draw up medications into a syringe using sterile techniques and filter straw when medications are located in a glass sealed vial.

- Using sterile technique, assemble needle, extension tubing, and empty syringe.

Close extension tubing clamp to prevent air from entering pump reservoir.

- Place the plastic template over the pump, aligning the edges of the template with the edges of the pump. Alternatively, use ultrasound transducer with a sterile sleeve to locate the reservoir access port (only if appropriately trained and competency certified by physician pump manager.

- If needed anesthetize the area over reservoir port.

- Insert the needle firmly through the reservoir access port until the needle tip cannot advance any further and abuts the firm surface of the back of the pump."

- Open the clamp and slowly withdraw the fluid from the reservoir using continuous, negative pressure. Empty reservoir completely, until air bubbles are visible in extension tubing.

- While maintaining negative pressure, close clamp and remove syringe from extension tubing.

Compare actual residual volume with expected residual volume from interrogation.

- Attach intrathecal medication filled syringe and filter to extension tubing.

- Open clamp and slowly inject fluid into pump (inject no faster than 1 ml per 3 seconds).

- Remove needle from pump and discard all components after the refill procedure.

-Safely dispose reservoir aspirate in a non-retrievable form and document appropriate waste of old medication

- Cleanse and dry skin and apply bandage if necessary.
-Program pump with the appropriate volume and daily dose and if indicated patient activated dose and frequency and bridge bolus if needed.
-Place program sheet into patient chart after dual provider confirmation of the program.
-Provide a copy of the program sheet to the patient and review the program changes made and the alarm date with the patient. Instruct the patient to make an appointment for another pump refill before the alarm date. If the refill interval is different than they expected patients are instructed not to leave the facility until they have resolved the matter with a pump refill provider.
-After refill procedure is completed, the patients should be monitored for 30 minutes after the procedure to monitor for possible pocket fill (per PACC guidelines)[2] and confirm that accurate programming has been performed before the patient leaves the facility.

References

[1] McGlothlen, Gail, "Intraspinal Drug Delivery Reservoir Refill Procedure by Non-Physician Clinicians: A Nation-Wide Survey of Training, Pocket Fill Experience, and Life-Long Learning Behaviors: Neuromodulation Vol:20, Issue7 October 2017 Pages 727-732

[2] The Polyanalgesic Consensus Conference (PACC): Recommendations on Intrathecal Drug Infusion Systems Best Practices and Guidelines.: Deer TR, Pope JE, Hayek SM, Bux A, Buchser E, Eldabe S, De Andrés JA, Erdek M, Patin D, Grider JS, Doleys DM, Jacobs MS, Yaksh TL, Poree L, Wallace MS, Prager J, Rauck R, DeLeon O, Diwan S, Falowski SM, Gazelka HM, Kim P, Leong M, Levy RM, McDowell G II, McRoberts P, Naidu R, Narouze S, Perruchoud C, Rosen SM, Rosenberg WS, Saulino M, Staats P, Stearns LJ, Willis D, Krames E, Huntoon M, Mekhail N. Neuromodulation. 2017 Feb;20(2):96-132

[3] Medtronic. (2014). Refill kit for use with Medtronic implantable programmable infusion pumps: Instructions for use. Minneapolis, MN: http://manuals.medtronic.com/content/dam/emanuals/neuro/M964645A_c_001_view.pdf

[4] http://www.flowonix.com/sites/default/files/pl-21794-01_-_prometra_infusion_systems_refill_kit_ifu_flowonix_-_us_commercial_-_final.pdf

[5] Pharmaceutical compounding—sterile preparations (general information chapter 797). In: The United States Pharmacopeia, 36th rev., and the National Formulary, 31 ed. Rockville, MD: The United States Pharmacopeial Convention; 2013: 361–98.

[6] American Society of Health-System Pharmacists Guidelines on Preventing Medication Errors in Hospitals; https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-medication-errors-hospitals.ashx