STANDARDIZED PROCEDURE

REPROGRAMMING AND REFILLING INTRATHECAL BACLOFEN PUMPS and ACCESSING THE CATHETER ACCESS PORT (Adult,Peds)

I. Definition

The purpose of this procedure is to allow the Advanced Health Practitioner (AHP) to reprogram and refill intrathecal Baclofen pumps, as well as access the catheter access port for those AHPs that need to do so. An intrathecal Baclofen pump is indicated for patients with severe spasticity who do not respond to oral Baclofen. Baclofen is delivered directly into the intrathecal space via a surgically implanted infusion system. Direct delivery of Baclofen into the CSF allows higher drug concentrations to be achieved than with oral Baclofen therapy. In adults, there is no average dose of intrathechal baclofen, and dosage can vary between 25 mcg/day to over 1,000 mcg/day. In children, the average dose of intrathecal Baclofen ranges from 100 mcg/day to 500 mcg/day, though some children require higher or lower doses to treat their spasticity.

II. Background Information

A. Setting:

The setting (inpatient vs outpatient) and population (adults vs pediatrics) for the Advanced Health Practitioner (AHP) is determined by the approval of the privileges requested on the AHP Privilege Request Form. If the procedure is being done on a Pediatric patient, make sure Child Life is involved and use age appropriate language and age appropriate developmental needs with care of children, as appropriate to the situation.

B. Supervision

The necessity of the procedure will be determined by the AHP in verbal collaboration with the attending physician or his/her designee. Direct supervision will not be necessary once competency is determined, as provided for in the procedure. At that time, general or indirect supervision is acceptable.

Designee is defined as another attending physician or fellow who works directly with the supervising physician and is authorized to supervise the AHP.

C. Indications

- Evaluation and adjustment of Baclofen dose based on patient's neurological condition and response to therapy
- Maintenance refills of Baclofen pump

D. Precautions/Contraindications

Notify supervising physician for signs/symptoms of Baclofen withdrawal or toxicity, infection or CSF leak. Signs of Baclofen withdrawal include irritability, rigidity, vomiting, seizure activity and fever. Signs of Baclofen toxicity include somnolence, hypotonia, respiratory depression and urinary retention.

Notify supervising physician for inability to reprogram pump, access pump or if pump is alarming.

III. Materials

Medtronic refill kit with ampule of Baclofen (verify appropriate volume and concentration)
SynchroMed programmer
2 sets of sterile gloves
Sterile gauze pads
Povidone-iodine swabs
Alcohol swabs
20ml syringe with straw to draw up baclofen
Filter
20ml syringe with needle to withdraw residual baclofen in pump
Sterile fenestrated drape.

IV. Procedure for Refilling and Reprogramming Intrathecal Baclofen Pump

A. Pre-treatment evaluation

Assess patient's general medical condition and response to therapy. Identify the need for dose titration. The dose should never be increased or decreased by more than 20% of the current dose. The daily dosage is based on the patient's symptoms and neurological exam. Assess site for any swelling, redness, drainage, tenderness or kinking/disconnection of catheter.

B. Set up (if applicable)

Gather materials and set up sterile field.

C. Patient Preparation

Instruct family to place EMLA cream over pump reservoir and cover with Tegaderm 45 minutes prior to refill.
Have patient lie flat and supine on exam table.
Explain procedure to patient and family. Involve Child Life as needed to help prepare child for procedure.

Alternatively: Lidocaine 1% subcutaneous may be used to numb the pump reservoir area.

D. Procedure

INTERROGATE PUMP FOR CURRENT STATUS

- Turn on the SynchroMed programmer and select pump icon from Therapy Selection Screen.
- Select SynchroMed I vs. SynchroMed II programming session.
- Select "interrogate" on the Patient Information Screen.

- Place programming head over pump and select "ok" for interrogation (attach enclosed magnet to programming head for SynchroMed I devices).
- When telemetry is complete, select "ok" to continue.
- Verify current pump settings, including reservoir volume, drug and concentration, dose and alarm settings.

ENTER PROGRAMMING CHANGES

- Select the Rx icon from Infusion Mode Screen to change reservoir volume and/or drug concentration.
- Select Rx~ icon to change daily dose and/or infusion mode.
- Select "alarm bell" icon to verify alarms are on and reservoir alarm volume.
- Select "programmer" icon to view new pump settings.
- Select "update pump," "yes" and "ok" to perform telemetry (place programming head over pump during telemetry).
- Review "pump status after update" screen to verify all data is accurate.
- Print data and place in patient's chart.

PERFORM REFILL

- Remove EMLA cream and Tegaderm, or inject Lidocaine 1% subcutaneous into the area to be injected.
- Open ampule of Baclofen.
- Open refill kit and put on sterile gloves.
- Assemble 20ml syringe with straw and draw Baclofen into syringe.
- Remove straw and attach filter to syringe.
- Place sterile syringe in sterile preparation tray and remove gloves.
- Palpate pump area and prepare injection site with povidone-iodine swabs.
- Put on a new pair of sterile gloves and place sterile drape over patient.
- 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.
- Insert the needle into the center reservoir fill port.
- 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 Baclofen 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.
- Cleanse and dry skin and apply bandage if necessary.

E. Post-procedure

If Baclofen dose is changed, inform patient / family about possible side effects related to Baclofen withdrawal or toxicity. Make sure that patient has a supply of oral Baclofen in case of an emergency. Notify patient and family about next refill date.

F. Follow-up treatment

Phone follow-up in 1-2 days if Baclofen dose adjusted in clinic. Document response to change in therapy and notify supervising physician for any adverse effects.

G. Termination of treatment

Patient having an adverse reaction to Baclofen.
Inability to interrogate, withdraw fluid, or inject fluid into Baclofen pump.
Immediately notify supervising physician for further evaluation.

V. Emergency Procedure to Empty Pump Reservoir

A. Equipment

1. 22- gauge needle
2. 20-ml syringe
3. Antiseptic agent

B. Procedure

1. Locate the pump (right or left abdomen) by palpation. The reservoir fill port is located in the CENTER of the pump.

2. Prepare the injection site by cleansing the area using an antiseptic agent.

3. Locate the reservoir fill port and insert the needle with attached syringe through the skin and into the reservoir fill port septum until the needle touches the needle stop. If you encounter resistance during needle insertion, reassess placement. Do not force the needle; use of excessive force in this port may damage the needle tip.

4. Withdraw fluid from reservoir using gentle, negative pressure. Empty the reservoir until air bubbles are apparent in syringe. Depending on the reservoir volume, more than one syringe may be needed to empty the pump.

5. Remove the needle from the septum.

6. Record in patient chart the amount of fluid emptied from the reservoir.

VI. Accessing the Catheter Access Port (For Intraspinal Applications Only)

A. Equipment

From the Medtronic Model 8540 Catheter Access Port Kit:

1. Extension tubing set with clamp
2. 0.22-micron filter
3. 10-ml empty syringe
4. Fenestrated drape
5. Appropriate template and non-coring needle

   The template and needle are pump-specific. The name on the template matches the name of the pump. Match the color and gauge of the needle to the color and gauge indicated on the template.

Other supplies needed:

6. Syringe containing prescribed fluid (10ml minimum)
7. Syringe with 5 ml saline (for flushing if desired)
8. Cleansing agent
9. Sterile gloves
10. Alcohol pads or swabs
11. Adhesive bandage (optional)

B. Preparing the Access Site

1. Identify the pump model, reservoir volume, and location of the reservoir fill port and catheter access port.

2. Prepare the injection site by cleansing the area.

3. Open the kit and glove packages. Put on the sterile gloves.

4. Place the drape, exposing the pump site.

5. Place the template over the pump, aligning the edges of the template with the edges of the pump. Locate the catheter access port septum.

C. Accessing the Access Site

1. Using sterile procedure, assemble the needle, extension tubing, and empty syringe.

2. Close the clamp and gently insert the needle into the catheter access port septum until the needle touches the needle stop.

3. Open the clamp and aspirate approximately 1 to 2 ml to ensure removal of drug from the catheter access port and catheter. Refer to the specifications in the appropriate catheter technical manual for the catheter volume.

4. Close the clamp and remove the syringe.

   Note: Keep the needle in the catheter access port septum and the clamp closed for the procedure that follows.

5. Attach the filter to the syringe containing the prescribed fluid and purge the air from the fluid pathway.

6. Attach the syringe with the prescribed fluid and filter to the extension tubing set.

7. Open the clamp and inject directly at an infusion rate not greater than 5 ml per minute.

8. During the infusion, check the needle puncture site for swelling.

9. When the drug has been injected, close the clamp, and carefully removed the syringe.

D. Flushing the Catheter Access Port

1. If flushing is desired, attach the syringe containing 5 ml of sterile saline to the extension tubing.

2. Open the clamp and inject directly at an infusion rate not greater than 5 ml per minute.

3. During injection, check the needle puncture site for swelling.

   Note: Flushing the catheter access port also flushes the drug from the catheter. Drug therapy from the pump will be lost until the catheter is refilled by the drug flow from the pump. Refer to the appropriate pump technical manual for instructions on calculating the time required for drug to advance to the catheter tip.

4. Upon completion of the flush, close the clamp and carefully remove the needle from the catheter access port septum.

5. Remove the cleansing agent from the patient's skin using an alcohol pad.

6. Apply an adhesive bandage, if desired.

7. Discard all components of the kit.

VII. Documentation

A. Documentation is in the electronic medical record.

1. Documentation of the pretreatment evaluation and any abnormal physical findings. Print interrogation data and place in patient's chart.
2. Record the time out, indication for the procedure, procedure, the outcome, how the patient tolerated the procedure, medications (drug, dose, route, & time) given, complications, and the plan in the note, as well as any teaching and discharge instructions.

B. All abnormal or unexpected findings are reviewed with the supervising physician.

VIII. Competency Assessment

A. Initial Competence

1. The Advanced Health Practitioner will be instructed on the efficacy and the indications of this therapy and demonstrate understanding of such.
2. The Advanced Health Practitioner will demonstrate knowledge of the following:
   a. Medical indication and contraindications of Baclofen Pump
   b. Risks and benefits of the procedure
   c. Related anatomy and physiology
   d. Consent process (if applicable)
   e. Steps in performing the procedure
   f. Documentation of the procedure
   g. Ability to interpret results and implications in management.
3. Advanced Health Practitioner will observe the supervising physician perform each procedure three times and perform the procedure **three** times under supervision.
4. Supervising physician will document Advanced Health Practitioner's competency prior to performing procedure without supervision.
5. The Advanced Health Practitioner will ensure the completion of competency sign off documents and provide a copy for filing in their personnel file and a copy to the medical staff office for their credentialing file.

B. Continued Proficiency

1. The Advanced Health Practitioner will demonstrate competence by successful completion of the initial competency.
2. Each candidate will be initially proctored and signed off by an attending physician. Advanced Health Practitioner must perform this procedure at least **three** times per year. In cases where this minimum is not met, the attending, must again sign off the procedure for the Advanced Health Practitioner. The Advanced Health Practitioner will be signed off after demonstrating 100% accuracy in completing the procedure.
3. Demonstration of continued proficiency shall be monitored through the annual evaluation.
4. A clinical practice outcomes log is to be submitted with each renewal of credentials. It will include the number of procedures performed per year and any adverse outcomes. If an adverse outcome occurred, a copy of the procedure note will be submitted.

IX. RESPONSIBILITY

Questions about this procedure should be directed to the Chief Nursing and Patient Care Services Officer at 353-4380.

X. HISTORY OF PROCEDURE

Revised August 2012 by Subcommittee of the Committee for Interdisciplinary Practice
Reviewed August 2012 by the Committee on Interdisciplinary Practice
Prior revision June 2008, February 2012
Approved August 2012 by the Executive Medical Board and the Governance Advisory Council.