INTRATHECAL BACLOFEN ALGORITHM

Baclofen Pump Initial Asessment

DCMC Evidence-Based Outcomes Center

Consistent with patient signs and symptoms and history and physical findings consider the possibility of:

	WITHDRAWAL	OVERDOSE	INFECTION	CSF LEAK
Signs and Symptoms	• **INCREASE** in muscle tone and spacity, muscle rigidity • Return to baseline spasticity and rigidity • Pruritus without a rash • Paresthesia • Fever • Altered mental status including confusion, agitation, seizures • Diaphoresis – excessive sweating	• **DECREASED** tone or flaccid paralysis • Altered mental status including confusion, agitation • Nausea/Vomiting • Respiratory depression • Seizures	• Fever (temp >38C)	• Postural headaches
Hx Red Flags & Physical Exam Findings	• Flushed appearance • Hypertension • Tachycardia • Tightness/posturing • Rigidity • Rhabdomyolosis • Multi-organ failure	• Flaccidity/hypotonia • Respiratory depression • Hypotension • Bradycardia, tachycardia, or other cardiac abnormalities	• Redness or inflamation of wound • Swelling around pump	• Swelling around pump and abdomen • Swelling in lower back, around pump • Clear fluid discharge around surgical sites

NOTE: For all patients with an intrathecal pump, the pump must be interrogated on admission. Charge RN's (3South and 4South) are trained to interrogate ITB pumps.

Interrogating the ITB pump: This will provide the most up-to-date information on the status of the pump. Pump interrogation will provide low reservoir alarm date, volume of expected baclofen left in pump, dose and concentration of ITB and it will also show any alarms or events that have occurred with the pump programming; battery life, low volume warning, malfunctions. It is important to note the program report is not inclusive of all possible ITB complications.

INTRATHECAL BACLOFEN ALGORITHM

Withdrawal – Hospital (ED or Inpatient Unit)

DCMC Evidence-Based Outcomes Center

INCLUSION CRITERIA

- Patient presenting to the ED or is hospitalized with questionable intrathecal baclofen WITHDRAWAL

EXCLUSION CRITERIA

- Patients with indwelling pumps delivering any medication other than baclofen

Withdrawal Symptoms

- **INCREASE** in muscle tone and spacity, muscle rigidity
- Return to baseline spasticity and rigidity
- Pruritus without a rash
- Paresthesia
- Fever
- Altered mental status including confusion, agitation, seizures
- Diaphoresis – excessive sweating

Patient presents in the ED, is directly admitted or is found to have an acute change

Assess patient for symptoms of baclofen withdrawal.
ABC's: Maintain airway, breathing and circulation

Do symptoms suggest Intrathecal Baclofen as source of issues?

- Yes
- No → Differential Diagnosis → Alternate source of symptoms identified → Treat off algorithm

Does patient present with ***INCREASED*** tone? (increase in spasticity or spasms)

- No
- Yes

Check with patient or care giver: Ask if the patient/family heard the ITB alarm or is the pump due for refill?

Pump should be interrogated and Communication Tool used to acquire pertinent Hx/physical exam and information **prior to** contacting the ITB Team (Pedi PM&R consult) [1]

Contact the Pedi PM&R on call

--IN DISCUSSION WITH ITB PUMP TEAM--

Do symptoms, Hx, and physical exam still suggest Intrathecal Baclofen as source of issues?

- Yes

Administer baclofen as recommended by ITB Pump team:

Start enteral dose of Baclofen

- IF >1000mcg/day at 30mg TID, increase to 30mg QID if not adequate. If overly floppy decrease to 20mg TID. Diazepam 1mg q4h prn spasms.
- IF <1000 > 500mcg/day start at 20mg TID, increase or decrease as needed. Diazepam 1mg q4h prn spasms.
- IF <500mcg/day 10mg TID, increase or decrease as needed.

(May consider if unable to reach ITB Pump Team)
Alternate with benzodiazepines (as needed)

Advanced management options (only if recommended by ITB team):
-LP IT bolus 50 mcg
-ITB pump programmed bolus

Note: Charge RN's (3South and 4South) are trained to interrogate ITB pumps [1]

Improvement with enteral baclofen?

- Yes → Continue enteral baclofen (PO/GT/GJT/NGT) every 6 hours
- No

- Additional information may be required to either evaluate the severity of potential baclofen withdrawal (and additional supportive measures that may be required) or to expand DDx
- Consider IV benzodiazepine or dantrolene
- Draw CK
- Maintain adequate hydration due to risk for rhabdomyolysis

Admit/transfer to appropriate level of care for continued management, workup and treatment

Contacting Pedi PM&R:

- The daytime process is to TigerText "Pediatric PM&R" or use AMION/MedLink to page "PM&R Consult".
- After hours, the process is to use AMION/MedLink to page "PM&R Consult"

INTRATHECAL BACLOFEN ALGORITHM

Overdose – Hospital (ED or Inpatient Unit)

DCMC Evidence-Based Outcomes Center

INCLUSION CRITERIA

- Patients presents to the ED or is hospitalized
- Patient has know implanted intrathecal baclofen pump

EXCLUSION CRITERIA

- Patients with indwelling pumps delivering any medication other than baclofen
- Patients receiving intrathecal baclofen not presenting to the ED

Overdose Symptoms

- **DECREASED** tone or flaccid paralysis
- Altered mental status including confusion, agitation
- Nausea/Vomiting
- Hypotension
- Bradycardia, tachycardia, or other cardiac abnormalities
- Respiratory depression
- Seizures

Patient presents in the ED or is hospitalized with suspected intrathecal baclofen (ITB) ***OVERDOSE***

Assess patient for symptoms of baclofen overdose. (ABC's) Maintain airway, breathing and circulation

Does patient present with *DECREASED* tone?

- No → ITB overdose unlikely, work up for presenting problem. Treat off algorithm.
- Yes → Recent ITB pump replacement, revision, refill, or dose/concentration change within the past week?
  - No → ITB overdose unlikely, work up for presenting problem. Treat off algorithm.
  - Yes → Pump should be interrogated and Communication Tool used to acquire pertinent Hx/physical exam and information **prior to** contacting the ITB Pump Team (Pedi PM&R on call) [1]

Note: Charge RN's (3South and 4South) are trained to interrogate ITB pumps [1]

Do symptoms, Hx, and physical exam still suggest Intrathecal Baclofen as source of issues?

- No → ITB overdose unlikely, work up for presenting problem. Treat off algorithm.
- Yes → --IN DISCUSSION WITH ITB PUMP TEAM--

Contact the ITB Pump Team (Pedi PM&R on call)

ITB Pump team should consider if patient presents significantly obtunded or floppy:

Advanced Management Options
- ITB pump reprogramming to minimal rate or stop Tap (LP/CAP) for withdrawal of CSF
- Continue supportive care

Consider Admission If overdose is suspected and patient is clinically compromised (decreased mentation/consciousness, respiratory depression) for continued management, workup and treatment

Contacting Pedi PM&R:

- The daytime process is to TigerText "Pediatric PM&R" or use AMION/ MedLink to page "PM&R Consult".

- After hours, the process is to use AMION/MedLink to page "PM&R Consult"

INTRATHECAL BACLOFEN ALGORITHM
Symptoms/Diff dx – Hospital (ED or Inpatient Unit)

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Baclofen is a skeletal muscle relaxant acting centrally as a presynaptic gamma-amino-butyric acid-B (GABA-B) receptor agonist. In recent years, it has been proven that intrathecally administered baclofen has beneficial effects in the treatment of severe and medically refractory spasticity.[2] INTRATHECAL BACLOFEN (ITB) delivered by a programmable, implantable drug infusion system is commonly used to relieve medically intractable spasticity of spinal or cerebral origin.[2]

ITB Withdrawal

Intrathecal baclofen withdrawal can occur secondary to pump malfunction, premature battery failure, medication interactions (SSRI's are especially notorious for decreasing effects), wrong dose/wrong bolus/wrong concentration errors, and most commonly catheter malfunctions (kink/micro/macro leak, scarring, migration, and infection).

Withdrawal of intrathecal baclofen presents with a wide spectrum of severity and symptoms. It is important to act quickly if withdrawal is suspected, as symptoms can quickly escalate. Treat suspected baclofen withdrawal as a medical emergency.

When a patient presents with withdrawal symptoms which are secondary to an underlying problem causing discomfort, giving oral baclofen will reduce the tone and create the false sense that this is baclofen withdrawal.

Differential Diagnoses of ITB Withdrawal:

Because the underlying pathophysiology and treatments differ, ITB withdrawal should be differentiated from Autonomic Dysreflexia, Malignant Hyperthermia (MH), and Neuroleptic Malignant Syndrome (NMS).

- Noxious pain (e.g. fracture, constipation, wound, infection)
- Autonomic Dysreflexia – (only part of DDx if patient has a concomitant spinal cord injury higher than T7)
  (bradycardia, sometimes followed by tachycardia, hypertension, absence of fever, lack of increase spasticity, normal level of consciousness)
- Malignant Hyperthermia
  (acute onset during or after anesthesia, familial disorder, tachycardia, hypertension, normal body temperature, decreased level of consciousness, muscle activity is generalized/sustained, rigorous (tetanic), muscle contractions)
- Neuroleptic malignant syndrome
  (use of dopamine blocking neuroleptic drugs or abrupt withdrawal of dopamine agonist, tachycardia, Hypertension, body temp is elevated followed by hypothermia, decreased level of consciousness, muscle activity tremor, worsening to profound generalized rigidity)
- Serotoninergic syndrome (selective serotonin reuptake inhibitor [SSRI] overdose, myoclonus, elevated liver function tests [LTFs])
- Sepsis
- Meningitis

ITB Overdose

Overdose may appear insidiously or suddenly.

Baclofen overdose, although it occurs infrequently, is often associated with pump failure (rare), baclofen refill error, or sensitivity to a rate change. Patients who are treated for baclofen overdose must be watched closely for rebound withdrawal once the pump is stopped and the drug load is decreased. It is essential that this assessment process begin with a question:

"When was your last refill and was there a rate change?"

Differential Diagnoses of ITB Overdose:

- Sepsis
- Hypoglycemia
- Electrolyte Imbalance

ITB Pump Program - Malfunction Handoff (Communication Tool)

Initial evaluation:

A child with an ITB pump may present to ED for a number of reasons, many of these reasons will not be related to ITB therapy.

The following steps are recommended in the initial assessment of the child who is clinically ***stable*** but showing signs of intrathecal baclofen dysregulation:

History:

Clinical reason to present to ED/service
When was the pump placed?
Clinician who manages pump (last time seen)
Current ITB dosing
Last refill date, next refill date
Any alarms or beeping sounds
Changes in tone, sudden or slow onset
Any ongoing/concurrent medical issues or problems? (UTI? Fracture? Cold? Etc)
Any medical procedures in the last week? MRI? LP? Surgeries?

Signs and symptoms: **(report which the pt presents with)**

Exaggerated/increased spasticity & muscle rigidity *Itching* Alt in mental status/irritability Fever (temp >38C) Seizures	Sleepiness Dizziness/drowsiness Seizures Loss of consciousness Lightheadedness	Fever (temp >38C)	Postural headaches

Physical examination: **(report any pertinents)**

Flushed appearance Hypertension Tachycardia Tightness/posturing Rigidity	*Flaccidity/hypotonia* Respiratory depression	Redness or inflammation of wound Swelling around pump	Swelling around pump and abdomen Swelling in lower back, around pump insertion site Clear fluid discharge around surgical wound

Interrogate pump:

Dose confirmation
Low reservoir alarm date

-- Contact PMR On Call to discuss the case with the above information. --

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Ascension

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References:

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2. Tunali, Y., Hanimoglu, H., Tanriverdi, T., Hanci, L., & Hanci, M. (2006). Intrathecal Baclofen Toxicity and Deep Coma in Minutes. The Journal of Spinal Cord Medicine, 29(3), 237–239.
3. Saulino, M., Anderson, D. J., Doble, J., Farid, R., Gul, F., Konrad, P., & Boster, A. L. (2016). Best Practices for Intrathecal Baclofen Therapy: Troubleshooting. Neuromodulation, 19(6), 632–641. https://doi.org/10.1111/ner.12467