

Intrathecal Baclofen Pump Guideline

Site Applicability

All VCH Acute and Residential Care sites

Practice Level

RN: Basic Skill

- Requires additional training for assessment of symptoms, side effects and pump settings.
- Train the Trainer sessions are provided by GFS Baclofen clinic nurse.

Need to Know

Baclofen

Baclofen, which is normally taken orally, has proven to be safe and effective in controlling spasticity in some patients. However, it is not effective in a number of patients because the high doses required result in undesirable side effects, such as drowsiness and fatigue.

Research has shown that baclofen administered into the spinal canal in high concentrations by means of a pump greatly decreases spasticity, undesirable side effects, resulting with an increase in quality of life.

Spasticity

Spasticity is an increase in muscle tone that occurs in many patients with upper motor neuron syndromes. Spasticity is a term that refers to both rigidity and spasms. Rigidity is when muscles tighten up. Spasms are involuntary muscle contractions or movement. Spasticity is caused by hyper excitable stretch reflexes. With multiple sclerosis and spinal cord injuries, spasticity is a common complication. Most patients with mild to moderate spasticity are managed effectively with a combination of physiotherapy and oral drug therapy.

Advantages to Spasticity

- o maintain muscle tone
- help support blood circulation
- assist with activities of daily living
- may prevent blood clots

Disadvantages of Spasticity

- o interfere with SLEEP and activities of daily living
- may lead to contractures and joint dislocations
- o risk of skin breakdown due to shearing
- associated pain with spasms and stretching
- may impair respiratory function

Baclofen Test Dose

Date: July 2014

This procedure is done to screen if intrathecal baclofen will work for a patient before a pump is implanted. It is a 6 to 10 hour out-patient procedure at UBC. The physician injects intrathecal baclofen into the spinal fluid via a lumbar puncture. Then, the patient is monitored for 6 to 10 hours. The patient's response to intrathecal baclofen is monitored in order to determine if he/she will benefit from the intrathecal baclofen therapy.



Pump Implantation

The pump is implanted underneath the skin into the fatty tissue. The sterile procedure is performed in the operating room under a general anesthetic. An incision is made in the mid-back area where the pump catheter is placed in the spinal canal. Then, the radiopaque silicone catheter is tunnelled under the skin from the back and connected to the pump located in the front left or right lower abdomen. Both catheter and pump sites are securely sutured and are completely covered under the skin. There are two incision lines, one in the back and one in the front. The battery operated pump is implanted about one inch below the surface of the skin. The pump is approximately one inch thick, three inches in diameter, weighs about six ounces: the size of a hockey puck.

Note: Spinal headache may occur from 24 hours to 2 weeks due to spinal fluid leaking around the catheter site in lumbar area (see <u>complication for interventions</u>).

Pump Programming

The pump is programmed by the Baclofen Pump Team (nurse or physician) using an external Programmer. This is done by holding the programmer wand over the implanted pump in the lower abdomen. The programming procedure is painless. Radio signals from the programmer wand are transmitted to the pump and relayed onto the programmer's screen. The nurse/physician uses this method to change the dose and the timing of baclofen administration.

Practice Guideline

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Following admission to an acute or residential care:

- Notify the Baclofen clinic that the patient is admitted to hospital (see information below)
- Ensure the Baclofen nurse contact information is available to staff.
- The Baclofen nurse will ensure follow up occurs with the patient and that necessary arrangement for next pump refill is arranged.
- If any complications are noted, report them to the Baclofen nurse (see complications section).
- **A.** Daily Assessment should occur for up to 2 weeks post procedure.

Daily assessment should include:

- 1. Temperature every shift and prn (notify physician and also report to the Baclofen clinic if above 38°C, (see <u>complication</u> if infection is suspected).
- 2. Check both lumbar and abdominal site every shift for drainage. Wash hands prior to coming in contact with the outer dressing.
 - If dressing wet, reinforce or change initial dressing and report findings to <u>Baclofen clinic</u>. If frequent dressing changes are required before day 3 post op, please notify the clinic immediately (see <u>complications</u>).
 - If dressings are dry, change dressing on 3rd post-op day and change dressing to both sites
 approximately every 3 days for 2 weeks. Notify physician if sites are red, swollen, or infection
 suspected (see <u>complications</u>).
- 3. Use abdominal binder x 24 hrs for 2 weeks. Loosen binder every 8 hours for 20 to 25 mins preferably when lying or resting.
- 4. Sponge bath only for 2 weeks post-op (keep both dressing and lumbar/abd site dry).
- 5. Avoid excessive bending until one month post-op to decrease risk of catheter dislodging.
- 6. Assessment for complications will be done each shift (see patient complications section below).

Additional assessment for muscle tone and spasms will be completed by Baclofen clinic nurse.



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Modified Ashworth Scale

Score	Degree of Muscle Tone
1	No increase in tone
2	Slight increase in tone, giving a "catch" when affected part is flexed/extended
3	More marked increase in tone, but affected part easily flexed
4	Considerable increase in tone; passive movement difficulty
5	Affected part(s) rigid in flexion/extension

Frequency of Spasms

Score	Frequency of Spasms
0	No spasms
1	No spontaneous spasms, vigorous sensory & motor stimulation results in spasms
2	Occasional spontaneous & easily induced spasms
3	Less than 1, but greater than 10 spontaneous spasms per hour
4	Less than 10 spasms per hour

- **B.** Complications. If patient experience any of the complications (see chart below), please contact:
 - Baclofen Clinic / GF Strong Rehab Centre: (Monday to Friday, from 7:00 am to 3:00 pm) 604-734-1313 – 2193 Contact Baclofen Nurse or physician for assistance.
 - After 5 pm & weekends, please contact the GFS physician on call or go to the nearest emergency if
 life threatening complications occur and have the ER physician call VGH (604-875-4111) and request
 to speak to the GF Strong Rehab doctor on call to help you with your pump.

**** 24 HOUR TECHNICAL SERVICE: 1-800-707-0933 ****

Complication	Assessment and Intervention	
1. Incisional Bleeding	Assessment:	
	Swelling or redness at the site	
	Large amount of bright red (frank) blood noted on dressing or hematoma	
	Changes in Motor and Sensory assessment (numbness or tingling to	
	extremities) or changes in sensation to lower extremities	
	Action:	
	 Call Baclofen nurse and most responsible physician (MRP) or NP as well as 	
	surgeon	
	Reinforce dressing and monitor vital signs	
	Residential care sites only: If significant changes in vital signs (BP below)	
	90/50) consider transfer to ED	
2. Incisional Infection	Assessment:	
	Temperature greater than 38°C	
	 Purulent drainage noted to dressing or at the pump insertion site 	
	Action:	
	Call Baclofen nurse and MRP or NP	
	Patient may require wound culture and sensitive swab as per MRP or NP	



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		order ND ND ND		
		Patient may require additional blood work as per MRP or NP order Patient may require antibiotic as per MRP or NP order		
2	Indicional pain and	Patient may require antibiotic as per MRP or NP order Assessment:		
ე.	Incisional pain and	1		
	discomfort	Location and type of pain Fraguency and intensity of pain		
		Frequency and intensity of pain Assess numbers appropriate doos		
		Assess pump to ensure it is administering appropriate dose Action:		
		Call Baclofen nurse and MRP or NP		
4.	Increase Spasticity	Assessment:		
	(caused by Noxious	Factors that may increase spasticity		
	Stimuli)	 urinary tract infection (if frequent UTI's – r/o bladder kidney stones) 		
	Stilliuli)	• menses		
		bowel changes (impaction, constipation, diarrhea)		
		deep vein thrombosis		
		pneumonia		
		wounds or infections		
		• PAIN		
		Progression of disease		
		Stress		
		Ingrown nails		
		Restrictive clothing		
		• FATIGUE		
		Psychological factors		
		Change in temperatures or humidity		
		Action:		
		Call Baclofen nurse and avoid these noxious stimuli.		
		Have MRP or NP assess medical conditions that are considered noxious A time disconnection and PVT and and attraction and account of the conditions and the conditions are considered as a condition of the conditions. A time disconnection and the conditions are considered as a condition of the conditions. A time disconnection are considered as a condition of the conditions are considered as a condition of the conditions. A time disconnection are considered as a condition of the condition of the conditions. A time disconnection are considered as a condition of the conditi		
5.	Baclofen Overdose	stimuli (pneumonia, infection and DVT) and order treatment as required Assessment: CNS Depression symptoms		
3.		Drowsiness, lightheadedness, dizziness/hypotension		
	Symptoms (see Appendix A)	Blurred vision		
	Most common causes:	Nausea, vomiting		
	programming error	Action:		
	 sensitivity to drug 	Call the Baclofen nurse		
	 oral titration 	Notify the Baclofen nurse immediately if:		
	oral intration	Legs are flaccid, progressive weakness in upper limbs		
		Decreasing conscious level		
		Decrease in breathing		
		Coma		
		Symptoms are progressive from drowsiness to coma		
		Action:		
		Residential Care: Arrange transfer to ED (residential care)		
<u></u>	Control has a deader	Acute Care: Call attending physician (acute) Action:		
6.	Spinal headache	Action:		
		 Rest post-op with head down. Headaches will occur when sitting up. Take Tylenol as ordered 		
		Lay down when spinal headache occurs		
		 If headache persists for greater than 24 hrs or changes in intensity or 		
		neurological changes are noted, call Baclofen nurse or MRP or NP		
7.	Spinal epidural	Assessment:		
	hematoma	Swelling at lumbar site		
L		1 3		



	Neurological or sensitivity changes		
	• Neurological of sensitivity changes Action:		
	Call Baclofen nurse immediately as well as MRP		
8. Spinal Hydgromas	Assessment:		
	Swelling noted to the spine		
seromas			
	Neurological and sensitivity changes Action:		
	Action:		
	Call Baclofen nurse Call average who implies the product of the profession of		
O Boolefor With drawel	Call surgeon who implant immediately and transfer to ED (residential care		
9. Baclofen Withdrawal	Most common causes:		
Symptoms	Catheter dislodgement can be partial/complete		
(see <u>Appendix A</u>)	Catheter blockage can be partial/complete, rarely pump stall.		
	MUST RULE OUT BLADDER INFECTION		
	MUST RULE OUT DEVELOPING SKIN ULCERS		
	Bacterial meningitis may mimic withdrawal symptoms		
	Assessment:		
	An increase in spasms (can be sudden or gradual)		
	Severe headaches		
	Disorientation / confusion		
	Agitation / restlessness		
	Itchy, prickly skin		
	Hyperthermia		
	Dysautonomia (autonomic dysreflexia for spinal cord patients)		
	Hallucinations		
	Seizures		
	Action:		
	NOTIFY THE BACLOFEN nurse immediately if:		
	Symptoms are progressive from a gradual increase to sudden onset of		
	spasms to seizures		
10. Bacterial Meningitis	Assessment:		
Symptoms	Temperature 38°C or greater		
(see Appendix A)	Stiff neck		
Most common causes	Sensitivity to light		
are:	Nausea and/or vomiting		
 after any pump refill or 	Action:		
pump procedures up to	NOTIFY THE BACLOFEN CLINIC IMMEDIATELY if patient experience one or		
14 days post-op pump	more of these symptoms:		
implant or procedures	Will need CSF to confirm diagnosis and be treated with antibiotics (TB team		
	can withdrawal CSF from catheter access port).		
	Residential care: Transfer to ED would be required		
	Acute care: Physician may obtain CSF from LP below spinal catheter		
	entry under fluoroscopy to avoid puncturing catheter, or a qualified pump		
	clinician may obtain CSF through the side port of the pump system.		

C. Medtronic Pump refill

The Medtronic pump uses an external device called a programmer which is used to transmit
messages to the battery-powered pump, pump refills are completed by Baclofen nurse and the
Baclofen nurse will schedule refills and please contact her directly when required.

Expected Patient/Client/Resident Outcomes

To decrease spasms and comfort

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Patient/Client/Resident Education

Post-op Discharge Instructions – Intrathecal Baclofen Pump: Appendix B

Documentation

For Acute Care or Residential Care Setting:

- Document daily assessments, all symptoms and actions to mitigate problems (i.e. contact Baclofen nurse or MRP)
- Make sure the MAR reflects the latest dosing of the pump (as per Baclofen nurse assessment).
 Confirm with the latest pump strip or documentation provide by the Baclofen nurse

Baclofen Nurse will Chart:

- Her assessments when she review the patient
- · Chart pump dosing changes
- Chart any procedures related to the pump (i.e. pump refills)

References

Medtronic 2004" Intrathecal Baclofen for the Management of Severe Spasticity, clinical reference guide. Medtronic, Inc, Minneapolis, MN

Medtronic 2004" Surgical procedures, clinical reference guideline. Medtronic, Inc, Minneapolis, MN

Richard Penn (1996), Janet M. Giano, Michelle M. York, Judith A. Paice, "Intrathecal Drug Therapy for Spasticity and Pain", Practical Patient Management, New York, 1196 Springer-Verlag

Developed by

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Clinical Nurse Educator. Spine - Spinal Cord Unit, VGH Clinical Nurse Educator, Seniors Program, Coastal Clinical Nurse Educator, Neurosciences, VGH

Endorsed by

Date: July 2014

VCH: (Regional SharePoint 2nd Reading)
Health Authority Profession Specific Advisor

Health Authority Profession Specific Advisory Council Chairs (HAPSAC)

Health Authority & Area Specific Interprofessional Advisory Council Chairs (HAIAC)

Operations Directors

Professional Practice Directors

Final Sign-off & Approved for Posting by

Vice President Professional Practice and Chief Clinical Information Officer, VCH

Date of Approval/Review/Revision

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Appendix A: 3 Pump Symptoms

Baclofen Overdose Symptoms: Central Nervous System Suppression (CNS) Symptoms Symptoms are progressive from drowsiness to coma**

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Drowsiness, Lightheadedness, dizziness / hypotension

- Blurred vision
- Nausea, vomiting
- Legs are flaccid, progressive weakness in upper limbs***notify clinic nurse/physician immediately
- Decreasing conscious level***go to nearest ER
- Decrease in breathing***go to nearest ER
- Coma***go to nearest ER

(most common causes; program error, sensitivity to drug, oral titration)

2. Baclofen Withdrawal Symptoms:

Symptoms are progressive from a gradual increase to sudden onset of spasms to seizures** Notify clinic nurse/physician immediately

- An increase in spasms (can be sudden or gradual)
- Severe headaches
- Disorientation / confusion
- · Agitation / restlessness
- Itchy, prickly skin
- Hyperthermia
- Dysautonomia (autonomic dysreflexia for spinal cord patients)
- Hallucinations
- Seizures

(Most common causes; catheter dislodgement can be partial/complete, or catheter blockage can be partial/complete, rarely pump stall. Must rule out bladder infection, developing skin ulcers, and bacterial meningitis because they may mimic withdrawal symptoms.)

3. Bacterial Meningitis Symptoms:

Notify clinic nurse/physician immediately if experience one or more of these symptoms:

need CSF to confirm diagnosis and be treated with antibiotics
may obtain CSF from LP below spinal catheter entry (x-ray, not to puncture catheter) or a qualified pump clinician may obtain CSF through the side port of the pump system.

- Temp. 38°C or greater
- Stiff neck

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- · Sensitivity to light
- Nausea and /or vomiting

(most common cause: after pump refill and up to 14 days post-op pump implant)

Baclofen Clinic/ GF Strong Rehab Centre

(Monday-Friday, from 7:00 am to 3:00 pm) **604-734-1313 - 2193 Contact Baclofen Nurse and Baclofen Physician**

On Stat Holidays, after 5pm & weekends please contact the GFS physician on call or go to your nearest emergency if life threatening and have your ER physician call VGH (604-875-4111) and request to speak to the GF Strong Rehab doctor on call to help you with your pump.

****24 HOUR TECHNICAL SERVICE: 1-800-707-0933****



Appendix B: Post-op Discharge Instructions - Intrathecal Baclofen Pump

Before leaving Vancouver Hospital, please know your next appointment with Intrathecal Baclofen Clinic or telephone ASAP to make arrangements to be seen within 5 days after hospital discharge:

Intrathecal Baclofen Clinic (Monday to Friday, from 7 am to 3 pm)

Your next appointment: Date:		Time:	
Location:	GF Strong Rehab Centre 4255 Laurel St.		
	Vancouver, BC V5Z2G9 Telephone: 604-734-1313 ex	# 2102	

ON YOUR FIRST VISIT

- We will at this time evaluate your spasticity, adjust your Intrathecal Baclofen daily dosage, your oral medications, and check both incision sites. The pump will also be checked for accurate functioning.
- 2. For the next 4 to 8 weeks, you will visit the clinic frequently to adjust your daily intrathecal Baclofen dosage until you and the doctor/nurse feel your spasms are at a comfortable level.
- 3. Your follow-up appointments will last approximately 30 to 45 minutes and are scheduled your needs and the amount of Baclofen you are receiving.
- 4. Bring a **CURRENT LIST OF MEDICATIONS YOU ARE ON**:

NEVER STOP TAKING YOUR ORAL ANTISPASTIC MEDICATION ABRUPTLY. ABRUPT WITHDRAWAL OF THESE MEDICATIONS CAN BE VERY DANGEROUS. WE WILL GIVE YOU A SCHEDULE TO DISCONTINUE THESE MEDICATIONS GRADUALLY.

- 5. Complete & mail your <u>alert Bracelet/necklace application</u>. If you want, bring the application with you, and the nurse can help you fill in the appropriate information.
- 6. On discharge from VGH, you will have received a **temporary Medtronic registration card**. Please carry this in your wallet with you at all times. It identifies the specifics of your pump. You will receive a permanent card through the mail from Medtronic.
- 7. Please make a follow up appointment with your surgeon after 6 weeks from the day of your surgery!

AT HOME

- 1. Take your **temperature daily**, preferably in the evening, the same time each day until your visit the Intrathecal Baclofen Clinic. If your temperature is 38°C (101°F) or greater, call your intrathecal Baclofen nurse or doctor immediately, after clinical hours go to Vancouver General Hospital Emergency Department.
- 2. Your physician **may order an abdominal binder** to wear 24 hours per day. The binder is worn to support the pump while the incision line heals and to decrease any swelling that may occur at the pump site.
- 3. Wear your **abdominal binder** at a comfortably snug level to support the pump while both incision lines heal. You may have **some swelling at both incisional sites**, this is normal. So that is why it is important to wear the binder. You may loosen the binder every 8 hours for 20 to 25 minutes, preferable when lying or resting, and then re-tighten binder to the same comfortable snug level. If you are concerned about the swelling, and have a lot of pain, call the clinic as soon as possible, and proceed to nearest emergency department.



- 4. **Sponge bathing** is for approximately 2 weeks! Do not take a bath or shower until your nurse or doctor say you may. It is very important to prevent any infections. If your bandages become wet due to washing or get soiled, please replace with dry bandages to prevent any infections.
- 5. **Check your pump and back bandages daily** for any drainage. Keep your bandages dry. Only change when soiled. If you have any fresh drainage coming from your back accompanied with, persistent headaches, or you experience persistent incisional pain; take and report your temperature, and call your nurse or doctor immediately. After clinical hours, go to Vancouver General Hospital to the Emergency Department.

Wound site infection:

Any drainage, redness, or increase in swelling at the pump and back site area – *notify the clinic ASAP*

- 1. **Avoid wearing tight clothing** such as elastic waistbands and belts that may irritate your back and pump incisions.
- 2. You may experience **headaches** after surgery when sitting up. This may last from one day to 2 weeks. Your headaches will be relieved by lying down and report this to your clinic. If lying down does not relieve your headaches, please notify your nurse/physician during clinical hours. After clinical hours please go to VGH Emergency Department.

ACTIVITY

Until your incision has completely healed, avoid activities requiring excessive bending (over 45) at the waist, frequent transfers, and heavy lifting. These activities may cause stress on the incisions and may dislodge the catheter for about 2 to 4 weeks. Avoid activities in which your incision lines may get wet for 2 weeks after your surgery. After your incisions have healed you may resume your regular activities as tolerated (work, recreation, sexual activities, hobbies). Ask your nurse/doctor when your may resume normal activities.

ADVERSE EFFECTS

During clinical hours (7 am to 3 pm)

Have your clinic nurse or doctor paged (604-734-1313) for the following adverse effects:

After clinical hours go to your nearest Emergency * If life threatening, go to your nearest emergency and have them contact the GF Strong doctor on call to assist you with your pump at 604-875-4111.

Possible Overdose:

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Drowsiness
Lightheadedness
Progressive weakness in upper limbs
Decreasing conscious level
Decrease in breathing
Coma

Possible Withdrawal:

Sudden onset of pain/spasms Severe headaches Disorientation Seizures

Central Nervous System Suppression symptoms for overdose symptoms



Possible Bacterial Meningitis

Temperature 38° C (101° F) or greater Persistent headaches

Stiff neck

Sensitivity to light Nausea and/or vomiting

Please notify in advance two working days to Pharmacy (604-873-5511) and then the clinic nurse to make another refill date.

Please notify the baclofen clinic nurse if you are hospitalized at any time.

*** If you have any further questions or concerns, please contact your **Baclofen Nurse**:

BACLOFEN NURSE

Monday to Friday (7 am to 3 pm):

if urgent please call (604-734-1313) or page me during clinical hours (If unable to contact me, please contact your Baclofen physician during clinical hours)

BACLOFEN PHYSICIANS - CALL 604-734-1313 MONDAY TO FRIDAY

See contact information above.

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AFTER CLINICAL HOURS

Please call **VGH Emergency (604-875-4111)** and ask for the GF Strong doctor on call for pump assistance, or go to **your nearest Emergency Department in a life threatening situation and ask them to contact the GF Strong doctor on call to assist you with your pump!**

EMERGENCY INSTRUCTIONS

You will receive a **Pump Implantation Card**, **Pump Booklet Information**, and **3 Pump Symptoms** sheet when you are discharged from the hospital. Bring your 3 Pump Symptom sheet with you if you are admitted to an Emergency Department to assist with your pump care.

In an emergency situation, such as extreme drowsiness, breathing problems, or an abrupt onset of s pasticity, go to your nearest hospital emergency department for medical intervention and have them **call Vancouver**General Hospital (604-875-4111) and ask to speak to the GF Strong doctor on call for assistance.

Extreme drowsiness may be the result of an overdose and require immediate medical attention which may include a significant decrease in dose, monitoring heart and respiratory function. Notify the baclofen pump team immediately. The ITB team will check the system's performance, possibly turn the pump to minimal rate, or stop the pump. Medical support measures may be required such as intubation, and intravenous medications.

FOR 24 HOUR MEDTRONIC TECHNICAL ASSISTANCE CALL 1-800-707-0933



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MISCELLANEOUS

- 1. **Inform family members and close friends** of your Baclofen pump, its purpose, and make them aware of the 3 pump symptoms that may occur.
- 2. **Notify your baclofen pump clinic nurse** and remind your primary physician and dentist that you have an implanted pump **prior to any medical or dental treatments** such as MRI's, lithotripsy, ultrasound, etc. to prevent pump damage or medical adverse effects.
- 3. Call the Baclofen Clinic if you should hear a **beeping sound (alarm or noise)** coming from your pump.
- 4. If you plan to travel for your holidays, notify your nurse in advance so a refill can be arranged.
- 5. On **your first refill**, you will receive 40 mLs of medication.
- 6. It is critically important to **keep ALL your refill appointments** to **avoid adverse effects**. The drug is prepared by pharmacy and it is only good for 24 hours.
- 7. Please notify the clinic nurse if you cannot make your appointment before 10:00 am the day before your pump refill or call Laurel Pharmacy at 604-873-5511. You will be charged for the medication, if you miss your refill appointment.