STANDARDIZED PROCEDURE
BOTULINUM TOXIN THERAPY (Adult, Peds)

I. Definition:

The purpose of this procedure is to allow the Allied Health Professional to administer botulinum toxin injections. Botulinum toxin is indicated for patients with focal spasticity that is refractory to oral medication. In patients diagnosed with spasticity, botulinum toxin is injected by a trained nurse practitioner directly into the affected muscles blocking overactive nerve impulses that trigger these disabling contractions to reduce the severity of increased muscle tone.

Additionally, botulinum toxin it is indicated for people with sialorrhea, which is a common and disabling symptom in neurological disorders such as amyotrophic lateral sclerosis (ALS) or Parkinson's disease. A trained nurse practitioner injects into the parotid and/or submaxillary glands to reduce sialorrhea in appropriate patients.

Direct delivery of botulinum toxin into affected muscles or glands helps alleviate symptoms without the side effects of oral medications such as weakness and sedation.

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 a Pediatric procedure is being done, 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 this procedure. At that time, general or indirect supervision is acceptable.

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

The Advanced Health Practitioner will notify the physician immediately upon being involved in any emergency or resuscitative events or under the following circumstances:

1. Patient decompensation or intolerance to the procedure
2. Bleeding that is not resolved
3. Outcome of the procedure other than expected

C. Indications:
For the treatment of focal spasticity when oral therapy is ineffective and/or not

tolerated. Also for the treatment of sialorrhea when oral therapy causes undesirable adverse effects.

D. Precautions / Contraindications:
Allergy to botulinum toxin.

III. Materials:

1. Botulinum toxin A or B
2. Preservative-free Normal Saline
3. 1-ml syringes
4. 3-ml syringes
5. 1.5-inch and 2-inch, 21-23 gauge needles
6. 1.25 inch, 27 gauge needles
7. 1/2 inch, 27 and 30-gauge needles
8. 3/8 inch, 26-gauge needles
9. Nonsterile gloves
10. Alcohol wipes
11. Cotton balls
12. Bandaids.

IV. Treatment of Spasticity

A. Pre-treatment evaluation:

1. History- spasticity refractive to oral therapy.
2. Patient evaluation: focused exam, including testing for motor strength, presence of spasticity, abnormal posturing, or contractures, and gait evaluation.
3. Determine the appropriate sites for injection. Select dose based on muscles affected, severity of muscle activity, prior response to treatment, and adverse event history.

B. Set up: Gather necessary supplies

C. Patient preparation:

1. Position the patient for optimal access to target muscles.
2. Informed Consent

Discuss the risks, benefits, and anticipated outcomes. The main adverse effect is excess weakness in the injected muscle. This weakness is temporary and wears off. Additional risks are injection site pain, bleeding, erythema, and infection. Rarely, the effects of botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of

botulism. Those symptoms include potentially life-threatening swallowing, breathing difficulties, and even death.

In some individuals treated with BoNT, antibodies may develop, bind to the drug, and inactivate it. This renders that particular serotype of BoNT ineffective. To prevent antibodies from developing, the following principles will apply:

a, The smallest amount of BoNT necessary to achieve therapeutic benefit will be used.

b. The time interval between treatment sessions will be at least three months.

c. The use of "booster" injections will be avoided.

D. Perform the procedure

1. Dilute the botulinum toxin in a 1:1, 2:1, 3:1, or 4:1 fashion (as appropriate for each specific muscle) with preservative free 0.9% normal saline.
2. Confirm the appropriate site(s) for injection. Small muscles may be injected in only one or two sites. Larger muscles may require three to four injection sites.
3. Clean the injection site with alcohol pad and allow to dry.
4. Electromyography (EMG) guidance: (In large or accessible muscles, confirmation of appropriate placement of the injection into the target muscle may be achieved by feeling the muscle. In small or deep muscle groups, electromyography (EMG) or electrical stimulation may be required to confirm appropriate placement.)
   Attach syringe with appropriate botox dose to an EMG needle. Insert the needle into the muscle. The electrode in the EMG needle will transmit signals via a wire to a computer so that muscle activity can be identified as both an electrical waveform and a crisp sound. Once muscle penetration is confirmed, pull back on the plunger to check for blood return. If there is no blood return, inject botox slowly, as tolerated, and withdraw the needle. If blood return is seen when pulling back the plunger, withdraw the needle and start again.
5. If EMG is not used: Place the smallest needle possible into the target muscle. Pull back on the plunger to observe for blood return. If no blood return observed, inject slowly and withdraw the needle. If blood return is seen when pulling back the plunger, withdraw the needle and start again.

E. Follow-up treatment

The patient is to call the clinic in 2 weeks' time to inform about his/her response to this treatment regimen.

V. Treatment of Sialorrhea

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A. Pre-treatment evaluation:

1. History- sialorrhea refractive to oral therapy.
2. Patient evaluation: Look for drooling. Inquire about how much drooling and if the patient is still eating. Do a focused exam.
3. Determine the appropriate sites for injection. parotid (posterior to the palpated masseter muscle and anterior to the external ear) and submandibular glands (anterior and medical to the genu of the mandible).

B. Set up: Gather necessary supplies

C. Patient preparation:

1. Position the patient for optimal access to target area.
2. Informed Consent

Discuss the risks, benefits, and anticipated outcomes. The main adverse effect is excess weakness in the injected area. This weakness is temporary and wears off. Additional risks are injection site pain, bleeding, erythema, and infection. Rarely, the effects of botulinum toxin may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism. Those symptoms include potentially life-threatening swallowing, breathing difficulties, and even death.

In some individuals treated with BoNT, antibodies may develop, bind to the drug, and inactivate it. This renders that particular serotype of BoNT ineffective. To prevent antibodies from developing, the following principles will apply:

a, The smallest amount of BoNT necessary to achieve therapeutic benefit will be used.

b. The time interval between treatment sessions will be at least three months.

c. The use of "booster" injections will be avoided.

D. Perform the procedure

1. Dilute the botulinum toxin in a 1:1 or 2:1 fashion with preservative free 0.9% normal saline.
2. Confirm the appropriate site(s) for injection.
3. Clean the injection site with alcohol pad and allow to dry.
4. Place appropriately sized needle into the target gland. Pull back on the plunger to observe for blood return. If no blood return observed, inject slowly and withdraw the needle. If blood return is seen when pulling back the plunger, withdraw the needle and start again.

E. Follow-up treatment

The patient is to call the clinic in 2 weeks' time to inform about his/her response to this treatment regimen.

VI. Documentation

A. Documentation is in the electronic medical record

1. Documentation of the pretreatment evaluation
2. Record the time out, indications, date of patient's last botox injection, procedure, location, number and dose of injections, and total dose of administered units, unavoidable waste, EBL, the outcome, patient tolerance, medications given, and the plan in the note, as well as any self-care or discharge instructions.

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

VII. 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 Botulinum Toxin Therapy.
   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.

VIII. RESPONSIBILITY

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

IX. HISTORY OF PROCEDURE

Written May 2012
Revised June 2012 by Subcommittee of the Committee for Interdisciplinary Practice
Reviewed June 2012 by the Committee on Interdisciplinary Practice
Prior revision - none
Approved by the Executive Medical Board and the Governance Advisory Council.