Document Control

Title

Botulinum Toxin use in Facial Dystonia Clinics (Ophthalmology Department) Standard Operating Procedure

Author	**Author's job title** Consultant Ophthalmologist
Directorate Surgery	**Department** Ophthalmology **Team/Specialty** Ophthalmology

Version	Date Issued	Status	Comment / Changes / Approval
1.0	May 2016	Draft	Initial version for consultation
2.0	June 2016	Final	Approved and published
3.0	May 2021	Final	Approved at Specialty Governance Change to section……

Main Contact Consultant Ophthalmologist North Devon District Hospital Raleigh Road Barnstaple, North Devon, EX31 4JB	**Tel: Direct Dial** – **Tel: Internal** – **Email**:
Lead Director Director of Surgery	
Document Class Standard Operating Procedure	**Target Audience** Ophthalmology Department Health Practitioners
Distribution List Senior Management Ophthalmology Department Health Practitioners	**Distribution Method** Trust's internal website
Superseded Documents None	

Issue Date	Review Date	Review Cycle
May 2021	May 2024	Three years

Consulted with the following stakeholders: (list all) • Ophthalmology Consultants • Clinical Pharmacy Manager • Orthoptist	**Contact responsible for implementation and monitoring compliance:** Consultant Ophthalmologist **Education/ training will be provided by:** Consultant Ophthalmologist
Approval and Review Process • Ophthalmology Specialty Governance	

Local Archive Reference G:\ ORTHOPTICS \ CLINICAL FOLDER \ EXTENDED CLINICAL ROLE \ SOP'S \ VERSION 3 \ MAY 21 **Local Path** Orthoptic Extended Role folder **Filename** G:\ Orthoptics \ Clinical Folder \ Extended Clinical Role \ Sop's \ Version 3 \ May 21	
Policy categories for Trust's internal website (Bob) Ophthalmology	**Tags for Trust's internal website (Bob)** Botox Botulinum Toxin Blepharospasm Hemifacial Spasm Facial Dystonia

CONTENTS

1. Background

Facial dystonia refers to blepharospasm and hemifacial spasm. Patients with both conditions present to the ophthalmology department. Blepharospasm is a condition in which there is sustained, forced, involuntary closure of the eyelids. Hemifacial spasm is a movement disorder that causes the muscles on one or both sides of the face to contract involuntarily and for sustained periods. Both of these conditions are debilitating with a significant impact on functioning and quality of life. Chemodenervation using botulinum toxin has been the mainstay of treatment for these conditions for over 20 years.

Practitioners authorised to inject botulinum toxin for treatment of facial dystonia include doctors and orthoptists with appropriate training as outlined below:

- Must be trained to take consent for this procedure
- Must have up to date training in Basic Life Support
- Must be familiar with Standard Infection Control Precautions
- Must have been trained in the use of botulium toxin A for the management of facial dystonia or perform the procedure under supervision by another clinician trained in its use
- Orthoptists administering botulinum toxin independently must have received training regarding botulinum toxin, including knowledge of the mode of action, therapeutic uses, normal dosage, side effects, precautions and contra-indications and had practical instruction on the correct technique of botulinum toxin administration and be signed of as competent.
- The orthoptist must not alter the botulinum toxin A injection site and/or dosage for patients with benign essential blepharospasm and hemifacial spasm. Any decision to alter dosage/site of injection must be made by and documented in the medical records by the Consultant. The orthoptist should seek verbal consent from the patient for any change.

2. Purpose

2.1. The Standard Operating Procedure (SOP) has been written to:

- Identify the procedure for the delivery of a facial dystonia service within an out-patient setting
- This SOP covers the use of Botox® for the treatment of blepharospasm and hemifacial spasm only.

3. Scope

3.1. This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the delivery of this service:

- Orthoptists
- Medical staff

4. Location

4.1. This Standard Operating Procedure can be implemented in all clinical areas where competent staff are available to undertake this role.

4.2. Staff undertaking this procedure must be able to demonstrate continued competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

Botulinum Toxin A

- At North Devon Healthcare Trust, Botox® (Allergan Ltd) is the standard form of Clostridium botulinum toxin A used. It comes in a powder form in a vial to be reconstituted with normal saline 0.9%. 100 unit or 50 unit vials are available. The vial should be refrigerated at 2°C-8°C, or stored in a freezer at or below -5°C. Its reconstituted shelf-life is 24 hours at 2 - 8 degrees C.
- Botox is licensed by the Medicines & Healthcare products Regulatory Agency (MHRA) for use in blepharospasm and hemifacial spasm for adults. It must not be administered in patients younger than 18 years of age without discussion with a consultant ophthalmologist.

Other equipment required for preparation

- 2 mL Luer lock syringe
- One vial of botulinum toxin (Dysport 500 units) or (Botox 100 units) or (Xeomin 50 or 100 units)
- One sterile sodium chloride 0.9% ampoule 5mL
- 2 mL syringe
- Injection tray
- 23G (green) needle
- 0.5ml 30 gauge insulin syringe
- Antiseptic wipes
- Proxymethacaine eye drops

6. Procedure

Procedure prior to Botox administration

<u>Doctor Facial Dystonia Clinics – New Patients</u>

- All new patients are seen by a doctor.
- Gather a medical and ophthalmic history and current medications from the patient at the initial visit.
- A full anterior segment examination must be carried out to assess the impact of dry eye and meibomian gland disease
- Careful testing of corneal sensation in previously operated eyes is mandatory
- Caution must be taken in patients with significant dry eye, persistent epithelial defect and corneal ulceration (especially in those with VIIth nerve disorders).

- Give the patient the relevant botulinum toxin information leaflet prior to the first toxin administration.
- Take valid written consent for the procedure in accordance with the Trust's Consent Policy having explained the rationale, procedure and possible complications. This consent form must be placed in the patient's health records.
- Ensure that there are no contraindications or an allergy to botulinum toxin use
- The expiry dates of all medicines and equipment must be checked prior to use.

Facial Dystonia Clinics – Repeat Treatment Patients

- For orthoptist-delivered clinics, the orthoptist must check that the patient is suitable for treatment in this clinic rather than a doctor clinic.
- The doctor must have prescribed the units of Botox required on the Medisoft EPR.

The following patients are only suitable for treatment by a doctor:

- Patients whose dystonia is not stable on treatment
- Significant dry eye
- Persistent epithelial defect
- Corneal ulceration (especially in those with VIIth nerve disorders)
- Neuromuscular junction disorders e.g. myasthenia gravis
- Defective neuromuscular transmission e.g. difficulty in swallowing or breathing
- Patient pregnant
- Patient breast-feeding
- Check medical status and medications have not changed
- Document any adverse reaction or allergy to previous Botox treatment
- Examine the anterior segment of patients with significant dry eye, persistent epithelial defect and corneal ulceration (especially in those with VIIth nerve disorders).
- If an orthoptist is administering treatment, he/she must consult the prescription for Botox®.
- Check the patient's details verbally and verify with the patient record to ensure correct identification.
- If consent has been obtained at a previous visit, ensure that the consent form is present, correct and valid for the current visit.
- Check recorded treatment plan and the identified injection sites.
- The expiry dates of all medicines and equipment must be checked prior to use.
- The orthoptist must not alter the botulinum toxin A injection site and/or dosage for patients with benign essential blepharospasm and hemifacial spasm. Any decision to alter dosage/site of injection must be made by and documented in the medical records by the Consultant.
- A senior clinician should review the patient if contraindications to treatment are identified, if there is a significant change in the clinical findings, if a request has been made to see a doctor or if the treatment has failed to achieve the desired effect.

Preparation of Botox

- *To mix Botox (100 units per vial):*
  - Reconstitute the Botox vial with 2mL of sodium chloride 0.9% using a 23G (green) needle
  - Gently invert or rotate the bottle. Do not shake

- *The resultant concentration is 5 units in 0.1mL*
  - This reconstituted solution may be stored for up to 24 hours at 2 to 8°C.
  - Nevertheless the product should be used immediately

Injection Procedure

- Check previous recorded treatment plan and the identified injection sites
- Wash hands
- If the patient has a low pain threshold, tetracaine 4% gel (Ametop) can be applied to the injection sites. This needs to remain in place for a period of twenty minutes
- Put a drop of proxymethacaine 0.5% into each eye
- Prep the area around the eye using an antiseptic wipe and leave for 30 seconds
- All injection sites must be 1 cm away from the lateral canthus / medical canthus in both the upper and lower lids except for the lower lid mid pupil site, where the injection site must be 0.5 cm from the lower lid margin
- The appropriate dose should be drawn into a 0.5mL insulin syringe with a 30G needle.
- Lightly dab the injection site as too much pressure may distribute the injection beyond the identified location

Disposal and Handling

- Unused Botox® vials should be inactivated with 2% hypochlorite solution (Milton) and disposed of in the purple-lidded sharps bin.
- Botox® in used vials or syringes should be inactivated using 2% hypochlorite solution (Milton) and disposed of in the purple-lidded sharps bin.

Follow up Arrangements

- Follow up appointment is given to patient for 2 – 6 months in a doctor or orthoptist-delivered facial dystonia clinic.
- If the dose is changed, the patient should be contacted **after 2 weeks** to assess the efficacy of treatment and to determine whether further treatment is necessary

Recording Treatment

- Document injection sites, dose, expiry date and batch number of botulinum toxin given following injection.
- Sign and print name and designation.

- Any complications, incidents and near misses must be entered in the patient's health records and on a Trust Electronic Incident Form in accordance with the Trust Incident Reporting Policy.

Splitting of Vials

- Vials should not be split between patients to minimise the risk of clinical error.
-

7. References

- Moorfields Eye Hospital, Botulinum Toxin Manual, Version 2.0 (2015)

8. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for :

- Obtaining patient consent
- Infection Control Policy
- Competency Statement
- Injectable Medicines Policy
- PGD to administer Tetracaine Gel
- PGD to administer Proxymetacaine Eye drops
- Proxymetacaine SOP
- Medicines Policy
- Waste Management Policy