Botulinum Toxin Injections Standard Operating Procedure UHL Spasticity Service (LocSSIPs)

Change Description	**Reason for Change**
☐ Change in format	☒ Trust requirement

APPROVERS	**POSITION**	**NAME**
Person Responsible for Procedure:	Deputy Clinical Director	Dr Amit Mistri
SOP Owner:	Consultant in Stroke Medicine	Dr Rachel Marsh
Sub-group Lead:	Consultant in Neuro-Rehabilitation	Dr RS Prasad

Appendices in this document:

Appendix 1: UHL Safer Surgery Spasticity Clinic Checklist
Appendix 2: Patient Information Leaflet for Botulinum toxin for muscle spasticity

Introduction and Background:

This Local Safety Standard for Invasive Procedures (LocSSIP) covers injections of Botulinum toxin injections in adults. This is used in various areas including.

1. Spasticity management.

National Guidelines-Royal College Of Physicians 2018-Spasticity in Adults: Management using Botulinum toxin

https://www.bsrm.org.uk/downloads/spasticity-in-adultsfinal-version-published23-4-18.pdf

2. Focal Dystonia

3. Chronic Migraine
   Botulinum toxins for the prevention of migraine in adults
   Cochrane Systematic Review - Intervention Version published: 25 June 2018
   https://doi.org/10.1002/14651858.CD011616.pub2

4. Chronic Sialorrhea in patients with a neurological problem

When a referral for a Botulinum Toxin injection is made:

The minimum dataset required for booking an appointment is as follows:

- Referral date
- Patient name
- Hospital or NHS number
- Procedure
- Site of concern identified Diagnosis
- Abbreviations of laterality (i.e. L and R for left and right) will not be used.

Outpatients

Patient lists are set up in line with consultant job plans and each session runs for 3- 4 hours. Any changes to a list are communicated via email to the responsible clinician and administration team. Patients who DNA or cancel more than twice, in line with the Trust access policy, are discharged back to the referrer unless clinician deemed medically necessary.

Appointment booking rules as are as follows:

- All patients irrespective of site injection – single time slot

The administration teams on within the day case/outpatient areas are responsible for ensuring the lists are booked with adequate notice to patients. In line with the Trust leave policy there is a minimum of 6 weeks' notice required to cancel a list.

Patient preparation:

Define situation/condition	Patients seen in inpatients and in out-patient clinic. For the treatment of: • Focal upper limb spasticity/ spastic dystonia arising from an upper motor neurone lesion • Focal lower limb spasticity/spastic dystonia arising from an upper motor lesion • Symptomatic relief of blepharospasm, hemifacial spasm and idiopathic and secondary cervical dystonia (spasmodic torticollis) • Sialorrhea

Criteria for inclusion	• Patients with focal spasticity with identified goals for treatment. • Patients 18 years and over and patients16 years and over if treated or have been treated on BIU/NRU or transitioning from children's services. • Procedure and possible effects explained to the patient and other carers / family if present. • Clinical need for injection of Botulinum toxin identified by the Consultant.

Exclusion criteria	• Contracture. • Patient refuses treatment • Adjacent osteomyelitis • Pregnancy and breastfeeding • Known allergy to Botulinum toxin or any excipients of the injection • Local or systemic infection • Generalised disorders of muscle activity e.g. myasthenia gravis except in the disorders of sialorrhea. • Any significant adverse effect from previous injection of botulinum toxin e.g. dysphagia, dyspnoea.

Action if excluded	Refer to Consultant and document in medical notes.
Action if patient declines	Document in medical notes treatment offered and if known the reason for decline. Make appointment with Consultant if patient or clinician feels it is indicated.

Main Side effects of Botulinum Toxin are:

Local muscle weakness from toxin spread to nearby muscles. This may cause temporary functional loss. Local muscle atrophy may occur. Rarely, more generalised muscle weakness may be seen, particularly if high doses are given in multiple muscles (Bakheit, Ward *et al* 1997).

Dysphagia occurs mainly when high doses are used around the neck or proximal upper limb.
Nevertheless, it should be remembered that patients with brain injury or stroke may have impaired swallowing reflexes. Care should be taken when injecting larger doses of BoNT-A in patients with a history of dysphagia, especially if they do not have percutaneous gastrostomy (PEG) feeding tubes. Some patients with spastic or dystonic dysphagia may improve.

Respiratory failure has not been reported in adults, although there have been isolated case reports in children with cerebral palsy. Nevertheless, it remains a theoretical risk for higher dose treatments, and should be considered when planning injections for patients with profound neuromuscular compromise.

Autonomic dysfunction, if it occurs, is almost always sub-clinical. Once again, however, it is something to bear in mind in patients who may already have a degree of autonomic dysfunction, eg some patients with Parkinson's disease or diabetes.

'Flu-like' symptoms for up to a week, at some point in the month after injection. These are transient and mild.

Other rarely reported side effects are rashes, altered taste, and brachial neuritis (very rare) following local injections.

Patients on Anticoagulants Need careful assessing to determine the risk of Bleeding from Injection versus the benefit of the same in each case as this is a Relative Contraindication.

Workforce – staffing requirements:

Qualifications/ Training required	Had specific training with a qualified injector
Additional Requirements	SpR's to do DOPS/ all require to maintain adequate CPD in Spasticity Management.

Minimum Staffing:
The minimum requirement of safe staffing is two staff when injecting a patient (one of them should be a qualified injector).
In outpatient spasticity clinic there should be a doctor and a therapist in the clinic, however an actual injection can be given by one of the above and an assistant.

The physiotherapist/occupational therapist should have the following:

Qualifications required	Health and Care Professions Council (HCPC)
Additional requirements	Completed and passed post-graduate training course in Injection Therapy (Neurology). Local PGD training and competency assessment completed.
Continued training and competency requirements	Annual update on CPR PGD training as per the PGD policy and competency update when PGD changes. Actively partaking in CPD and annual Individual Performance Review

Ward checklist, and ward to procedure room handover:

Not Applicable.

Procedural Verification of Site Marking:

A UHL Safer Surgery Spasticity Clinic Checklist is to be used in spasticity clinic, when the decision as to which muscles are injected is made clinically at the time by the injector. For in patients, the decision regarding which muscles to inject is made by a doctor often in collaboration with Physiotherapist.
Whilst multiple injection sites can be used. A marker will be used to confirm laterality.

Team Safety Briefing:

The 'Team Safety Briefing' must occur at the start of any elective, unscheduled or emergency procedure session to check the identity of the patient and the reason for the referral.

Sign In:

'Sign In' refers to the checklist completed at the patient's arrival into the procedure area.

- That the patient will be encouraged to participate where possible
- That omissions, discrepancies of uncertainties must be resolved before proceeding

See UHL Safer Surgery Spasticity Clinic Checklist (Appendix 1)

Time Out:

'Time Out' is the final safety check that must be completed for all patients undergoing botulinum toxin injections just before the start of the procedure. The UHL Safer Surgery Spasticity Clinic Checklist will be completed prior to the procedure and the patient will be encouraged to participate where possible.
See the UHL Safer Surgery Spasticity Clinic Checklist in Appendix 1 (at the end of the document)

- Informed consent gained prior to procedure, written for new and verbal for follow up.
- That all team members must be present and engaged as it is happening
- That it will occur immediately before the procedure start
- That any omissions, discrepancies or uncertainties must be resolved before starting the procedure
- Medication prescription and dose is confirmed and prescribed.
- UHL Safer Surgery Spasticity Clinic Checklist completed and filed in notes

Performing the procedure:

As per Royal College of Physicians National Guidelines on Spasticity in Adults: management using Botulinum Toxin January 2018-

A Service for Spasticity Management using Botulinum Toxin should be a Coordinated Multidisciplinary Service with integrated Physiotherapy input for selecting appropriate patients for treatment, arranging Stretching or delivering post injection Physiotherapy and ensuring appropriate provision of Splinting with good links with Physical Therapy Departments in referring units and in community.

Principles of Coordinated Spasticity management

The management of Spasticity should be undertaken by a Coordinated Multidisciplinary Team and that Botulinum Toxin should only be injected by Clinicians who have appropriate understanding of functional anatomy experience in assessment and management of Spasticity and use of Botulinum Toxin in this context, knowledge of appropriate dosing regimes and ability to manage any potential complications

Patients should be selected for Botulinum Toxin on basis of focal/ multifocal problems due to spasticity

Patients and families / carers to be given appropriate information (hence the Patient Information Leaflet (PIL)- Botulinum Toxin Injection for Spasticity Management In Adults (Having Botulinum toxin injection for muscle spasticity (leicestershospitals.nhs.uk) attached), have an understanding of realistic goals for treatment and agree with treatment goals before Botulinum Toxin is given.

Informed Consent must be obtained from Patients before treatment/ written for New and verbal for follow up

Each patient who has contact with the service has a patient recorded outcome measure (PROMs) which is agreed with them before the injection and monitored to ascertain the clinical effectiveness of then treatment. The aims of treatment with BT is clearly explained to patients and carers and communicated to GPs along with the actual muscles injected, dose of BT used and name of the injector. Appropriate patients are referred for Therapy and specialist services as required.

Monitoring:

No special monitoring is needed apart from checking that all injection sites are not bleeding and that the patient is fit to leave as occasionally patients may feel unwell and/or dizzy after the injection.

Prosthesis verification:

Not Applicable.

Prevention of retained Foreign Objects:

Not Applicable.

Radiography:

Ultrasound Guidance for Injection:

Patients may have Ultrasound Guided Injections, and Infection Control Procedures are followed(Ultrasound Probe wrapped in Disposable Single use Sterile Sleeve using Non Touch Technique)

Sign Out:

'Sign Out' must occur before the patient leaves the operative/procedure area.
Sign out should include:

- Discussion of post-procedural care and any concerns.
- Post procedural advice regarding stretching +/- importance of splint wearing.
- Monitor for any immediate side effects.

Handover:

Not Applicable.

Team Debrief:

A 'Team Debrief' should occur at the end of all procedure sessions.
All team members should have a debrief at the end of each clinic.

See UHL Safer Surgery Spasticity Clinic Checklist (Appendix 1)

Post-procedural aftercare:

Post Injection Follow up

All injections should receive education to the patient and family about importance of stretching exercise. If appropriate, a referrral for therapy review and/or splinting in community. MDT review at 3-4 months to plan future management.

Discharge:

A discharge letter and any changes to medication or actions needed by GP, to be completed on ICE or DIT3
Follow-up is given on the discharge letter.

Governance and Audit:

Yearly spot audit will be undertaken.
To submit monthly Safe Surgery Audit and WHOBARS assessment as Per Safe Surgery Quality Assurance & Accreditation programme.

Training:

Staff attend appropriate training for injectors and continue to retain skills by injecting and attending Refresher Course

Documentation:

To have clear documentation of procedure in the notes.

References to other standards, alerts and procedures:

National Safety Standards for Invasive Procedures, NHS England 2015:
https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/09/natssips-safety-standards.pdf
UHL Safer Surgery Policy: B40/2010
UHL Consent to Treatment or Examination Policy A16/2002
UHL Delegated Consent Policy B10/2013
UHL Guideline: Anticoagulation management ("bridging") at the time of elective surgery and invasive procedures (adult) B30/2016

National Guidelines-Royal College Of Physicians 2018-Spasticity in adults: Management using Botulinum toxin

https://www.bsrm.org.uk/downloads/spasticity-in-adultsfinal-version-published23-4-18.pdf

Botulinum toxin type A (Botox®) is accepted for use within NHS Scotland.
Indication under review: focal spasticity, including the treatment of wrist and hand disability due to upper limb spasticity associated with stroke in adults.
In a placebo-controlled study, botulinum toxin type A was significantly superior to placebo in terms of the disability assessment scale and efficacy was maintained across repeated

injections in an open-label extension study with a duration of one year.
SMC No. (80/03) Botulinum Toxin

Cochrane review Botulinum Toxin A therapy for blepharospasm. April 2004. Cochrane comment:

Botulinum therapy is probably the second most important discovery in movement disorder therapy after levodopa. Few drugs have such an obvious benefit as Botulinum has in some dystonias. The strength of this effect in blepharospasm has probably been responsible for the paucity of RCTs comparing BtA with placebo. Even though we do not have high quality, randomised, controlled data, indications are that BtA is indeed effective and safe in blepharospasm.

Cochrane review Botulinum Toxin A therapy for hemifacial spasm. January 2005.
Author conclusions (implications for practice): All studies available strongly suggest that BtA is effective and safe for treating hemifacial spasm (HFS). Despite the absence of large RCTs, the efficacy of BtA for HFS is not in doubt.

MTRAC review Botulinum Toxin A summary sheet. October 1995. Conclusion: Botulinum toxin is effective in the treatment of both blepharospasm and hemifacial spasm. Administration should be performed by those with a thorough knowledge of the anatomy and pathophysiology of the condition being treated, with experience of selection and administering the appropriate dose and managing potential adverse effects. It is not therefore suitable for general prescribing in general practice.

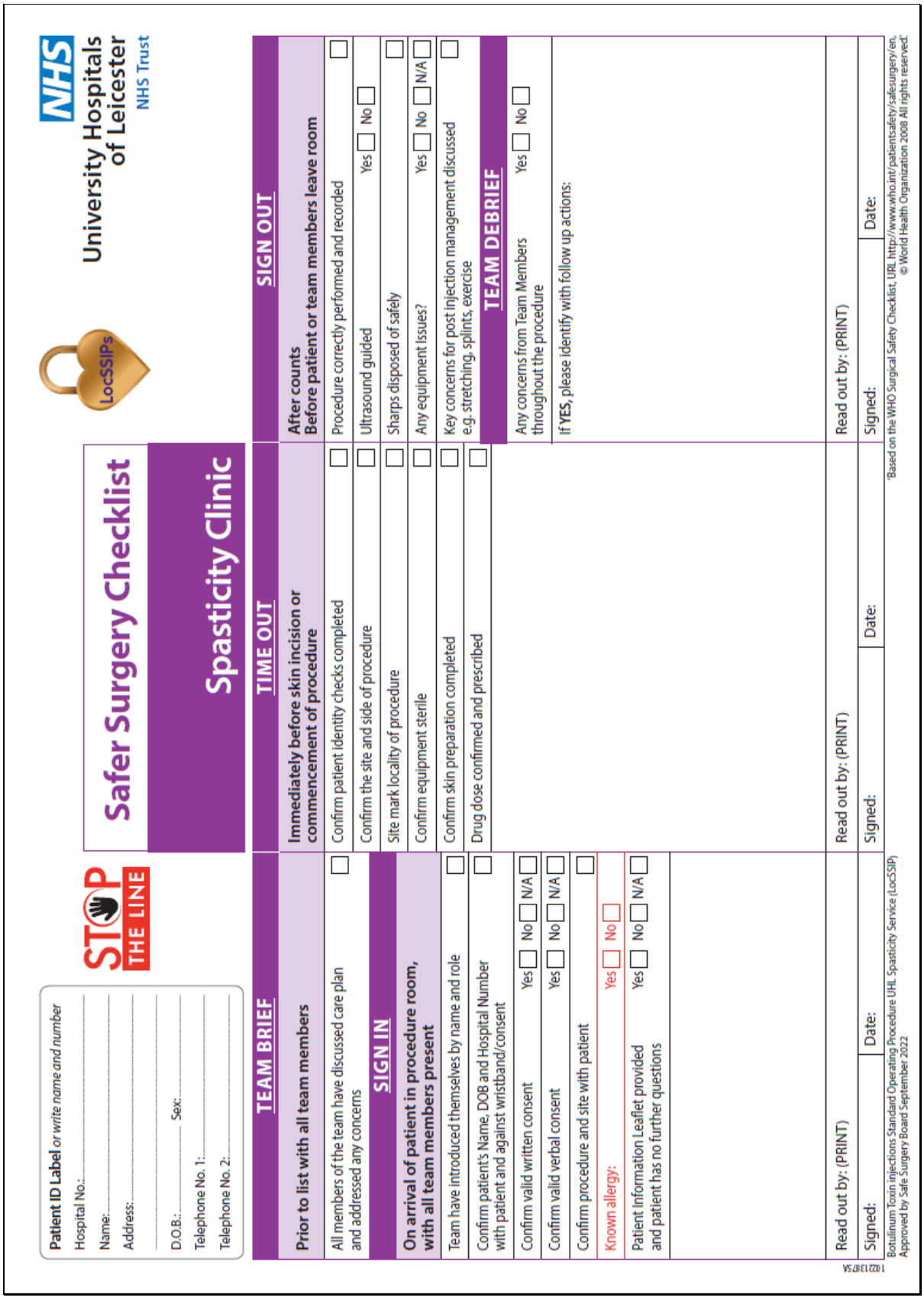
Cochrane review Botulinum Toxin A therapy for cervical dystonia. January 2005. Cochrane conclusion (Implications for practice):
Despite the variety of trial formats, virtually all the trials individually, and each outcome measure separately, suggested that a single injection cycle of BtA is effective and safe for treating cervical dystonia. Enriched trials (using patients previously treated with BtA), suggest that further injection cycles continue to work for most patients.
Appropriate injections of BtA into cervical muscles at therapeutic doses are well tolerated, and although adverse effects occur they are transient and rarely severe

NHS England Deep Brain Stimulation (DBS) commissioning policy. Page 8 April 2013.
Before using DBS patients need to have tried and failed botulinum toxin treatment.
http://www.england.nhs.uk/wp-content/uploads/2013/04/d03-p-b.pdf Page 8

NICE TA 260 Botulinum toxin type A for the prevention of headaches in adults with chronic migraine. June 2012. (headaches on at least 15 days per month of which at least 8 days are with migraine)
Botulinum toxin type A is recommended as an option for the prophylaxis of headaches in adults with chronic migraine:
• that has not responded to at least three prior pharmacological prophylaxis therapies **and**
• whose condition is appropriately managed for medication overuse.

END

Appendix 1: UHL Safer Surgery Spasticity Clinic Checklist



Patient ID Label *or write name and number*
Hospital No.:
Name:
Address:
D.O.B.: Sex:
Telephone No. 1:
Telephone No. 2:

STOP THE LINE

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LocSSIPs

Safer Surgery Checklist

Spasticity Clinic

TEAM BRIEF

Prior to list with all team members

All members of the team have discussed care plan and addressed any concerns ☐

SIGN IN

On arrival of patient in procedure room, with all team members present

Team have introduced themselves by name and role ☐

Confirm patient's Name, DOB and Hospital Number with patient and against wristband/consent ☐

Confirm valid written consent Yes ☐ No ☐ N/A ☐

Confirm valid verbal consent Yes ☐ No ☐ N/A ☐

Confirm procedure and site with patient ☐

Known allergy: Yes ☐ No ☐

Patient Information Leaflet provided and patient has no further questions Yes ☐ No ☐ N/A ☐

Read out by: (PRINT)

Signed: Date:

TIME OUT

Immediately before skin incision or commencement of procedure

Confirm patient identity checks completed ☐

Confirm the site and side of procedure ☐

Site mark locality of procedure ☐

Confirm equipment sterile ☐

Confirm skin preparation completed ☐

Drug dose confirmed and prescribed ☐

Read out by: (PRINT)

Signed: Date:

SIGN OUT

After counts Before patient or team members leave room

Procedure correctly performed and recorded ☐

Ultrasound guided Yes ☐ No ☐

Sharps disposed of safely ☐

Any equipment issues? Yes ☐ No ☐ N/A ☐

Key concerns for post injection management discussed e.g. stretching, splints, exercise ☐

TEAM DEBRIEF

Any concerns from Team Members throughout the procedure Yes ☐ No ☐

If **YES**, please identify with follow up actions:

Read out by: (PRINT)

Signed: Date:

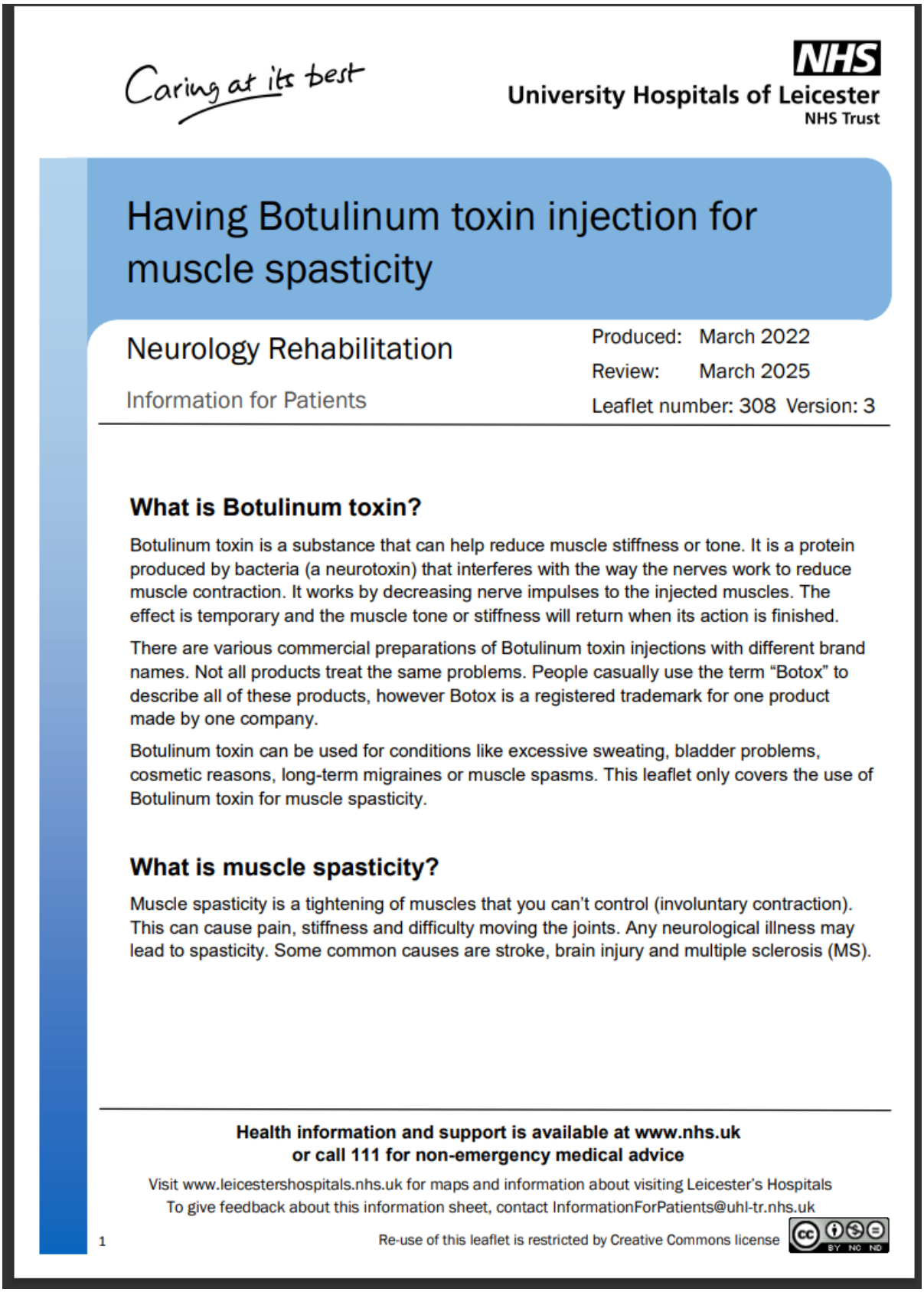
Botulinum Toxin injections Standard Operating Procedure UHL Spasticity Service (LocSSIPs)
Approved by Safe Surgery Board September 2022

'Based on the WHO Surgical Safety Checklist, URL http://www.who.int/patientsafety/safesurgery/en.

VS/JB/122013

Appendix 2: Patient Information Leaflet for Botulinum toxin for muscle spasticity

Available at: [Having Botulinum toxin injection for muscle spasticity (leicestershospitals.nhs.uk)]



Caring at its best

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Having Botulinum toxin injection for muscle spasticity

Neurology Rehabilitation

Information for Patients

Produced: March 2022
Review: March 2025
Leaflet number: 308 Version: 3

What is Botulinum toxin?

Botulinum toxin is a substance that can help reduce muscle stiffness or tone. It is a protein produced by bacteria (a neurotoxin) that interferes with the way the nerves work to reduce muscle contraction. It works by decreasing nerve impulses to the injected muscles. The effect is temporary and the muscle tone or stiffness will return when its action is finished.

There are various commercial preparations of Botulinum toxin injections with different brand names. Not all products treat the same problems. People casually use the term "Botox" to describe all of these products, however Botox is a registered trademark for one product made by one company.

Botulinum toxin can be used for conditions like excessive sweating, bladder problems, cosmetic reasons, long-term migraines or muscle spasms. This leaflet only covers the use of Botulinum toxin for muscle spasticity.

What is muscle spasticity?

Muscle spasticity is a tightening of muscles that you can't control (involuntary contraction). This can cause pain, stiffness and difficulty moving the joints. Any neurological illness may lead to spasticity. Some common causes are stroke, brain injury and multiple sclerosis (MS).

Health information and support is available at www.nhs.uk or call 111 for non-emergency medical advice

Visit www.leicestershospitals.nhs.uk for maps and information about visiting Leicester's Hospitals
To give feedback about this information sheet, contact InformationForPatients@uhl-tr.nhs.uk

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What are the benefits of having Botulinum toxin injections for muscle spasticity?

This will be discussed with you before the treatment begins and may include the following:

- Can help you with your personal care due to increased flexibility of treated limb or reduce discomfort during moving and handling.
- Can reduce muscle spasms.
- May improve positioning of your limbs.
- May reduce pain caused by muscle spasticity.

Is Botulinum toxin right for me?

Botulinum toxin injection is not suitable for you if you:

- are pregnant or breastfeeding.
- have an infection near the injection site.
- have a condition/ disorder which causes general muscle weakness (like myasthenia gravis, with changing muscle weakness).
- are very unwell with an infection that isn't under control.
- have widespread or general spasticity involving many parts of your body.

You may not be able to have Botulinum toxin injections if you are taking blood thinning medication like warfarin or rivaroxaban or apixaban. The risks and benefits to you would need to be discussed in this case.

What can I expect from this treatment?

It can take up to 2 weeks after having the injections before you notice a difference.

The effects can last up to 6 months though it usually wears off after 3 to 4 months in many cases. Treatment can be repeated after 3 to 4 months, if the goals for treatment continue to be met.

The amount or 'dose' used varies according to what you need, and may change over time.

What are the side effects?

Common side effects include:

- Flu-like symptoms such as headache, fever and feeling tired. These are minor and do not last long.
- Muscle weakness usually in the injected muscles, but may rarely affect other nearby muscles due to spread of Botulinum toxin.

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- If injections are given into neck muscles, 10% of patients have difficulty swallowing (dysphagia) but this side effect doesn't last long.

Other side effects include:

- Reaction at injection site including pain and collection of blood (hematoma formation). This is more likely if you are taking blood thinning medication like warfarin.
- Dry mouth, difficulty sleeping (insomnia), and joint pain.

Rare side effects:

- Antibody formation to Botulinum toxin. This means that the injection may no longer work for you.

Very rare side effects:

- Due to weakness of swallowing, material from the mouth or stomach may enter lungs (aspiration) leading to a chest infection.
- A significant swallowing disorder where you would need tube feeding.
- Severe muscle weakness.
- Death is very rare and happens in less than 1 in 10,000 patients.
- Breathing difficulties.

What aftercare advice do I need to follow?

To get the most benefit from the injection, you should carry out daily stretching of the injected muscles or use a splint to stretch them. Some patients may be referred for physiotherapy, a home exercise programme, or occupational therapy so that a suitable splint can be provided.

اگر آپ کو یہ معلومات کسی اور زبان میں درکار ہیں، تو براہِ کرم مندرجہ ذیل نمبر پر ٹیلی فون کریں۔
على هذه المعلومات بلغةٍ أخرى، الرجاء الاتصال على رقم الهاتف الذي يظهر في الأسفل
જો તમને અન્ય ભાષામાં આ માહિતી જોઈતી હોય, તો નીચે આપેલ નંબર પર કૃપા કરી ટેલિફોન કરો
ਜੇ ਤੁਸੀ ਇਹ ਜਾਣਕਾਰੀ ਕਸਿ ਹੋਰ ਭਾਸ਼ਾ ਵਚਿ ਚਾਹੁੰਦੇ ਹੋ, ਤਾਂ ਕਰਿਪਾ ਕਰਕੇ ਹੇਠਾਂ ਦੱਤਿ ਗਏ ਨੰਬਰ 'ਤੇ ਟੈਲੀਫੋਨ ਕਰੋ।
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If you would like this information in another language or format such as EasyRead or Braille, please telephone 0116 250 2959 or email equality@uhl-tr.nhs.uk

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