

Toxin Standards

Box 1. Identified risk level and cooling off	
Defining risks to patient	<p>Botulinum toxin injection carries an element of risk which should be explicitly explained to the patient. Quantification of the risk should be given where possible.</p> <p>Risk according to anatomical site</p> <ul style="list-style-type: none"> • Minimal risk mild transient symptoms — Upper face, Neck, Hyperhidrosis • Moderate transient symptoms/impairment — Periocular, Perioral <p>Risks according to product</p> <ul style="list-style-type: none"> • **Inadvertent systemic toxic effect can be life threatening (as per manufacturer) • To assist quantifying risk, please refer directly to the manufacturer’s safety information. • “Off-license” use of botulinum toxin must only be performed by practitioners who are qualified to prescribe the drug. <p>A detailed consent form must be used, as described in ‘Consent’.</p> <p>Risks according to environment</p> <ul style="list-style-type: none"> • The clinical environment and mode of practice must be kept to a minimum standard as described in the overarching principles and in Box 3 and Box 6 to ensure safe practice. <p>Risks according to patient comorbidities</p> <ul style="list-style-type: none"> • Screening for changes to medical history, changes in health status, skin condition, or new medications must be performed prior to any new treatment • Patients must not be administered botulinum toxin if under the influence of alcohol or illicit substances. • Careful consideration should be taken if peer pressure is suspected from friends or partners to protect the welfare of patients. • So called ‘botulinum toxin parties’ or variations of this

	<p>theme/name/branding, neglect these principles are considered unethical practice.</p> <p>Other considerations</p> <ul style="list-style-type: none"> • A needle-stick policy must be in place • All staff must be aware of needle-stick injury policy • Needlestick injuries must be managed as per national guidance [1] • Both patient and practitioner must attend Accident & Emergency Department for blood borne virus screen. • A needle-stick injury can only be managed on-site if there is availability of occupational health to advise, the ability to take and process blood results and a robust and safe policy in place • All incidents must be reported and documented appropriately <p><u>References</u></p> <p>1. Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm</p>
<p>Risks to practitioner</p>	<p>Risks according to indemnity</p> <ul style="list-style-type: none"> • All practitioners require adequate practitioner indemnity as recommended by their training body (as per overarching principles) • The use of combination products may require specific insurance <p>Risks according to immunisation status</p> <ul style="list-style-type: none"> • Needlestick injury must be managed as per national guidance [1] • The practitioner has the immediate responsibility for any adverse event relating to physical administration including needlestick injury. If the practitioner is under supervision, this must be escalated to the accountable practitioner/prescriber • Practitioner immunisation status must be as per overarching principles <p>Risks according to environment</p> <ul style="list-style-type: none"> • The clinical environment and mode of practice must be kept to a minimum standard as described in Box 3 and Box 6 to ensure safe practice. <p><u>References</u></p> <p>1. Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm</p>

<p>Consent</p>	<ul style="list-style-type: none"> • During consent, the risks and benefits of a procedure must be discussed and documented with a patient according to GMC and Department of Health guidance [1][2] • There must be full explanation of what the treatment consists of, the expected after-effects, desired outcomes and risks • Consent for administration of botulinum toxin must be written. Patient's must be informed, and must be aware of all other alternatives before proceeding • Written consent must be confirmed at every new treatment • 'Top up' treatment is included in the written consent for the initial administration of botulinum toxin. This can be performed without the prescriber present within four weeks of the initial treatment. Any treatment beyond four weeks is considered new treatment and requires written consent • A generic consent form listing the risks of botulinum toxin administration must be used. This should allow space for additional specific risks relating to each patient • A copy of the consent form must be offered to the patient at every stage. Refusal of this offer must be documented. • It is vital to address patients' expectations at this stage to avoid future distress <p><u>References</u></p> <ol style="list-style-type: none"> 1. GMC Consent Guidance. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_other_sources_of_information.asp 2. Department of Health Consent for Examination or Treatment https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
<p>Cooling off</p>	<p>As per overarching principles</p> <p>No cooling off period is required if patients are attending the same practitioner following previous treatment with botulinum toxin.</p> <p><u>References</u></p> <ol style="list-style-type: none"> 1. Considering cosmetic surgery? http://www.bapras.org.uk/public/patient-information/cosmetic-surgery/considering-cosmetic-surgery

Box 2. Premises requirements

Premises	Premises As per overarching principles
Procedure room	Procedure room As per overarching principles and additionally: <ul style="list-style-type: none"> • Room layout must allow for safe practice • Adequate lighting must be available • A clinical couch offering good support and allowing for adjustment must be used • All surfaces must be wipe clean and kept clear • A sink must be present for hand-washing • Sharps bin must be present and disposed of appropriately when full • Mobile botulinum toxin administration outside of clinical premises is not endorsed by the CPSA
Equipment	As per overarching principles and additionally: Equipment must be available to ensure safe practice. Procedure <ul style="list-style-type: none"> • Non-latex, non-powder non-sterile gloves • Alcohol wipes • Sterile saline • Single use hypodermic needles • Single use syringes • Drug labels • Gauze • Dressings • Adhesive tapes • Denaturing kit for spilled / excess toxin Storage <ul style="list-style-type: none"> • Fridge must be maintained and cleaned regularly - this must have a lock to ensure safe storage • Fridge temperature must be audited and recorded • All medicines must be managed as per the overarching principles • Appropriate disposal (see below) Resuscitation equipment

	<ul style="list-style-type: none"> • As per the overarching principles and additionally: • Resuscitation equipment must be within the premises and checked daily • Practitioners must know where the nearest AED is located
<p>Clinical waste and sharps requirements</p>	<p>As per overarching principles and additionally:</p> <p>Disposal of peels and sharps</p> <ul style="list-style-type: none"> • A sharps bin should be available for peel glass bottles and microneedles • Peels and blood soaked gauze should be disposed of in orange bags [1] • Extra peel should be soaked up before disposal • Sharps and waste should be collected by licensed practitioners • Needle stick injuries should be managed as per national guidance [2] <p>References</p> <ol style="list-style-type: none"> 1. Classify different types of waste. https://www.gov.uk/how-to-classify-different-types-of-waste/healthcare-and-related-wastes 2. Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm
<p>Toxin management</p>	<p>As per overarching principles and additionally:</p> <p>Medical fridge</p> <ul style="list-style-type: none"> • Temperature gauge, monitoring and recordings as per manufacturers requirements for brand of toxin • Lock to ensure safe storage <p>Administration</p> <ul style="list-style-type: none"> • All storage, prescription and dispensing of botulinum toxin must be recorded by accountable officer • Vial sharing between patients is not advocated by the manufacturer or MHRA, they are single-use products (see overarching principles) • It is acknowledged there is discrepancy in the guidance provided to differing professions. Practitioners with a governing body should only use botulinum toxin within their guidance, and are held accountable for any practice beyond license • Denaturing kit for spilled / excess toxin must be available

Conference demonstrations	<ul style="list-style-type: none"> • The clinical environment, waste disposal and hygiene standards must be the same for demonstrations as clinical practice • It is more appropriate to record in a clinical environment and then view in a teaching environment than perform a live demonstration if these conditions cannot be met
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Box 3. Education and Training requirements

Degree requirements and qualifications	<p>As per the overarching principles and additionally:</p> <ul style="list-style-type: none"> • Entry levels as recommended in the HEE framework must be met [1] • Refer to <i>Supervision Matrix</i> for supervision details <p><u>References</u></p> <ol style="list-style-type: none"> 1. HEE Report on implementation of qualification requirements for cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery. https://www.hee.nhs.uk/sites/default/files/documents/HEE%20Cosmetic%20publication%20part%20two%20update%20v1%20final%20version_0.pdf
Accredited courses	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • Content of the course should be in line with the CPSA standards and HEE framework • Should include teaching in the assessment of Body Dysmorphia Disorder and mental health assessment • Reflective practice should be included in teaching
Resuscitation	<p>As per overarching principles</p>
Logbook and case numbers	<p>Prerequisite numbers of procedures for initial validation</p> <ul style="list-style-type: none"> • Practitioners in training must keep a logbook of cases • Training must involve a minimum of 10 observed cases and 10 supervised cases before qualification • Up to 1/3 can be achieved through simulation, as long as course accredited with qualified assessors. <p>Prerequisite numbers of procedures for ongoing validation</p> <ul style="list-style-type: none"> • Qualified practitioners must perform a minimum of 40 cases a year to maintain practice accreditation

<p>Continual professional development (CPD)</p>	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • Practitioners must demonstrate continued professional development (CPD). • Practitioners must demonstrate evidence of revalidation under their respective governing body. • Aesthetic practitioners should be held to the same standard as non-aesthetic practitioners • A minimum of 50 hours CPD must be demonstrated annually, clinicians of which an element is aesthetic • All practitioners who wish to organise or teach on courses should meet The JCCP Education and Training Standards which are cited on the JCCP website entitled 'The JCCP Education and Training Providers Register Standards' • Teaching, research, management and leadership can be included as part of CPD.
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<p>Box 4. Supervision - See <i>Supervision Matrix</i></p>	
<p>Assessment of patient</p>	<ul style="list-style-type: none"> • Supervisors must be a named and appropriately trained as per <i>Supervision Matrix</i> • Supervision – will vary according to practitioner background – as per <i>Supervision Matrix</i> • Pre-procedure patient assessment must be performed by the prescriber, not by a third party. • Remote consultation is not acceptable for the first consultation • Remote consultation is not recommended for follow up
<p>Selection of treatment</p>	<ul style="list-style-type: none"> • Prescription of a treatment can only occur after face-to-face assessment of patient, not after a remote/telemedicine consultation • Treatment plan for the patient must be in consultation with the prescriber and with documentation of injection site dosage
<p>Administration of toxin</p>	<p>See <i>Supervision Matrix</i></p> <ul style="list-style-type: none"> • This depends on HEE level and professional background of practitioner

Box 5. Administration

Patient positioning	<ul style="list-style-type: none"> • At the discretion of the practitioner • Couch must be available
Drawing up toxin	<ul style="list-style-type: none"> • Sterile equipment and gloved hands, performed in a clinical environment.
Skin preparation	<ul style="list-style-type: none"> • Removal of make-up. • Minimum skin prep - normal saline, can use alternatives (e.g. chlorhexidine with caution near eye) this is at the discretion of the practitioner.
Administration of toxin	<ul style="list-style-type: none"> • Single use sterile needle • Single use sterile syringe
Gloves	<ul style="list-style-type: none"> • Examination gloves (non-latex, non-powder non sterile)
Toxin records	<p>As per overarching principles and additionally:</p> <p>The following must be recorded:</p> <ul style="list-style-type: none"> • Dilutant • Batch • Expiry • Product name • Dose • Operating practitioner • Patient details • Date • Time • Skin preparation • Skin quality • Anatomical site • Adverse effects/reaction • Post-op instructions

Box 6. Record of procedure	
Records	As per overarching principles
Photographs	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • Pre and post photographs must be taken pre intervention, and at all stages of treatment • The minimum views are Anterior-Posterior(AP)/lateral • Consent attained at first treatment and then verified at each stage • Images/videos should be stored as per national guidance [1] <p><u>References</u></p> <ol style="list-style-type: none"> 1. Information for Health Organisations. https://ico.org.uk/for-organisations/health/
Storage	As per overarching principles

Box 7. Patient follow-up	
Appropriate follow up	<ul style="list-style-type: none"> • 2 – 4 week follow up must be offered and if declined this must be documented • This is for review of; efficacy, aesthetic outcome assessment and correction of asymmetry, and photography
Patient given contact telephone number	<ul style="list-style-type: none"> • Local content with standardised information. • Contact details for both in and out of hours. • All patients given 24/7 emergency contact number • Ideally the practitioner should be available for 24 hour consultation • If practitioner is unavailable, there should be access to a deputising practitioner
Supply written information	<ul style="list-style-type: none"> • Both pre-procedure and aftercare instructions should be provided in an understandable, written format • With contact number

Informed of complications to look for	<ul style="list-style-type: none"> • Written aftercare instructions must contain descriptions of complications to look out for, and what to do if they develop
What to do in an emergency	<ul style="list-style-type: none"> • Written aftercare instructions should contain information describing what to do in an emergency
Patient given opportunity to feedback, complain or compliment	As per overarching principles

Box 8. Logbook and Case Numbers

Logbook	<ul style="list-style-type: none"> • Practitioners should keep individual records of activity. Must be contemporaneous • Either digital or paper • Additional information to be included: <ul style="list-style-type: none"> ○ Date ○ Time ○ Non-identifiable patient ID Number ○ Practitioner name ○ Practitioner ID ○ Indication ○ Product /technique used ○ Anatomical location ○ Complications/adverse events
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Box 9. CPD and appraisal

Related annual conference, teaching or leadership role	<p>Practitioners must perform 50 hours of CPD per year, of which 20 hours need to be external:</p> <ul style="list-style-type: none"> • Internal: e.g. reading journals, e-learning, internal training, internal management or leadership • External: courses, conferences, external teaching, management or leadership • No number of CPD points is specified

Logbook	See Box 9
Annual audit	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • Annual audit by clinic or individual must be produced of activity and complications • Audits should be discussed at regular morbidity and mortality meetings • We would recommend practitioners working in a group/supported environment rather than as lone practitioners
Patient reported outcome measures (PROMs)	<ul style="list-style-type: none"> • Every patient must be given the opportunity to feedback their outcomes at the end of every patient episode and formal quantitative and qualitative PROMs are recommended
Review of complaints and compliments	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • Must have a local quarterly review of outcomes • Must have an annual appraisal where outcomes are discussed
Annual appraisal including this scope of work	<p>As per overarching principles and additionally:</p> <ul style="list-style-type: none"> • There must be an annual appraisal of performance activity and audit
<p>For PSRB professionals:</p> <p>Five yearly revalidation including this scope of work</p>	<ul style="list-style-type: none"> • Nurses must revalidate every 3 years, in line with their professional body [1] • Doctors must revalidate every 5 years, in line with their professional body [2] • Revalidation in keeping with your training body, otherwise every 3 years <p><u>References</u></p> <ol style="list-style-type: none"> 1. http://revalidation.nmc.org.uk/what-you-need-to-do 2. http://www.gmc-uk.org/doctors/revalidation.asp