 

Unit Specification

UMA4 – Principles and practice of botulinum toxin use in aesthetic procedures

Unit reference number: M/618/1674

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| **Level: 7****Guided Learning (GL) hours: 35****Credit value: 12** |

## **Learning aim**

The aim of this unit is to enable learners to comprehend the use of botulinum toxin within aesthetic medicine, developing an awareness and understanding of the biochemistry and pharmacology of the product.

Additionally learners will gain a cognisance of the required competent performance indicators of botulinum toxin administration, associated responsibilities of administration, risk identification and management. Upon completion, learners will develop the capacity to adapt, individualise and deliver procedure protocols to meet the patients’ needs.

## **Learning outcomes**

On completion of this unit, learners will:

LO1 Have integrated knowledge and understanding of the biochemistry and physiological effects of botulinum toxin

LO2 Comprehend how to safely administer botulinum toxin

LO3 Evaluate procedure risks and the management of adverse events

LO4 Formulate individualised procedure plans for the use of botulinum toxin

LO5 Demonstrate proficiency in the administration of botulinum toxin

# Unit content

## LO1 Have integrated knowledge and understanding of the biochemistry and physiological effects of botulinum toxin

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| Professional knowledge  |
| Taught content to include: |
| **1.1. Pharmacology of different Botulinum Toxin products to include:*** Botulinum Toxin Type A
* Botulinum Toxin Type B
* Formulation variances – mechanism of action, different components in each formula and the implied differences. Antigenicity and latest evidence
* Suitability for procedure area
* Anticipated longevity or duration of effects
* Precautions and contra-indications
* Reconstitution – including the various options for reconstitution and rationale for each, amount of dilution, advantages and disadvantages of bacteriostatic saline (unlicensed)
* Unit equivalence
* Storage
* Dosage
* Longevity and expiry
* Management of spillages/excess product
* Safe disposal
* Audit and accountability
* Botulinum toxin is a neurotoxin protein derived from the clostridium botulinum bacterium. When injected its action is to cause localised chemical denervation due to inhibition of acetylcholine release at the neuromuscular junction

**1.2. Key components of neuromuscular synaptic transmission** * For example, depolarisation, enzyme activation and presynaptic; receptors, vesicles, neurotransmitters, ion channels, ions, synaptic machinery/proteins, tethering, docking and exocytosis. Postsynaptic; receptors and activation

**1.3. Botulinum toxin mechanism of action, structure and variation between brands** * For example, bind site, binding, reversibility and effects upon; synaptic machinery/proteins, tethering, docking, exocytosis, synaptic transmission and postsynaptic activation, metabolism
* Licensed use for medical and cosmetic purposes for the different toxin brands licensed for use in the UK
* Pre-injection preparation techniques for botulinum toxin products: storage, dilution, concentration and syringe preparation

**1.4. Dosage range of botulinum toxin products** * For example, adherence to manufacturers’ instructions (and rationale for deviating from) and common formulations. Licensed dosages vs best practice guidance

**1.5. Pharmacodynamics of botulinum toxin** * For example, diffusion, migration, half-life, desired effects, undesired effects, therapeutic window, duration of action, dose-response curves and toxicity

**1.6. Neuromuscular physiology after procedure with botulinum toxin** * Changes in the pre-synaptic structure and function, changes in the motor end plate and changes in the recovery of muscle fibres
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## LO2 Comprehend how to safely administer botulinum toxin

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| Professional knowledge  |
| Taught content to include: |
| **2.1. Selection and use of appropriate PPE/C*** Identified and determined through risk assessment
* Training and information on the safe use of PPE/C provided to all employees /practitioners
* Proper use and storage of PPE/C in place
* PPE/C maintained and replaced

**2.2. Infection control skills** * For example, practitioner handwashing, instrument sterilisation/disposal and use of chlorhexidine. Use universal infection control precautions including but not limited to; Aseptic No Touch Technique (ANTT), handwashing and appropriate skin preparation to minimise risk of infection
* Demonstrate aseptic technique during administration of agreed procedure
* Use of Personal Protective Equipment/Clothing (PPE/C)

**2.3. Preparation of appropriate equipment and environment for agreed procedure** * The premises (structure, fabric, fixtures and fittings) safe and healthy (suitable, maintained and kept clean) as per direction from Cosmetic Practice Standards Authority (CPSA)
* The working environment (temperature, lighting, space, ventilation, noise) is an appropriate, safe and healthy one
* Welfare facilities (separate toilet facilities for patients, washing, drinking, eating, changing) provided as appropriate and maintained
* Access to dedicated hand wash facilities that must be for hand washing only. The sink must not be dual purpose, for example, a kitchen or bathroom sink
* Multiple use equipment and devices cleaned or decontaminated between use
* Single use and single person devices are not re-used or shared
* Appropriate laundry facilities and supplies of clean linen/towels sufficient for each procedure and for additional use for modesty reasons as required
* Substances which fall under the Control of Substances Hazardous to Health Regulations 2002 in a suitable storage container with safety data sheet
* Exposure to hazards from physical, chemical and biological agents adequately controlled
* Facilities are provided to ensure modesty and privacy appropriate to the procedure

**2.4. Identification of procedure site** * How to identify the area of the muscle with maximum contraction, identification of requirements and technique for intradermal and subdermal placement and intramuscular delivery; dependent on muscle size, motor plaque, skin thickness and location relating to anatomy and anatomical planes for example, frontalis muscle superior to and overlaying corrugators medially, therefore inject corrugators deeper

**2.5. Product selection based upon professional judgment and patient needs** * For example, consideration of patient; goals, preferences and medical history
* Interpret manufacturers’ usage guidelines across a range of botulinum toxin products, for example, product dependent, patient dependent with adherence to manufacturers’ guidelines

**2.6. Administration of botulinum toxin** * For example, adhere to patient consented care plan, demonstrate; safe syringe preparation, safe and accurate reconstitution and withdrawal into syringe, accuracy referring to injection site depth, volume and dosage and safe techniques. Ease of flow, minimal plunger pressure. When to withdraw and reinsert

**2.7. Safe and appropriate injection techniques** * Awareness of areas to avoid, understanding the diffusion and migration of the product, how this is affected by dilution and the nearby structures (muscles) to avoid for example, low lateral frontalis, Muller’s levator palpebrae, depressor labii inferioris, modiolus, etc. The benefit of marking safety zones

**2.8. Procedure delivery** * These may include dynamic rhytides of the face caused by the action of
* Glabellar complex
* Frontalis
* Orbicularis occuli
* Compensatory mechanisms for lifting or lowering eyebrow

**2.9. Patient Comfort** * Positioning of patient. Use of compression to reduce bleeding and discomfort. Risks and benefits (comfort) of diluting with bacteriostatic saline. Avoidance of vigorously massaging the site. Pain management: use of anaesthetic (local or topical), speed of injection
* Requirements of changing the needle to minimise discomfort

**2.10. Aftercare and effects** * Effects 2-3 days, 1-2 weeks post application

**2.11. Minimising the risk of side effects*** Avoiding heat or activity that might cause flushing – tanning, massage, waxing, etc., exercise, alcohol, to reduce risk of product migration or side effects
* Avoid rubbing the treated areas for 24 hours and maintain hygiene, including the avoidance of make-up for a minimum of 4 to 6 hours
* Botulinum toxin resistance: antibodies

**2.12. Expected results and future procedure planning** * Expected results in static and dynamic lines, when, how and why touch up procedures are required. Response variations between static and dynamic lines. Possibility of alternative procedures to achieve the desired effect in static lines
* Advice on the expected longevity of procedure specifically tailored to the patient, return of muscle function

**2.13. Recording details of procedure*** Clearly and contemporaneously record procedure provided as per professional guidance
* Pre-procedure/baseline image recording
* At procedure episode: brand, product name, batch code, expiry date, diluent, volume injected, dosage, site, technique, depth, volume injected, needle administration, additional products/medicines injected. Adverse events. Device specification as applicable
* Take post procedure images for comparisons for procedure impact and evaluation of procedure outcome. Ensure images are captured in the same manner as pre-procedure images were recorded
* Aftercare advice and follow-up information or advice given verbally, in writing, e-mail or text

**2.14. Developing an aftercare plan** * For example, provide recommendations for outcome, promoting maintenance and risk mitigation. Contact patient GP (if appropriate)
* Post procedure aftercare advice and follow up information or advice given verbally, in writing, e-mail or text
* Provide necessary post-procedure medicines/equipment and information regarding/ supporting prompt adverse event (emergency plan) and what to do in the event of absence (contingency plan), reporting and management. Identify to the patient: required follow-up appointments, available support networks and referral options. Document within the patient records: aftercare plan discussions, considerations and conclusions and consent guidance as per General Data Protection Regulation (GDPR)

**2.15. Disposal techniques for all used equipment** * Safely and appropriately following relevant guidance
* Medicine waste should be stored securely until disposal
* Suitable arrangements for the disposal of medicines and medical devices must be in place. The Department of Health ‘Management and disposal of healthcare waste (HTM 07-01)’ guidance should be followed

**2.16. Evaluating effectiveness of procedure(s) provided*** Reasons for reviewing efficacy and outcome of procedure at follow-up appointments. Correct asymmetry where required, taking further images with patient consent ensuring that ‘review’ procedure, where required, is administered within 4 weeks of original procedure
* How to evaluate their own practice against recognised standards, (defined number of patients following CPSA guidance) this process should facilitate quality improvement. If areas of improvement are identified, a plan should be made to implement change and re-audit performance. Identify issues for continuous quality improvement including review of accepted protocols
* Treating other practitioners’ patients: must ensure that, prior to any procedure, medical records are obtained of any previous/recent procedure. Know the product, dose and area of procedure
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| Professional skill |
| Taught content to include: |
| **2.17. Use of needle*** How to utilise safe and appropriate injection techniques in line with product characteristics/licensed and off licence indications, of available botulinum toxins to suit the patient’s aims, presenting factors and consultation outcomes. Methods of monitoring the health and wellbeing of the patient during and post procedure
* Reconstituting and storing botulinum toxin products, for example, product dependent and requires adherence to manufacturers’ guidelines
* Adjusting botulinum toxin dosage in accordance with individualised procedure plans: for example, analyse patient facial muscle size and associated impact on injection sites
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## LO3 Evaluate procedure risks and the management of adverse events

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| Professional knowledge |
| Taught content to include: |
| **3.1. Risks associated with a range of common procedures** For example, risks associated with; glabellar frown lines, crows’ feet and lower face  procedures, identifying and avoiding danger zones appropriate to procedure **3.2. Potential adverse effects*** For example, bruising, swelling, ecchymosis, pain, headache, surface oedema, periorbital oedema, facial paresis, facial asymmetry, ptosis, dry eyes, dry mouth, drooling, lip drooping, difficulty swallowing, difficulty speaking, allergic/anaphylactic reaction and respiratory distress

**3.3. Management options for emergency/adverse events*** The importance of adhering to the emergency plan in the event of an adverse reaction. Using evidence-based protocols. Procedures for ‘cooldown’ period, follow-up appointments and onward referral

**3.4. Solutions to address a range of suboptimal therapeutic outcomes using knowledge of facial muscle interactions*** For example, with consideration of the primary muscles within the glabellar complex; patient communication and consultation, alternative brand/drug administration, follow-up appointments and top-up dosages
* The role of patient occupation upon adverse effect orientated management options: for example, aftercare and continuity of care implications for internally facing and externally facing roles

**3.5. Threshold for onward referral*** For example, outside scope of practice, debridement and wound healing
* Understanding of emergency expert consensus guidance
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| Professional skill |
| Taught content to include: |
| **3.6. Storing of medicines*** Cold link chain and storage for specific brands of botulinum toxin
* Where medicines are held as stock they must be:
* Procured through recognised wholesalers, i.e. registered UK pharmacy
* Administered against a valid prescription date, full prescriber details, full patient details, full drug details, and signature. Issued in line with PSRB recognised standards for prescribing in cosmetic medicine
* Stored securely and in the correct environment as recommended by the manufacturer (temperature monitoring and cold chain, standards and guidelines for example, CPSA)
* Audited at regular intervals
* Recorded appropriately when administered
* Where a patient’s medicines are held this must be agreed by the patient and administered to the named patient only

**3.7. Emergency medicines*** Those medicines listed in Schedule 19 of the Human Medicines Regulations may be administered without a prescription for the purpose of saving life in an emergency
* Medicines stocked for the purpose of emergency use must be risk assessed. The practitioner must be competent to administer the medicines

**3.8. Controlled drugs (CDs)*** The Misuse of Drugs Regulations 2001 place additional controls on medicines that could be misused
* Controlled drugs may be subject to:
* Additional prescription writing requirements
* Additional storage requirements
* Additional record keeping requirements
* Home Office licence requirements
* Directions for use in accordance with the manufacturer’s guidance. Over the counter doses must not be exceeded unless there is a prescription. Patients must not be asked to:
* Stockpile medicines
* Exceed recommended doses and/or recommended surface area coverage
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## LO4 Formulate individualised procedure plans for the use of botulinum toxin

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| Professional knowledge |
| Taught content to include: |
| **4.1. Individualised procedure plans*** Application and documentation of clinical knowledge to formulate medically sound clinical judgements based on outcomes of consultation alongside assessment of facial shape, skin and symmetry of feature to distinguish between dynamic and static rhytids. Understanding basic and advanced application techniques and working within the scope of training, to formulate an individualised procedure plan. Understand the need for objectivity and discretion to avoid enhancing the patients natural insecurities

**4.2. Facial proportions*** For example, patient goals/aims, whole face assessment, upper, middle and lower face proportion assessment; relating to skin changes, lip thinning, fat pad migration, muscle atrophy/hypertrophy and bone demineralisation

**4.3. Skin folds/rhytides*** For example, patient goals/aims, whole face skin fold assessment; relating to location, depth, length and intercepts. Consideration of impact; textural and perceptual. Assessing: glabellar lines, crows’ feet, horizontal forehead lines, lower lid, upper lip, depressor angularis oris, platysmal bands, nasalis/upper lip, nasal scrunch and flare, patient goals/aims

**4.4. Assessment tools** Aesthetic scales or tools as appropriate, including but not limited to; Merz scales, Glogau rhytids assessment scale, Visual Analog Scale (VAS), Fitzpatrick skin typing, ethnic skin typing kinetic classification (kinetic, hyperkinetic and hypertonic)**4.5. Pre and post-procedure patient photographs*** For example, to: evidence procedure impact, evaluate procedure outcome, identify recovery expectations, demonstrate adherence to initial patient aims/goals. Capture as a minimum: lateral/anterior/posterior photograph angles. Include a range of patient facial expressions; why consent for imagery to be taken must be given
* Legal requirements under data protection and mandatory registration with The Information Commissioner's Office (ICO) if holding any form of patient information

**4.6. Setting a review date for outcomes of procedure*** Reviewing efficacy and outcome of procedure at follow-up appointment and correct asymmetry where required, taking further images with patient consent ensuring that ‘review’ procedure where required is administered within 4 weeks of original procedure
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| Clinical competence |
| Taught content to include: |
| **4.7. In line with patient consultation information, assess presenting factors*** Assess and document specific aesthetic concerns
* Skin quality, type and local condition
* Skin disease – use diagrams and annotate discussion
* Patient’s anatomy and any common variation on anatomy that may impact on procedure
* Muscle tonicity and degree of movement
* Ethnicity
* Gender
* Intrinsic and extrinsic ageing factors
* Facial shape/proportions

**4.8. Prescribe appropriate procedure*** In accordance with prescribing legislation and Professional Records Standards Body (PRSB) medicine management guidance, meeting aims and objects of desired outcomes. Prescribers must practise in accordance with the Royal Pharmaceutical Society “A Competency Framework for all Prescribers” and other PRSB guidance and signposting
* Mechanisms of prescribing to include ‘Patient Specific Direction’ and stock holding reference the independent prescribers, options for digital and written prescriptions
* Determine product selection based upon professional judgment and patient needs
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## LO5 Demonstrate proficiency in the administration of botulinum toxin

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| Clinical competence |
| Taught content to include: |
| **5.1. Prepare the procedures area (environment)** * Select and utilise appropriate PPE/C
* Apply universal infection control precautions (ANTT)
* Prepare for procedure selecting effective hygiene products
* Prepare appropriate equipment and environment for agreed procedure

**5.2. Consult*** Introduce themselves
* Undertake a concise and comprehensive medical and cosmetic consultation
* Determine the patient’s competence to understand the intervention assessment process and their capacity to give valid consent
* Utilise pre-procedure patient photographs
* Identify realistic outcomes to be achieved, describing limitations and managing expectations
* Establish absolute and relative contra-indication timescales, downtime, cooling-off period
* Identify if any additional information is needed from other clinicians

**5.3. Assess the skin*** Visually assess the procedures area cosmetically and medically
* Demonstrate ability to identify relevant anatomical landmarks related to agreed procedure
* Implement use of marking out tools as required
* Agree a suitable procedure plan and appropriate care for the individual patient, obtaining informed consent
* Determine product selection based upon professional judgment and patient needs

**5.4. Deliver*** Demonstrate aseptic techniques during administration
* Prepare the area to be treated to ensure it is hygienic
* Apply topical anaesthetic if appropriate
* maintaining patient privacy and dignity
* Adhere to patient consented care plan
* Demonstrate
* Safe syringe preparation
* Safe and accurate reconstitution
* Safe withdrawal into syringe
* Demonstrate accuracy referring to injection
* Site depth
* Volume
* Dosage
* Demonstrate safe and appropriate injection techniques
* Reconstitute and store botulinum toxin products
* Monitor individual’s health, wellbeing and reactions
* Take prompt corrective actions if required
* Conclude the procedure in line procedure protocols
* Record details of procedure
* Take and utilise post-procedure patient photograph
* Develop and discuss aftercare plan
* Provide post procedure aftercare advice (gain written confirmation)
* Confirm post procedure review appointment date
* Provide necessary post-procedure medicines/equipment
* Dispose of all used equipment safely and appropriately
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| Guide to taught content |
| The content contained within the unit specification is not prescriptive or exhaustive but is intended to provide helpful guidance to teachers and learners, with the key areas that will be covered within the unit and relating to the kinds of evidence that should be provided for each assessment objective specific to the unit learning outcomes. |

# Assessment methods

**Formative clinical case studies**

Externally set, internally marked and externally quality assured.

The case studies contribute to the assessment outcome of the qualification. This is an evidence requirement which must be completed prior to learners undertaking the final practical assessment

* A minimum of 10 observations of botulinum toxin procedures\*
* A minimum of 10 supervised botulinum toxin procedures\*\*

\*Observed procedures can be completed on a 1:10 ratio. No more than 10 learners per observation.

\*\*Supervised procedures must be completed on a ratio of 1:1

**Summative external objective examination (MA7D1.EX1)**

Externally set and externally marked examination.

The examination assesses knowledge and understanding from the breadth of the content within this unit. The external objective examination contributes to the assessment outcome of the qualification. The external objective examination will take place at the end of the period of learning.

**Summative final practical assessment (MA7D1.PE1)**

Externally set, internally marked and externally quality assured. Overarching assessments that assesses the learner’s technical skills and abilities. The final practical assessment contributes to the assessment outcome of the qualification. The practical assessment will take place on the final case study supervised procedure, at the end of the period of learning.

Learners will be required to undertake a practical assessment for the following procedures

* 1 administration of botulinum toxin

# Scope/range related to performance criteria

Gender

1. Male
2. Female

Essential areas of treatment

1. Glabellar complex
2. Frontalis
3. Orbicularis occuli

Desirable areas of treatment

1. Compensatory mechanisms for lifting or lowering eyebrow

Techniques

1. Intradermal (blanching)
2. Subdermal
3. Intramuscular

Assess presenting factors

1. Facial shape
2. Upper, middle, lower face shape assessment
3. Whole face assessment
4. Patient goals/aims
5. Rhytids, for example static lines, sleep lines, dynamic lines
6. Skin thickness and elasticity
7. Associated UV damage
8. Impact on outcomes

**Document History**

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| **Version** | **Issue Date** | **Changes** | **Role** |
| v1.0 | 14/07/2020 | First published | Product and Regulation Manager |
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