INTERFACE

AESTHETICS

# LEVEL 7

## DIPLOMA IN INJECTABLES

# CONTENT

## PREFACE

This manual is designed to be used in conjunction with the Interface Aesthetics Level 7 Diploma in Injectables. It contains the core syllabus as well as important aspects of the principles and practice of aesthetics that you must cover as part of your progression to Level 7 graduate as an aesthetic practitioner. The manual should be used alongside the Interface Aesthetics video modules.

Medical aesthetics is a rapidly expanding, innovative and exciting industry, and aesthetic treatments continue to grow in popularity across all demographic sections of society. For practitioners, it can be a hugely rewarding career, in both professional and financial terms. How you forge your career depends greatly on your approach to patients on a professional level, your training strategy, and your ability to synthesise your knowledge, skills and artistic flair in your practice.

At Interface Aesthetics, we will encourage you to develop your skills in all of the aforementioned areas, with training pitched to the level of qualified healthcare professionals. As healthcare professionals, our patients are at the centre of everything we do. The huge sense of professional fulfilment that can be achieved by positively influencing a patient's life is a feeling that drives healthcare professionals; making a person feel better and more confident about their appearance is one manner in which we can do this, and thus allows us to promote this positive feeling through practising aesthetics safely and competently.

The Level 7 Diploma in Injectables is an important step to achieving competency within aesthetics, though it may only represent the beginning of a long and exciting journey. We sincerely hope that you are inspired by the effect that carefully considered treatments can have on patients seeking the care of an aesthetic clinician.

**Mr James Olding**
Director

# **UNIT 1:** PRINCIPLES OF HISTORY, ETHICS & LAW IN AESTHETIC MEDICINE

## 1.0 HISTORICAL AND ECONOMIC CONTEXT OF AESTHETIC PRACTICE

### 1.1 HISTORICAL BACKGROUND

The field of medical aesthetics has greatly expanded over recent decades. This growth has been particularly pronounced over the past decade, with greater awareness among patients, better accessibility to a wide range of treatments and a diversification of the treatments available, including through technological advances.

Aesthetics can be classed as surgical or non-surgical. Historically, surgical aesthetics was the most important area, with surgical procedures being used to counter the ageing process or to provide enhancements desired by the patient. Surgery continues to play an important role, and as you will learn, remains the only option in certain clinical presentations. Nonetheless, it is important to understand that non-surgical treatments now make up over 90% of all aesthetic treatments which are sought in the United Kingdom.

History of Botulinum toxin:

- 1817: First description of Botulism by Justinus Kerner, a disease caused by the consumption of sausages (Germany) [1]
- 1895: Isolation of clostridium botulinum by Émile von Ermengem (Belgium) [2]
- 1925: Extraction of Botulinum toxin by Karl Friedrich Meyer (California)
- 1977: First patient with strabismus treated with Botulinum toxin A by Alan B Scott (California)
- 1987: Jean and Alastair Carruthers use Botulinum toxin to reduce frown lines [3]
- 1990s: FDA approves Botulinum Toxin A for use in wide range of medical and aesthetic treatments during the 1990s[4]

History of dermal fillers:

- Late 19th Century: First autologous fat used as a filler5
- Early to mid-20th century: Paraffin used as a filler - with poor side-effect and complication profiles
- Hyaluronic Acid discovered by Karl Meyer (USA) in 1934 from Cow's vitreous body. Note: HA is now produced via streptococcal fermentation
- Silicon Oil as a filler - 1960s
- Bovine collagen approved as a filler in 1980s

In 1975 the French endocrinologist Dr J.J. Legrand coined the term "aesthetic medicine". This soon was followed by the creation of the Belgian, Italian, and Spanish society for aesthetic medicine. In 1976 these four national societies founded the Union International de Médecine Esthéthique (UIME), which now has members from 32 European and non-European countries.

History and anthropology show that, throughout time, the concept of beauty has been dependent on both culture and era. Despite this, youthfulness has remained a constant desirable characteristic. Some important aspects to mention include:

- 20th Century history – the advances in facial reconstruction after the World Wars was huge, and strategies to deal with disfigurement have advanced greatly.
- Technology – as technology has advanced and become more widely available, wider society is now more able to access such treatments and achieve aesthetic or anti-aging objectives more easily. Examples may include laser hair removal or injectable hyaluronic acid.
- Media – dissemination of images and information regarding celebrities has made information on beauty treatments mainstream, and individuals are now more exposed to high standards of beauty on a daily basis in both written and online media sources. This has made beauty and the pursuit of youth a much more mainstream pursuit, with a more homogenous idea in western society of what represents 'beauty' for both men and women.

Aesthetic medicine (non-surgical aesthetics) can be subdivided into categories:

- Injectables - Botulinum toxin A and dermal fillers
- Laser treatments and devices - an area of rapid technological advancement and may include hair or tattoo removal, teeth whitening and collagen stimulation.
- Minimally invasive cutting and suturing - minor procedures such as hair transplant or PDO thread lifts.

### 1.2 ECONOMIC CONTEXT

Non-surgical aesthetics accounts for 90% of all aesthetic procedures undertaken, representing 75% of the market value. Non-surgical interventions are now widely accessible in financial terms, and as GDP, individual wages and public awareness continue to rise, the value of this industry will likely grow accordingly. The industry has an estimated value of £3 billion, and ideas and attitudes to non-surgical treatments change, the public will become more open to undergoing procedures. The industry is set to grow even further as wider and more diverse demographic groups begin to have treatments. The effect of potential regulation on future growth must be considered, with any legislation on the provision of treatments or the status of currently non-prescription products (eg: dermal fillers) likely to have an influence on future growth and economic valuations in the sector.

### 1.3 ETHICAL CONTEXT

Healthcare professionals must always take an ethical approach to practice. This is especially true within medical aesthetics, where there may be vulnerable patients attracted to treatments due to the nature of the industry. This highlights the need for adherence to best practice with regulatory bodies to ensure that practitioners uphold ethical principles and practice.

The four principles of medical ethics (Tom Beauchamp, James Childress)6 provide an ethical framework upon which practitioners can base their decision making. There is no guide nor indeed consensus as to which, if any, of the principles is the most important. Each individual scenario will require a tailored approach, and a right or wrong answer will scarcely be reached in a definitive way, Nevertheless, a four principles-approach to medical decision making ensures practitioners are systematic, paying due attention to often competing interests that may be presented when a patient seeks aesthetic treatments.

The principles are:

**Autonomy** - this can be understood as the right to self-determination. A patient has the right to make decisions over his or her body, and importantly must be supported to do this through informed consent, use of non-jargon language, cooling-off periods, presentation of alternative treatments and absence of coercion. In this context, we must remember that consent is required just to touch the patient, and that patients can withdraw consent at any time. Patients can refuse treatment at any stage, and treatments provided must protect the patient's ability to function physically, socially and economically.

**Beneficence** - this states that healthcare professionals must as far as is possible do good for the patient. This requires a high level of skill, knowledge and experience on the part of the practitioner. It also necessitates an individualised tailored approach - doing good (physically and/or psychologically) for one patient may be very different to doing good for another patient with different opinions, needs and objectives.

**Non-Maleficence** - a widely known principle which can be understood as "do no harm." This principle must be the absolute bottom line for practitioners, and must account for both the individual patient as well as other people/society. The treatment strategy proposed must minimize risk, and treatments should be avoided in non-suitable patients.

**Justice** - this states that fairness must be a factor in all healthcare decisions. Again, this is relevant to both the individual and to wider society as a whole. Justice has a fundamental role to play in service provision in large healthcare networks (eg: within an NHS trust) and can often be competing against other principles. The balance between patient and societal needs with resource availability is where justice must be carefully considered, and crucially all patients must be treated equally without discrimination.

A competent and ethical aesthetic practitioner should be aware of all the aforementioned principles, with non-maleficence and the promotion of societal well-being at the forefront of decision-making.

# **UNIT 1:** PRINCIPLES OF HISTORY, ETHICS & LAW IN AESTHETIC MEDICINE

The GMC has published guidance to aesthetic practitioners, whereby 7 standards were described:

- Directly seek patient consent
- Offer patients time for reflection
- Consider your patient's psychological needs
- Make sure patents have the information they want and need
- Work within your competence
- Take particular care when dealing with children and young people
- Market your services in a responsible way

Read more on the GMC website

## 2.0 REGULATORS IN AESTHETIC PRACTICE

## 2.1 ROLE OF THE GENERAL MEDICAL COUNCIL (GMC)

The General Medical Council (GMC) has published guidance on the delivery of injectable aesthetic treatments - Interface Aesthetics has designed its training to adhere to this guidance, ensuring our delegates go on to practice to the highest standards as demanded by both professional and regulatory bodies, as well as by patients. In the past, the role of the GMC was minimal due to lack of regulation – this is now changing as more regulation begins to be implemented.

The GMC specifically governs registered doctors, and it has a register containing doctors who possess a license to practice. This has as its ultimate aim the protection of patients and the public. The GMC has Fitness to Practice (FTP) panels which can suspend or remove doctors from the register, due to reasons including: professional performance below the expected and safe standard; a criminal conviction; physical or mental health issues which could impair performance.

The GMC highlights areas of key importance in its publication 'Good Medical Practice.' These include good record keeping, with clear and legible notes which are contemporaneous, and stored in confidential manner, as well as a clear duty of confidentiality to the patient.

The GMC has collaborated with Health Education England (HEE) to develop standards of training and practice within the aesthetics industry. Commissioned by the Department of Health, The Keogh Report set out clear recommendations which were subsequently used by experts from the aesthetics sector to formulate training requirements. It is from this important process that the Level 7 in Injectables arose.

Some key limitations involving the GMC include its lack of oversight of non-GMC practitioners, as well as how treatment outside hospital/ traditional clinical settings can be monitored and audited. The issue of remote prescribing also looms large and is an area still to be brought under control despite clear regulation, legislation and codes of conduct.

Interface Aesthetics has developed its training to adhere to the standards set out by the GMC and HEE.

## 2.2 ROLE OF THE ADVERTISING STANDARDS AGENCY (ASA)

Established in 1962, the ASA exists to enforce professional advertising standards, and can take legal action against professionals or business which are in contravention of these standards. Historically, its role was minimal, but as regulation has increased it has come to play a more important role. Its roles include enforcing advertising standards, best practice and codes of practice relevant to the area. It has a more reactive enforcement strategy (as opposed to proactive – see case below).

Marketing is a huge and important part of working in aesthetics, and as such it is crucial that practitioners understand how to advertise within the bounds of the ASA standards. An example of marketing rules within aesthetics is the prohibition of time-limited inducements. Offering discounts to get patients into your clinic is not permitted; nonetheless, it is not hard to find a practitioner flouting this rule on a nearby high street or social media page. The ASA has successfully prosecuted healthcare professionals in the past for advertising in a misleading way. This includes how one's qualifications are presented.

See link for a case of successful prosecution by the Advertising Standards Authority

Two sister organisations of the ASA have been created to maintain the UK Code of Non-broadcast Advertising Sales Promotion and Direct Marketing (CAP) and setting standards for television and radio advertisements (BCAP).
Follow the links to Committee of Advertising Practice (CAP)
Follow the link to the Broadcast Committee of Advertising Practice (BCAP)

## 2.3 ROLE OF THE CARE QUALITY COMMISSION (CQC)

Since its formation in 2009 the CQC's stated role is to make sure that hospitals, care homes, dental and general practices and other care services in England provide people with safe, effective and high-quality care, and to encourage those providers to improve. It carries out this role through checks during the registration process which all new care services must complete, as well as through inspections and monitoring of a range of data sources that can indicate problems with services.

## 2.4 ROLE OF THE JOIN COUNCIL FOR COSMETIC PRACTITIONERS (JCCP)

The JCCP has been established as a vehicle to promote patient safety in the world of non-surgical aesthetics and hair restoration surgery. It achieves this by the provision of information/advice to the public and its 'Practitioner Register'. Practitioners must meet stringent entry requirements, sign up to a strict Code of Practice and operate within a new set of standards and competences. The registration is voluntary, and the requirements can be found on the JCCP website:
Premises Standards for Botulinum Toxin

## 2.5 KEY LEGISLATION

There are legislation and controls in place that impact professional standards and commercial aspects of practice and are relevant to all healthcare professionals, such as:

- Local Government (Miscellaneous Provisions) Act 1982
- The London Local Authorities Act 1991
- Registration with Information Commissioners Office (ICO) for guidance on holding and protecting personal information and the General Data Protection Regulation (GDPR)
- Human Medicines Regulations 2012
- Medical devices regulations

## 2.6 LEGISLATION RELEVANT TO THE AESTHETIC INDUSTRY

The Human Medicines Regulations 2012 consolidated pre-existing legislation relating to the use of medicines in humans, with minor amendments. It is the key piece of legislation in this area and can be found here:
The Human Medicines Regulations 2012 (SI 2012 /1916)

HEE guidance presented some key points for consideration. For practitioners administering injectable treatments for the purpose of aesthetics, the key aspects are:

**Dermal Fillers** - classed as a medical device. As such they do not require a prescription and can be purchased and used by trained practitioners on completion of training.

**Botulinum Toxin A** - a prescription-only medicine (POM). Consultation must be face-to-face before prescribing. Remote prescribing is against the law.

**Prescribing Botulinum Toxin for cosmetic purposes** - this can only be done by doctors, dentists, pharmacists independent prescribers and nurse/midwife independent prescribers.

# **UNIT 1:** PRINCIPLES OF HISTORY, ETHICS & LAW IN AESTHETIC MEDICINE

Cosmetic insurance - can be obtained either through defence unions (eg: MDU, DDU) or from cosmetic unions (eg; Hamilton Fraser, Cosmetic Insure). Cosmetic unions tend to offer cheaper quotations as they specialise in this area. Regardless of where it is obtained, malpractice insurance is an absolute necessity for practitioners.

Law relating to a duty of care within the private sector takes a contractual basis; it is the responsibility of a practitioner or practice to allocate resources, work within their own competency, and put in place procedures and systems to enable smooth functioning. Where practitioners do not meet the standards set out in the contract (in aesthetics, upon discussion and payment) then the practitioner may be in breach of their duty. Importantly, regardless of the law or the role carried out, healthcare professionals have a duty to patients and must behave accordingly.

Prescription Only Medicine (POMs) must only be administered against a valid prescription written by

- a doctor
- a dentist
- a supplementary prescriber
- a nurse independent prescriber
- a pharmacist independent prescriber
- other Health and Care Professions Council (HCPC) registrants following administration, appropriate records should be made in the patient's notes

## 2.7 STANDARD OPERATING PROCEDURES

A standard operating procedure (SOP) is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations. SOPs should be in place covering all aspects of the medicines process, should be easily understandable and regularly be reviewed and updated.

## 3.0 MARKETING REGULATIONS IN AESTHETIC PRACTICE

## 3.1 MARKETING REQUIREMENTS

Marketing must be factual, non-exploitative, clear and not misleading and age appropriate. The practitioner should provide time to cool off and not pressurise the individual. Promotional tactics should not be used to pressure ill-considered ideas or mislead patients as to possible risks from procedure.

The Advertising Standards Authority has published guidance on the use of promotional offers in non-surgical aesthetics – this detailed guidance can be found at: www.asa.org.uk

Importantly it must be highlighted that POMs such as Botulinum toxin must not be advertised. Marketing in this sector must be ethical given the potential for vulnerable patients and the nature of the treatments. There is a delicate balance to be struck between client coercion and market competition.

## 4.0 HEALTH AND SAFETY REQUIREMENTS IN AESTHETIC PRACTICE

## 4.1. PRETREATMENT CONDITIONS THAT MUST BE IN PLACE

Before proceeding to treat a patient, all elements of good medical practice must have been addressed. These include:

- Voluntariness/absence of coercion
- Consideration of goals and objectives
- Medical history and risk status
- Allergy status
- Patient psychological needs considered and addressed
- Alternative professionals/authorities consulted, as required
- Procedural information and contact information provided
- Conflict of interests addressed
- Informed consent obtained
- Disclaimers signed
- Clinic suitably staffed and equipped to provide the service

## 4.2 PRODUCT LIABILITY WITHIN AESTHETIC MEDICINE

A number of botulinum toxin A products are licensed for use in aesthetic medicine. Examples include: Botox® , Bocouture® , and Azzalure®. These products are often used in an 'off-license' manner, using divergent doses and applying product in different treatment areas (eg: brow lift). It is important to be clear with patients that products may be used in an off-license manner.

Where there is an issue with a product, it is the responsibility of healthcare professionals in aesthetics to alert the MHRA (Medicine & Healthcare products Regulatory Agency). This may include product which does not function, or that causes and adverse reaction in a patient. The expiry and LOT number of all products used must be recorded in the patient notes and information of the product should be given to the patient (often in the form of a sticker).

## 4.3 PREMISES REQUIREMENTS IN AESTHETIC MEDICINE

Premises where most non-surgical aesthetic treatments are provided are not regulated by the CQC (Care Quality Commission). As such it is largely left up to the individual with clinical oversight of the premises to ensure compliance with health and safety regulation, occupational health, environmental protection and public health laws and regulations. It is crucial that practitioners identify and comply with all relevant regulation at their place of work. Any breach could result in notification of the practitioner's regulatory body (GMC, GDC, NMC).

The requirements for a safe and healthy working environment include:

- Appropriate temperature, lighting, space, ventilation and noise for patients and practitioners
- Dedicated handwash facilities (no dual purpose e.g. kitchen or bathroom sink) need to be provided
- Welfare facilities (toilet, washing, eating, changing)
- 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

There exist optional registration schemes which provide impartial accreditation to clinics. These schemes require evidence including mandatory training, professional registration details, ICO (information Commisioner's Office) registration, insurance details and forms and documents used, among other things. An audit on-site is carried out before accreditation is awarded. While this process is not mandatory, it represents a higher standard that patients will seek out more in medical aesthetics.

For any premises where medical aesthetics is practiced, equipment must be safe and regularly checked, equipment and surfaces must be cleansable, the premises must be safe and secure, with sufficient staffing for the services provided. There must be compliance with regulatory and legal requirements (eg: refrigeration of medicines, storing of medicines in a secure place). Note there are some specific requirements in Scotland that should be analysed in greater detail for practitioners working in the country.

Personal protective equipment and clothing (PPE/C) must be provided free of charge to all employees and practitioners as determined through risk assessment. Staff must be trained and informed on the safe use of PPE/C. PPE/C must be properly used, stored, maintained and replaced if necessary.

# **UNIT 1:** PRINCIPLES OF HISTORY, ETHICS & LAW IN AESTHETIC MEDICINE

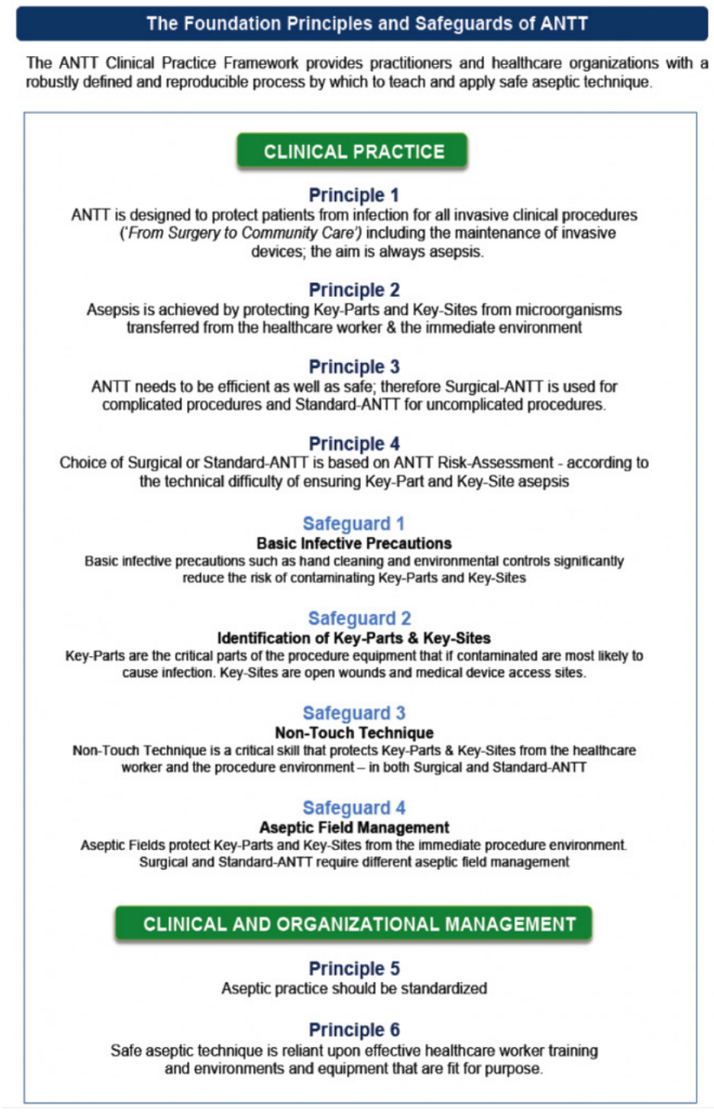
## 4.4 INFECTION CONTROL AND ASEPTIC NON TOUCH TECHNIQUE

Before beginning any treatment, it is advisable to prepare a tray with the syringe with the expected dosing and any additional necessary items, such as cleansing agents and antiseptics. Hands should be thoroughly cleaned. Avoiding contamination is essential while preparing patients for treatment and during procedures.

A headband may be used to secure the patient's hair. Two general steps for facial preparation are cleansing and antisepsis. Dirt and make-up may be removed from the area using a wipe, cleanser or saline. Alcohol wipes or antiseptic-dampened gauze pads may be used to apply antiseptic solutions. Cotton balls, commonly used in dressing pack, should be avoided as they can leave strands of cotton on the skin.
When using alcohol or chlorhexidine as an antiseptic, caution should be exercised, for they are both extremely irritating to the cornea.

Chlorhexidine in particular, when spilled into the eyes, can cause significant chemical burns to the cornea in the form of keratitis. To minimise risks when using chlorhexidine or alcohol, it is important to prevent excess fluid dripping on the conjunctiva or cornea by using dampened, not soaked, gauze or wipes. A safe and effective alternative to chlorhexidine is povidone–iodine.

Regardless of the choice of antiseptic, it is important to be familiar with and adhere to the Aseptic Non-Touch Technique (ANTT®), sometimes called the no-touch technique, in the context of facial injections means that the sterilised area should not be touched again, except with the needle. In daily practice, wiping of the treatment area with antiseptic is only advocated if the site where the needle is to be introduced has been touched in the process of stabilising for injection in the adjacent area. This is to avoid contamination from repeated touching of the treatment area during the procedure.

# UNIT 2: PRINCIPLES & PRACTICE OF AESTHETIC PATIENT ASSESSMENT

## 1.0 PROFESSIONAL RESPONSIBILITIES

## 1.1 PROFESSIONAL BEHAVIOUR

As professionals, aesthetic practitioners have to adhere to the professional ethics set out by the GMC. This means acting with:

- Probity
- Honesty
- Integrity
- In the patient's best interest

Together with:

- Duty of candour
- Commitment to educational development
- Accountability

## 1.2 IDENTIFICATION

Every practitioner should introduce themselves with name, role, qualifications and expertise. It must be clear to the patient who the practitioner providing the procedure is, if there will be assistants and if it is a training case, consent must be acquired. It is illegal to use titles or prefixes which are incorrect or misleading.

## 1.3 RISK AVOIDANCE STRATEGIES

Acquiring a thorough medical history and assessing risks is necessary to plan for emergencies. Every practitioner should be able to provide first aid and basic life support in case of an emergency. An emergency plan is the responsibility of the regulated independent prescriber. The emergency plan includes the appropriate onsite response, healthcare referral process and access to an emergency kit suitable to deal with adverse reactions or incidents. The regulated independent prescriber has a duty of care to their patients to follow regulatory guidelines set by their Professional, Statutory and Regulated Body.

## 1.4 THE CLIENT-CENTERED APPROACH

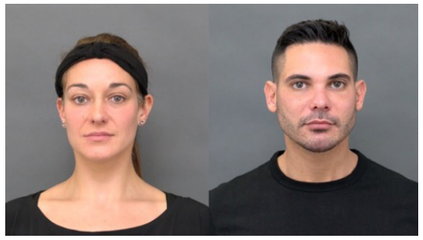
The client-centred approach must involve:

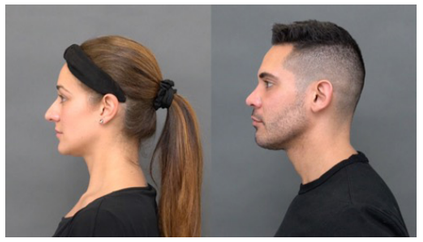
- Client aims/goals
- Medical history
- Psychological needs
- Skin condition and anatomy of face
- Recovery/post-procedure needs

As with any aspect of healthcare, individualized care is a fundamental component of medical aesthetics. Working in conjunction with your patient is necessary for several reasons:

- The patient will feel listened to, and their autonomy respected
- The patient will be more likely to approve of the treatment plan, without feeling coerced or ignored
- The patient will feel more comfortable sharing information
- There is less probability of any misunderstanding or lack of communication resulting in an undesired outcome
- The treatment plan will be tailored to the current patient's needs and desires

Clinicians should avoid making assumptions about what a patient may wish to have treated, nor about their motives for seeking treatment. Letting the patient lead the consultation with open questions can be highly informative and is more likely to allow the clinician to devise an appropriate plan. Important areas to consider include the patient's goals, their psychological needs, recovery requirements (eg: any big events within the next few days) as well as objective clinical assessment such as concomitant health issues and skin conditions.





Appreciation of Sexual Dimorphism

Geometrical Facial Assessment

## 1.5 KEY ASPECTS OF THE AESTHETIC CONSULTATION

Adopting a systematic approach to the aesthetic consultation will bring about higher standards of practice, better outcomes and greater patient satisfaction. The treating practitioner must discuss the proposed procedure with the patient in person, without delegating this to any other practitioner or individual.

Being systematic in your approach to facial analysis is an important first step. The overriding principle is that facial analysis must be holistic, taking into account both other aspects of the face as well as the patient as a whole, including their desires, objectives, medical co-morbidities. Excellent communication is fundamental to successful and safe practice; importantly, it must be two-ways, with the practitioner ensuring that they are actively listening as well as clearly discussing the procedure, risks and expected outcomes in a non-jargon manner.

The overall aesthetic assessment can be divided into a number of steps, and these can be followed to ensure you remain systematic and holistic in each and every consultation with a patient.

1) Geometrical Facial Assessment

Facial analysis requires an appreciation of facial anatomy and the morphology of ageing. A good approach is to divide the face into facial thirds with horizontal lines, with a single vertical line dividing the face again into halves (left and right) as illustrated.
The facial thirds are:

- Upper: Hairline to glabella
- Mid: Glabella to subnasale
- Lower: Subnasale to pogonion

The facial thirds should be equal in both length and dominance.
It is also important to assess for symmetry, looking for any obvious asymmetry. It should be noted that most faces are asymmetrical, and that while addressing any obvious asymmetry is good, perfect symmetry is not necessarily more attractive.

2) Appreciation of Sexual Dimorphism

The features of a typical male and typical female face are depicted in the diagram below. Dividing the face into thirds, we can appreciate some important differences:

Male:
- Prominent, wide mandibular angle
- Wide chin
- Low set brow
- Square face with cheek bones in a vertical line with the mandibular angle

Female:
- V-shaped face
- Narrow chin ending in a point
- Higher set brows
- High and wide set malar prominence

3) Illumination

Pay attention to the contours of the patient's face, as well as hollows and any areas of sagging tissue. Excellent lighting is paramount here, as is viewing the patient from different positions including from the side and leaning forward.

4) Skin Health assessment

Aesthetic practitioners must be aware of the important aspects of a skin assessment. These include:

- Medical history
- Medication history and previous dermatological treatments
- Sun exposure
- Other external factors (work, environmental exposures)
- Current skincare regimen
- Assessment of skin using assessment tools
- Clinical photography
- Patient expectations and concerns

# **UNIT 2:** PRINCIPLES & PRACTICE OF AESTHETIC PATIENT ASSESSMENT

### Fitzpatrick Scale

- Classification scheme for human skin colour
- Developed by plastic surgeon Thomas B. Fitzpatrick in 1975
- Developed to estimate response to UV light exposure
- Initially designed based on skin and eye colour, but since amended to include patient's report of how skin responds to the sun.

5) Patient's own perceptions

Ask the patient how they think others perceive them and try to elucidate what emotional attributes they connect to their appearance. For example, does the patient feel that they look tired (under eye hollowing), sad (Marionette lines) or unfeminine (loss of cheek volume)?

The assessment should take place in optimal conditions, with good light (ideally natural), with the patient sat up, without excess makeup, and with hair away from the face. The patient's face should be assessed from various angles, and assessment should take into account the patient's age, skin condition, and anatomical features.

In a process which is ubiquitous, volume loss of the face occurs with resultant signs of ageing appearing in conjunction. Volume loss is from both bone and soft tissue; it is important to identify where the suspected loss has occurred and to what degree. In a younger patient volume loss may be less pronounced and strategies may consist in prevention of the signs of ageing as opposed to revolumisation of an older patient's face.

| Group | Age | Skin Characteristics | |
|---|---|---|---|
| Type 1<br>Early Wrinklers | 20s - 30s | Early photo-aging, mild pigment changes, minimal wrinkles, no 'age spots' |  |
| Type 2<br>Wrinkle in Motion | 30s - 40s | Early to moderate photo-aging; appearance of smile lines; early brown 'age spots'; skin pores more prominent; early changes in skin texture | |
| Type 3<br>Wrinkles at Rest | 50s & older | Advanced photo-aging; prominent brown pigmentation; visible brown 'age spots'; prominent small blood vessels; wrinkleseven at rest | |
| Type 4<br>Only Wrinkles | 60s or 70s | Severe photo-ageing, yellow-grey skin colour; prior skin cancers; pre-cancerous skin changes actinic keratosis; wrinkles everywhere | Type 1 Type 2 Type 3 Type 4 |

Figure: Glogau Scale. The Glogau Scale is a visual analogue scale used to assess photoageing.


Figure: The Fitzpatrick Scale

# **UNIT 2:** PRINCIPLES & PRACTICE OF AESTHETIC PATIENT ASSESSMENT

Once facial assessment has taken place, and the objectives and expectations of the client have been established, it is the responsibility of the practitioner to discuss the benefits, risk, alternatives and timeframes involved. An understanding of the patient's background including medical history, occupation, upcoming work and social schedule, are all of great importance when conducting this discussion. For example, a personal trainer who is working following a botulinum toxin treatment will not be able to adhere to aftercare and as such should rearrange the treatment for a time when they can rest for the necessary time period. Another example would be a patient who has an important social event in the days following a procedure; the potential for swelling or bruising means they should leave plenty of time post-treatment to recover fully.

These discussions, as well as the consent, must be written down and signed by both the patient and practitioner. The costs of treatments should be transparent and clear, and writing this down in the discussion can also be a way to avoid confusion or disputes. Above all, be clear and open with patients about the cost of treatments and in the estimation of what will be required to realistically achieve their goals.

Patients should be given enough time to make a decision on the treatment proposed - what can be referred to as a 'cooling-off' period. This ensures patients are able to fully assimilate the information, which can be provided in written format too. Treatment decisions must not be rushed or subject to duress and offering time to make a decision goes some way to making it less likely that the patient feels coerced in any way. This will also allow ample time to discuss any anxieties the patient may have about proceeding and allows the practitioner to better set realistic expectations. Where the patient declines a cooling off period it must be clearly documented that a full and frank discussion of risks, alternative procedures, side effects and the merits of a cooling off period has taken place and that the patient had declined to take up said cooling off period.

## 1.6 COMBINATION PROCEDURES

Combination treatments can present a way for patients to reach their desired goal while saving some money. However, care must be taken to ensure unnecessary procedures are not being forced on to the patient. There is a murky area surrounding monetary incentive and over-treating a patient, and as such all such treatments must be accompanied by a thorough consultation and meticulous documentation, with a cooling off period offered. Negatives may include increased risk to the patient, increased cost that may be unaccounted for initially, increased aftercare implications and greater severity of minor adverse effects (eg: bruising, pain).

When appropriate and well executed, combination treatments can be excellent for patients, depending on goals and expectations. They can increase the physical and psychological benefits perceived by the patient, increase treatment efficacy for a specific objective, and help through coordination of post-treatment recovery time (rather than multiple treatments apart). An example of a combination treatment may be pre-periostially placed filler on the zygomatic arch with nasolabial filler. Another example could be botulinum toxin to the depressor anguli oris (DAO) and the platysma muscle.

## 1.7 INFORMED CONSENT

The GMC has stated that practitioners should give patients 'the time and information they need to reach a voluntary and informed decision' (GMC 2016). Importantly, the time and information they need is procedure-specific; the more invasive the procedure, the greater the time and information requirements (see 'Good Medical Practice' on the GMC website).

The ability to make an informed decision is both person-specific and decision-specific. In the clinical setting The Mental Capacity Act 2005 sets out clearly the conditions required for an individual to be deemed to possess capacity to make a decision. These conditions must all be met, and are listed as follows:

- Ability to understand the information
- Ability to retain the information
- Ability weigh up the pros and cons to arrive at a decision
- Ability to communicate the decision

The assumption of capacity exists, and anything stating the contrary must be established by the practitioner through the framework set out in the Mental Capacity Act.

Importantly, the decision-specific nature of capacity dictates that patients may have capacity to make some decisions and not others. Patients may also have capacity at one point in time, but not at another. For these reasons, a thorough understanding of the principles of capacity and informed consent are required by aesthetic practitioners, and all aspects of the consent process must be documented with justification for any decisions.

Capacity and competence are not directly interchangeable terms, with the latter being a legal term that may refer to an individual's ability to make decisions on all or specific matters (eg: financial). Incompetence must be established by a court. Competence is presumed in English Law in all adults (18 years or over). Competence may be established in minors, as per the Common Law in Gillick v West Norfolk & Wisbech 1986. The court judgment stating the process by which competency in minor can be established became known as 'Fraser competence', taking its name from the ruling judge.

Where an individual is assessed to lack competency (by a court of law) or capacity (in a clinical setting), the principle of patient autonomy cannot be fully adhered to, and as such the principle of 'best interests' is invoked. This is an extremely complex area and establishing an individual's best interests is notoriously controversial and difficult. In medical aesthetics, the situation is rather simpler, in that in the absence of capacity or competency, the least invasive option must be chosen, which in the case of an aesthetic procedure, will be no treatment. As such, in the absence of all the conditions for a competent decision being made, with informed consent, the practitioner should not carry out aesthetic treatments.

Informed consent cannot take place if the patient cannot give such consent freely and with sufficient information. Examples of such situations may include:

- If a patient does not meet the standard set by the Mental Capacity Act 2005
- If a patient is subject to coercion
- If a patient is provided with insufficient information or time
- If a patient is treated by a practitioner uninvolved with the consultation/consent process

Invalidation of consent due to one of the above points has grave legal and ethical consequences for both practitioner and patient. Adherence to best practice guidance as set out by the GMC, and as described in this manual, is fundamental in medical aesthetics, ensuring practice is safe for all parties involved.

Where minors (under 18) are involved, while capacity can be presumed from age 16, it must be carefully assessed, and in view of legislation passed in 2021 which prohibits the treatment of under-18s for purely cosmetic reasons, any decision to treat should also be firmly backed up as medically necessary and with input from colleagues.

## 1.8 SHARED DECISION MAKING IN AESTHETIC MEDICINE

The importance of shared decision-making has been alluded to, and nowhere is this more important than in ensuring consent is informed. Practitioner-patient rapport and greater discussion will ensure that the patient feels comfortable asking about treatments in greater detail and will create a positive environment where communication is more open. Active listening and a systematic approach to the aesthetic consultation are important in establishing and building on the practitioner-patient relationship.

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## 1.9 DOCUMENTATION AND RECORD KEEPING

Record-keeping must be thorough, with sufficient detail and times and dates to all documents. This provides a way of monitoring treatment and outcomes over long periods, while also providing legal records where there is dispute or complication.

Consent must be obtained in three key ways for legal and insurance purposes:

- Verbal - required after discussion
- Written - with documentation of what is agreed, risk, benefits, and alternatives. Must be signed and dated by patient and practitioner.
- Photographic - both relaxed and contracted state for botulinum toxin treatment. Follow up at 2 weeks should involve another photograph. With dermal filler, the after should be taken immediately.

All communications, consultations and agreed plans of care need to be documented in line with the guidance of the Cosmetic Practice Standards Authority (CPSA)

## 1.10 SUPPLEMENTARY PATIENT INFORMATION

The purpose of written information is to include relevant information about the medicines or devices used, the area treated, care plan and any information necessary to allow continuity of care. This information should, with the patients consent, be sent to their GP and any other clinician involved in their care if it is likely to affect their future healthcare.
Any supplementary information should be provided after the initial consultation and read during the cooling off period, with ample opportunity to ask questions before the procedure. The information needs to be up to date, accurate, understandable, realistic, truthful and not misleading.

## 1.11 PRE-PROCEDURE INFORMATION PROVISION

Providing verbal and written information pre-treatment is an important part of meeting the requirements for informed consent. Patients may not always absorb verbal information, especially when they may be nervous as is normal during a consultation. Clear information provision in multiple formats, with checking of understanding, forms the core of a client-centred approach to practice. It promotes client decision-making based on valid and relevant information and means patient may be less likely to make decisions that they later regret. Such an approach will also benefit practitioners from an ethical and legal perspective.

## 1.12 DECISION MAKING - PROVISION OF TIME

As per GMC guidance, this will ensure that consent is valid through the absence of duress or coercion, and the time offered will be dependent on the invasiveness of the procedure. For surgical procedures this should be minimum 2 weeks. It is advisable and preferable for the patient seeking non-surgical treatment to have a 'cooling-off' period, and not to undergo treatment on the day of the initial consultation. In practice, patients often do undergo treatment on the day, and if patients are sufficiently informed and meet the aforementioned criteria, treatment may be carried out.

## 1.13 COMMUNICATION AND EXPECTATION SETTING

Taking a client-centred approach through the consultation and consent processes will enable a assessment of the patient's expectations. Information can be conveyed, and a discussion had to ensure the expectations are realistic before proceeding. It is the practitioner's responsibility to accurately convey the possible or likely outcome of treatment, and to not mis-sell a treatment.

If it is felt that the patient's expectations are not correspondent with what can be offered by the practitioner, it is always best to discuss this and not proceed with the treatment. It is the responsibility of the practitioner to ensure realistic expectations are set, and this is more likely to be the case where communication is open, person-centred, informative and objective.

## 1.14 REPORTING AND FEEDBACK

Patient reported outcome measures (PROMs) assess the quality of treatment delivered from the patient's perspective. It is the duty of a good aesthetic practitioner to seek feedback from patients and act on it accordingly, including the patient's satisfaction, physical and psychological wellbeing. When feedback is considered, and treatment appropriately amended the outcome can be improved for all patients. In order to do that PROMs such as satisfaction questionnaires should be given to each patient. These PROMs can then be reviewed and discussed with peers or a professional body to improve practice.
The information sought includes:

- Effectiveness of procedures provided
- Overall procedure quality
- Post-procedural care provided
- Identifying issues for continuous quality improvement

Reflective practice assists in personal learning, identifying and addressing future personal and professional development, and validation requirements in line with regulatory body and CPSA requirements. It is just as important to identify issues of concern and exercise accountability and whistleblowing requirements of Professional Statutory and Regulatory Bodies (PSRB) and CPSA.

## 1.15 AFTERCARE AND CONTINUITY OF CARE

Continuity of care is fundamental to improving outcomes for patients. Issues are more likely to be identified and dealt with sooner, which in turn mitigates risk and produces greater patient satisfaction in both the treatment received and the outcome observed. Continuity of care is in the best interests of all involved, and it is important to emphasize the positive effect on the patient experience.

As a key aspect of continuity of care, aftercare should be provided routinely to all patients - regardless of the procedure or treatment. Good aftercare instructions reduce the risk of a complication occurring and promote positive outcomes from the treatment undertaken. If aftercare is given and observed, it can reduce downtime and prevent unwanted temporary issues. Importantly, it is important medicolegally to ensure a patient is given both verbal and written instructions following treatment.

Other aftercare measures may include written discharge summaries or information on the procedure undertaken, medication used, etc. Follow up appointments should be arranged and documented, and the patient must have a contact number through which to advise of any concerns that may require immediate attention.

## 1.16 THE CLINICIAN'S ROLE IN PROMOTING POSITIVE LIFESTYLE CHANGES

Healthcare professionals have a privileged access to the concerns, worries and feelings of patients. It is important to use this privileged position to positively encourage lifestyles and life choices which benefit our patients. Wellbeing is a broad and nuanced concept, and each individual has their own conception of what wellbeing represents. But health can be objectively measured in respect to many behaviours and parameters. Examples would include a persistently elevated blood pressure, a poorly controlled blood glucose or an obvious demonstration of ideas representing body dimorphic disorder (BDD). If a healthcare professional picks up any health concern, it is of the utmost importance that we try to positively engage with patients to bring about changes in a way that is interactive and empathetic. Signposting to important sources of support or other services with greater expertise forms an important component of health promotion.

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## 1.17 EMERGENCY COVER

The provider of aesthetic treatment is responsible for offering emergency care even out of hours, unless there are clear arrangements made with a nominated covering practitioner. Cross cover should be provided by a practitioner who is appropriately trained and of a similar level of expertise. For high-risk procedures a formal handover of the patient is required. Patients should have clear instructions on who to call in case of emergencies.

## 1.18 COMMON HEALTH CONDITIONS IN AESTHETIC MEDICINE

Patient co-morbidities are common in medical aesthetics; indeed, as the demographic groups seeking aesthetic treatments continue to grow and diversify, medical conditions will become more common in the patients we are treating. As such it is extremely important to appreciate and understand the significance of important and common conditions.

Common and important conditions are listed below, with key considerations for each:

Diabetes Mellitus

- Is the patient insulin-dependent?
- Which other medications do they take - aspirin, clopidogrel?
- Has the patient taken their usual medications, and have they eaten?
- Does the patient have a history of poor glycaemic control or recurrent infections?
- Does the patient check their own BMs; if so, what was the last one?
- Does the patient suffer with any complications of Diabetes (vision, vasculature, kidneys)?

Hypertension

- Which medications does the patient take and have they taken them as normal?
- Do they take any blood thinners such as aspirin, clopidogrel, Warfarin or newer medications such as apixaban/ rivaroxaban?

Immunocompromise or transmissible diseases

- Is the patient more likely to suffer an infection?
- In the event of a needle stick injury, understand the procedures to follow and how to act

Alcohol/Drug Abuse

- Know how to recognise the signs of alcohol and substance misuse and offer support as appropriate
- Ensure no recreational drug use preceding any treatment and advise on no alcohol pre- and post-treatment; if doubtful of patient's ability to comply, do not undertake the treatment
- Never carry out treatments on a patient you suspect may be currently intoxicated
- Understand the effects that drug and alcohol misuse can have on important body systems (blood clotting, renal, liver, etc.)

Autoimmune diseases

- Which disease(s) and what are the manifestations/symptoms?
- Are there any skin manifestations?
- Are the facial muscles affected at all - must ask specifically
- Which medications are taken - steroids, biological therapy and monoclonal antibodies all cause a myriad of side effects and must be asked specifically about.

Drug interactions[7]

- Is the patient taking any medication?
- Some drugs may interact with botulinum toxin:

| Drugs | Interaction |
|---|---|
| Antibiotics (Gentamycin) | Potentiate Botulinum toxin |
| Acetylcholinesterase inhibitors | Decrease effect of Botulinum toxin |
| Succinylcholine | Potentiate Botulinum toxin |
| Calcium channel blockers | Mechanism not explained |
| Cyclosporin | Potentiate Botulinum toxin |
| Penicillamine | Potentiate Botulinum toxin |

If you are unsure of the significance of a health condition or a medication, it is your responsibility to have support networks and to seek colleague/senior support. Additionally, it is your obligation to recognise, respond and refer appropriately in relation to any concerns disclosed or identified, including but not limited to psychological disorders (e.g. body dysmorphic disorder), safeguarding issues, skin lesions and dermal abnormalities. This information can only be shared in compliance with confidentiality and consent guidance and the General Data Protection Regulation (GDPR).

## 1.19 VASOVAGAL RESPONSE

The vasovagal response is a physical response to a stimulus which can result in symptoms including:

- Light headedness
- Tunnel vision
- Clamminess
- Loss of bladder control
- Near fainting
- Tinnitus
- Fainting (referred to as syncope)

Symptoms last for seconds before possible resolution or loss of consciousness. Dropping to the floor is a response which allows redistribution of blood flow and the return of consciousness. Practitioners should be able to recognise pre-syncopal and syncopal vasovagal responses, and importantly be able to differentiate between other more serious pathology such as a seizure or cardiac syncope.

It is mediated by the Vagus nerve, and often occurs as a result of exposure to needles or standing in hot environments for prolonged periods, though there are many different triggers for this response. Management consists in allowing the patient to lay flat, reassurance and, if loss of consciousness occurs, ensuring they are accompanied and supported for this short time, and given hydration and support afterwards.

Always ask patients about previous fainting, or any issues with needles. Also, encourage patients to be hydrated, and ensure the treatment area is not to warm or stuffy. If there is any concern regarding the fainting episodes (ie: minimal stimulus or suspicion of other pathology) then onward referral to the patient's GP is required.

## 1.20 NEEDLE-STICK INJURY

Needle-stick injury is a risk in clinical practice which must be appreciated and understood. In medical aesthetics, the use of injectables necessitates a solid understanding of how to prevent such injuries, and also how to deal with them if they do occur.

A needle-stick injury could occur on mixing botulinum toxin, on injecting the patient, on handling the needle/syringe or on disposal of the needle. Incorrectly disposed of sharps or overfilled sharps bins also pose risks. The effects of a needle-stick injury can be physical , psychological and pathological.

Key points to consider in the prevention of sharps injuries are as follows:

- Never resheath a needle
- Dispose of sharps at the point of use
- Close the sharps container when 2/3 full
- Ensure source and date completed on the sharps container

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Key points to follow upon sustaining a sharps injury are as follows:

- Squeeze the wound to make it bleed
- Clean the wound thoroughly with running water
- Apply a waterproof dressing
- Inform the line manager
- Complete an incident report form
- Report to occupational health or A&E
- Refer to local policy for further detail
- Note need to discuss status of patient and seek consent for blood tests

Post incident debriefing and reflective practice are important steps in the process of dealing with a sharps injury. The effects of a sharps injury can be significant. Not including the obvious risk of transmission of infectious diseases, the intervening time period between blood tests can place stress on the practitioner, including psychological and emotional stress. There is also the difficult situation of discussing the incident with the patient, and seeking consent to obtain blood tests can be particularly challenging, especially in a medical aesthetic setting. The most important way of avoiding this is by following the above guidance and always adhering to safe practice and local policies regarding sharps.

## 1.21 ROLE OF CLINICAL AUDIT

As one of the pillars of clinical governance, audit is a fundamental part of clinical practice, and an understanding of how audit should be undertaken is of crucial importance and a professional requirement. Audits can concern both quantity and quality. Audit can guide future improvement to patient care through identifying where accepted standards are not being met. Remedial measures can be implemented and a re-audit can ascertain the response to changes made. Audit also informs professional development, and may guide training needs for the practitioner.

## 2.0 PRINCIPLES OF COSMETIC PSYCHOLOGY IN AESTHETIC MEDICINE

## 2.1 THE DRIVERS FOR COSMETIC PROCEDURES AND PSYCHOLOGICAL THEORIES OF ATTRACTIVENESS

Non-surgical aesthetic treatments have grown in popularity over the past 2 decades; rapidly become the new normal and widely accessible to most people in society. There are multiple facets to this recent change in demand and behaviour. Some important client-dependent factors are:

- More accessible
- More affordable (economic factors)
- More safe
- Not permanent
- More acceptable to undergoing surgery
- Less of a taboo around treatment (more acceptable)
- Social media and other influences (reality TV shows etc.) which may represent both media pressure and peer-pressure
- Personal aspirations

Attractiveness is dependent on many factors, and cultural differences exist. Over recent years, individuals have been empowered to seek the changes they desire and are able to access aesthetic services at an affordable cost. Other factors are also important, and these may not necessarily be desirable. The advent of social media and reality TV has undoubtedly had an effect on the psychological pressure to conform to a certain image that is portrayed as 'attractive'. The difficult part of being an aesthetic practitioner is practising in our patients' best interests while respecting their autonomy in so far as they do not exhibit any disorder which may adversely affect their decision making and their mental wellbeing. Other drivers of cosmetic interventions may be based on psychological theories of attractiveness and appearance which include:

- Theories of ego and self
- Theories of identity
- Theories of attractiveness
- Theories of group behaviour

## 2.2 THE TWO-WAY RELATIONSHIP BETWEEN SOCIAL CHANGES AND AESTHETIC MEDICINE

The two-way relationship between social trends and changes with aesthetic medicine is easily observed by looking at images of famous people widely regarded as beautiful over the past decades.
Over time it is easy to observe changes in fashion and beauty, with a clear acceleration of change over the past 2 decades. The movie and music industries have always exerted a strong influence on perceptions of beauty, however more recently changing behaviours and trends with regard to reality TV and social media have undoubtedly further accelerated changes, as well as diversifying the sources which influence societal perceptions of beauty.

As aesthetic medicine has moved from dealing with anti-ageing alone, towards also providing enhancements for younger patients, the impact of societal change becomes even more apparent. High contoured cheek bones, larger lips, and a defined jaw and chin are now the objectives of most westerners seeking cosmetic treatments. As cosmetic practitioners are performing these more, more people undergo these treatments and the influence turns back onto society, and so forth.

Changing trends are a normal part of social evolution, and aesthetics is no exception. Nevertheless, caution is required where young and potentially vulnerable members of society may feel pressure to change their appearance without consideration or under coercion. As the guardians of aesthetic treatment provision, we must always be alert to vulnerable people who may go on to regret their decision or who may be making an ill-informed decision.

Furthermore, social changes now move at a rapid pace and are made visible to all (young and old) in a way that was never possible before through the internet and social media. There is also broad coverage of celebrities undergoing treatments with photos (good and bad results) for the public to see. As such, the two-way relationship between society and aesthetics has never been stronger or more rapidly changing.

## 2.3 THE IMPACT OF COSMETIC PROCEDURES ON PSYCHOLOGICAL WELLBEING

The relationship between physical appearance and wellbeing is fairly well established. The roots of this link are likely evolutionary and can be observed in those individuals who are victims of life-changing accidents. Evidence supporting the positive impact of cosmetic procedures on psychological wellbeing has been presented by clinics and in certain publications.[8]

There is some evidence regarding cosmetic surgery and its effect on wellbeing.[9] Certain procedures (breast augmentation) have been shown to produce greater improvements in wellbeing than others (rhinoplasty), however the picture is extremely complex and there are no black and white conclusions[10]. Many factors need to be accounted for such as expectations, reasons for seeking treatment (social pressure, mental health issues) and complexity of the procedures performed.

Given that non-surgical aesthetics is still a relatively new field, there is an even greater deficit in the evidence base, with most findings being subjective. The motivations and characters of patients seeking non-surgical treatments may also differ, in that these treatments are now widely accessible and financially viable for a much larger group of people. There is still a lack of objective data on the effect of aesthetic procedures on psychological wellbeing. Most data is subjective

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or anecdotal, and cannot form a basis upon which practitioners should alter practice on a grand scale. In addition, such data may be produced by clinicians in the area, and as such may be biased. Measuring psychological wellbeing is also problematic, in that it can be transient and is also highly subjective. There is a definite need for greater research in the field to ensure that practitioners continue to act ethically and in a way that promotes psychological wellbeing rather than being detrimental to it.

There are some "at risk" groups that practitioners should readily identify and know how to deal with. All practitioners must be able to identify these groups and behave accordingly. These groups may be more likely to suffer psychological problems rather than wellbeing as a result of treatment. In some cases, such as minors, proceeding to treat could result in criminal legal proceedings.

## 2.4 "AT RISK" GROUPS IN AESTHETIC MEDICINE

The key groups that warrant special consideration include the following:

### Children

Legally, this means under 18, while in a medical context usually means under 16. Previously, it was not advisable to perform procedures in this group even if parental consent is obtained. There are great ethical and legal issues in treating this group and as such it should be avoided. This is now a legal matter in view of the passing of a law governing this area in 2021. This legislation prohibits the treatment of minors for purely aesthetic reasons (The Botulinum Toxin and Cosmetic Filler (Children) Act 2021).

### Young people

A vague term but including legal adults who may be more influenced by external pressures such as social groups, social media, etc. Careful assessment and consultation are required including the views of the individual and their parents, driving influences like social media, peer pressure and low self-esteem.

### Capacity concerns

The Mental Capacity Act 2005 framework should be followed. Defer to senior advice if any doubts. Handling capacity issues can be sensitive. Always ensure that you are completely confident that a patient has the capacity to make the decision over treatment.

### Mental health issues

Such conditions do not necessarily preclude treatment, but additional care and time must be taken to ensure the decision is reasoned and the consequences of treatment are understood and appreciated. Patients suffering from mental health issues should be involved in shared decision making of their care plan. Any medical professionals involved in their care and their families can be consulted. In cases where a mental health issue is newly suspected by the practitioner an onward referral to the appropriate service is necessary. It is the right of the practitioner to refuse treatment at any point.

**Obsessive Compulsive Disorders (OCD)** - discussion with other healthcare professionals, with consent, may be indicated (eg: the clinician caring for the patient's OCD). If the patient does not wish for this to happen, a practitioner must be ready to decline to treat.

**Depressive Disorder** - identification is key - screening can include questions about low mood, anhedonia (loss of enjoyment in doing things) , sleep disturbance (early morning waking), fatigue, loss of concentration.

**Body Dysmorphic Disorder (BDD)** - take extra care where such a disorder is not yet diagnosed - always be alert for behaviour that suggests BDD (mirror gazing, negative comments about own appearance, seeking drastic changes, clinician "shopping'). NICE obliges practitioners to screen for this disorder.

**Patients who are "addicted"** - practitioners must recognise when patients return with increasing frequency or to have evermore drastic procedures. All decision must not be rushed, and an understanding of risks must be appreciated.

For more information follow the NICE guidance for procedures of mental health and behavioural conditions.

## 2.5 MENTAL HEALTH CONDITIONS IN AESTHETIC MEDICINE

There are some important mental health conditions that must be understood by aesthetic practitioners. It is also important to know how two recognise and respond to these disorders. These have been alluded to in the previous section, but the information is reiterated here with reference to definitions.

**OCD** - repetitive, uncontrollable thoughts, acts or routines, which result in severe anxiety

**Depressive Disorder** - characterised by low mood, low self-esteem and anhedonia.

**BDD** - obsessive preoccupations with certain aspects of one's own appearance - finding that this is severely flawed. Associated with the desire for seeking exceptional or drastic measures to remedy this.

NICE is clear about what practitioners should do when consulting with patients. Recognition of undiagnosed disorders is important, and practitioners must be ready to refer onward to other professionals. This should be before treatment occurs. Currently, BDD is the only condition that NICE obliges practitioners to screen for (see NICE Guidance on OCD and BDD in references). The guidance, updated in 2019, states that in people "who are seeking a cosmetic or dermatological procedure, healthcare professionals should routinely consider and explore the possibility of BDD."

See here for NICE guidance

Where a mental health condition is diagnosed or suspected, carrying out treatment may still be appropriate, however special consideration of informed consent, including an in-depth discussion of expectations and insight into possible risks, is warranted and all must be clearly documented. In these cases, it may always be appropriate to have a cooling-off period. Multidisciplinary working is advocated, and involvement of other professionals must be sough (with the patient's consent) eg: psychiatrist, GP, liaison nurse.

## 2.6 THE PRESENTATION OF A MENTAL HEALTH CONDITION

The following must be looked for in all consultations, as a means of screening for a mental health condition:

- Inability to make/communicate a decision during consent (fails to meet MCA 2005)
- Anxious/depressive behaviour (poor eye contact, irritability, low & monotone voice, unkempt)
- Obsessive/compulsive behaviours (observed or from the patient's questioning)
- Suicidal ideation/attempts - if a mental health disorder is diagnosed or suspected
- Maladaptive emotional bias
- Appearance fixation - BDD
- Social avoidance - OCD, Depressive disorder, BDD
- Sleep disturbance - Depressive Disorder
- Self-worth doubts - Depressive Disorder
- Home life instability
- Unrealistic expectations

## 2.7 SCREENING TOOLS TO IDENTIFY "AT RISK" GROUPS

Aesthetic practitioners must screen for BDD. The BDDQ is a tool used widely in aesthetics for this purpose. It becomes clear that only one initial question is required to determine whether the remainder of the tool needs to be completed.

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Other disorders should be considered and screened for as appropriate. Screening tools are modality specific and may look for specific disorder such as depressive disorder. The PHQ-9 tool is a questionnaire used widely, including in General Practice, to screen for, diagnose and monitor depression. It asks questions about the important symptoms of depression such as low, mood, low self-esteem, fatigue, sleep disturbance etc. It also asks about frequency of these symptoms and arrives at a score that can be used by healthcare professionals to identify a depressive disorder, or to monitor its course.

It is important to note that practitioners without formal training cannot use screening tools, and it is possible that untrained practitioner screening can actually harm patients through generating false positives and false negatives.

As previously alluded to, upon identification of a patient as “at risk” there must be thorough consultation and evaluation, involvement of the multidisciplinary team and onward referral as appropriate.

## 2.8 PROFESSIONAL BOUNDARIES IN COSMETIC PSYCHOLOGY

Like any practitioner-patient relationship, professional boundaries in aesthetic medicine are paramount. Reasons for upholding this professional boundary include:

- Professional Codes of Practice (GMC/GDC/NMC, etc.)
- Clear ethical considerations: occupying a position of responsibility vis-a-vis vulnerability of the patient
- Value for the practitioner-patient relation: honesty and openness, confidentiality, holistic care
- Managing patient expectations becomes easier and more honest
- Promotes adherence to legislation and protects against legal action.
- Assists with key aspects such as establishing informed consent and promoting client treatment awareness.

Overstepping professional boundaries is a serious issue which can have far reaching implications for both the practitioner and the patient. If a practitioner feels that a patient’s behaviour is inappropriate, the consultation should be terminated and treatment should not take place. It may be appropriate to refer to a colleague, or seek to review the patient with a chaperone/colleague.

It is important to note that practitioners without formal training cannot use screening tools, and it is possible that untrained practitioner screening can actually harm patients through generating false positives and false negatives.

## 2.9 PROVIDING PSYCHOLOGICAL AND EMOTIONAL SUPPORT

The pathways for psychological support start with the initial practitioner-client consultation, and should focus on fostering a good professional relationship, open discussion, informed consent, screening questions, and onward referral to other professionals as required. Post-treatment, there must be clear aftercare with access to the practitioner. Review of the patient is also a key aspect. At all stages, decision-making must be shared, and continuity of care should form the foundation of practice for clinicians, with a clear plan for immediately following treatment, and how to get in touch in the event of any concerns. Where there is a concern regarding the psychological state of the patient, ample time must be given to discussion of this, being as it is a sensitive topic.

## 2.10 PSYCHOLOGICAL STRATEGIES TO MANAGE POST-PROCEDURE CONCEPTIONS OF UNMET EXPECTATIONS AND POST-PROCEDURE POST-DECISIONAL REGRET.

There are some important ways in which unmet expectations can be addressed:

- Detailed client consultation - fully documented, with evaluation of patient realism
- Screening for and identification if any psychological issue
- Referral to pre-treatment discussion (documents)
- Ensuring shared decision making at all steps
- Referral to aftercare plan as documented
- Consider onward referral to psychological services
- Offering a cooling-off period
- Taking an individualized approach to decision-making

Above all, excellent communication, documentation and shared decision making are fundamental to this process of managing unmet expectations post-treatment. Ensure enough time is set aside to deal with your patient and any questions they may have, engage in meaningful discussion, and compare pre- and post-treatment images with the patient.

# UNIT 3: ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 1.0 THE SKIN

### 1.1 FUNCTION AND STRUCTURE OF THE SKIN

The skin is the largest organ in the body, accounting for 15% of total body weight. It possesses multiple functions which are layer dependent, which include:

- Physical protection (as a barrier)
- Thermoregulation
- Waste excretion
- Sensation
- Vitamin D synthesis
- Tensile strength
- Compressive strength and viscoelasticity

The skin consists of three main layers:

- Epidermis
- Dermis
- Hypodermis (also known as Subcutaneous layer)

Other important structural components include epidermal appendages:

- Sweat glands
- Pilosebaceous unit
- Sensory apparatus including nerve endings

#### Epidermis

- Contains no blood vessels
- Main function is as a barrier. Characteristics of this barrier can be summarised as followed:
- Physical: keratinocytes, attached via junctions, with associated cytoskeletal proteins
- Chemical: lipids, antimicrobial peptides, acids, enzymes
- Immunological: Humoral & cellular components
- Anti-pathogenic: low water content, pH 5 and presence of non-pathogenic organisms makes this a hostile environment for pathogens
- It is a keratinised Stratified Squamous epithelium
- Important role in protection against UV light – Langerhans cells become depleted with UV radiation, as well as with advancing age and of steroids. Langerhans cells are involved in skin immunity.
- Made up of Keratinocytes & Non-Keratinocytes (eg: melanocytes, Langerhans cells, lymphocytes)
- Composed of 4 or 5 layers depending on anatomical site

##### Stratum Corneum

- Cornified layer - 10 to 30 layers of anucleic (without nucleus) corneocytes (final stage of differential of keratinocytes)
- Palms and soles have more layers than elsewhere on body
- Corneocytes are surrounded by a protein envelope - these proteins are filled with water-retaining keratin proteins
- Corneocytes are attached together by desmosomes
- Cells are surrounded by extracellular lipids
- This layer is responsible for the majority of the barrier function

##### Stratum Lucidum

- Clear layer
- Found only in palms/soles (makes up the 5 layers in these areas)

##### Stratum Granulosum

- Granular layer
- Keratinocytes lose their nuclei
- Cytoplasm appears granular
- Lipid barrier formed - lipids released from lamellar bodies

##### Stratum Spinosum

- Keratinocytes become connected through desmosomes
- Start to produce lamellar bodies enriched in enzymes, phospholipids
- Langerhans cells (immune cells) located here

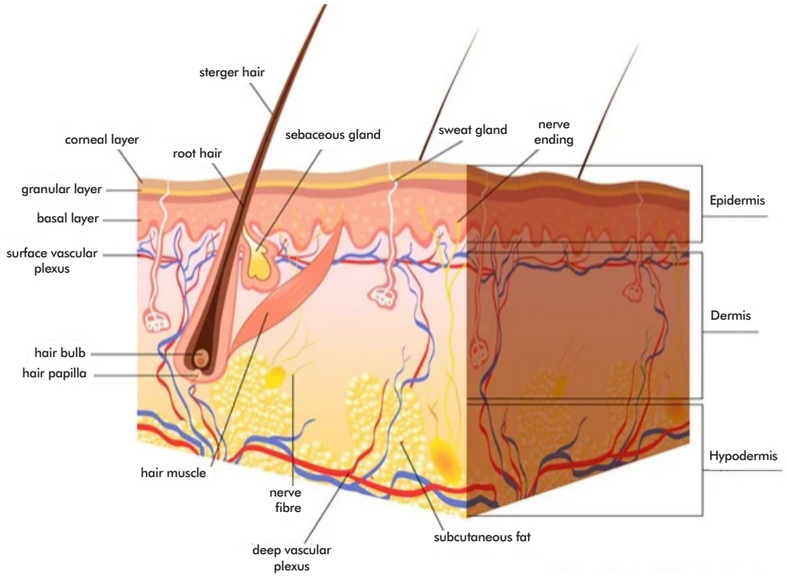



Figure 1: The structure of the skin

##### Stratum Basale

- Proliferating and non-proliferating keratinocytes
- These are attached to the basement membrane by hemi-desmosomes
- Melanocytes are present
- Merkel cells present - large numbers particularly in sensitive areas (fingers)

#### Dermis

- Blood vessels - note contrast to epidermis which is avascular.
- Sweat glands - note the use of botulinum toxin A to treat excessive sweating
- Hair follicles
- Nerve endings
- Sebaceous glands

The epidermis and dermis together create a durable and viscoelastic barrier which facilitates protection, homeostasis and thermoregulation. Despite being referred to as 'dermal fillers', most fillers are in fact placed sub-dermally in either the subcutaneous or pre-periosteal layer.

The muscles of facial expression are connected to the dermis via the superficial musculoaponeurotic system (SMAS) in order to allow movement of the skin. These fibrous septa divide the subcutaneous fat into separate fat pads.

#### Hypodermis (subcutis)

- Fat cells
- Connective tissue
- Large blood vessels
- Nerves

#### Anatomical layers of the scalp (Mnemonic: SCALP)

- Skin
- Connective tissue
- Aponeurosis
- Loose areolar connective tissue
- Periosteum

#### Anatomical layers of the face:

- Skin (epidermis and dermis) layer
- Superficial fat (subcutaneous) layer
- SMAS (superficial musculoaponeurotic system)
- Retaining ligament and spaces
- Deep fat layer (absent on the forehead)
- Periosteum, deep fascia
- Bone

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

**Important parameters in aesthetics**

### Skin ranges

- This depends on multiple factors including UV exposure, geography, age, race, circulation, stratum corneum thickness
- All of the above will influence the ageing process, and an understanding of intrinsic and environmental factors is crucial

### Skin thickness

- Age: the skin thins with age, as well as with hormonal changes or exposure to corticosteroids
- Site: the skin thickness varies widely even between small distance on the face. Infraorbital skin can be less than 0.8mm thick while cheek skin can be 3mm thick

### Subcutaneous fat

- Age: subcutaneous fat decreases with age
- Anatomical site: superficial and deep fat pads are found at specific sites in the face (eg: buccal fat pad, malar fat pad)
- BMI: The amount of subcutaneous fat will also vary depending on overall BMI/body fat
- Sex: Females tend to have more subcutaneous fat

### Wrinkles/Kraissl's lines

- Dynamic - becoming static over time. These appear perpendicular to the muscle contraction force.
- Can be part of the normal ageing process and normal facial movement

### Striae

- Collagen disruption due to stretching -> haemorrhage within dermis followed by poorly vascularised scar tissue
- Note weight changes, pregnancy and genetic component

## 1.2 FUNCTION AND STRUCTURE OF HAIR

Hair is made of keratin - a protein. The hair shaft consists in a cuticle and a cortex of hard keratin, surrounding a soft keratin medulla. Hair contains pigment (melanin) which is found in the cortex and medulla but absent from surrounding cuticle sheath.

A hair follicle unit consists in a hair shaft, a root and a bulb, plus the arrector pili muscle and the sebaceous gland. The hair bulb is the dilated part of the hair follicle, which in term contributes to the dermal papilla. This rests within the dermis, as the name would indicate.

Within the bulb, cells divide and grow, producing the hair shaft. These cells are living with a blood supply. Hormones modify hair growth via this blood supply. This can modify growth during different times of life. Hair growth occurs in a cycle with 3 phases:

- Anagen: GROWTH PHASE - several years
- Catagen: TRANSITIONAL PHASE - growth slows over weeks follicle shrinks
- Telogen: RESTING PHASE - hair growth stops, old hair lost and replaced by new hair

**Function of hair**

- Protection
- Thermoregulation
- Sensation
- Water loss via perspiration
- Role in wound healing

The Arrector Pili muscle is involved in making the hair erect upon contraction. It is smooth muscle, which joins to the deep part of the hair follicle and to the papillary layer of the dermis. These muscles are innervated by sympathetic nerves (autonomic nervous system regulation) in response to cold or emotion - resulting in the 'goose pimple' appearance.

Pilioerection (hair standing up) is a method of thermoregulation, to trap a layer of warm air close to the skin and to increase insulation.

The hair has an important additional role in contributing to wound healing. During the healing process, it contributes cells to the epidermis, aiding wound healing. It has been noted that hair containing areas tend to heal more quickly.

## 1.3 THE SKIN MICROBIOME

Microorganisms in the form of both bacteria and fungi can be either:

- Physiological (Non-pathogenic) Flora
- Commensal - no harm
- Mutualistic - offer benefit eg: competing with pathogens for nutrients, or stimulating the immune system (eg: Common skin flora include Staphylococcal Species (eg: Epidermis), and Corynebacterium)
- Pathological
- Pathogens eg: include Staphylococcus Aureus (cause of impetigo) and Strep Pyogenes (Erysipelas, cellulitis).

Normal skin flora is mostly gram positive, and usually non-pathogenic. Gram positives include both commensals (Staph. Epidermidis) and pathogens (Staph. Aureus). Gram negatives include Acinetobacter calcoaceticus and Pseudomonas aeruginosa.

It is important to appreciate the possible pathogens affecting the skin in aesthetic practice. Possible infections must be identified and treated appropriately.

Biofilms are a collective of one or more types of microorganisms that can grow on many different surfaces. Microorganisms that form biofilms include bacteria, fungi and protists. One common example of a biofilm is dental plaque, a slimy build-up of bacteria that forms on the surfaces of teeth. Another example relevant to aesthetics includes organisms implant via injection of dermal filler where asepsis has not been observed or products have been contaminated. Dermal filler can also activate a biofilm. Biofilm microorganisms are surrounded by extracellular polymeric substance (EPS) which acts as an extracellular matrix, making the organisms particularly difficult to reach with conventional antibiotics.

When using injectables, a biofilm can be embedded in tissues, predisposing to injection and abscess formation. As such, it is important to follow an aseptic non-touch technique (ANTT) with dermal filler. Important components of aseptic practice include: hand washing, barrier protection, sterile instruments, removing contaminants and reducing bacterial load from skin surfaces via cleansing the skin surface. Dermal filler is a medical device which will remain in tissues for prolonged periods. Any contamination of the product can result in embedding of microorganisms within tissues, leading to early or late complications. An early complication would be an acute infection, while a late complication could be a chronic infection due to biofilm activation, nodules or abscesses. There may be local or systemic infection, an inflammatory response or granuloma formation.

Once activated, the biofilm can cause persistent symptoms of chronic infection which may include discomfort or pain and poor aesthetic result (erythema, swelling). Importantly, as previously discussed this will be difficult to treat with antibiotics and prolonged courses or removal of the product may be necessary.
High risk patients in this regard include those with any form of reduced immune response including diabetes mellitus, HIV, or those on immunosuppressive medications.

# 2.0 FACTORS AND CONDITIONS THAT AFFECT THE SKIN

## 2.1 INTRINSIC AND EXTRINSIC SKIN AGEING

Ageing is a normal and ubiquitous process. Signs of ageing are often most visible on the skin, and these may include wrinkles and sagging. We have previously discussed ageing in reference to the tissue involved (bone, fat, skin) and the processes in each of these (eg: volume loss). We will now pay closer attention to the ageing process and skin.

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

Signs of ageing in the skin include:

- Skin looks thinner and paler, and translucent (thickening of stratum corneum, reduction of dermal collagen reduction in hyaluronic acid, reduced number of melanocytes)[11]
- Skin becomes pigmented with spots (liver spots/lentigo, especially in sun-exposed areas)
- Reduced skin strength and elasticity
- Haemangiomas and purpura (fragile blood vessels and vasodilation in dermis)
- Dry and itchy skin (reduced sebaceous gland activity)
- Increased skin fragility (thinning of subcutaneous layer/fat)
- Formation of static rhytides

## Intrinsic ageing

Known as chronological ageing. This is degenerative, internally driven by genetics. It is a result of declining physiological functions and leads to cutaneous ageing of the skin. There may be both quantitative and qualitative changes, for example, regarding important proteins such as collagen and elastin. Other important features include telomere shortening and reduced rates of cell recycling and protein turnover.

It is important to understand the functional and aesthetic impact of intrinsic ageing. Functionally, the skin will be less able to perform its functions (eg: protective, thermoregulatory) and will appear to be thinner, dryer and more wrinkled. Both functional and aesthetic changes can lead to distress for individuals.

## Extrinsic ageing

This is also known as photo ageing, and it is degenerative and externally driven. Key external drivers include:

- UV light - most widespread evidence - hence extrinsic ageing also known as photoageing. This accounts for 80% of the process
- Smoking
- Pollution
- Stress

Exposure to UV radiation results in ageing beyond that which would be expected due to intrinsic or genetic factors. The result is cutaneous manifestations with pigmentation, loss of skin turgor, lentigines, and progression of rhytids. Importantly, UV radiation damages genetic material in cells and increase the risk of developing neoplastic lesions (cancer).

UV radiation can be sub-grouped as follows:

- UVA Longwave: responsible for deeper dermal penetration and ageing
- UVB Shortwave: responsible for sunburn

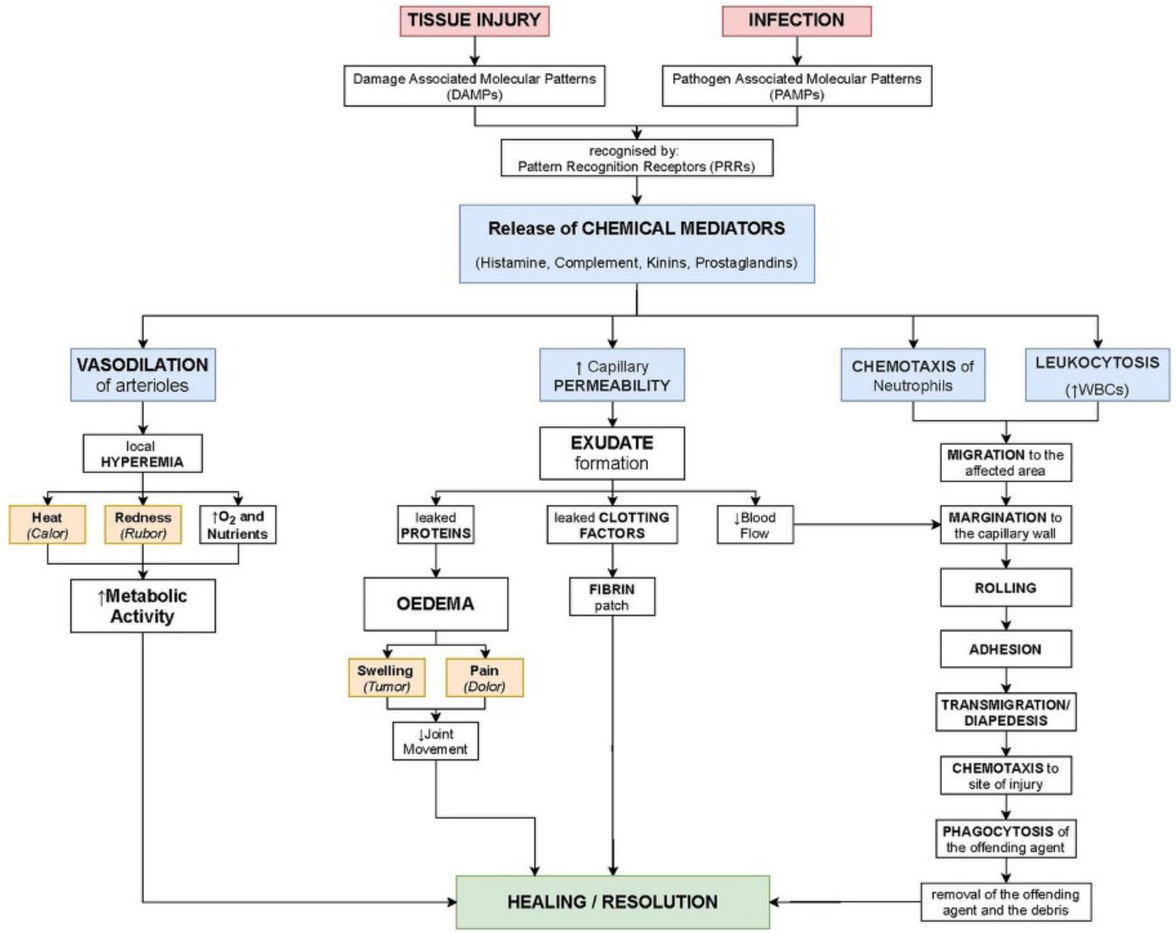
Both UVA and UVB are responsible for genetic damage (to DNA in cells). All UV radiation damages collagen and elastin and reduces the structural association of both with hyaluronic acid, leading to less water binding capacity. There are local and systemic effects on cell-mediated immunity, which has a role in the local development of neoplasms. There is also a functional impact on fibroblasts.

It is important to compare and contrast the intrinsic and extrinsic causes of ageing, appreciating the key component within each. Ultimately, both cause histological, structural and biochemical changes which manifest as signs of ageing. Practitioners must be able to advise patients on how to best care for their skin to ensure safety and to reduce the signs of ageing.

## The Inflammatory process

Inflammation is a physiological response of body tissues to harmful stimuli such as pathogens (bacteria, virus, parasites), damaged cells (wounds, burns, infections) or irritants (allergens, chemicals). It is a protective response involving immune cells, blood vessels and molecular mediators.

Tissue injury and pathogens cause the release of inflammatory mediators such as histamine, prostaglandins and the complement system which affect vessels and cells. They cause vasodilation of vessels in the area causing increased blood flow and increased permeability of the vessels allowing cells to migrate to the area of the insult. Nerve cells are sensitised which leads to the effect of increased



# UNIT 3: ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

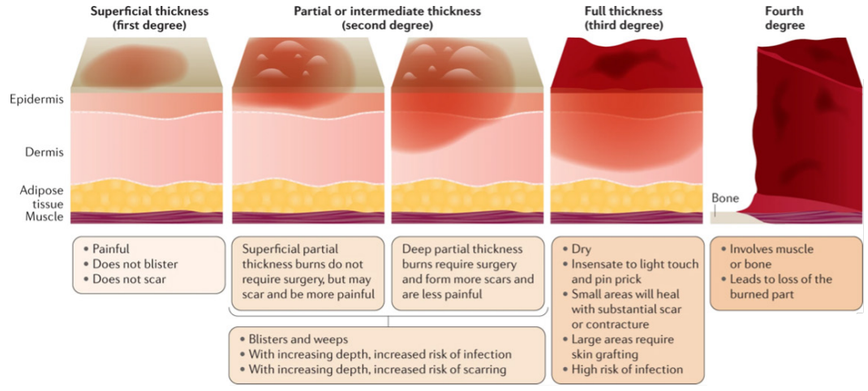



Figure: Burn depths found in Jeschke et. al 25

pain in areas of infection or wounds. Leukocytes are attracted to the affected area, releasing further chemical mediators, removing the offending agent and debris which will eventually lead to resolution. In order to neutralise pathogens leukocytes produces enzymes, free radicals and chemicals that damage the skin.[12]

## 2.2 MEDICAL CONDITIONS AFFECTING THE SKIN

### Dermatological conditions

Conditions which affect or manifest on the skin have significant functional and aesthetic consequences for patients. Lesions on the skin may be itchy, painful or associated with dryness or crusting. There may also be an increased risk of infection, resulting in exacerbations and a deterioration in appearance and function. Some important conditions with dermatological manifestations are listed below. Any dermatological condition should be thoroughly documented and discussed with the GP or Dermatologist if appropriate.

#### Atopic Eczema[13]

Symptoms include red, dry and itchy skin, which is prone to crack and get infected. There is a propensity to affect the flexural surfaces (inside elbows, back of knees) and hands.
'Atopy' refers to sensitivity to allergens - no clear single cause has been identified. Often coexists with other allergic or atopic conditions Treatment is with emollients or corticosteroids (topical or systemic).

#### Melasma[14]

Melasma is a dark skin discolouration thought to be caused by sun exposure, genetic predisposition, hormone changes and skin irritation. While it can affect anyone, it is particularly common in women especially during pregnancy or undergoing hormone replacement therapy. Treatments include topical depigmentation agents such as hydroquinone, chemical peels and laser treatment.

#### Psoriasis[15]

Symptoms include patches of red, flaky, dry skin covered with scales. It affects the extensor surfaces mainly. Around 2% of people in the UK are affected. Propensity also to affect scalp, behind ears and back. Caused by heightened immune response against own skin cells which leads to increase turnover of cells (occurring in around 7 days rather than around the usual 4 weeks).
Note extra-cutaneous manifestations, most notably arthritis which can affect the hand and large joints. Treatment can involve Topical Corticosteroids or Vitamin D analogues, UV light treatment, or systemic treatments which can include corticosteroids or biological treatments.

#### Acne[16]

Common skin condition which affects most people at some point. When it does occur, the face is almost always involved. There are several types, and it can be classified as mild, moderate or severe. The appearance of cysts and nodules requires specialist input due to the possibility of scarring.

Multifactorial - hormones, skin type, lifestyle and diet have all been implicated, as have certain bacteria. Abnormal sebum production is thought to alter the activity of a normally harmless bacteria called P. Acnes.

Treatment can involve retinoids, azeleic acid, topical or systemic antibiotics, isotretinoin tablets (Roaccutane®) or the oral contraceptive pill in women. Note that patients on Roaccutane® require close monitoring by a dermatologist with regular blood tests to check liver and renal function. Female patients must also use a contraceptive as it is teratogenic.

#### Rosacea[17]

Long-term skin condition which mainly effects the face, and can cause flushing, burning, redness, pustule formation and superficial blood vessels becoming more visible.
The cause is unknown, but triggers have been identified which can include, sunlight, stress, caffeine, alcohol, and certain foods (eg: spicy).

#### Herpes simplex[18]

Herpes simplex is a viral infection which can affect the face or mouth. It may result in small blisters in groups (cold sores) but also sore throat and if the eye is involved even blindness. Triggers include local injury (e.g. injection needle), exposure to wind, ultraviolet light or sunlight. Management involves analgesia and antiviral drugs such as acyclovir.

#### Seborrheic keratosis[19]

Seborrheic keratosis is a benign skin tumour that is seen more often as people age. These round or oval, flat or slightly elevated lesions range in size from very small to 2.5cm in diameter and are typically light tan to black coloured.

#### Lipomata[20]

A Lipoma is a benign tumour made of fat tissue. They are generally soft to the touch, movable and painless. Commonly found in the upper back shoulder and abdomen and less than 5cm in size, lipomata are a common chance finding.

#### Systemic Lupus erythematosus (SLE)[21]

Systemic Lupus erythematosus is an autoimmune disease which causes a wide range of symptoms as the body's immune system mistakenly attacks healthy tissue in many parts of the body. Apart from painful joints, fever, chest pain, hair loss and swollen lymph nodes it also causes a typical 'butterfly rash' in the face and mouth ulcers. There is no cure for SLE but treatments include corticosteroids, immunosuppressants, hydroxychloroquine and methotrexate.

### Skin cancers

#### Basal cell carcinoma[22]

This semi-malignant tumour is the most common type of skin cancer and often appears as a painless raised area of skin, which may be shiny with small blood vessels running over it. Risk factors include sun exposure, lighter skin and tanning beds. As this type of cancer has the ability to spread to other areas, treatment is typically by complete surgical removal.

#### Squamous cell carcinoma[23]

This lesion usually presents as a hard lump with a scaly top or ulcer on sun-exposed areas such as nose and lips. SCC tend to arise from premalignant lesions like actinic keratosis. Treatment includes surgical removal with or without radiation therapy, chemotherapy or immunotherapy.

#### Melanoma[24]

This type of skin cancers arises from the pigment-producing melanocytes and are typically dark in colour. The primary cause of melanoma is ultraviolet light from the sun or tanning beds. Surgical removal can cure the patient but if the cancer has spread, immunotherapy, radiation therapy or chemotherapy may improve survival.

#### Burns[25]

A burn is an injury of the skin or other tissues caused by heat, cold, electricity, chemicals, friction or ultraviolet radiation. Most burns are due to heat from hot liquids (scalding), solids or fire. The severity of burns is classified in 4 degrees (see fig above)

At temperatures greater than 44 degrees Celsius, proteins begin to disintegrate. This results in cell and tissue damage. Many of the direct health effects of a burn are secondary to disruption in the normal functioning of the skin: water loss through evaporation, inability to control body temperature.
As with any emergency, resuscitation of burn victims begins with the assessment and stabilisation of the person's airway, breathing and circulation. Small first- and second-degree burns are best managed with cold (15 degree) water running over the burnt area. Larger and full thickness burns need to be referred to a burns centre. There, tissue perfusion through intravenous fluids, escharotomy of severely burnt compartments and specific wound care can be undertaken.

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## Dental conditions

### Caries[26]

Caries is the demineralisation of dental enamel and dentine caused by acid produced by bacteria that break down carbohydrates like glucose and fructose. Caries can be prevented by thorough dental hygiene and a protective diet. Treatment involves removal of carious dental tissue and restoration with a wide variety of dental materials.

### Gingivitis[27]

Gingivitis is a disease that causes inflammation of the gums and is most common in response to bacterial biofilms (plaque). It is therefore preventable and reversible with good oral hygiene, it can however progress to periodontitis, in which the inflammation of the gums results in tissue destruction and bone resorption.

### Dental infection[28]

Odontogenic infections originate within a tooth or in the closely surrounding tissues. Most commonly caused by caries or periodontal disease the infection starts localised but can spread to adjacent or distant areas. Dental infections should be treated with antibiotics and the tooth in questions can either be extracted or root canal treated. In severe case of spreading infections involving the airway an urgent referral to the maxillofacial department at the nearest hospital is necessary.

## Systemic diseases

### Hepatic diseases[29]

As the liver is the organ responsible for producing a plethora of important enzymes in the human body, diseases of the liver are often noticed due to absence of functioning enzymes. Most notably among those are the coagulations factors necessary for a controlled clotting of blood. This is important to be aware of as an aesthetic practitioner and patient that suffer from liver diseases should be treated with additional care as increased bleeding and bruising might be a side effect of injection.

### Allergies[30]

Allergies are a number of conditions caused by hypersensitivity of the immune system to typically harmless substances in the environment. They include hay fever, food allergies, atopic dermatitis, allergic asthma and anaphylaxis. For the aesthetic practitioner it is important to ask about any allergies before treatment. Especially allergies to latex gloves, numbing gels or any adverse reaction to previous Botulinum toxin or filler treatment must be noted and taken seriously.

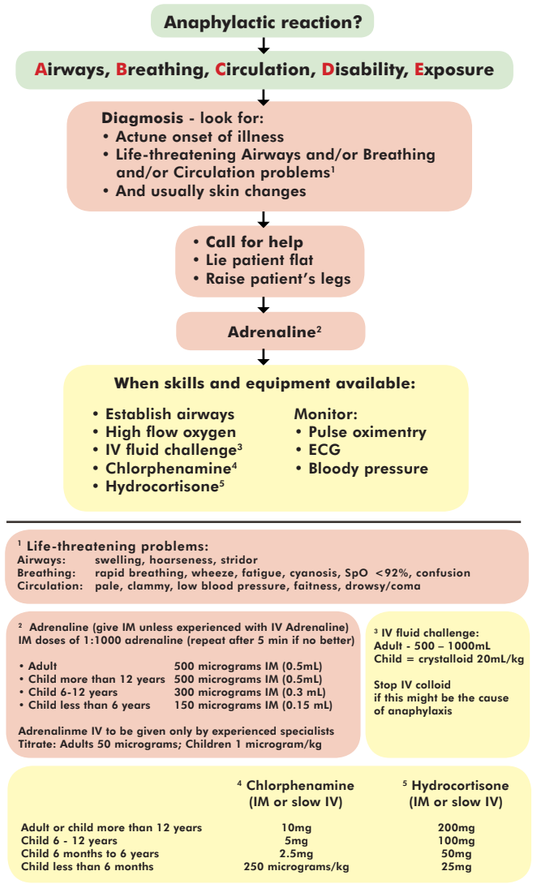



Fig.1: Emergency treatment of anaphylactic reaction algorithm by the UK resuscitation council

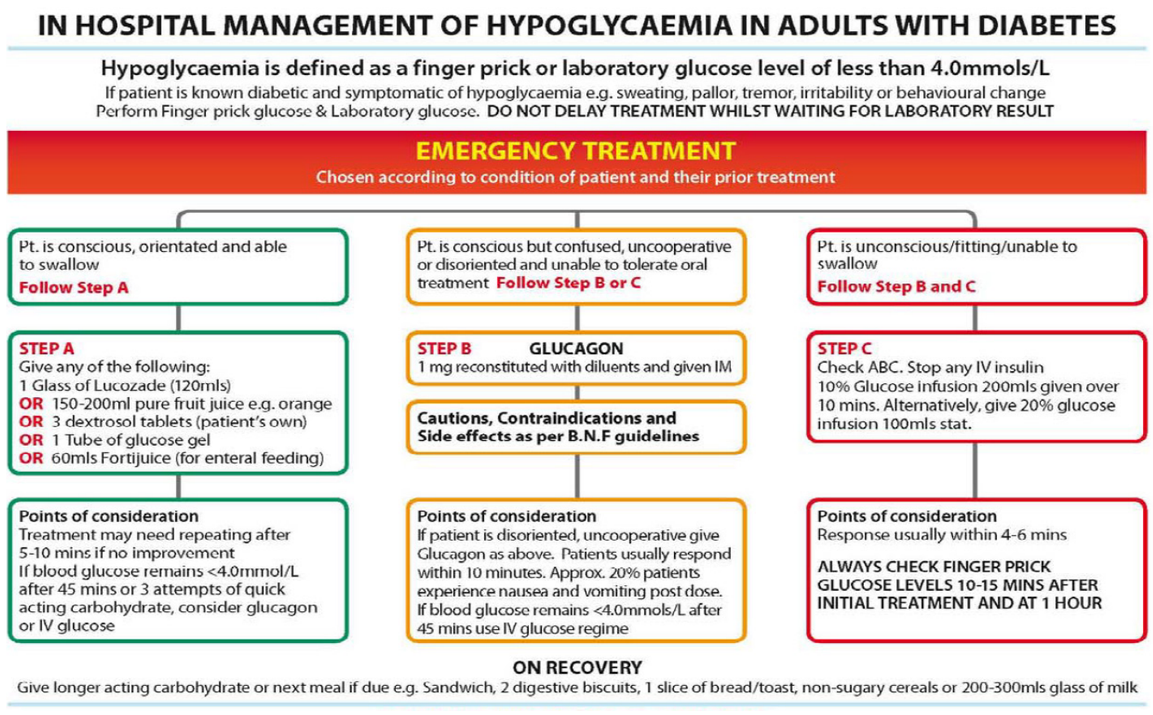



Figure 2: Management of hypoglycaemia (from: https://www.dbth.nhs.uk/wp-content/uploads/2017/07/PAT-T-49-v.2-Hypo-Protocol-final.pdf)

In case of an anaphylactic shock, the immediate management includes airway management, administration of adrenaline, antihistamines and/or steroids.

### Diabetes[31]

Diabetes mellitus is a metabolic disorder characterised by high blood sugar levels due to the inability of the body to produce insulin (Type I) or the body not responding properly to insulin (Type II). Symptoms include frequent urination (polyuria) and increased thirst (polydipsia). If left untreated the increased blood sugar levels can have many severe health complications. Acute complications include diabetic ketoacidosis; long-term complications are

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

cardiovascular disease, stroke, chronic kidney disease, foot ulcers, damage to nerves and eyes. Diabetic patients are more likely to have acute hypoglycaemia which manifests itself as drowsiness and even loss of consciousness.

### Cardiovascular diseases[32]

Cardiovascular diseases (CVD) are a class of diseases that in volve the heart or blood vessels. CVD includes coronary heart diseases such as angina and myocardial infarction but also stroke, heart failure and abnormal heart rhythms. Distinguishing between the different entities is difficult and the first action in an emergency should always be the call for help on 999.

### Pulmonary disease[33]

Pulmonary or lung diseases are a group of conditions affecting the organs and tissue responsible for the gas exchange. They include self-limiting diseases like the common cold, influenza and COVID-19 and chronic lung diseases such as COPD and Asthma. Patients with known chronic lung diseases might carry and inhaler in case of emergencies and should use it promptly if they show symptoms like shortness of breath or increased difficulty in breathing.

### Increased bleeding risk

An increased bleeding risk can be caused by a disease (autoimmune or acquired) or due to anticoagulative medication. Patients with cardiovascular diseases such as atrial fibrillation or artificial heart valves are often on long-term blood thinning medication. These patients require special attention when performing non-surgical aesthetic treatment as complications such as bruising, and bleeding are much more common. Patients should be warned about these risks, pressure should be applied after injection and a low threshold to seek advice from the GP is recommended.
For more information visit: https://www.anticoagulationuk.org/admin/resources/downloads/aesthetics-treatment-facts.pdf

### Autoimmune disorders[34]

An autoimmune disease is a condition arising from an abnormal immune response to a functioning body part. There is a wide variety of autoimmune diseases that can affect almost all parts of the body. Some autoimmune diseases such as lupus have a genetic component whereas others may be triggered by infections or other environmental factors. The symptoms depend on the condition but tiredness and low grade fever are typical symptoms of all autoimmune diseases.

### Scarring[35]

A scar is an area of fibrous tissue that replaces normal skin after an injury. They arise from the biological process of wound repair. In cases where the body overproduces collagen during wound repair a hypertrophic scar may occur which is raised above the surrounding skin. Keloid scars are a more serious form of excessive scarring because they can grow indefinitely and extend over the originally injured area. Keloid scar can occur in anyone but are more common in dark-skinned people. Patient with a history or family history of keloid or hypertrophic scars are more likely to develop unsightly scars after non-surgical aesthetic treatment although the injection sites are small and scarring is rare.

### Systemic infection[36]

A systemic infection means that it affects the entire body and is also called sepsis. Sepsis as a very severe disease characterised by fever, increased respiratory and heart rate and increased or decreased white blood cells. Septic patients need urgent hospital care with fluid resuscitation and intravenous antibiotics. In order to reduce infection risk and therefore sepsis risk in non-surgical aesthetic treatment, (sterile) gloves should be worn, skin should be disinfected and all instruments should be handled in an aseptic manner.

### Tetanus vaccine[37]

There are no indications for a cross reaction between botulinum toxin and tetanus vaccine.

**Adult Basic Life Support Algorithhm for Healthcare Providers**

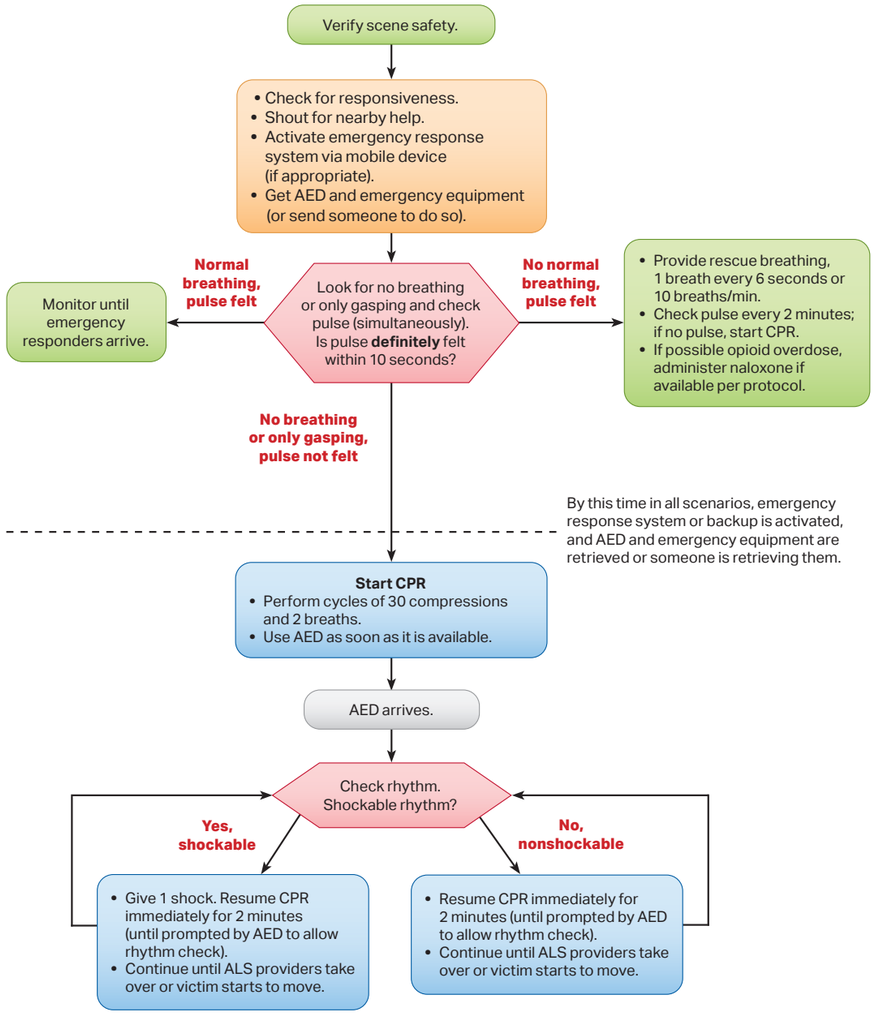





Figure 3: Adult basic life support algorithm (American heart association)

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 2.3 SKIN CARE PRODUCTS AND COSMECEUTICALS

### Sun-Protection Factor (SPF)

A topical product in the form of cream, oil or spray usually. It protects against damage caused by the sun's UV rays. Both UVA and UVB are often accounted for, however the level of protection for each will vary between products. In the short term, use of SPF protects against sunburn, while in the medium to long term it will protect against ageing induced by the sun (photoageing). It must be used diligently and consistently to have these desired effects, and fair-skinned individuals need to take extra precaution including using higher factor cream, staying out of the sun where possible and regular application. SPF can also help to prevent skin cancers such as malignant melanoma and squamous cell carcinoma (SCC). Worryingly these cancers are on the rise in the west.

### pH Balancers

The skin possesses an acid mantle - a thin protective layer on its surface. The mantle is composed of sebum (excreted by skin) mixed with lactic and amino acids. This creates the skin's pH which should be around 5.5 (slightly acidic). With age, this becomes more acidic, and lifestyle factors are important in this process too. If the pH balance of the skin is disturbed, skin conditions can occur (dermatitis, eczema). If a product claims to be 'pH balanced,' the best way to check is to use a home pH testing kit to see if it is pH 5.5. Reducing exposure to this which break down the acid mantle (pollution, UV light, water) is a key way to protect your skin.

### Anti-ageing products

There is an overall lack of proven efficacy with these products, and some claims may be spurious at best. Anti-aging products such as moisturizers aim to increase skin hydration, but do not have any impact on the intrinsic or extrinsic aging process.

### **Cosmeceuticals**

What is a cosmeceutical?

- A cosmetic product consisting of biologically active ingredients
- These ingredients may have or may have a claim to have a medicinal property
- They are not classified as drugs - no need for a prescription
- The ability of active ingredients to cross the epidermis is important.
- Examples of cosmeceuticals with good evidence include retinoids and vitamin C
- Other cosmeceuticals include peptides, steroids, and AHAs (alpha-hydroxy acids)

### Retinoids

- A Vitamin A (Retinol) metabolite
- Mediates functions of Vitamin A which is needed for growth and development
- Vitamin A naturally occurs in skin
- Tretinoin is the biologically active form, and is approved as a prescription-only medicine (POM)
- Tretinoin aids epithelial proliferation and keratinisation
- Tretinoin is teratogenic - contraindicated in pregnancy. They also increase photosensitivity

### Antioxidants

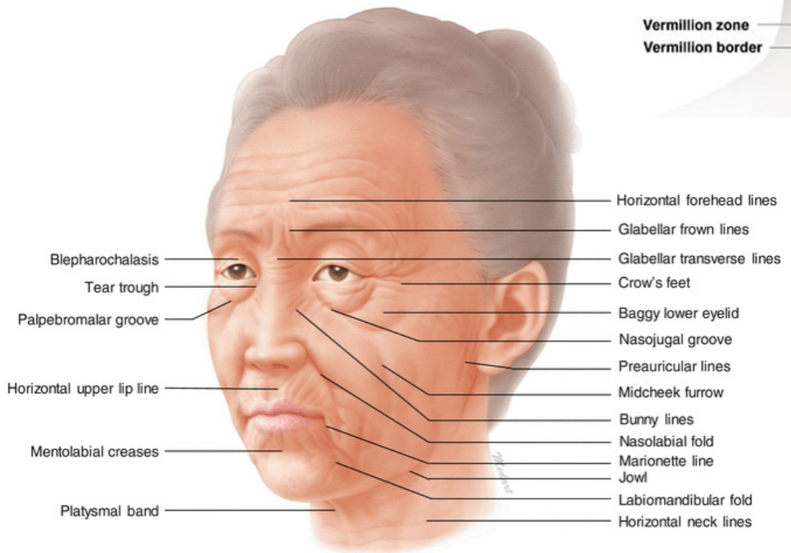
- Oxidation is a chemical reaction resulting in free radical production - free radicals are harmful to cells
- Antioxidants inhibit the oxidation of molecules
- The skin has its own naturally occurring anti-oxidants such as Vitamins A, C and E - these do become depleted with age.
- Antioxidant preparations must be able to penetrate the water and lipid phases of the epidermis. Antioxidants able to do this are: Vitamin C, Vitamin E, Vitamin B3, Selenium, Lipolic Acid.

### Growth Factors

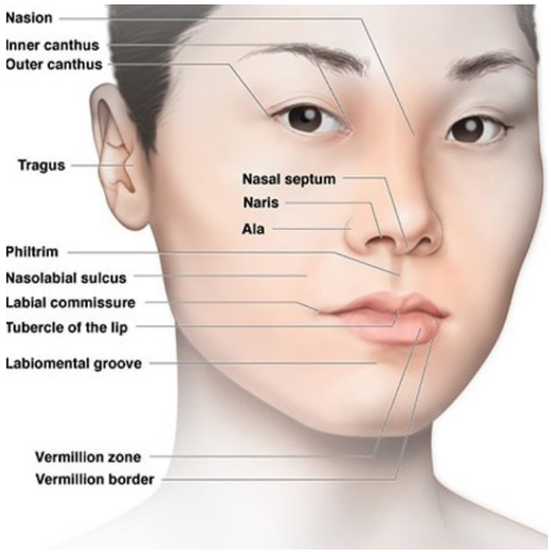
- Proteins that regulate cellular growth, proliferation and development. They also have a role in differentiation.
- They are secreted by all cell types of the epidermis and dermis.
- Topical skin products containing growth factors that are endogenous are used as cosmeceuticals.
- Growth factors mixed with peptides have been shown to add efficacy to skin care products containing just standard ingredients.

## 3.0 SURFACE ANATOMY OF THE FACE

## 3.1 RHYTIDS OF THE FACE




## 3.2 SURFACE ANATOMICAL REGIONS OF THE FACE



# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 4.0 MUSCLES OF THE FACE

The facial muscles are supplied by cranial nerve VII - the facial nerve. These muscles of facial expression are highly dynamic, enabling humans to produce a wide range of expressions. In facial aesthetics, the upper face is the area most commonly treated with botulinum toxin. Rhytids in the skin appear always perpendicular to the direction of muscle contraction.

## 4.1 FOREHEAD

### Frontalis

The frontalis muscle pulls the eyebrows up and thereby creates horizontal rhytids on the forehead

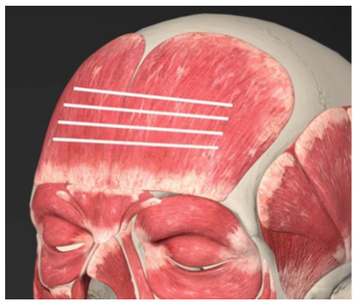


Figure 3: Frontalis muscle
(from: module 1 section 3 video)

## 4.2 BROW (GLABELLA)

### Procerus

The procerus muscle with its vertical muscles fibres causes horizontal lines in the glabella region when it pulls the eyebrows downwards.

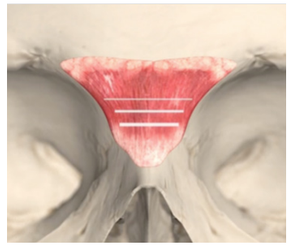


Figure 3: Procerus
(from: module 1 section 3 video)

### Corrugator Supercilii

This paired muscle moves the brows downwards and inwards upon contraction resulting in the formation of vertical and oblique lines in the glabella region

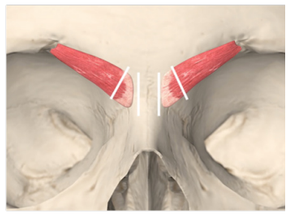


Figure 4: Corrugator supercilii
(from: module 1 section 3 video)

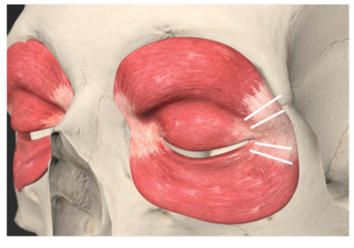
### Depressor Supercilli

This small muscle lies beneath the corrugator supercilii and is considered by some a part of the orbicularis oculi muscle.

## 4.3 EYES (CROW'S FEET)

### Obicularis Oculi

This is a circumferential muscle that is involved in closing the eye. When it contracts, it forms dynamic lines perpendicular to the force of contraction. These lines are called lateral canthal lines or crow feet.



## 4.4 MOUTH

### Orbicularis oris

This circumferential muscle is very superficial and inserts into the lips. Contraction will lead to vertical lines of the upper lip (barcode lines)

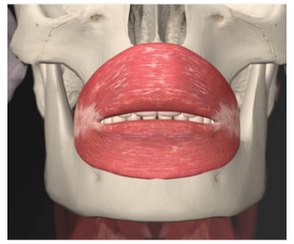


Figure 6: Orbicularis oris
(from: module 1 section 4 video)

### Depressor anguli oris

This muscle is acting to draw down the corners of the mouth and partly responsible for the formation of marionette lines.

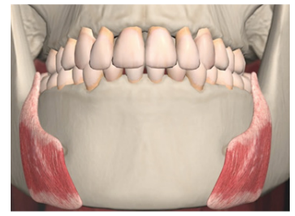


Figure 7: depressor anguli oris
(from: module 1 section 4 video)

### Mentalis

This muscle elevates the chin and everts the lower lip. Contraction results in dimpling on the skin and deepening of the labiomental crease.

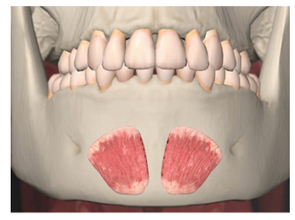


Figure 8: Mentalis
(from: module 1 section 4 video)

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 5.0 BONES OF THE FACE

Bone metabolism is a continual cycle of bone growth and resorption that is carefully orchestrated by the dynamic relationship between osteoclasts, osteoblasts and array of hormonal and regulatory influences. One of these regulators is the tartrate-resistant acid phosphatase (TRAP), produced by osteoclasts, osteoblasts and osteocytes, that acts as a regulator of mineralisation.[38]

The craniofacial skeleton tends to expand continuously during and individual's lifetime with aging, but it is important to note that some areas suffer resorption with age. The maxilla, including the piriform aperture of the nose, the superomedial and inferolateral portions of the orbital rim are all more susceptible to this resorption.
It is also important to note that different ethnicities have varying bone structures. For example, black men have a higher bone density, larger bones and thicker cortices than white and Asian men and are less affected by bone resorption with age.[39]

This bone resorption leads to biometric volume loss in different ways depending on the area of resorption.

## 5.1 MID-FACE:[40]

Maxillary bone resorption leads to reduced anterior projection, resulting in an undermining of the structural soft tissue support in this region. The pyriform and glabella angles also decrease, with localised bone loss in these areas contributing to the classical features of mid-facial ageing.

Overlying fat compartments in both the superficial and deep layers are affected by mid-face bone loss. An example of a common process involves a loss of zygomaticomaxillary bone, which undermines the medial and lateral sub-orbicularis oculi fat (SOOF), resulting in infraorbital hollowing and loss of lower lid support. A worsening of the palpebromalar sulcus may also be observed.

It should be emphasised that maxillary and zygomatic bone resorption has wide-reaching effects, leading to soft tissue descent and lower face ageing, as well as geometrical alterations of the entire face in both vertical and horizontal dimensions.

## 5.2 ORBIT

The orbit has been shown to undergo greatest resorption in two key areas. Firstly, selective reabsorption at the inferolateral quadrant of the orbit may occur in middle age, leading to a lengthening of the lid-cheek junction, as well as herniation of the infraorbital fat. These periorbital issues are common reasons for patients seeking aesthetic treatment. Secondly, resorption at the superomedial aspect of the orbit results in a comparative lift of the medial brow, with an associated lower position of the lateral brow. This resorption usually occurs later in life, around the fifth and sixth decades.

## 5.3 THE MANDIBLE

Previously, the mandible was believed to increase in size with age, however, recent longitudinal studies looking at linear measurements have shown that the process is more complex, with concurrent expansion and resorption occurring. In both males and females, linear measurements of the bigonial width appear to remain relatively constant with age, while mandibular length and height decrease.  The effect of reduced mandibular anteroposterior and vertical dimensions, coupled with overlying soft tissue changes, will contribute to the progression of jowls, and an exacerbation of the pre-jowl sulcus. There is a clear correlation between tooth loss and alveolar bone resorption of the mandible. Tooth loss can result in reduced vertical dimension and a reduced lower facial third length, as well as leading to the appearance of perioral concavity and perioral lines.

## 6.0 THE SUPERFICIAL MUSCULAR APONEUROTIC SYSTEM (SMAS) OF THE FACE

The subcutaneous tissue is not homogenous but divided into numerous small fat pads. They are separated by very thin fibrous septa that are, in fact, simply projections of the superficial muscular aponeurotic system (SMAS). The SMAS connects the facial muscles to the dermis. It consists of a three-dimensional fibrous network of collagenous and elastic fibres and adipose tissue which has multiple projections into the dermis.

Two SMAS types exist. Type I SMAS occurs in the forehead, parotid, zygomatic, and infraorbital areas (lateral to the nasiolabial fold) and comprises fibrous septae. Type II SMAS is a dense mesh of collagen, elastin, and muscle fibres and is found medial to the nasiolabial fold. SMAS thicknesses vary throughout the face from 2 to 3 mm.[41]

Anatomically, the SMAS lies inferior to the zygomatic arch and superior to the muscular belly of the platysma. The fibromuscular layer of the SMAS integrates with the superficial temporal fascia and frontalis muscle superiorly and with the platysma muscle inferiorly. The SMAS is even often described as a fibrous degeneration of the platysma muscle itself.

The SMAS connects the facial muscles to the dermis, and its purpose is to transmit, distribute, and amplify the activity of all facial muscles. It has a close relationship with the most superficial fascial planes of the face and neck area. The SMAS is described as a central tendon for a coordinated muscular contraction of the face and providing a functional role of movement for expression.[42]

During the natural ageing process the SMAS loses vitality and relaxation properties, directly affecting the elasticity of the epidermis and leading to the formation of various types of wrinkles.
Different facial regions show specific morphological characteristics, which is why different surgical manipulation techniques of the SMAS are used in facial rejuvenation.

SMAS plication facelifting is a technique invented in the 1970s that involves the folding of the SMAS with subsequent suturing in order to apply tension. Manipulation of the SMAS offers long lasting facial rejuvenation and facelift results.

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 7.0 RETAINING LIGAMENTS[43]

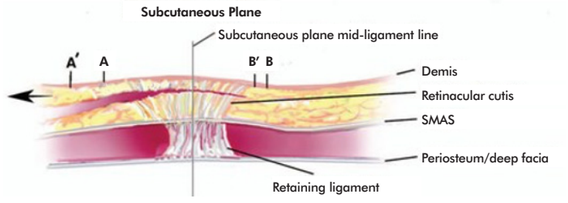
The retaining ligaments of the face are strong and deep fibrous attachments that originate from the periosteum or deep facial fascia and travel perpendicularly through facial layers to insert onto the dermis. These ligaments act as anchor points, retaining and stabilizing the skin and superficial fascia (SMAS) to the underlying deep fascia and facial skeleton in defined anatomic locations. Microscopically, each ligament is rooted in a tree-like distribution as a periosteal or deep fascial thickening that divides as it approaches the SMAS into numerous branches, which insert onto the dermis. This branching network of fibres is called the retinacular cutis, which is part of a larger complex system of fibrous septa in the subcutaneous layer.

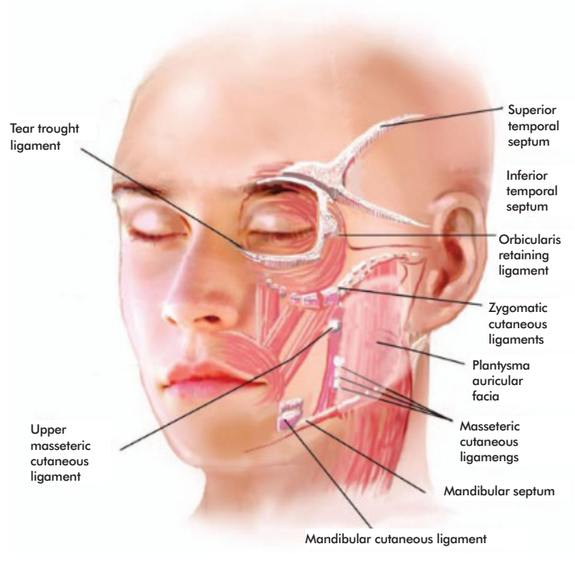
The retaining ligaments of the face can be classified as true or false. True retaining ligaments are a series of fibrous bands that run from the periosteum to the dermis. False retaining ligaments on the other hand, tether the intervening facial tissue layers to each other.
The ligaments are made up of cells and extracellular matrix.
The extracellular matrix is made up of fibres in a protein and polysaccharide matrix, secreted and organised by cells in the extracellular matrix. Variations in the composition of the extracellular matrix determine the properties of the connective tissue.

Facial aging results from a combination of soft tissue descent and volumetric deflation. The loss of tissue elasticity combined with repetitive motion from muscle contraction and gravity is believed to cause tissue descent. The role of the retaining ligaments in this process is not well defined. Some authors believe that laxity of the retaining ligaments results in laxity and descent of the soft tissue they support. Another school of thought suggests that the ligaments remain relatively strong while the unsupported tissue in between descends with time. This phenomenon is responsible for the "stigmata" of facial aging, manifested in bulges and grooves. The location of the retaining ligaments is where these grooves show.

The main significance of the retaining ligaments relates to their surgical release in order to achieve the desired aesthetic outcome. Furthermore, they have a sentinel role in their anatomic relationship to facial nerve branches.

When performing facial aesthetic surgery, plastic surgeons should decide on a plane of dissection, release the appropriate ligaments depending on the desired aesthetic goals, and avoid nerve injury by using the ligaments as anatomic landmarks.




## 8.0 NERVES OF THE FACE

The nervous system is divided into the central (brain and spinal cord) and peripheral nervous system. The peripheral nervous system consists of 12 pairs of cranial nerves and 31 pairs of spinal nerves.

The facial nerve (7th cranial nerve) is the motor nerve of the face, and it supplies the muscles of facial expression.

The facial nerve exits the skull through the stylomastoid foramen and enters the parotid gland where it divides into its 5 main branches: Temporal, Zygomatic, Buccal, Mandibular, Cervical.

In the lateral part of the face, below the zygomatic arch, the branches remain deep to the investing deep fascia. In the anterior face and above the lower border of the zygoma the branches become more superficial in relation to the muscles they innervate.

As mentioned above the retaining ligaments of the face act as fix points for the course of the facial nerve branches. The transition in levels through the layers of the skin occurs at the retaining ligament boundary. The greatest level of protection for the nerve is at this junction.[43]

See video ***Practice of Dermal Filler Injection***

The sensory nerve of the face is the Trigeminal nerve (5th cranial nerve). This nerve has three main divisions - ophthalmic, maxillary and mandibular. Important branches of these divisions include:

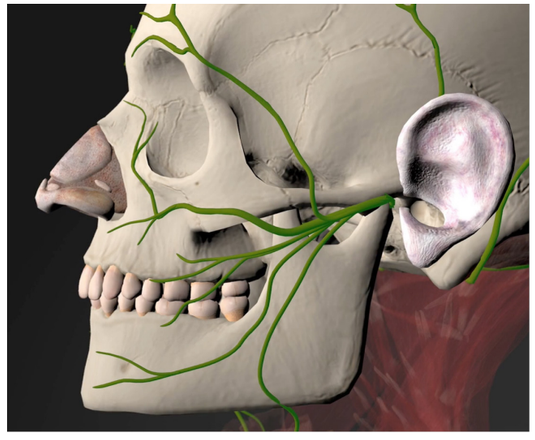


Figure 9: Facial nerve (from Module 1 Section 6)

# **UNIT 3:** ANATOMY & PHYSIOLOGY FOR AESTHETIC PROCEDURES

## 8.1 SUPRATROCHLEAR NERVE (V1)

- Branch of the frontal nerve <- Ophthalmic division of Trigeminal nerve.
- Supplies skin of medial lower forehead, conjunctiva and skin of the upper eyelid

## 8.2 SUPRAORBITAL NERVE (V1)

- Branch of the frontal nerve <- Ophthalmic division of Trigeminal nerve.
- Emerges from supraorbital foramen and is lateral to the Supratrochlear nerve
- Supplies frontal sinus and skin of forehead more lateral to midline and up to the scalp

## 8.3 INFRAORBITAL NERVE (V2)

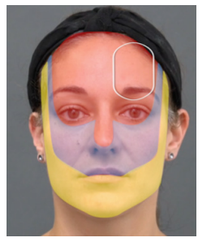
- Terminal branch of the maxillary division of the trigeminal nerve
- Supplies sensation to the lower eyelid, upper lip and part of the nasal vestibule
- Exits through infraorbital foramen of maxilla
- Divides into 4 terminal branches: superior labial, internal nasal, external nasal, inferior palpebral

## 8.4 MENTAL NERVE (V3)

- Terminal branch of inferior alveolar nerve of the mandibular division of the trigeminal nerve
- Exits through the mental foramen of the mandible
- Supplies sensation to lower lip, chin and gums

### TRIGEMINAL NERVE DIVISIONS

OPTHAIMIC
MAXILLARY
MANDIBULAR



Supraorbital Nerve

Infraorbital Nerve

Mental Nerve



## 9.0 THE VASCULATURE OF THE FACE

**Branches from the External Carotid Artery (ECA)**

## 9.1 FACIAL ARTERY

- Crosses the lower border of the mandible travelling superomedially - can be palpated at this point just anterior to the anterior border of masseter (ask patient to clench jaw)
- Gives off INFERIOR LABIAL branch 1cm lateral to oral commissure
- Gives off SUPERIOR LABIAL branch slightly cranial to the Inferior Labial branch
- Ascends towards the nasal ala where to gives off the LATERAL NASAL branch
- Continues (in the majority of people) as the ANGULAR artery

## 9.2 ANGULAR ARTERY

- Terminal branch of the facial artery
- Ascends to medial canthus along with the angular vein.
- Anastomoses with branches of infraorbital artery on cheek
- Ends by anastomosing with dorsal nasal branch of the ophthalmic artery

## 9.3 INFRAORBITAL ARTERY

- Terminal branch of the MAXILLARY ARTERY
- Supplies the cheek and anastomoses with the Angular artery

## 9.4 SUPERFICIAL TEMPORAL ARTERY

- Terminal branch of the ECA
- Supplies upper and lateral parts of the scalp

**Branches from the Internal Carotid Artery (ECA)**

## 9.5 SUPRATROCHLEAR ARTERY

- One of the terminal branches of the OPHTHALMIC ARTERY itself a branch of the Internal carotid artery (ICA)
- At risk when treating the glabella with soft tissue filler (Vascular Occlusion) and the connection with the central retinal artery (via the Ophthalmic artery) makes visual disturbance/loss a possible outcome where filler is injected into this vessel.

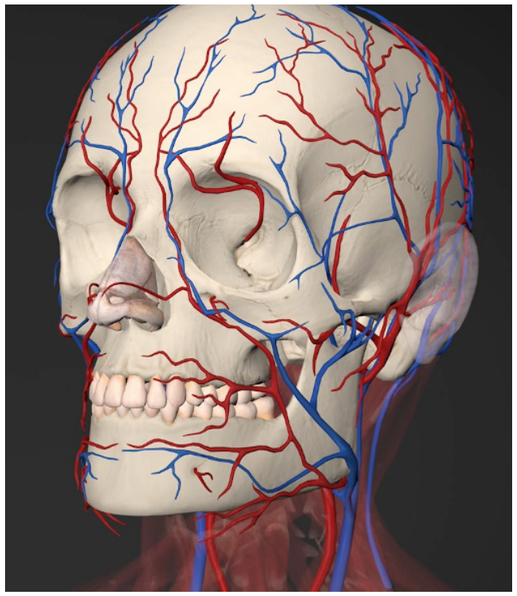


Figure 10: Vasculature of the face (Module 1 Section 5)

# **UNIT 4:** PRINCIPLES OF BOTULINUM TOXIN IN AESTHEIC MEDICINE

## 1.0 PHARMACOLOGY OF BOTULINUM TOXIN

### 1.1 NEUROMUSCULAR SYNAPTIC TRANSMISSION

Neuromuscular synaptic transmission involves a number of important steps, all taking place at the neuromuscular junction:

- Action potential induced depolarisation of the neurone (nerve) pre-synaptically
- Pre-synaptic enzyme activation via ion channel opening, vesicles containing acetyl choline (ACh) are moved towards the synapse.
- Vesicles fuse with the presynaptic membrane (exocytosis) and ACh is released into the synapse. This involves synaptic machinery including SNARE proteins and SNAP 25.
- ACh diffuses across the synaptic cleft, binds the post-synaptic membrane, activating ACh receptors and causing ion channel opening – if threshold levels are reached, axon potential propagates along post-synaptic axon, resulting in muscle contraction.
- ACh within the synaptic cleft is degraded by the enzyme acetylcholineesterase and taken back up out of the synapse.

### 1.2 MECHANISM OF ACTION OF BOTULINUM TOXIN

Botulinum toxin is a neurotoxin produced by the bacteria Clostridium Botulinum. There are 7 serotypes ranging from A to G, of which type A and B are approved for human use. Botulinum toxin type A is approved for cosmetic use and botulinum toxin type B is used for different types of muscle diseases, such as cervical dystonia.

Botulinum toxin A is composed of a heavy chain and a light chain. When it is administered to a target muscle, the toxin is endocytosed at the pre-synaptic membrane. The light chain then goes on to cleave (break) the SNARE proteins which are required for vesicles containing ACh to bind to the pre-synaptic membrane for exocytosis and release into the synapse. As such, there is no synaptic transmission nor post-synaptic activation of the ACh receptors, and muscle activation and contraction do not occur. Importantly, botulinum toxin A acts by deactivating the pre-synaptic SNARE proteins. The effects are nevertheless reversible with time, leading to reactivation of the intoxicated neuron.

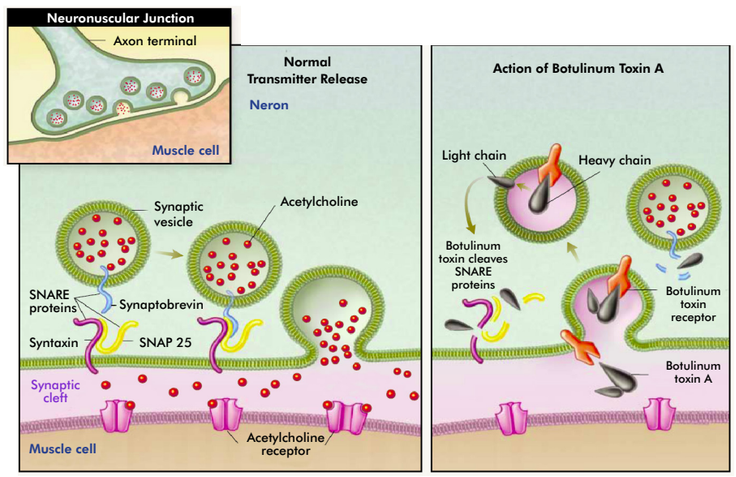



Figure: Mechanism of action of botulinum toxin A

**Formulation variances:**[44]

Studies show that onabotulinumtoxinA, abobotulinumtoxinA, and incobotulinumtoxinA are comparable in terms of clinical efficacy. Differences between the products relate to the botulinum neurotoxin complexes, specific biological potency, and their immunogenicity. Protein complex size and molecular weight have no effect on biological activity, stability, distribution, or side effect profile. Complexing proteins and inactive toxin (toxoid) content increase the risk of neutralizing antibody formation, which can cause secondary treatment failure, particularly in chronic disorders that require frequent injections and long-term treatment. These attributes could lead to differences in therapeutic outcomes, and, given the widespread aesthetic use of these three neurotoxin products, physicians should be aware of how they differ to ensure their safe and effective use.

Table 1

Comparison of botulinum neurotoxin type A formulations

| Botulinum toxin type A | ABO | ONA | INCO |
|---|---|---|---|
| Brand name | Azzalure®, Dysport® | Botox®, Vistabel® | Xeomin®, Bocouture® |
| Approved aesthetic indication | Moderate to severe glabellar lines | Moderate to severe glabellar lines and crow's feet | Moderate to severe glabellar lines and crow's feet |
| Presentation | Freeze-dried (lyophilized) powder for reconstitution | Vacuum-dried powder for reconstitution | Freeze-dried (lyophilized) powder for reconstitution |
| Isolation process | Precipitation and chromatography | Precipitation | Precipitation and chromatography |
| Composition | *Clostridium botulinum toxin* type A; HA and non-HA proteins | *Clostridium botulinum toxin* type A; HA and non-HA proteins | *Clostridium botulinum toxin* type A |
| Excipients[a] | 500 U vial: human serum albumin 125 µg; lactose 2.5 mg | 100 U vial: human serum albumin 0.5 mg; NaCl 0.9 mg | 100 U vial: human serum albumin 1 mg; sucrose 4.6 mg |
| Molecular weight (neurotoxin), kDa | Not published (150) | 900 (150) | 150 |
| Approximate total clostridial protein content (ng per 100 U) | 4.87 | 5.0 | 0.44 |
| Neurotoxin protein load (ng neurotoxin per 100 U[a]) | 0.65 | 0.73 | 0.44 |
| Specific neurotoxin potency (U/ng) | 154 | 137 | 227 |
| Shelf-life | 2–8 °C 2 years | 2–8 °C 2–3 years[b] (or freezer) | Room temperature 3–4 years[b] |
| Storage (post-reconstitution) | 2–8 °C 4 h | 2–8 °C 24 h | 2–8 °C 24 h |

*ABO* abobotulinumtoxin A, *HA* hemagglutinin, *INCO* incobotulinumtoxin A, *ONA* onabotulinumtoxin A

# **UNIT 4:** PRINCIPLES OF BOTULINUM TOXIN IN AESTHETIC MEDICINE

## 1.3 PRE-INJECTION PREPARATION OF BOTULINUM TOXIN

See video on ***Botulinum Toxin Preparation***

### Storage[45]

Botulinum toxin A is composed of a heavy and a light chain. The bonds holding these chains together are heat labile, and as such the product should be stored between 2 and 8 degrees Celsius (CF: Bocouture® which can be stored at room temperature). This should be done in a medical fridge, and temperatures should be audited. Recent studies have shown that botulinum toxin remains stable for 14 days at 25 degrees Celsius.

Allergan recommends to use reconstituted Botox within 24h after adding saline if stored at 2 to 8 degrees Celsius. Studies have shown that four-week old solution was as effective as fresh solution.

### Dilution

Note the dilution for both the Allergan product (Botox) and the Merz products (Bocouture/Xeomin) are the same. The Galderma product (Dysport/Azzalure) uses Speywood units which are slightly different. Azzalure was derived from Dysport for use exclusively in the aesthetics industry. It is important to familiarise yourself with the dilutions for the specific product you decide to use. Note that not all products have interchangeable units.

Botulinum toxin can be reconstituted with normal saline or bacteriostatic normal saline. The bacteriostatic saline contains benzyl alcohol, which has some anaesthetic properties and makes the injection less uncomfortable for the patient.

### Preparation

- Check product and expiry
- Draw up into a luer lock syringe the required quantity of bacteriostatic sodium chloride (2.5ml of saline for 100units of Botulinum toxin
- Clean the top of the bung of the botulinum toxin A vial using an alcohol swab
- Insert the bacteriostatic sodium chloride via a needle into the botulinum toxin A vial
- Once all the product has dissolved (do not shake the vial as the product is fragile), remove the bung carefully and draw up into syringes for injection (ideally microfine insulin syringes 30-32G).

## 1.4 THE PHARMACODYNAMICS OF BOTULINUM TOXIN

Under-dosing with botulinum toxin will result in incomplete treatment of the target area/muscle. If dosing is not symmetrical it can result in an uneven outcome. If dosing is carried out in isolation without reference to the whole face and neighbouring muscles, there can be unwanted effects such as overactivity of adjacent muscles or inadvertent paralysis of adjacent muscles. Botulinum toxin can diffuse to around 1cm from its injection point under normal conditions. Injecting into a vessel or at the wrong depth can increase the diffusion. Botulinum toxin doses used in aesthetics are far below those required to risk systemic toxicity. Nevertheless, sound knowledge of facial anatomy is required to avoid inadvertent injection into a vessel. Onset of action is around 3-5 days, with maximal effect reached at 14 days. The time taken for botulinum toxin's effect to wear off depends on the speed with which the pre-synaptic receptors are regenerated; this is usually between 3 - 5 months.

## 2.0 SAFE ADMINISTRATION OF BOTULINUM TOXIN

## 2.1 CONTRAINDICATIONS FOR THE USE OF BOTULINUM TOXIN

There are certain aspects of the patient history which will alert you to possible contraindications to treatment. It is important to take a full history face to face with all patients, as well as to examine the face closely to look for any potential issue. The main contraindications are:

- History of previous allergic reaction to botulinum toxin
- Pregnancy/lactation
- Infection at injection site
- Existing or previous neuromuscular disorder (eg: Myasthenia Gravis)
- Serious mental health concerns
- Patients using muscles relaxants or aminoglycosides

## 2.2 RISKS AND POTENTIAL ADVERSE EFFECTS OF BOTULINUM TOXIN ADMINISTRATION

Risks can be divided into general and specific risks. General risks can occur in any area treated, and are connected to the use of a needle and botulinum toxin, which can result in allergic reactions, tissue trauma, etc. General risks include:

- Bruising (ecchymoses)
- Swelling (oedema)
- Pain
- Headache
- Infection
- Micro-wounds

For the above risks, simple measures such as pressure over a bleed, avoiding areas of infection or inflamed skin, and advising the use of paracetamol for any post-procedure discomfort are usually sufficient.

Specific risks are related to the treatment area and will be subdivided as follows to reflect the adverse outcome specific to a certain anatomical area:

### Blepharoptosis

- Also known as lid ptosis/droop
- Due to action of botulinum toxin affecting the muscle levator palpebrae superioris
- Can be a result of infecting too low when treating frontalis (in the danger zone) OR too deeply and laterally when injecting the tail of corrugator supercilii muscle as part of glabella treatment.
- A small amount of botulinum toxin diffusing to the levator palpebrae superioris muscle can cause a drooping eyelid
- Patient will complain of drooping or a sensation of heaviness, worse at the end of the day
- Drooping may be noticable from photos
- Some patients have mild or subclinical ptosis to start with - taking good pre-treatment photography is crucial for this reason

If this complication occurs, there are some important management steps:

- Reassure the patient, however be realistic about the time for resolution
- Compare with pre-treatment photos to confirm
- Prescribe Iopidine 0.5% eye drops to take 2-3/day: This stimulates Muller's muscle which also helps to elevate the eyelid.
- Explain that even without eye drops, it usually starts to improve within weeks.

### Heavy Brow

- Not the same as blepharoptosis - usually bilateral, provided there has been equal dosing to frontalis
- A consequence of botulinum toxin to frontalis in a patient that has a compensated brow ptosis
- They compensate for a heavy brow by raising their eyebrows (with frontalis)

# **UNIT 4:** PRINCIPLES OF BOTULINUM TOXIN IN AESTHETIC MEDICINE

- Botulinum toxin can undo this compensation, leaving patients complaining of heaviness and a low brow
- Increased risk with isolated frontalis treatments - highlights importance of treating the face holistically including the glabella and obicularis oculi
- It is important to fully assess patients before treatment, and decide if they have a compensated brow ptosis. It is also important to warn that brow heaviness can occur, especially with isolated frontalis treatments.

If a patient returns complaining of heaviness, the steps to follow include:

- Reassurance that this will be temporary and will resolve as the treatment wears off
- Explain that different patients can have different dose requirements, and especially if this is the first occasion, it could explain more paralysis and heaviness than expected (for this reason always dose conservatively and review).
- If a patient has had an isolated treatment of frontalis, they may benefit from treatments of the glabella and obicularis oculi.

### Ocular Complications

- The nearer to the eye the injection, the greater the risk
- Paralysis of the ocular muscles (extra-ocular muscles responsible for eye movement) eg: causing diplopia – requires immediate ophthalmology referral

### Temporary unwanted weakness of nearby muscles

Eg: injection of the neck – leading to weakness of the neck especially when attempting to lift head.

### Spock Eyebrows

- Reverse-tick eyebrows - excess lateral elevation of the eyebrow giving an unnatural look
- A relatively common adverse outcome especially with inexperienced injectors
- Due to insufficient dosing/no dosing in lateral frontalis
- Part of the art of facial aesthetics is setting a target and understanding how to achieve this - getting the balance right between brow heaviness and insufficient dosing causing excessively raised eyebrows is an important example of this
- If this does occur, you will be told by your patient or you will pick it up on the two-week review.
- Explain to the patient that it is easy to resolve by injecting a small (2 unit) amount of product laterally where the muscle is activating excessively

### Secondary non-responsiveness to treatment[46]

Studies have shown that the use of botulinum toxin can lead to the formation of neutralising antibodies directed specifically against the neurotoxin part of the botulinum neurotoxin. This can lead to non-responsiveness to further treatment.

## 2.3 SOLUTIONS TO ADDRESS SUBOPTIMAL THERAPY OUTCOMES

When suboptimal therapeutic outcomes occur, it is important to know how these can be addressed, ensuring patients feel confident with the strategies proposed. Knowledge of facial anatomy and muscle interactions is crucial for building a coherent strategy. Other important aspects include knowledge of products and brands, pharmacodynamics and time-dependent factors.

Examples of scenarios are:

*Patient is unhappy with the outcome as they feel they look different, despite the practitioner-observed outcome being excellent.*

This can be resolved through thorough practitioner-patient discussion prior to treatment. The practitioner should advise of the possible changes. This issue commonly reported around the eyes and on smiling, as long as the correct muscles have been injected, should only be minor. The patient should be reminded that the discussion pre-treatment warned of such changes. In any case, highlight that the changes are temporary.

*Patient is unhappy with outcome, patient did not want treatment of all areas of upper face (eg: frontalis or glabella in isolation).*

You will have advised treatment of both in initial consultation – remind the patient of this and explain the aesthetic concern (eg: low brows or overly raised brows) can be addressed by more comprehensive treatment including an additional area.
Ideally, treatment with all three main areas (including obicularis oculi) should be proposed

*Despite standard dosing, the therapeutic effect has not been sufficient for the patient.*

- Take a systematic, step-wise approach
- Ensure a 2 week review with repeat photographs
- Provide a 'top-up' at this point if necessary

If ongoing difficulty in achieving desired effect, consider use of alternative brands (of botulinum toxin) or if an alternative treatment type would better suit the challenge (dermal filler, skin treatments, etc).

## 2.4 CLIENT OCCUPATION AND ADVERSE EFFECT MANAGEMENT

The lifestyle and occupation of the patient can be an important factor in (or indeed barrier to) successful aftercare. The patient must be able to strictly observe aftercare instructions such as physical movement limitations (bending forward) or lifestyle limitations (avoid alcohol and sunlight) for the specified time periods. Any inability to fulfil the post-procedure requirements should be noted and the associated risks discussed and accounted for.

Patients should be made aware of the possibility of short-term adverse outcomes on physical appearance such as swelling or bruising, and this should be discussed in the context of the patient's occupation and any upcoming important events (weddings, parties, etc.).

Practitioners must assess the ability of the patient to attend follow up, as well as ensuring that they are advised when to make contact after treatment. If a patient will be restricted in attending (eg. travelling abroad shortly after treatment) there must be a frank discussion and consideration of postponement of treatment.

If patients have client-facing or front of house occupations, all risks associated with treatments must be clearly discussed in relation to this occupation, as any minor issue such as a bruise could become very problematic. Impacts can be perceived or actual, and they are heavily person-dependent. Ensuring a clear discussion with all aspects written within the consent form will help to protect both the patient and practitioner from any subsequent distress and disappointment. Such patients may be more likely to require a follow-up, time of work to recover and increased doses of topical products such as arnica.

## 3.0 PRACTICE OF BOTULINUM TOXIN IN AESTHETIC MEDICINE

These learning objectives will also be met on the Foundation Course & on face-to-face mentorship days, as well as by working through the Interface Aesthetics online video learning. The video learning material has been created specifically to meet the Level 7 Diploma in Injectables learning objectives.

Please see ***Video Tutorials***

# **UNIT 4:** PRINCIPLES OF BOTULINUM TOXIN IN AESTHETIC MEDICINE

## 3.1 DANGER ZONES

Before any injection the practitioner should be aware of any danger zones. In the forehead, this would be the supratrochlear and supraorbital arteries and the temporal artery.

There is also a danger zone lateral to the midpupillary line and within 2 cm of the eyebrow. BoNT injection in this area can potentially affect the levator palpebrae superior leading to blepharoptosis.

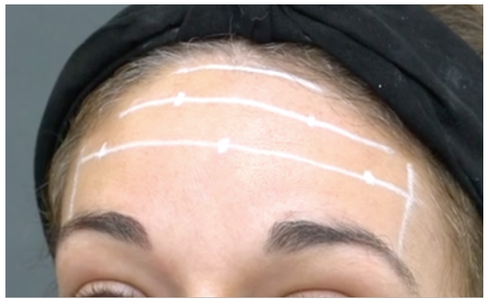
## 3.2 PROCEDURE SITE

The three main areas when injecting the upper face are the forehead, glabella and periocular.
Any makeup should be removed, and the skin cleaned with a alcohol swab.

### Identifying the area for injection

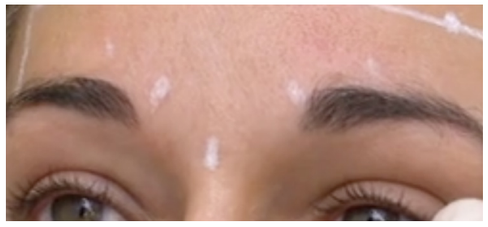
**Frontalis muscle:**

- Ask the patient to raise their eyebrows
- Identify the uppermost rhytid
- Draw a horizontal line 1cm above this rhytid (superior limit of frontalis activity)
- Draw a horizontal line halfway between this line and the eyebrows (inferior treatment line)
- Draw a horizontal line halfway between the inferior treatment line and the superior limit of frontalis activity (superior treatment line)
- The lateral limits are the temporal fusion lines
- An M-shaped injection pattern on these lines should be injected with a total of 20 units (4 units per point)



**Glabella:**

- Procerus muscle: single point in the midline over the muscle bulk felt when frowning
- Corrugator supercilii: Feel the medial bulk of the muscle when frowing, inject at least 1cm above the bony orbital ridge (the injection should be deep)
- Feel the lateral end of the muscle about 1.5cm above the bony orbital ridge (the injection should be superficial)
- Inject 4 units per point to a total of 20 units



**Periocular region:**

- Draw 1 injection point 1.5cm lateral to the lateral canthus of the eye
- Draw two injection points 1cm superior and inferior at a 30 degree angle from the lateral canthus
- Inject 4 units in each point (total of 24 units over both eyes)

# **UNIT 4:** PRINCIPLES OF BOTULINUM TOXIN IN AESTHETIC MEDICINE

## 3.3 INJECTION TECHNIQUE

- Always adhere to the consented care plan
- Position the patient so that the treatment is comfortable for the patient and yourself
- Do not inject directly through the markings to avoid tissue tattooing and contamenation
- Always warn the patient before injecting
- Stretch the skin
- Injections should be slow and controlled with minimal plunger pressure
- Avoid vigorously massaging the site
- Adhere to the aseptic no-touch technique to avoid infection

## 3.4 AFTERCARE

- Explain the aftercare to the patient and give them an information leaflet
- 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

## 3.5 RECORD KEEPING

- Keep a clear and contemporaneous record as per professional guidance
- Take photos before and after treatment
- Record brand, product name, batch code, expiry date, diluent, volume injected, dosage, site, technique, depth, volume injected, needle administration, additional products/medicines injected, Adverse events.

## 3.6 REVIEW APPOINTMENT:

- Two weeks after the initial treatment
- Review efficacy and patients view on results
- Correct any asymmetries

## 3.7 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

# UNIT 5: PRINCIPLES OF DERMAL FILLER IN AESTHETIC MEDICINE

## 1.0 BIOCHEMISTRY AND PHYSOLOGICAL EFFECTS OF DERMAL FILLERS

## 1.1 MECHANISM OF ACTION

Dermal filler is a broad term used to describe a wide range of materials used in an injectable form to volumise tissue. They can act in the form of temporary occupiers of space, or as stimulatory fillers acting on native fibroblasts (however crossover does exist between the two).

- The temporary space-occupiers yield temporary results and must be re-injected regularly. Collagen production is evoked but to a lesser degree than stimulatory fillers.
- The stimulators induce a foreign-body inflammatory reaction which promotes fibroblast proliferation and activity, leading to autologous collagen production. Neocollagenesis results in improvements in both volume and quality of the connective tissue, and as such is believed to yield better long-term effects.

Dermal fillers can be divided into permanent, semi-permanent, and temporary fillers.

## 1.2 CLASSIFICATION OF DERMAL FILLERS

### Permanent dermal fillers

- Man-made polymers that are not degradable
- These fillers yield longer lasting results, but are less forgiving and are associated with higher rates of granuloma formation. The effects are also irreversible, which is highly undesirable in the event of an emergency.
- Permanent fillers will also not adapt to changes in the face that occur naturally over time, possibly resulting in unfavourable outcomes

#### Example 1: Bellafill

- Bovine collagen combined with PMMA (polymethylmethacrylate)
- Used to treat acne scars with results lasting up to 5 years
- PMMA beads (microspheres), when injected under the skin, are not absorbed, metabolised nor excreted by the body
- There is an increased risk of inflammatory reactions with this filler type

#### Exampe 2: Silicone

- Used to volumise lips and treat scarring from acne
- Long history of use

### Semi-permanent dermal fillers

#### Example 1: Sculptra®

- Contains Poly-L Lactic Acid (PLLA) which is biodegradable and immune inert
- Sculptra works as a dermal stimulant, resulting in the production of lactic acid monomers which are incorporated into glucose.
- The result after injection is neo-collagenosis, leading to volumisation of 3-9 months and lasting up to 2 years.
- NOT RECOMMENDED in temporal or galeal areas
- NOT RECOMMENDED for mid dermal or superficial injections, or lips (risk of nodule formation)

#### Example 2: Autologous fat transfer

- Where fat is taken from one part of the body and placed in in another part to volumise.
- Requires harvesting, and therefore an intervention elsewhere in the body

#### Example 3: Radiesse®

- Calcium hydroxylapatite (CaHA)
- An inert, biocompatible filler
- Used for deep injections, jaw augmentation at pre-periostial level
- Microsphere which stimulates fibroblasts inducing neo-collagenosis
- Effect of around 1-2 years with lower granuloma risk than Sculptra.
- Not recommended for superficial placement in view of stimulatory effect
- Is a stimulatory filler, but also provides an initial volumising effect.

### Temporary dermal fillers

- Hyaluronic acid (HA) is a biodegradable gel-like substance which is found naturally in connective tissue
- It is a replacement filler, providing volume
- It is an energetically stable mucopolysaccharide, which is broken down over 6-12 months
- It is hydrophillic, contributing to tissue hydration
- It promotes fibroblast proliferation and collagen production
- In its natural form, HA is vulnerable to free-radical degradation and the enzyme hyaluronidase (hyalase), resulting in it being broken down in around 12-48 hours
- The HA used in aesthetics is cross-linked, making it resistant to this rapid breakdown
- HA based fillers are classed as medical devices, and therefore do not require a prescription
- There are many different brands, and a variety of fillers within brands with varying consistencies, for use in different areas and for different purposes.
- Unlike botulinum toxin, dermal fillers which are HA based are reversible with the use of hyaluronidase (enzyme) which immediately starts to break down the product.
- HA-based fillers can last from 6-24 months, depending on the individual product.

## 1.3 TOPICAL ANAESTHETIC AND DERMAL FILLERS

Treatment pain anxiety can have a significant effect on patients returning after a procedure and may affect treatment uptake. Topical anaesthesia is commonly used in medical aesthetics, applied as standard in dermal filler procedures and optionally where botulinum toxin is used. Common agents include EMLA 5% cream (Lidocaine and Prilocaine combined) and Lidocaine 4% cream (brand name LMX).

LMX cream should be applied to the area, without the need for an occlusive dressing when used in adults on the face. It should be applied with a moderate coating and left. It starts to work in around 20-30 mins. Avoid leaving it on the skin for more than 60 minutes. The effect can last for around 60 minutes.

Note any allergies before using anaesthesia on the patient, and always have anaphylaxis medicines to hand in case an allergic reaction is precipitated. The topical anaesthetic can also cause some mild inflammation at the site of application, so be aware of this and use only where necessary. Other rare but possible risks include oedema, blanching and erythema. It must be stored in a cool dry place and locked away out of reach of the general public and children. The obvious major advantage in topical anaesthetic use is the greater comfort and patient experience.

Alternatives to local anaesthesia include ice application (alone or in combination with a topical anaesthetic), reducing needle size, minimizing injection volume and improved practitioner technique. Ice has the additional advantage of causing local vasoconstriction.

## 1.4 LOCAL ANAESTHETIC AND DERMAL FILLERS

Local anaesthetic is an important consideration when providing aesthetic treatments with dermal filler. Topical anaesthetics have been discussed previously. Many products now incorporate lidocaine into

# **UNIT 5:** PRINCIPLES OF DERMAL FILLER IN AESTHETIC MEDICINE

the dermal filler itself, to provide anaesthesia upon injection. The advantages of such formulations include the greater patient comfort both during and directly after the procedure. This is of particular benefit for sensitive treatment areas such as in the temples or lips. Disadvantages include greater cost and allergy risk. It is important for patients to be aware that the anaesthetic will wear off within hours, and some discomfort may then ensue. Clear instructions regarding when to contact the practitioner post procedure must be given in the context of the patient being anaesthetised for 1-2 hours post procedure.

## 2.0 RELEVANT ANATOMY FOR THE ADMINISTRATION OF DERMAL FILLERS

## 2.1 VASCULATURE

Knowledge of facial anatomy is a pre-requisite for any practitioner injecting dermal filler. There are certain 'danger zones' which must be appreciated and accounted for on planning and executing treatments. Furthermore, knowledge of arterial supply is especially important in consideration of the occurrence of blanching or purple discolouration of areas of skin following treatment with filler, as this could represent arterial compromise. End arteries may provide the sole vascular supply to some areas of the face, and any occlusion or compromise of these will result in pain and blanching, leading to tissue necrosis if not treated.

### Arteries

### Branches from the External Carotid Artery (ECA)

#### FACIAL ARTERY

- Crosses the lower border of the mandible travelling superomedially - can be palpated at this point
- Gives off INFERIOR LABIAL branch 1cm lateral to oral commissure
- Gives off SUPERIOR LABIAL branch slightly cranial to the Inferior Labial branch
- Ascends towards the nasal ala where to gives off the LATERAL NASAL branch
- Continues (in the majority of people) as the ANGULAR artery

#### ANGULAR ARTERY

- Terminal branch of the facial artery
- Ascends to medial canthus along with the angular vein.
- Anastomoses with branches of infraorbital artery on cheek
- Ends by anastomosing with dorsal nasal branch of the ophthalmic artery

#### INFRAORBITAL ARTERY

- Terminal branch of the MAXILLARY ARTERY
- Supplies the cheek and anastomoses with the Angular artery

#### SUPERFICIAL TEMPORAL ARTERY

- Terminal branch of the ECA
- Supplies upper and lateral parts of the scalp and forehead

### Branches from the Internal Carotid Artery (ICA)

#### SUPRATROCHLEAR ARTERY

- One of the terminal branches of the OPHTHALMIC ARTERY, itself a branch of the Internal carotid artery (ICA)

### Danger areas

Where the facial artery crosses the lower border of the mandible:

- Avoid deep injections at the bone level at this area
- Facial artery can be palpated just anterior to anterior border of the masseter muscle (ask patient to clench jaw to feel this muscle)
- Intravascular injection here will affect the facial artery supply which is large

Where the facial artery ascends superomedially by the nasal ala and becomes the angular artery:

- The angular artery is the end artery of the facial artery
- Occlusion results in blanching, necrosis and scarring of the external nose, septum, cheek and forehead and has the potential to cause blindness through embolisation
- The angular artery may also be affected when injecting the tear trough medially
- Occlusion may also affect the nasal ala where it affects the facial artery (more proximally)

In the glabella region where the supra-trochlear artery may be affected:

- The supra-trochlear artery is an end vessel of the ophthalmic artery
- Injecting the glabella with dermal filler is high risk for vascular occlusion
- Occlusion can cause ischaemia and necrosis of the forehead, while retrograde embolisation can affect the ophthalmic artery itself, resulting in blindness and loss of normal ocular movements.

### Veins

Venous drainage largely follows arterial supply, with corresponding veins to match the facial, angular, supratrochlear, and supraorbital arteries. The facial vein is formed at the medial canthus of the eye from the supraorbital and supratrochlear veins, descending the face alongside and deep to the facial artery. This facial vein then passes the lower border of mandible and moves posteriorly, where it joins with the retromandibular vein to form the common facial vein, which drains into the internal jugular vein. The infraorbital vein drains the mid-cheek area, which is supplied by the infraorbital artery, also passing via the infraorbital foramen.

Danger triangle of the face – the area of the face from the nasal bridge to the corners of the mouth. Superficial venous drainage here is via the facial vein, which has connections deep into the cavernous sinus vial ophthalmic veins. This communication poses the risk of superficial injections in this area moving deep intracranially and causing encephalitis, venous, sinus thrombosis, meningitis, or an abscess.

There are areas with rich venous plexuses which are prone to bleed and bruise, and these include the under-eye region, which its high risk for bruising after any treatment. Another high-risk area is the temple, where the superficial temporal veins can be prone to trauma. Always look out for superficial veins overlying an injection site, taking care not to cause unnecessary trauma that could cause bruising.

## 2.2 NERVES

The facial nerve is the motor nerve of the face, and it supplies the muscles of facial expression. There are five main branches to the facial nerve: Temporal, Zygomatic, Buccal, Mandibular, Cervical.

The actions of each of the five branches can be seen, along with the relevant vascular anatomy also demonstrated:

The sensory nerve of the face is the Trigeminal nerve (CN V). This nerve has three main divisions - ophthalmic, maxillary and mandibular. Important nerves within these divisions include:

#### Supratrochlear nerve (V1)

- Branch of the frontal nerve <- Ophthalmic division of Trigeminal nerve.
- Supplies skin of medial lower forehead, conjunctiva and skin of the upper eyelid

# **UNIT 5:** PRINCIPLES OF DERMAL FILLER IN AESTHETIC MEDICINE

### Supraorbital nerve (V1)

- Branch of the frontal nerve <- Ophthalmic division of Trigeminal nerve.
- Emerges from supraorbital foramen and is lateral to the Supratrochlear nerve
- Supplies frontal sinus and skin of forehead more lateral to midline and up to the scalp

### Infraorbital nerve (V2)

- Terminal branch of the maxillary division of the trigemial nerve
- Supplies sensation to the lower eyelid, upper lip and part of the nasal vestibule
- Exits through infraorbital foramen of maxilla
- Divides into 4 terminal branches: superior labial, internal nasal, external nasal, inferior palpebral

## 2.3 FAT PADS

### Cheek

FOUR Superficial fat compartments
- Nasolabial
- Medial
- Middle
- Lateral-temporal

### Deep Cheek

THREE deep fat compartments
- SOOF (Sub-obicularis oculi fat)
- Deep medial cheek
- Buccal

### Forehead

THREE compartments
- Central
- Two lateral

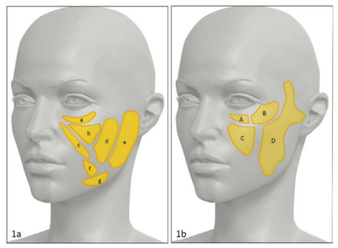
### Orbital

THREE inferior intraorbital compartments
- Medial
- Central
- Temporal (Lateral)

TWO superior intraorbital compartments
- Medial
- Central

### Subcutaneous periorbital area

THREE subcutaneous fat compartments
- Superior
- Inferior
- Lateral




**Superficial Cheek Fat Compartments**

a) Infraorbital fat
c) Nasolabial fat
e) Lateral cheek fat

b) Medial Cheek fat
d) Middle cheek fat
f) Superior jowl fat
g) Inferior jowl fat

**Deep Cheek Fat Compartments**

a) Medial sub-orbicularis oculi fat
b) Lateral sub-orbicularis oculi fat
c) Deep medial cheek fat
d) Buccal fat

Figure 11: Fat compartments of the face (from: Module 1 Unit 1 video)

An understanding of the anatomy of the fat of the face is crucial to understanding the morphology of facial ageing. Key fat pads to note are the nasolabial compartment, the superior and inferior jowl compartments, and the middle cheek compartment (all superficial). The descent of these fat pads contributes to the coarsening of the nasolabial, marionette and jowl areas – some of the most commonly mentioned areas of concern for clients. It is important to understand the relationship between fat compartments, as well as bone loss, in the ageing process, and fat descent and loss of contour can be attributed to both fat and bone changes.

At the deeper layer, changes to the sub-obicularis oculi fat (SOOF) are responsible for worsening of the tear trough deformity, while changes to the buccal fat pad can cause a gaunt, hollow look in the mid face. Turning finally to the orbital region, fat herniation from the orbital fat compartments can exacerbate a tear trough defect, and it is important to assess for fat herniation as this will impact of the treatment plan to deal with peri-orbital ageing (eg: recommending surgical review).

## 2.4 AGE RELATED ANATOMICAL CHANGES

The morphology of ageing dictates where product should be placed. In the first instance, a thorough assessment must be undertaken to account for individual changes resulting from both genetic and environmental factors. The problem areas identified or suggested by the patient will guide product selection, volume used, depth of placement and use of other modalities such as botulinum toxin. The emulation of fat pads with soft tissue fillers is called Biomimicry. Common areas that need to be addressed as part of the ageing process include:

### Midface volume loss

- Zygomatic and maxillary bone loss
- Midface fat volume loss
- Temporal volume loss

Downward migration of fat causing increased lower face volume. The above is addressed with mid face dermal filler placed pre-periostally on the cheekbone in the first instance. A volumising filler should be used.

### Perioral/lip volume loss

- Loss of volume of both lips, upper more than lower
- Loss of perioral volume creating fine lines and a sunken appearance
- Increased distance between subnasale and upper lip

The above is addressed with dermal fillers in the lip body/border/periorally, using an appropriate filler.

### Deep creases

- Deep crease development over areas of dynamic movement
- Creases from descent of tissue and subcutaneous volume loss
- May be exacerbated by environmental factors and facial shape

The above is addressed with tailored placement of an appropriate product to soften line appearance, while addressing any underlying cause such as mid face volume loss. Placement should be at the depth appropriate for the severity/depth of the crease.

## 3.0 SAFE ADMINISTRATION OF DERMAL FILLERS

## 3.1 INJECTION TECHNIQUES

See *E-Interface Video Modules & Case Library*

# **UNIT 5:** PRINCIPLES OF DERMAL FILLER IN AESTHETIC MEDICINE

### Linear Threading

- A retrograde slow injection while withdrawing a needle
- Measure the needle against the area to be injected, visualising where the entry point should be
- Determine the injection angle, stretch the skin and insert the needle until it is at the desired depth, and then flatten the needle
- Maintain the needle bevel up, and with the needle now flat advance to where is required
- At this point, you must ASPIRATE - looking for any blood which may indicate intra-arterial positioning. If blood is aspirated, WITHDRAW IMMEDIATELY WITHOUT INJECTING
- Once happy with position and safety, start injecting the product slowly as you withdraw
- Avoid injecting until withdrawal as this will waste product (inject until 3/4 of needle has been withdrawn)
- Aim to inject small amounts at a time - 0.1ml at each pass.

### Bolus

- An injection of a determined amount of product in a single point
- Used commonly at the bone (pre-periostial) depth
- The deep anatomical landmark should be identified and marked, accounting for any movement of overlying tissues
- Injection is usually perpendicular to the skin (eg: onto the cheek bone) and when the desired level is reached, aspiration should be performed
- When satisfied with the site and safety, injection is carried out slowly, delivering the desired amount of product in a single location, before withdrawing

### Fanning

- The initial stages of lining up and inserting the needle here are identical to the linear threading technique
- This is often used in conjunction with linear threading
- The difference to linear threading regards needle direction and movement
- Whilst inserted, the needle orientation is changed before being withdrawn
- At each new position, aspiration must take place
- This change in orientation can take place multiple times to cover a larger area through a single entry point
- Injecting the product is linear retrograde (as with linear threading)
- This fan effect can provide greater support to certain areas (eg in the nasolabial area)

### Cross-hatching

- Injections take place at right angles
- This can provide support and volume
- Useful in the marionette region
- Linear threads are placed at 90 degree angles to each other

## 3.2 NEEDLES AND CANNULAS

### Needle

Injecting with a needle is the more traditional method of product placement, and can take the form of any of the injection methods listed in the previous section. An aseptic non-touch technique (ANTT) must be used throughout.

#### Advantages

When used appropriately, this method is accurate, and it is also often the method in which practitioners are most confident, which can lead to better outcomes.

#### Disadvantages

By nature of the sharpness of the needle it can cause more trauma, resulting in a higher risk of bruising or swelling. In addition, for covering large areas, a needle may require multiple puncture sites leading to greater discomfort for the patient. There may be less depth control resulting in unevenness, and importantly, there will be an increased of arterial puncture and vascular compromise.

### Cannula

This is the more recent method used for filler placement, and is becoming more popular with time. It is particularly suited to certain treatments where minimal trauma and placement over a large area is preferable. A cannula is a round ended tube which is inserted into the subcutaneous layers via puncture site made with a small needle. The cannula is progressed through the tissues in a plane using minimal pressure to find a path of low resistance. Cannulas come in varying gauges and lengths.

#### Advantages

Less traumatic, and as such can pose a lower risk of brushing, swelling or arterial puncture/injection. The lower bruising risk and reduced downtime makes the cannula especially useful for patients with externally facing roles, while the safety aspect makes it very appropriate for using around the eyes. There are also fewer administration/injection points which is good for patient comfort. Depth controls is good as injecting is in a horizontal plane, thus resulting in better evenness of distribution.

#### Disadvantages

The cannula itself is more costly and must be bought separately. There is also a significant learning curve associated with use, with some increased complexity and greater training requirements involved. Most of the advantages of using a cannula are dependent on the practitioner developing and having the necessary skills, and reaching this level of competency takes time.

## 3.3 CONTRAINDICATIONS FOR THE USE OF DERMAL FILLERS

#### Contraindications

- Known hypersensitivity/allergy to product (including local anaesthetic if contained, or to gram positive bacterial proteins)
- Pregnancy
- Breast feeding
- Infection at injection site

#### Cautions

- Patient mental health concerns
- Anticoagulant Medications - Warfarin, aspirin, clopidogrel
- Vitamin E high dose, omega 3 oil high dose, and aspirin (if permitted to stop) should be stopped 7 days pre-treatments

## 3.4 HIGH-RISK TREATMENT AREAS

**Nasolabial folds** - injecting deep into this area poses a risk of intravascular injection into the facial/angular artery, causing vascular occlusion with associated ischaemia and necrosis of facial tissues if untreated

**Tear trough** - small vessels around eye plus the proximity of the angular artery when treating medially make this a high risk area of intravascular injection which, in the worst scenario, can lead to tissue necrosis or involvement of the ophthalmic artery and the eye itself.

**Glabella** - using filler to fill fine lines in this region can lead to intravascular occlusion affecting the supratrochlear or supraorbital vessels. Retrograde embolisation can even result in involvement of the eye and visual disturbance.

## 3.5 POTENTIAL ADVERSE EFFECTS AND THEIR MANAGEMENT

Adverse effects associated with dermal filler administration are more common than they ought to be, and the media regularly has stories of poorly performed filler procedures with often disastrous outcomes. It should be highlighted that despite not being a prescription-product, dermal filler can cause catastrophic damage to patents when it is not delivered by suitably trained healthcare professionals. Even when practitioners are suitably trained and experienced, adverse outcomes can still occur and it is crucial that practitioners understand how to recognise and deal with these.

# **UNIT 5:** PRINCIPLES OF DERMAL FILLER IN AESTHETIC MEDICINE

When we refer to dermal filler here, we are talking about hyaluronic acid (HA). Other fillers exist in the current aesthetic market, but for reasons elaborated on, currently we recommend that only HA is used for the purposes of your Level 7 training. HA is found naturally in our connective tissues, however it's quantity diminishes with age. It is a glycosaminoglycan which is turned over on a daily basis in the body. HA is also a component of the group A streptococcal extracellular capsule; it is from this bacteria that HA is produced for use in aesthetics. Importantly, HA can be dissolved by the enzyme hyaluronidase (hyalase) in the event of an emergency.

Adverse effects associated with dermal filler application include:

- Bruising
- Bleeding
- Swelling
- Vascular compromise
- Vascular occlusion/embolization
- Blindness
- Pain
- Headache
- Hypersensitivity/Allergy
- Granuloma/biofilm/nodules
- Suppuration/abscess/infection
- Anaphylaxis

Regarding bleeding and bruising, simple measures such as patient selection, avoiding aspirin/Vitamin E pre-treatment and pressure over areas during the procedure can help reduce this risk. Swelling can be especially evident with certain areas (eg; under eyes), but simple advice such as ice packs and sitting upright can ameliorate this. Allergy to HA is unlikely, while pain can be managed with paracetamol, however patients must be made aware that severe or worsening pain is a RED FLAG and must be reported to the practitioner immediately in the first 48 hours as a possible manifestation of vascular compromise. The use of aseptic non-touch technique and effective skin cleansing with alcohol or chlorhexidine is important to avoid contamination of the needle/cannula or implantation of bacteria or debris during injection. The result can be a biofilm and granuloma formation in the tissues. The single most important measures to avoid this are maintaining sterile conditions of the cannula/needle and adequate skin preparation. If a frank infection with suppuration is suspected, this must be managed rapidly and with appropriate steps to involve antibiotics and other healthcare professionals. Drainage may be required in certain circumstances, and at all times involvement of important structures as well as spread must be accounted for.

To elaborate on some of the most important adverse effects, we must turn to vascular compromise and vascular occlusion/embolization. When dermal filler is injected into an artery, it can either block the artery at the site or it can embolize to a more distant site. Both of these outcomes are catastrophic and can lead to tissue necrosis and/or blindness. To avoid this occurring, it is important to aspirate every time a needle is placed in a different site, and while cannulas do not remove the risk, they are significantly safer and less likely to pierce a vessel. Special care must be taken when treating 'danger zones' such as the nasolabial fold region, where there are vessels leading to an increased risk of arterial involvement. Other measures to reduce risk include injecting small volumes at each time (max 0.1ml), and linear threading is preferable to large boluses in the subcutaneous tissue. Where arterial compromise is suspected, the single most important measure is to inject hyaluronidase into the tissues to break up the filler. This must be done as a matter of emergency. Other important measures in the hyperacute phase include massage, warm compress, a stat dose of 300mg aspirin (if no contraindication) and discussion with a more experienced colleague. Important acute and subsequent measures include use of oral sildenafil, oral prednisolone and oral antibiotics, and subsequent daily doses of 75mg of aspirin. Specialist interventions including the use of hyperbaric oxygen therapy (HBOT) and surgical debridement must be considered, again with discussion with an experienced colleague. See recent evidence -based guidelines for more detailed information on managing vascular occlusion[47]

## 3.6 THE USE OF HYALURONIDASE IN SUSPECTED VASCULAR COMPROMISE

See video ***Vascular compromise & Hyalase***

Hyaluronidase (shortened to hyalase) is an enzyme that breaks down hyaluronic acid, starting to work instantly. It can be used to break down/dissolve HA-based dermal filler in both emergency and non-emergency situations.

### Emergency Indication

- Suspected vascular occlusion leading to necrosis of tissue or ocular complications

### Non-emergency Indications

- Excessive product present
- Nodules
- Poor aesthetic outcome
- Patient wishes to reverse treatment

Hyaluronidase comes in vials of 1500 units. Once opened, the contents must be mixed with bacteriostatic normal saline as per requirements/dilution required and either used or discarded immediately. There is a risk of allergy/anaphylaxis with hyalase, and as such for non-emergency indications there should be a patch test on the patient with a small amount injected sub-dermally onto an area of skin (eg: the arm) followed by 30 minutes observation.

When hyalase is injected it will dissolve product and remove nodules. It should be explained to the patient that hyalase can also affect native connective tissue. There can also be unintended dissolution of other filler treatments, and it is notoriously difficult to use hyalase is an accurate way to treat specific areas. Since hyalase is delivered by injection, there are associated risks of bruising, bleeding and swelling, and the patients should be warned that the injection can sting.

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 and the practitioner must be competent to administer the medicines.
https://www.legislation.gov.uk/uksi/2012/1916/schedule/19/made

There is debate regarding patch testing in the emergency situation. As long as adrenaline and oxygen are readily available (as should be the case) then the emergency situation requires that hyalase is injected as soon as possible to halt ongoing vascular compromise and impending tissue necrosis. Hyalase should be used to flood the area in emergencies, following along the area of injected filler as well as the course of the suspected vessel involved. Treatment should be repeated at frequent (1-3 hourly) intervals until capillary refill and symptoms are resolving. The patient should stay with you throughout this time for observation. Involvement of a more experienced professional/mentor should be considered as the progression and recovery can be challenging and unpredictable. Scarring can occur if this complication is not recognised or appropriately treated. In the worst scenario sight can be lost and permanent facial disfigurement can occur.

# RESOURCES & REFERENCES

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# APPENDIX

1. SAMPLE AFTERCARE INSTRUCTIONS
2. SAMPLE CONSENT FORM
3. SAMPLE MEDICAL WAIVER
4. GUIDANCE FOR DOCTORS

**Botulinum Toxin Injection Aftercare Instructions**

Treatment with Botulinum Toxin by experienced practitioners is safe and produces predictable results. There are a few instructions to follow following your procedure that should be observed to ensure that you obtain the best result and minimize the chance of any complications arising.

- For 3 hours after the treatment:
  - Avoid lying flat
- For 24 hours after the treatment:
  - Avoid rubbing the face excessively
  - Avoid strenuous exercise, saunas, steam rooms
  - Avoid Alcohol
  - Avoid using a sunbed
  - A headache can occur in some patients – you are able to take paracetamol for this
- For 48 hours after the treatment:
  - Avoid facial massages
  - Avoid microdermabrasion or any other skin treatment
  - Avoid flying

**Dermal Filler Aftercare Instructions**

Treatment with dermal filler by an experienced practitioner is safe, and any possible risks will have been discussed as part of the consultation. Following your treatment, there are a few points to note:

- Within the first 3 days, report any skin discolouration/darkness/greyness, or any change in sensation/tingling, to you practitioner at any point following the treatment
- Avoid rubbing the area treated excessively. Face washing and gentle makeup removal are permitted immediately
- Avoid alcohol for 24 hours
- If you have been treated in an area particularly prone to bruising (eg; tear trough region, lips), it may be advisable to apply ice following the treatment and as recommended by your practitioner.





**Patient Details**

Patient name:

DOB:

Address:

Contact number:

**Medical History**

Are you pregnant or breastfeeding? Y/N

Do you have a history of severe allergy/anaphylaxis? Y/N

Are you currently receiving any medical treatment? Y/N

If yes, please provide details,

_____

Have you previously received any aesthetic treatments? Y/N

If yes, please provide details of what was done and when,

_____

Have you ever suffered from any disease affecting the immune system? Y/N

Have you ever suffered with any skin problems (eg: acne, herpes, etc) Y/N

Are you currently taking steroids, aspirin, warfarin? Y/N

Do you suffer from any allergies, including to local anaesthetics? Y/N

Do you suffer from any disorders of the heart (arrythmia, conduction disorders)? Y/N

Do you develop hypertrophic scarring/keloids? Y/N

Do you suffer with any of the following: Epilepsy, Porphyria, Liver Disease, Kidney Disease? Y/N

Do you smoke? Y/N

Please provide further details here,

_____

Do you drink alcohol? Y/N Units/week:

BDD Screening:

1) Are you worried about how you look? Y/N
2) If Yes – do you think about you appearance problems a lot and do you wish you could think about it less? Y/N

If NO to either question – move on. If YES to both – carry out full BDDQ screening tool

**Consent Form – Botox ®**

Procedure(s)_____

Brief description of reason for seeking treatment _____

_____

**Botulinum Toxin**

I understand the aim is medium term (2-6 months) paralysis/relaxation of targeted muscles

**Risks may include, but not limited to:**

Transient headache, swelling, bruising, bleeding, pain, allergy including anaphylaxis (rare), asymmetry, temporary drooping of eyebrow/lid, temporary double vision. Theoretical risks of other complications not disclosed here exist.

**Alternatives:**

Topical creams, chemical peels, laser treatments, surgery, hyaluronic acid treatments, doing nothing.

**Limitations:**

Botulinum toxin treats dynamic facial lines, it will not affect static (fixed) lines. Sometimes it the effect wears off more quickly than anticipated, or may not have the desired effect from the outset.

**Follow up:**

A review is recommended at 2 weeks, with a free top-up if needed. After this point, further treatment will incur a charge. I will avoid rubbing my face, applying make-up, drinking alcohol, strenuous exercise, facials or hot environments for 24 hours. I will avoid excess UV exposure for 2 weeks. I will avoid lying flat for 3 hours.

**I confirm that I have been offered a cooling off period.**

**I understand that most treatments are given off label.**

**Additional procedure specific risks, limitations or follow up points:**

_____

**Patient signature_____ Date_____**

**Practitioner Signature_____ Date_____**

**Consent Form – Dermal Filler**

Procedure(s)_____

Brief description of reason for seeking treatment _____

_____

**Dermal Filler**

I understand that hyaluronic acid containing injections treat lines, replace lost volume and can hydrate the skin, in the medium term (6-18 months depending on temporary product used).

**Risks may include, but not limited to:**

Bleeding, bruising, haematoma, infection, allergy, including anaphylaxis (rare), lumpiness, pain, itching, asymmetry, swelling. Nodules may form immediately or later, and may rarely be permanent. Injections may trigger herpetic recurrence (lips). In rare instances, blood supply to areas of the face may be affected with necrosis or blindness, requiring reversal of treatment with Hyauronidase (enzyme). Disrupted blood supply can result in tissue necrosis (permanent scarring) or blindness (extremely rare). Local anaesthetic (lidocaine) contained in some preparations may cause allergy, cardiac arrythmias, anaphylaxis or, extremely rarely, death. Topical lidocaine can also cause allergy or irritation.

**Alternatives:**

Botulinum toxin, skin treatments including laser peels, doing nothing.

**Limitation:**

Hyaluronic acid fillers my not have the desired effect initially, or later on may cause further swelling dependent on the product used. The product may last for a longer or shorter time than usually expected.

**Follow up:**

I will avoid rubbing the treated area for 48 hours, and any chewing or hot drinks until all sensation has fully returned. In the event of any perceived adverse reaction including pain, severe swelling or skin changes, I will contact my practitioner. A review is recommended at 2 weeks.

**I confirm that I have been offered a cooling off period.**

**Additional procedure specific risks, limitations or follow up points:**

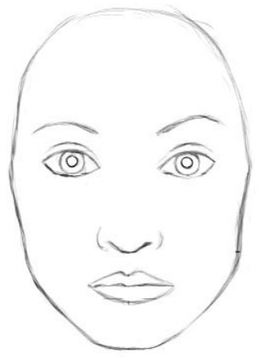
_____

**Patient signature_____ Date_____**

**Practitioner Signature_____ Date_____**

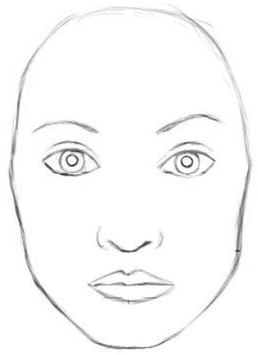


Interface Aesthetics: Patient Consent Form



**Care Plan**

Date:

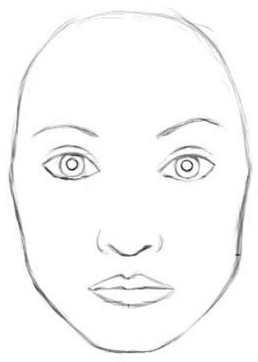


Date:

Procedure:

Product/Lot/Expiry:

Notes:



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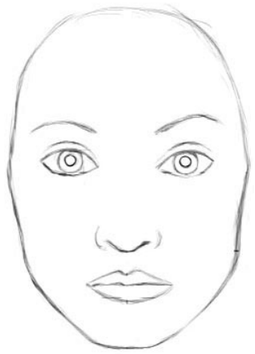
Procedure:

Product/Lot/Expiry:

Notes:



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Procedure:

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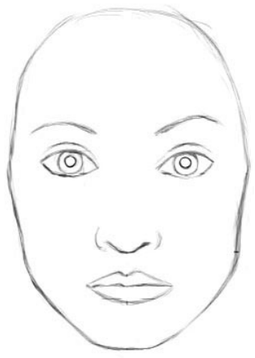
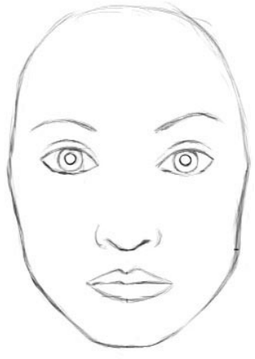


Date:

Procedure:

Product/Lot/Expiry:

Notes:



Date:

Procedure:

Product/Lot/Expiry:

Notes:





INTERFACE AESTHETICS

Medical Waiver

I understand there are risks associated with the proposed treatment(s). I have provided written consent on a separate form. I confirm that I have reads and understood all of this information, and that I am over 18 years of age.

I have been offered enough time to make an informed decision on treatment. I have been provided with alternative options.

I understand that I must follow specific aftercare instructions – provided in written and verbal format by my practitioner in a separate form. Failure to follow these could result in an undesirable or adverse outcome, for which the practitioner will not be held liable.

I release Interface Aesthetics (as subsidiary of JAO Medical Ltd) from all liability associated with this procedure/treatment. I understand that there are no guarantees as to how the result will be, or how long it will last for.

Nothing in this medical disclaimer will:

(a) limit or exclude our liability for death or personal injury resulting from negligence;

(b) limit or exclude our liability for fraud or fraudulent misrepresentation;

(c) limit any of our liabilities in any way that is not permitted under applicable law; or

(d) exclude any of our liabilities that may not be excluded under applicable law

Name:

Age:

Signature:

Location:

Date:

You can find the latest version of this guidance on our website at **www.gmc-uk.org/guidance.**

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General Medical Council

# Guidance for doctors who offer cosmetic interventions

## How this guidance applies to you

This guidance is for all doctors who offer cosmetic interventions.

The cosmetic sector is a rapidly expanding area of practice that has gone from being a niche market to a popular service that is now widely available. Cosmetic interventions can have a significant impact on the health and wellbeing of patients. There have been particular concerns about patient safety and whether the sector operates in an ethical manner. It is important that doctors have the right skills, the products used are safe, and patients get accurate information before they decide to have a cosmetic intervention. This guidance sets out a framework for practice to address these concerns.

By cosmetic interventions we mean any intervention, procedure or treatment carried out with the primary objective of changing an aspect of a patient's physical appearance. This includes surgical and non-surgical procedures, both invasive and non-invasive.

The key aims of this guidance are to make sure that doctors:

- are appropriately trained and experienced to practise safely
- work with each individual patient to make sure their expectations about the outcomes that can be achieved for them are realistic
- follow current guidelines or protocols for safe, effective provision of cosmetic interventions
- consider the psychological needs of their patients
- do not allow any financial or commercial interests in a particular intervention, or an organisation providing cosmetic interventions, to adversely affect standards of good patient care.

This guidance does not apply to interventions that amount to female genital mutilation (FGM), which is illegal in the UK. If you are not sure whether a particular cosmetic intervention falls within the legal definition of FGM[1] then you must seek advice, eg from your defence organisation or your employer's legal department.





## Using this guidance

This guidance incorporates principles from our existing guidance, and is structured under the four domains of *Good medical practice*. In some cases, it sets a higher standard than in our other guidance to address the specific safety issues and ethical concerns particular to the cosmetic sector, as recommended by Sir Bruce Keogh's *Review of the regulation of cosmetic interventions*.[2]

You must read this guidance alongside our other guidance[3] for a full understanding of the expected standards of practice. Throughout this document, we've highlighted certain paragraphs of our other guidance, which you must read to get the full picture. You can also find these extracts in the annex, beginning on page 13.

Throughout this guidance, we use the terms 'you must' and 'you should' in the following ways.

- 'You must' is used for an overriding duty or principle.
- 'You should' is used when we are providing an explanation of how you will meet the overriding duty.
- 'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

To maintain your licence to practise, you must demonstrate, through the revalidation process, that you work in line with the principles and values set out in this guidance. Serious or persistent failure to follow this guidance will put your registration at risk.

## Other sources of guidance

A number of organisations, including the Royal College of Surgeons, have produced guidance on the professional standards, skills and experience needed to carry out cosmetic interventions. The Committee of Advertising Practice has developed guidance on the advertising and marketing of cosmetic interventions. We have included references and links to these other sources of guidance, which complement our guidance for doctors.

- ***Professional Standards for Cosmetic Surgery***
  Published by the Royal College of Surgeons (2016), available at: **bit.ly/RCS_cosmeticsurgery**.
- ***Qualification requirements for delivery of cosmetic procedures***
  Published by NHS Health Education England (2015), available at: **bit.ly/HEEcosmeticqualreq**.
- ***Report on implementation of qualification requirements for cosmetic procedures***
  Published by NHS Health Education England (2015), available at: **bit.ly/HEEcosmeticqualreport**.

- **The codes of practice from**:
  - the British Association of Aesthetic Plastic Surgeons, available at **bit.ly/BAAPS_code**
  - the British Association of Plastic Reconstructive and Aesthetic Surgeons, available at **bit.ly/BAPRAS_code**.
- ***Marketing of Cosmetic Interventions***
  Published by Committee of Advertising Practice (2013), available at:
  **bit.ly/CAP_cosmeticmarketing**.

## Key points

If you offer cosmetic interventions, you must:

- seek your patient's consent to the procedure yourself rather than delegate
- make sure patients are given enough time and information before they decide whether to have an intervention
- consider your patients' psychological needs and whether referral to another experienced professional colleague is appropriate
- recognise and work within the limits of your competence, seeking advice when necessary
- make sure patients have the information they want or need, including written information that supports continuity of care and includes relevant information about the medicines or devices used
- take particular care when considering requests for interventions on children and young people
- market your services responsibly, without making unjustifiable claims about interventions, trivialising the risks involved, or using promotional tactics that might encourage people to make ill-considered decisions.

As with all doctors in all fields of medicine, you must also:

- work in partnership with patients, treating them with respect and dignity
- keep patients safe, work to improve safety and report safety concerns
- work effectively with colleagues
- keep up to date with and follow relevant law and guidance
- be open and honest about your skills, experience, fees and conflicts of interests.



Guidance for doctors who offer cosmetic interventions

## Knowledge, skills and performance

**1** You must recognise and work within the limits of your competence and refer a patient to another practitioner where you cannot safely meet their needs.

**2** Before carrying out an intervention for the first time yourself, or supervising others performing it, you must make sure you can do so safely, eg by undergoing training or seeking opportunities for supervised practice.[4]

**3** You must take part in activities to maintain and develop your competence and performance across the full range of your practice.

**4** You must keep up to date with the law and clinical and ethical guidelines that apply to your work. You must follow the law, our guidance and other regulations relevant to your work.

**5** You must seek and act on feedback from patients, including information on their satisfaction and physical and psychological outcomes. You must use this, and feedback from colleagues, to inform your practice and improve the quality of your work.

**6** You must make sure your annual appraisal covers the whole of your practice.

## Safety and quality

**7** To help keep patients safe you must follow the guidance on establishing and participating in systems and processes that support quality assurance and service improvement, as set out in *Good medical practice* and our related explanatory guidance. In particular, you must:

- **a** comply with any statutory reporting duties in place
- **b** contribute to national programmes to monitor quality and outcomes, including those of any relevant device registries
- **c** routinely monitor patient outcomes, and audit your practice, reporting at least annual data
- **d** report product safety concerns to the relevant regulator.[5]

**You must read paragraphs 7–10 alongside:**

- *Good medical practice, paragraphs 22 and 23*
- *Good practice in prescribing and managing medicines and devices, paragraphs 46–50*
- *Leadership and management for all doctors, paragraphs 24–29*
- *Raising and acting on concerns about patient safety, paragraphs 7–10.*

**8** You should share insights and information about outcomes with other people who offer similar interventions, to improve outcomes and patient safety.[6]

**9** You must tell patients how to report complications and adverse reactions.

**10** You must be open and honest with patients in your care, or those close to them, if something goes wrong and the patient suffers or may suffer harm or distress as a result.[7]

**11** You must carry out a physical examination of patients before prescribing injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video link, online or at the request of others for patients you have not examined.

**12** You must seek and act on evidence about the effectiveness of the interventions you offer and use this to improve your performance. You must provide interventions based on the best available up-to-date evidence about effectiveness, side effects and other risks.

**13** You should be satisfied that the environment for practice is safe, suitably equipped and staffed and complies with any relevant regulatory requirements.

**You must read paragraphs 7–10 alongside:**

- *Good medical practice, paragraphs 22 and 23*
- *Good practice in prescribing and managing medicines and devices, paragraphs 46–50*
- *Leadership and management for all doctors, paragraphs 24–29*
- *Raising and acting on concerns about patient safety, paragraphs 7–10.*





## Communication, partnership and teamwork[8]

**14** You must communicate clearly and respectfully with patients, listening to their questions and concerns and considering any needs they may have for support to participate effectively in decision making.

### Seeking patients' consent

**15** You must be familiar with the guidance in *Consent: patients and doctors making decisions together*. In the following paragraphs, we've highlighted key points from the guidance, which are important to protecting patients' interests in relation to cosmetic interventions.

### Responsibility for seeking consent for cosmetic interventions

**16** If you are the doctor who will be carrying out the intervention, it is your responsibility to discuss it with the patient and seek their consent – you must not delegate this responsibility. It is essential to a shared understanding of expectations and limitations that consent to a cosmetic intervention is sought by the doctor who will perform it, or supervise its performance by another practitioner.

### Responding to requests for cosmetic interventions

**17** If a patient requests an intervention, you must follow the guidance in *Consent*, including consideration of the patient's medical history. You must ask the patient why they would like to have the intervention and the outcome they hope for, before assessing whether the intervention is appropriate and likely to meet their needs.

**18** If you believe the intervention is unlikely to deliver the desired outcome or to be of overall benefit to the patient, you must discuss this with the patient and explain your reasoning. If, after discussion, you still believe the intervention will not be of benefit to the patient, you must not provide it. You should discuss other options available to the patient and respect their right to seek a second opinion.

**19** When you discuss interventions and options with a patient, you must consider their vulnerabilities and psychological needs. You must satisfy yourself that the patient's request for the cosmetic intervention is voluntary.

**You must read paragraph 17 alongside:**

- *Good medical practice, paragraphs 15 and 16*
- *Consent: patients and doctors making decisions together, paragraphs 44, 47 and 49.*

**You must read paragraph 19 alongside:**

- *Consent: patients and doctors making decisions together, paragraphs 41 and 42.*

**20** You must explain any monitoring or follow-up care requirements at the outset. You must tell patients if implanted medical devices may need to be removed or replaced and after how long.

**21** You must tell prospective patients if alternative interventions are available that could meet their needs with less risk, including from other practitioners.

## Discussing side effects, complications and other risks

**22** You must give patients clear, accurate information about the risks of the proposed intervention and any associated procedures, including anaesthesia and sedation,[9] following the guidance in *Consent* (paragraphs 28–36).

**23** You must talk to the patient about any adverse outcomes that may result from the proposed intervention, paying particular attention to those the patient is most concerned about.[10] You must talk about the potential adverse physical and psychological impact of the intervention going wrong or failing to meet the patient's expectations.

## Giving patients time for reflection

**24** You must give the patient the time and information they need to reach a voluntary and informed decision about whether to go ahead with an intervention.

**25** The amount of time patients need for reflection and the amount and type of information they will need depend on several factors. These include the invasiveness, complexity, permanence and risks of the intervention, how many intervention options the patient is considering and how much information they have already considered about a proposed intervention.

**26** You must tell the patient they can change their mind at any point.

**You must read paragraph 22 alongside:**

- *Consent: patients and doctors making decisions together, paragraphs 28–36.*

**You must read paragraph 25 alongside:**

- *Consent: patients and doctors making decisions together, paragraphs 52 and 53.*





**27** You must consider whether it is necessary to consult the patient's GP to inform the discussion about benefits and risks. If so, you must seek the patient's permission and, if they refuse, discuss their reasons for doing so and encourage them to allow you to contact their GP. If the patient is determined not to involve their GP, you must record this in their notes and consider how this affects the balance of risk and benefit and whether you should go ahead with the intervention.

## Being clear about fees and charges

**28** You must explain your charges clearly, so patients know the financial implications of any decision to proceed to the next stage or to withdraw.

**29** You must be clear about what is included in quoted prices and what other charges might be payable, including possible charges for revision or routine follow up.

## Treating adult patients who lack capacity

**30** If you consider providing an intervention for an adult who lacks capacity to make the decision about whether to go ahead with the intervention, you must follow the advice in paragraphs 62–79 of our *Consent* guidance. The advice in these paragraphs takes account of the legal requirements across the UK that govern decision-making with adults who lack capacity.

**31** You must seek and take account of the views of people close to the patient, as well as any information you and the healthcare team may have about the patient's wishes, feelings, beliefs and values. Your approach to consulting with those close to the patient should follow the advice on sharing information set out in paragraphs 18–25 of our *Consent* guidance.

**You must read paragraph 30 alongside:**

- *Consent: patients and doctors making decisions together, paragraphs 62–79.*

**You must read paragraph 31 alongside:**

- *Consent: patients and doctors making decisions together, paragraphs 18–25.*

## Treating children and young people[11]

**32** If providing treatment to children, you should be familiar with the detailed advice in *0–18 years: guidance for all doctors*, which includes the key points set out in this section of guidance. You should take particular care if you consider providing cosmetic interventions for children or young people – you should make sure the environment for practice is appropriate to paediatric care, and work with multidisciplinary teams that provide expertise in treating children and young people where necessary.

**33** You must only provide interventions that are in the best interests[12] of the child or young person. If a young person has capacity to decide whether to undergo an intervention, you should still encourage them to involve their parents in making their decision.

**34** A parent[13] can consent to an intervention for a child or young person who does not have the maturity and capacity to make the decision, but you should involve the child in the decision as much as possible. If you judge that the child does not want to have the cosmetic intervention, then you must not perform it.

**35** Your marketing activities must not target children or young people, through either their content or placement.

**You must read paragraph 32 alongside:**

- *0–18 years: guidance for all doctors, paragraphs 12 and 22.*

## Providing continuity of care

**36** You should consider whether you or a colleague will need to review the patient's response to the intervention and make sure the patient understands whether you recommend a follow-up appointment.

**37** You must make sure the patient has the medicines or equipment they need to care for themselves after an intervention.

**38** You must make sure that your patients know how to contact you or another named[14] suitably-qualified person if they experience complications outside your normal working hours.





**39** You should give patients written information that explains the intervention they have received in enough detail to enable another doctor to take over the patient's care. This should include relevant information about the medicines or devices used. You should also send this information, with the patient's consent, to their GP, and any other doctors treating them, if it is likely to affect their future healthcare. If the patient objects to the information being sent to their doctor, you must record this in their notes and you will be responsible for providing the patient's follow-up care.

**40** You should organise your records in a way that allows identification of patients who have been treated with a particular device or medicine in the event of product safety concerns or regulatory enquiries.

**41** You must keep records that contain personal information about patients securely and in line with:

- **a** any data protection law requirements.
- **b** our *Confidentiality: good practice in handling patient information* guidance.
- **c** guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.

**You must read paragraph 41 alongside:**

- *Confidentiality: good practice in handling patient information,* paragraphs 1–8 and 34–40

## Working with colleagues[15]

**42** You must make sure that anyone you delegate[16] care to has the necessary knowledge, skills and training and is appropriately supervised.

**43** You must work effectively with healthcare professionals and others involved in providing care. You must respect the skills of colleagues within multidisciplinary teams and support them to deliver good

patient care.

**44** You must ask for advice from colleagues if the patient has a health condition that lies outside your field of expertise and that may be relevant to the intervention or the patient's request.

**45** You must make sure you build a support network of experienced professional colleagues who can support and advise you. You should ask for advice when you treat patients who may need psychological or other expert assessment or support.

## Maintaining trust

### Honesty

**46** You must always be honest and never misleading about your skills, experience, qualifications, professional status and current role.

### Communicating information about your services

**47** When advertising your services, you must follow the regulatory codes and guidelines set by the Committee of Advertising Practice.[17]

**48** You must make sure the information you publish is factual and can be checked, and does not exploit patients' vulnerability or lack of medical knowledge.

**49** Your marketing must be responsible.[18] It must not minimise or trivialise the risks of interventions and must not exploit patients' vulnerability. You must not claim that interventions are risk free.

**50** If patients will need to have a medical assessment before you can carry out an intervention, your marketing must make this clear.

**51** You must not mislead about the results you are likely to achieve. You must not falsely claim or imply that certain results are guaranteed





from an intervention.

**52** You must not use promotional tactics in ways that could encourage people to make an ill-considered decision.

**53** You must not provide your services as a prize.

**54** You must not knowingly allow others to misrepresent you or offer your services in ways that would conflict with this guidance.

### Honesty in financial dealings

**55** You must be open and honest with your patients about any financial or commercial interests that could be seen to affect the way you prescribe for, advise, treat, refer or commission services for them.

**56** You must not allow your financial or commercial interests in a cosmetic intervention, or an organisation providing cosmetic interventions, to affect your recommendations to patients or your adherence to expected good standards of care.

# Annex

**The following are selected extracts from our other pieces of guidance for doctors, which you must read alongside this guidance.**

## *Good medical practice*

**15** You must provide a good standard of practice and care. If you assess, diagnose or treat patients, you must:

- **a** adequately assess the patient's conditions, taking account of their history (including the symptoms and psychological, spiritual, social and cultural factors), their views and values; where necessary, examine the patient
- **b** promptly provide or arrange suitable advice, investigations or treatment where necessary
- **c** refer a patient to another practitioner when this serves the patient's needs.

**16** In providing clinical care you must:

- **a** prescribe drugs or treatment, including repeat prescriptions, only when you have adequate knowledge of the patient's health and are satisfied that the drugs or treatment serve the patient's needs
- **b** provide effective treatments based on the best available evidence
- **c** take all possible steps to alleviate pain and distress whether or not a cure may be possible
- **d** consult colleagues where appropriate
- **e** respect the patient's right to seek a second opinion
- **f** check that the care or treatment you provide for each patient is compatible with any other treatments the patient is receiving, including (where possible) self-prescribed over-the-counter medications
- **g** wherever possible, avoid providing medical care to yourself or anyone with whom you have a close personal relationship.

**22** You must take part in systems of quality assurance and quality improvement to promote patient safety. This includes:

- **a** taking part in regular reviews and audits of your own work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary
- **b** regularly reflecting on your standards of practice and the care you provide
- **c** reviewing patient feedback where it is available.

**23** To help keep patients safe you must:

- **a** contribute to confidential inquiries
- **b** contribute to adverse event recognition
- **c** report adverse incidents involving medical devices that put or have the potential to put the safety of a patient, or another person, at risk





- **d** report suspected adverse drug reactions
- **e** respond to requests from organisations monitoring public health.

When providing information for these purposes you should still respect patients' confidentiality.

## *Good practice in prescribing and managing medicines and devices*

**46** Early, routine reporting of adverse reactions, incidents and near misses involving medicines and devices can allow performance and systems issues to be investigated, problems rectified and lessons learned. You must make reports in accordance with your employer or contracting body's local clinical governance procedures.

**47** You must inform the Medicines and Healthcare products Regulatory Agency (MHRA) about:

- **a** serious suspected adverse reactions to all medicines and all reactions to products marked with a Black Triangle in the British National Formulary and elsewhere using the Yellow Card Scheme
- **b** adverse incidents involving medical devices, including those caused by human error that put, or have the potential to put, the safety of patients, healthcare professionals or others at risk. These incidents should also be reported to the medical device liaison officer within your organisation.

**48** You should provide patients with information about how they can report suspected side effects directly to the MHRA.

**49** You should also:

- **a** check that all serious patient safety incidents are reported to the National Reporting and Learning System (in England and Wales), especially if such incidents are not automatically reported through clinical governance arrangements where you work
- **b** where appropriate, inform the patient's general practitioner, the pharmacy that supplied the medicine, the local controlled drugs accountable officer and the medicines manufacturers of relevant adverse drug reactions and patient safety incidents.

**50** You should respond to requests from the Drug Safety Research Unit for prescription-event monitoring data and information for studies on specific safety or pharmacovigilance issues.

## *Leadership and management for all doctors*

**24** Early identification of problems or issues with the performance of individuals, teams or services is essential to help protect patients.

### All doctors

**25** You must take part in regular reviews and audits of the standards and performance of any team you work in, taking steps to resolve any problems.

**26** You should be familiar with, and use, the clinical governance and risk management structures and processes within the organisations you work for or to which you are contracted. You must also follow the procedure where you work for reporting adverse incidents and near misses. This is because routinely identifying adverse incidents or near misses at an early stage can allow issues to be tackled, problems to be put right and lessons to be learnt.

**27** You must follow the guidance in *Good medical practice* and *Raising and acting on concerns about patient safety* when you have reason to believe that systems, policies, procedures or colleagues are, or may be, placing patients at risk of harm.

### Doctors with extra responsibilities

**28** If you have a management role or responsibility, you must make sure that systems are in place to give early warning of any failure, or potential failure, in the clinical performance of individuals or teams. These should include systems for conducting audits and considering patient feedback. You must make sure that any such failure is dealt with quickly and effectively.

**29** If you are managing or leading a team, you should make sure that systems, including auditing and benchmarking, are in place to monitor, review and improve the quality of the team's work. You must work with others to collect and share information on patient experience and outcomes. You must make sure that teams you manage are appropriately supported and developed and are clear about their objectives.

## *Raising and acting on concerns about patient safety*

### Duty to raise concerns

**7** All doctors have a duty to raise concerns where they believe that patient safety or care is being compromised by the practice of colleagues or the systems, policies and procedures in the organisations in which they work. They must also encourage and support a culture in which staff can raise concerns openly and safely.

**8** You must not enter into contracts or agreements with your employing or contracting body that seek to prevent you from or restrict you in raising concerns about patient safety. Contracts or agreements are void if they intend to stop an employee from making a protected disclosure.

### Overcoming obstacles to reporting

**9** You may be reluctant to report a concern for a number of reasons. For example, because you fear that nothing will be done or that raising your concern may cause problems for colleagues; have a negative effect on working relationships; have a negative effect on your career; or result in a complaint about you.

**10** If you are hesitating about reporting a concern for these reasons, you should bear the following in mind.

- **a** You have a duty to put patients' interests first and act to protect them, which overrides personal and professional loyalties.
- **b** The law provides legal protection against victimisation or dismissal for individuals who reveal information to raise genuine concerns and expose malpractice in the workplace.
- **c** You do not need to wait for proof – you will be able to justify raising a concern if you do so honestly, on the basis of reasonable belief and through appropriate channels, even if you are mistaken.

## *Consent: patients and doctors making decisions together*

### Sharing information

**18** How you discuss a patient's diagnosis, prognosis and treatment options is often as important as the information itself. You should:

- **a** share information in a way that the patient can understand and, whenever possible, in a place and at a time when they are best able to understand and retain it





- **b** give information that the patient may find distressing in a considerate way
- **c** involve other members of the healthcare team in discussions with the patient, if appropriate
- **d** give the patient time to reflect, before and after they make a decision, especially if the information is complex or what you are proposing involves significant risks
- **e** make sure the patient knows if there is a time limit on making their decision, and who they can contact in the healthcare team if they have any questions or concerns.

**19** You should give information to patients in a balanced way. If you recommend a particular treatment or course of action, you should explain your reasons for doing so. But you must not put pressure on a patient to accept your advice.

**20** You may need to support your discussions with patients by using written material, or visual or other aids. If you do, you must make sure the material is accurate and up to date.

**21** You should check whether the patient needs any additional support to understand information, to communicate their wishes, or to make a decision. You should bear in mind that some barriers to understanding and communication may not be obvious; for example, a patient may have unspoken anxieties, or may be affected by pain or other underlying problems. You must make sure, wherever practical, that arrangements are made to give the patient any necessary support. This might include, for example: using an advocate or interpreter; asking those close to the patient about the patient's communication needs; or giving the patient a written or audio record of the discussion and any decisions that were made.

### Involving families, carers and advocates

**22** You should accommodate a patient's wishes if they want another person, such as a relative, partner, friend, carer or advocate, to be involved in discussions or to help them make decisions. In these circumstances, you should follow the guidance in paragraphs 7–21.

### Obstacles to sharing information

**23** It is sometimes difficult, because of pressures on your time or the limited resources available, to give patients as much information or support in making decisions as you, or they, would like. To help in this, you should consider the role that other members of the healthcare team might play, and what other sources of information and support are available. These may be, for example, patient information leaflets, advocacy services, expert patient programmes, or support groups for people with specific conditions.

**24** You should do your best to make sure that patients with additional needs, such as those with disabilities, have the time and support they need to make a decision. In all cases, you must treat patients fairly and not discriminate against them.

**25** If you think that limits on your ability to give patients the time or information they need is seriously compromising their ability to make an informed decision, you should raise your concerns with your employing or contracting authority. See paragraph 25b of *Good medical practice* and the explanatory guidance *Raising and acting on concerns about patient safety*.

## Discussing side effects, complications and other risks

**28** Clear, accurate information about the risks of any proposed investigation or treatment, presented in a way patients can understand, can help them make informed decisions. The amount of information about risk that you should share with patients will depend on the individual patient and what they want or need to know. Your discussions with patients should focus on their individual situation and the risk to them.

**29** In order to have effective discussions with patients about risk, you must identify the adverse outcomes that may result from the proposed options. This includes the potential outcome of taking no action. Risks can take a number of forms, but will usually be:

- **a** side effects
- **b** complications
- **c** failure of an intervention to achieve the desired aim.

Risks can vary from common but minor side effects, to rare but serious adverse outcomes possibly resulting in permanent disability or death.

**30** In assessing the risk to an individual patient, you must consider the nature of the patient's condition, their general health and other circumstances. These are variable factors that may affect the likelihood of adverse outcomes occurring.

**31** You should do your best to understand the patient's views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. You must not make assumptions about a patient's understanding of risk or the importance they attach to different outcomes. You should discuss these issues with your patient.

**32** You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small. You should also tell patients about less serious side effects or complications if they occur frequently, and explain what the patient should do if they experience any of them.

**33** You must give information about risk in a balanced way. You should avoid bias, and you should explain the expected benefits as well as the potential burdens and risks of any proposed investigation or treatment.

**34** You must use clear, simple and consistent language when discussing risks with patients. You should be aware that patients may understand information about risk differently from you. You should check that the patient understands the terms that you use, particularly when describing the seriousness, frequency and likelihood of an adverse outcome. You should use simple and accurate written information or visual or other aids to explain risk, if they will help the patient to understand.

**35** If a patient does not want to know about the possible risks of a proposed investigation or treatment, you must follow the guidance in paragraphs 13–17.

**36** You must keep up to date with developments in your area of practice, which may affect your knowledge and understanding of the risks associated with the investigations or treatments that you provide.





## Ensuring that decisions are voluntary

**41** Patients may be put under pressure by employers, insurers, relatives or others, to accept a particular investigation or treatment. You should be aware of this and of other situations in which patients may be vulnerable. Such situations may be, for example, if they are resident in a care home, subject to mental health legislation, detained by the police or immigration services, or in prison.

**42** You should do your best to make sure that such patients have considered the available options and reached their own decision. If they have a right to refuse treatment, you should make sure that they know this and are able to refuse if they want to.

## Expressions of consent

**44** Before accepting a patient's consent, you must consider whether they have been given the information they want or need, and how well they understand the details and implications of what is proposed. This is more important than how their consent is expressed or recorded.

**47** In cases that involve higher risk, it is important that you get the patient's written consent. This is so that everyone involved understands what was explained and agreed.

**49** You should also get written consent from a patient if:

- **a** the investigation or treatment is complex or involves significant risks
- **b** there may be significant consequences for the patient's employment, or social or personal life
- **c** providing clinical care is not the primary purpose of the investigation or treatment
- **d** the treatment is part of a research programme or is an innovative treatment designed specifically for their benefit.

## Reviewing decisions

**52** Before beginning treatment, you or a member of the healthcare team should check that the patient still wants to go ahead; and you must respond to any new or repeated concerns or questions they raise. This is particularly important if:

- **a** significant time has passed since the initial decision was made
- **b** there have been material changes in the patient's condition, or in any aspect of the proposed investigation or treatment
- **c** new information has become available, for example about the risks of treatment or about other treatment options.

**53** You must make sure that patients are kept informed about the progress of their treatment, and are able to make decisions at all stages, not just in the initial stage. If the treatment is ongoing, you should make sure that there are clear arrangements in place to review decisions and, if necessary, to make new ones.

# Part 3: Capacity issues

## The legal framework

**62** Making decisions about treatment and care for patients who lack capacity is governed in England and Wales by the *Mental Capacity Act 2005*, and in Scotland by the *Adults with Incapacity (Scotland) Act 2000*. The legislation sets out the criteria and procedures to be followed in making decisions when patients lack capacity to make these decisions for themselves. It also grants legal authority to certain people to make decisions on behalf of patients who lack capacity. In Northern Ireland, there is currently no relevant primary legislation; and decision-making for patients without capacity is governed by the common law, which requires that decisions must be made in a patient's best interests. There is more information about legislation and case law in the legal annex to this guidance.

**63** The guidance that follows is consistent with the law across the UK. It is important that you keep up to date with, and comply with, the laws and codes of practice that apply where you work. If you are unsure about how the law applies in a particular situation, you should consult your defence body or professional association, or seek independent legal advice.

## Presumption of capacity

**64** You must work on the presumption that every adult patient has the capacity to make decisions about their care, and to decide whether to agree to, or refuse, an examination, investigation or treatment. You must only regard a patient as lacking capacity once it is clear that, having been given all appropriate help and support, they cannot understand, retain, use or weigh up the information needed to make that decision, or communicate their wishes.

**65** You must not assume that a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), their beliefs, their apparent inability to communicate, or the fact that they make a decision that you disagree with.

## Maximising a patient's ability to make decisions

**66** A patient's ability to make decisions may depend on the nature and severity of their condition, or the difficulty or complexity of the decision. Some patients will always be able to make simple decisions, but may have difficulty if the decision is complex or involves a number of options. Other patients may be able to make decisions at certain times but not others, because fluctuations in their condition impair their ability to understand, retain or weigh up information, or communicate their wishes.

**67** If a patient's capacity is affected in this way, you must follow the guidance in paragraphs 18–21, taking particular care to give the patient the time and support they need to maximise their ability to make decisions for themselves. For example, you will need to think carefully about the extra support needed by patients with dementia or learning disabilities.

**68** You must take all reasonable steps to plan for foreseeable changes in a patient's capacity to make decisions. This means that you should:

- **a** discuss treatment options in a place and at a time when the patient is best able to understand and retain the information
- **b** ask the patient if there is anything that would help them remember information, or make it easier to make a decision; such as bringing a relative, partner, friend, carer or advocate to consultations, or having written or audio information about their condition or the proposed investigation or treatment
- **c** speak to those close to the patient and to other healthcare staff about the best ways of communicating with the patient, taking account of confidentiality issues.

**69** If a patient is likely to have difficulty retaining information, you should offer them a written record of your discussions, detailing what decisions were made and why.

**70** You should record any decisions that are made, wherever possible while the patient has capacity to understand and review them. You must bear in mind that advance refusals of treatment may need to be recorded, signed and witnessed.

## Assessing capacity

**71** You must assess a patient's capacity to make a particular decision at the time it needs to be made. You must not assume that because a patient lacks capacity to make a decision on a particular occasion, they lack capacity to make any decisions at all, or will not be able to make similar decisions in the future.

**72** You must take account of the advice on assessing capacity in the Codes of Practice that accompany the *Mental Capacity Act 2005* and the *Adults with Incapacity (Scotland) Act 2000* and other relevant guidance. If your assessment is that the patient's capacity is borderline, you must be able to show that it is more likely than not that they lack capacity.

**73** If your assessment leaves you in doubt about the patient's capacity to make a decision, you should seek advice from:

- **a** nursing staff or others involved in the patient's care, or those close to the patient, who may be aware of the patient's usual ability to make decisions and their particular communication needs
- **b** colleagues with relevant specialist experience, such as psychiatrists, neurologists, or speech and language therapists.

**74** If you are still unsure about the patient's capacity to make a decision, you must seek legal advice with a view to asking a court to determine capacity.

## Making decisions when a patient lacks capacity

**75** In making decisions about the treatment and care of patients who lack capacity, you must:

- **a** make the care of your patient your first concern
- **b** treat patients as individuals and respect their dignity
- **c** support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care
- **d** treat patients with respect and not discriminate against them.

**76** You must also consider:

- **a** whether the patient's lack of capacity is temporary or permanent

b which options for treatment would provide overall clinical benefit for the patient

c which option, including the option not to treat, would be least restrictive of the patient's future choices

d any evidence of the patient's previously expressed preferences, such as an advance statement or decision

e the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them

f the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient's best interests

g what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.

### Resolving disagreements

**77** You should aim to reach a consensus about a patient's treatment and care, allowing enough time for discussions with those who have an interest in the patient's welfare. Sometimes disagreements arise between members of the healthcare team, or between the healthcare team and those close to the patient. It is usually possible to resolve them, for example by involving an independent advocate, consulting a more experienced colleague, holding a case conference, or using local mediation services. You should take into account the different decision-making roles and authority of those you consult, and the legal framework for resolving disagreements.

**78** If, having taken these steps, there is still significant disagreement, you should seek legal advice on applying to the appropriate court or statutory body for review or for an independent ruling. Patients, those authorised to act for them, and those close to them, should be informed as early as possible of any decision to start such proceedings so that they have the opportunity to participate or be represented.

### The scope of treatment in emergencies

**79** When an emergency arises in a clinical setting and it is not possible to find out a patient's wishes, you can treat them without their consent, provided the treatment is immediately necessary to save their life or to prevent a serious deterioration of their condition. The treatment you provide must be the least restrictive of the patient's future choices. For as long as the patient lacks capacity, you should provide ongoing care on the basis of the guidance in paragraphs 75–76. If the patient regains capacity while in your care, you should tell them what has been done, and why, as soon as they are sufficiently recovered to understand.

## *0–18 years: guidance for all doctors*

### Assessing best interests

**12** An assessment of best interests will include what is clinically indicated in a particular case. You should also consider:

a the views of the child or young person, so far as they can express them, including any previously expressed preferences

b the views of parents

c the views of others close to the child or young person





d the cultural, religious or other beliefs and values of the child or parents

e the views of other healthcare professionals involved in providing care to the child or young person, and of any other professionals who have an interest in their welfare

f which choice, if there is more than one, will least restrict the child or young person's future options.

### Making decisions

**22** You can provide medical treatment to a child or young person with their consent if they are competent to give it, or with the consent of a parent or the court. You can provide emergency treatment without consent to save the life of, or prevent serious deterioration in the health of, a child or young person.

## *Confidentiality*

### Ethical and legal duties of confidentiality

**1** Trust is an essential part of the doctor-patient relationship and confidentiality is central to this. Patients may avoid seeking medical help, or may under-report symptoms, if they think their personal information will be disclosed[19] by doctors without consent, or without the chance to have some control over the timing or amount of information shared.

**2** Doctors are under both ethical and legal duties to protect patients' personal information from improper disclosure. But appropriate information sharing is an essential part of the provision of safe and effective care. Patients may be put at risk if those who are providing their care do not have access to relevant, accurate and up-to-date information about them.

**3** There are also important uses of patient information for purposes other than direct care. Some of these are indirectly related to patient care in that they enable health services to function efficiently and safely. For example, large volumes of patient information are used for purposes such as medical research, service planning and financial audit. Other uses are not directly related to the provision of healthcare but serve wider public interests, such as disclosures for public protection reasons.

**4** Doctors' roles are continuing to evolve and change. It is likely to be more challenging to make sure there is a legal and ethical basis for using patient information in a complex health and social care environment than in the context of a single doctor-patient relationship.

In this guidance, we aim to support individual doctors to meet their professional responsibilities while working within these complex systems.

### Acting within the law

**5** Doctors, like everyone else, must comply with the law when using, accessing or disclosing personal information. The law governing the use and disclosure of personal information is complex, however, and varies across the four countries of the UK.

**6** In the legal annex to this guidance, we summarise some key elements of the relevant law, including the requirements of the common law, data protection law and human rights law. In the main body of the guidance, we give advice on how to apply ethical and legal principles in practice, but we do not refer to specific pieces of law unless it is necessary to do so.

7 If you are not sure how the law applies in a particular situation, you should consult a Caldicott or data guardian, a data protection officer, your defence body or professional association, or seek independent legal advice.

8 The advice in this guidance is underpinned by the following eight principles.[20]

a **Use the minimum necessary personal information.** Use anonymised information if it is practicable to do so and if it will serve the purpose.
b **Manage and protect information.** Make sure any personal information you hold or control is effectively protected at all times against improper access, disclosure or loss.
c **Be aware of your responsibilities.** Develop and maintain an understanding of information governance that is appropriate to your role.
d **Comply with the law.** Be satisfied that you are handling personal information lawfully.
e **Share relevant information for direct care** in line with the principles in this guidance unless the patient has objected.
f **Ask for explicit consent** to disclose identifiable information about patients for purposes other than their care or local clinical audit, unless the disclosure is required by law or can be justified in the public interest.
g **Tell patients** about disclosures of personal information you make that they would not reasonably expect, or check they have received information about such disclosures, unless that is not practicable or would undermine the purpose of the disclosure. Keep a record of your decisions to disclose, or not to disclose, information.
h **Support patients to access their information.** Respect, and help patients exercise, their legal rights to be informed about how their information will be used and to have access to, or copies of, their health records.

## Sharing information with those close to the patient

34 You must be considerate to those close to the patient and be sensitive and responsive in giving them information and support, while respecting the patient's right to confidentiality.

### Establishing what the patient wants

35 The people close to a patient can play a significant role in supporting, or caring for, the patient and they may want or need information about the patient's diagnosis, treatment or care. Early discussions about the patient's wishes can help to avoid disclosures they might object to. Such discussions can also help avoid misunderstandings with, or causing offence or distress to, anyone the patient would want information to be shared with.

36 You should establish with the patient what information they want you to share, with whom, and in what circumstances. This will be particularly important if the patient has fluctuating or diminished capacity or is likely to lose capacity, even temporarily. You should document the patient's wishes in their records.

### Abiding by the patient's wishes

37 If a patient who has capacity to make the decision refuses permission for information to be shared with a particular person or group of people, it may be appropriate to encourage the patient to reconsider that decision if sharing the information may be beneficial to the patient's care and support. You must, however, abide by the patient's wishes, unless disclosure would be justified in the public interest (see paragraphs 63–70).





38 If a patient lacks capacity to make the decision, it is reasonable to assume the patient would want those closest to them to be kept informed of their general condition and prognosis, unless they indicate (or have previously indicated) otherwise. You can find detailed advice on considering disclosures about patients who lack capacity to consent in paragraphs 41–49.

### Listening to those close to the patient

39 In most cases, discussions with those close to the patient will take place with the patient's knowledge and consent. But if someone close to the patient wants to discuss their concerns about the patient's health without involving the patient, you should not refuse to listen to their views or concerns on the grounds of confidentiality. The information they give you might be helpful in your care of the patient.

40 You should, however, consider whether your patient would consider you listening to the views or concerns of others to be a breach of trust, particularly if they have asked you not to listen to specific people. You should also make clear that, while it is not a breach of confidentiality to listen to their concerns, you might need to tell the patient about information you have received from others – for example, if it has influenced your assessment and treatment of the patient.[21] You should also take care not to disclose personal information unintentionally – for example, by confirming or denying the person's perceptions about the patient's health.

## References

1 The legal definition of FGM is very broad and may include procedures such as genital tattoos and piercing. It may be helpful to refer to guidance issued by government and the medical royal colleges, such as FGM Mandatory reporting duty (pdf) (accessed 7 March 2016).

2 Department of Health (England) (2013) Review of the Regulation of Cosmetic Interventions, available at: www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions (accessed 7 March 2016). See also the report of the Scottish Cosmetic Interventions Expert Group (Scottish Government, 2015), available at: www.gov.scot/Resource/0048/00481504. pdf (accessed 7 March 2016).

3 You can read all of our existing guidance on our website.

4 You can get advice on effective clinical supervision from sources such as the Care Quality Commission's *Supporting effective clinical supervision* (pdf) (accessed 7 March 2016).

5 Medicines and medical devices in the UK are regulated by the Medicines and Healthcare products Regulatory Agency (accessed 7 March 2016).

6 The Private Healthcare Information Network (PHIN) collects and publishes surgical information about independent healthcare to help patients make informed choices (accessed 7 March 2016).

7 See our guidance *Openness and honesty when things go wrong*.

8 See our Guidance for doctors acting as responsible consultants or clinicians.

9 See the Royal College of Anaesthetists' *Safe sedation practice for healthcare procedures* (accessed 7 March 2016).

10 See *Montgomery v Lanarkshire Health Board (Scotland)* [2015] UKSC 11.

11 See our guidance 0–18 years: guidance for all doctors for more information about the general principles you should follow, in addition to this guidance, when you treat children and young people.

12 See paragraphs 12-13 of 0–18 years: guidance for all doctors for guidance on assessing best interests.

13 'Parents' are people with parental responsibility.

14 See our Guidance for doctors acting as responsible consultants or clinicians

15 'Colleagues' include anyone a doctor works with, in and outside their team, whether or not they are also doctors.

16 See our guidance *Delegation and referral*.

17 The Committee of Advertising Practice (2013) *Marketing of Cosmetic Interventions* (pdf) (accessed 7 March 2016).

18 Treatments You Can Trust (2015) *Policy Statement on the Advertising and Promotion of Non-Surgical Cosmetic Injectable Treatments by providers on the Treatments You Can Trust Register* (accessed 7 March 2016).



Guidance for doctors who offer cosmetic interventions

19 In this guidance, 'personal information' means information from which individuals can be identified either in itself or in combination with other available information. 'Disclosure' means the provision or passing of information about a patient to anyone other than the patient, regardless of the purpose. Sharing information within healthcare teams is a form of disclosure, as is providing access to patients' records.

20 These principles are aligned with the Caldicott principles for information governance within health and social care.

21 Patients are also entitled to access their health records under data protection law. Article 15 of the *General Data Protection Regulation* gives patients the right to access their personal information, although exemptions apply in certain circumstances. Most exemptions are contained in the *Data Protection Act 2018*. For example, an exemption applies if providing subject access to information about an individual's physical or mental health or condition would be likely to cause serious harm to them or to another person's physical or mental health or condition. You also do not have to supply a patient with information about another person or that identifies another person as the source of the information, unless that other person consents or it is reasonable in the circumstances to supply the information without their consent. See the Information Commissioner's Office technical guidance, *Dealing with subject access requests involving other people's information* (Information Commissioner's Office, 2014).

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