Dermal Filler Standards
(Encompassing skin and soft tissue fillers)

Box 1. Identified risk level and cooling off	
Risks to patient	**Risk according to product** • World Health Organisation (WHO) classification of risks: • Product-specific risks e.g. higher with permanent/semi-permanent • Nomenclature of injectable fillers cf. 'dermal' fillers as anatomical injection may change/adjust **Risk according to anatomical site** • Upper face, nasal dorsum and periocular highest risk • Neck • Hands • Other sites **General risks of filler infiltration/injection** • Pain, bleeding, bruising, infection • Blindness • Vascular occlusion – of highest risk to upper face, dorsum of nose and periocular injection/treatment. • Anaphylaxis, hypersensitivity, • Granuloma • Capsule formation • Biofilm **Risk according to technique** • Level 7 training is essential for the use all fillers • Only doctors can administer semi-permanent or permanent fillers • Use of blunt-ended cannulas should be considered in high risk sites **Hyperbaric chamber** • Organisations must have a formal emergency protocol and list their nearest chamber

Risks to practitioner	• Personal protective equipment (PPE) must be offered for free and worn • Managing sharps injuries and practitioner responsibilities in line with national guidelines - as overarching principles • Ensuring adequate sharps practice – as per overarching principles [1]. • Blood borne viruses e.g. hepatitis B vaccination – recommend enforced hep B vaccination for all practitioners • Immunisation /occupational history - as per overarching principles • Adequate practitioner indemnity is required – professional indemnity mandatory - as per overarching principles **References** 1. Health and Safety (Sharp Instrument in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm
Consent	• Informed consent for the patient including adverse events and alternatives • Use of GMC [1] standard and Department of Health [2] guidance for consent • Consider having a set of essential criteria to consent forms for all patients about to have filler re: key information for consent ○ Consider standardised consent form for filler procedures with key risks pre-populated • Before and after photographs (AP/PA and lateral as minimum views) with individual consent for photography are recommended. This consent should be confirmed with each photography session **Consenting for fillers – specific risks** • Pain • Bleeding • Infection • Blindness • Vascular occlusion – of highest risk to upper face, dorsum of nose and periocular injection/treatment • Anaphylaxis • Hypersensitivity • Granuloma • Biofilm • Bruising **References**

	1. Consent. Patient and doctors making decisions together. Good medical practice. GMC. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp 2. Reference guide to consent for examination or treatment. Department of Health. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition
Cooling off	• Patients should be offered a cooling off period

Box 2. Premises requirements	
Premises **Procedure room**	**Premises** As per overarching principles **Procedure room** As per overarching principles and additionally: • Patient privacy and dignity must be respected at all times • Room must be a clinical room • There should be a clinical couch available with a reclining, multi-positioning back rest and access on three sides • A height adjustable stool or seat should be available if necessary for the practitioner • Knowledge of defibrillator location in relation to building • x2 EpiPens (International Standard) essential • Hyaluronidase x2 vials • Surfaces amenable/resistant to disinfectant – as per right column • The clinic couch, trolley and surfaces must be cleaned between patients • The floor must be impervious and easy to clean • Practitioners must use alcohol gel between patient consultations and wash hands between every procedure and/or examining a patient. • Dedicated handwashing facilities must be present in each room • Disposable paper towels • Sharps and clinical waste disposal must be provided
Equipment	As per overarching principles and additionally:

	• Designated medical refrigerator with monitoring temperature, which is recorded and audited • Lockable drugs cabinet • Hand wipes and cleanser • Within this room, one must be able to store appropriate equipment for the procedure • Must know where local hyperbaric oxygen chamber is • Practitioner should have the ability to manage complications • Need to have availability on the premises to a range of appropriate hypodermic needles available depending on procedure within the room. • Adequate moveable lighting • Must have availability of resuscitation equipment as per overarching principles
Clinical waste and sharps requirements	As per overarching principles and additionally: • A sharps bin must be available in the procedure room • Sharps managed as per regulation [1] • All bodily fluids/human tissue into clinical waste bins and appropriate disposal. Appropriate disposal according to regulations [2]. **References** 1. Health and Safety (Sharp Instrument in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm 2. Classify different types of waste. https://www.gov.uk/how-to-classify-different-types-of-waste/overview
Filler management	• Fillers must be stored as per manufacturers guidelines. • No storage of fillers once vial opened/seal broken. • Single patient, single indication, single use of specific filler • Safe disposal as above
Conference demonstrations	As per overarching principles • The clinical environment, waste disposal and hygiene standards must be the same for demonstrations as clinical practice • It is more appropriate to record in clinical environment and then view in a teaching environment than perform a live demonstration if these conditions cannot be met

Box 3. Education and Training requirements	
Degree requirements and qualifications	Entry levels as recommended in the HEE framework must be met [1]. **References** 1. HEE Report on implementation of qualification requirement for cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery. https://www.hee.nhs.uk/sites/default/files/documents/HEE%20Cosmetic%20publication%20part%20two%20update%20v1%20final%20version_0.pdf
Accredited courses	As per overarching principles and additionally: • Content of the course should be in line with the CPSA standards and HEE framework • Use of cannula in high risk sites/education of practitioners in use of cannulas vs needles • Trained in the use of Hyaluronidase • Should include teaching in the assessment of Body Dysmorphic Disorder and mental health assessment. • Reflective practice should be included in teaching
Resuscitation	As per overarching principles
Logbook and case numbers	**Prerequisite numbers of procedures for initial validation** • Practitioners in training must keep a logbook of cases • 10 treatments for 10 different patients precluding complex zones (as per HEE Part 1) in each area: 10 for lines and folds, 10 for volumising, 10 for complex zones. The above for facial fillers. Body (excluding head and neck): separate 10 injections treatments for body treatments. • Reflective practice dealing with topics including but not limited to complications, complaints, dysmorphic patients. • Set case studies to be discussed as part of assessment • Demonstration of progression and increasing complexity with case studies • Annual refreshment to maintain practice – as per Continual Professional Development (CPD) • Difficult to determine: may be dependent of speciality **Prerequisite numbers of procedures for ongoing validation**

	• Qualified practitioners must perform a minimum of 40 cases a year to maintain practice accreditation
Continual professional development (CPD)	As per overarching principles • Practitioners must demonstrate 50 hours per year of CPD. This can be divided into internal/external. • Teaching, management and leadership can be included as part of CPD.

Box 4. Supervision – *See Supervision Matrix*	
Assessment of patient	• Set out in HEE framework • Patient must be seen by person performing the procedure (and supervisor when relevant) face to face in real time • Patient must be seen by prescriber when the filler treatment is prescribed
Selection of filler	• Person assessing the patient should have an understanding of the type of filler given.
Administration of filler	See Supervision Matrix • This depends on HEE level and professional background of practitioner

Box 5. Administration	
Patient positioning	• Patients should be encouraged to recline on couch (unless medical contraindication)
Filler handling	• As per the manufacturer's guidelines • A policy must be in place to follow the manufacturer protocol within clinical parameters • Technique to minimum to minimise inadvertent needlestick • Sharps management as per National Guidance [1] **<u>References</u>** 1. Health and Safety (Sharp Instrument in Healthcare) Regulations 2013. http://www.hse.gov.uk/pubns/hsis7.htm

Skin preparation	• Sterile procedure • Aseptic Non Touch Technique (ANTT) • Removal of skin products/appropriately cleansed • Use of appropriate skin preparation
Administration of filler	• Sterile procedure • Sterile gloves • ANTT • Marking of danger zones as appropriate to procedure • Use of nerve blocks under ANTT when required – not always essential. Essential to be aware of appropriate anaesthetic agents and safe dosing of local anaesthetics • If administering any medicines – these must be managed as per overarching principles • For administration of filler: demonstrate filler to the patient in real time during the procedure • If using non-recombinant human filler, consider prick testing or patch testing as required • Prick test for patients at high risk based on PMHx strep
Gloves	• Sterile gloves • Non-powdered gloves • Latex-free in cases of allergy state
Filler records	As per overarching principles and additionally: • Brand • Lot/batch number • Expiry date • Product • Type of filler • Filler volume injected and details of dilutant • Specify re: use of cannula or needle • Additional products/medicine injected

Box 6. Record of procedure	
Records	As per over arching principles

Photographs	As per overarching principles • Pre and post photographs must be taken pre intervention, and at all stages of treatment • Minimum views are Anterior-Posterior (AP)/lateral • Consent attained at first treatment and then verified at each stage • Images/videos should be stored as per national guidance [1] **<u>References</u>** 1. Information for Health Organisations. https://ico.org.uk/for-organisations/health/
Storage	As per overarching principles

Box 7. Patient follow–up	
Appropriate follow up	• All patients must be offered a follow up appointment • Minimum: 1 follow up offered to all patients at any time post-procedure • Needs to have formal discharge of care.
Patient given contact telephone number	• All patients given 24/7 emergency contact number • Ideally the practitioner should be available for 24 hour consultation • If practitioner unavailable, there should be access to a deputising practitioner
Supply written information	• Both pre-procedure and aftercare instructions must be provided in an understandable written format
Informed of complications to look for	• Written aftercare instructions must contain descriptions of complications to look out for and what to do if they develop
What to do in an emergency	• Written aftercare instructions must contain information describing what to do in an emergency
Patient given	As per overarching principles

opportunity to feed back, complain or compliment	

Box 8. Logbook and Case Numbers	

Logbook	• Practitioners should keep individual record of activity.
	• Must be contemporaneous
	• Either digital of paper
	• Additional information to be contained:
	  ○ Date
	  ○ Time
	  ○ Non-identifiable patient ID number
	  ○ Practitioner name
	  ○ Practitioner ID
	  ○ Indication
	  ○ Filler used incl. mixture proportions and diluent
	  ○ Volume injected
	  ○ Anatomical location of injection
	  ○ Complications/adverse events.

Box 9. CPD and appraisal	
Related annual conference, teaching or leadership role	Practitioners must perform 50 hours of CPD per year, of which 20 needs to be external: • Validated and accredited CPD • A minimum of 10 hours of CPD specific to fillers • Internal: e.g. reading journals, e-learning, internal training, internal management or leadership • External: courses, conferences, external, teaching, management or leadership • No number of CPD points is specified
Logbook	See Box 9
Annual audit	• Essential for adverse events and complications, with audit of at least 10% of all cases audited • Based on literature data re: events
Patient	• Every patient must be given the opportunity to feedback

reported outcome measures (PROMs)	their outcomes at the end of every patient episode and formal quantitative and qualitative PROMS are recommended.
Review of complaints and compliments	As per overarching principles and additionally: • Must have a local quarterly review of outcomes • Must have an annual appraisal where outcomes are discussed
Annual appraisal including this scope of work	As per overarching principles • There must be an annual appraisal of performance activity and audit
For PSRB professionals: **Five year revalidation including this scope of work**	- Nurses must revalidate every 3 years, in line with their professional body [1] - Doctors must revalidate every 5 years, in line with their professional body [2] - Revalidation in keeping with your training body, otherwise every 3 years (JCCP) **References** 1. http://revalidation.nmc.org.uk/what-you-need-to-do 2. http://www.gmc-uk.org/doctors/revalidation.asp