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JCCP and CPSA Guidance for Practitioners Who Provide Cosmetic Interventions

Introduction

"Cosmetic interventions" means any intervention, procedure or treatment carried out with the primary objective of changing an aspect of a patient's physical appearance, and includes non-surgical procedures, both invasive and non-invasive. This guidance document relates specifically to those practitioners carrying out cosmetic interventions and has been developed jointly by the newly established Cosmetic Practice Standards Authority (CPSA) and the Joint Council for Cosmetic Practitioners (JCCP). These organisations have been established following the Keogh Review and are not 'mandatory or statutory regulate' bodies. As such, these guidelines should be seen as 'best practice' for cosmetic practitioners and not mandatory.

The guidelines have been developed following a wide-ranging consultation process of those involved in the provision of cosmetic treatments. In addition, where appropriate, reference has been made to existing guidelines issued by Professional Regulated Statutory Bodies (PRSB's) and this guidance does not replace the requirement for Clinicians, registered with any PRSB, to comply with their overarching obligations to that body. If, however, this guidance covers areas not included by their PRSB, this guidance must be followed in addition to that of their PRSB. A list of those additional resources, with links is included at the end of this guidance.

Cosmetic interventions can have significant positive and negative impacts on the health and wellbeing of patients. There have been major concerns in the media, the public and the professions about patient safety and whether the sector operates in an ethical manner. To that end, it is fundamental that all practitioners have the right skills, that they ensure that products used are clinically validated and appropriately licensed and that patients get accurate information before deciding to undergo a cosmetic intervention.

Any practitioner who undertakes non-surgical cosmetic treatments is embarking on a new career pathway, associated with significant risk of harm to patients and this document sets out guidelines appropriate to all levels of practitioner as to the risks involved and how to mitigate them. This document applies to all aesthetic practitioners, regardless of level of attainment. The guidance contained within this document applies equally therefore to those cosmetic practitioners who are registered clinicians and to those who do not have registerable status with a Professional Statutory Regulatory Body. The aim is to give a practitioner a sense of belonging to this applied area of practice and outline the duty of care to the public and to other practitioners. As such, the CPSA and JCCP agree that those who prescribe and treat should be working to the highest current standard and, as such, this guidance is based on the GMC guidance for doctors providing cosmetic interventions but has been amended to provide a framework for all aesthetic practitioners.

It has been agreed, following the Keogh Review, that patients deserve the highest level of protection in this sector and that this guidance should not be 'dumbed down' in any way.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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All practitioners who provide cosmetic interventions must perform audit annually and engage in either statutory or non-statutory appraisal, revalidation and CPD activities without which patient safety cannot be assured.

Practitioners who teach others to perform procedures covered by the JCCP framework of competences, shall be accredited as trainers by their national competent if not appropriate. Other practitioners who wish to train practitioners or assess the competence of others will need to hold current, nationally recognised, teaching/mentoring qualifications appropriate to the level of intervention at which they are training practitioners to perform.

All trainers must hold indemnity and liability insurance appropriate to the role. Non-clinical practitioners who provide clinical oversight (but NOT training), for other practitioners must be recognised as being competent to do so by the JCCP and hold indemnity and liability insurance appropriate for the role.

Key aims

This guidance has been produced to make sure that practitioners:

- are appropriately trained and experienced to practice safely
- are aware of their additional responsibilities if they have clinical oversight of other practitioners
- are aware of their additional responsibilities if they have prescribing privileges
- are aware of their additional responsibilities if you train or assess others in cosmetic interventions
- work with each individual patient to ensure they have realistic expectations of their outcome and that they make fully informed decisions and are appropriately consented
- follow current guidelines or protocols for safe, effective provision of cosmetic interventions
- consider the physical, social and psychological needs of their patients
- do not allow financial or commercial interests in any intervention, organisation, company or research group providing cosmetic interventions, to adversely affect the standards of good patient care.

Using this guidance

This guidance is structured around the four domains of the GMC Good Medical Practice (GMP). In some areas, it sets a higher standard than GMP to address the specific safety

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

issues and ethical concerns particular to the cosmetic sector, as recommended by Sir Bruce Keogh's Review of the regulation of cosmetic interventions*.

Throughout this guidance, the terms 'you must/shall' and 'you should' are used in the following ways:

- 'You must/shall' is used for an over-riding duty or principle.
- 'You shall' is used when we are providing an explanation of how you will meet an overriding duty.
- 'You should' is 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.

Key responsibilities

If you offer cosmetic interventions, you must:

- promote the safety and wellbeing of patients and promote public trust and not to bring the profession into disrepute
- at all times seek your patient's consent to the procedure yourself rather than delegate that responsibility
- make sure patients are given enough time and information before they decide whether to have an intervention. The patient will decide what is 'adequate time and information', not the practitioner and you must 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 to be used
- consider your patients' psychological needs and whether referral to another, experienced professional colleague is appropriate
- complete the necessary training before carrying out any treatment, at all times working within your competence, seeking advice, when appropriate, from a suitably qualified practitioner
- you must not work beyond the limits of your competence
- take particular care when considering requests for interventions on young people (16-18yrs) and usually not treat children under 18 yrs of age, unless it is required for a medical reason (e.g. Laser for hirsuitism)

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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- market your services responsibly, without making unjustifiable claims about interventions, your qualifications and experience, trivialising the risks involved, or using promotional tactics that might encourage people to make ill-considered decisions (including, but not limited to; prizes, BOGOFS and time limited offers); you must follow all guidelines from the ASA/CAP and the JCCP/CPSA

- maintain your registrations of professional and regulatory bodies as well as the JCCP/CPSA

- take part in nationally mandated audits and data collection

- take part in annual appraisal of your own practice

- conduct satisfaction surveys of at least 20 patients annually and include the findings in your appraisal

- have indemnity and liability insurance appropriate to the scope of you practice, including any training, assessment, oversight, managerial or other role you undertake

You must also:

- keep patients safe, work to improve safety and report safety concerns and adverse events as soon as you become aware of them to the appropriate authorities (e.g The MHRA and the CPSA)

- work in partnership with patients, treating them with respect and dignity

- work effectively and collaboratively with colleagues

- keep up to date with and follow all relevant laws and guidance

- be open and honest about your skills, experience, fees and conflicts of interests

- ensure all information, recommendations you give and treatments you provide are evidence based

- exercise your 'duty of candour' without delay

- 'whistle blow' if concerns about patient safety arise which are not taken seriously

- have transparent and robust complaints/redress policies in place and inform all patients of them

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

- comply with this Code of Practice and with your Professional Code if you are a registered clinical practitioner.

If you have clinical oversight of other practitioners you must also:

- ensure practitioners are appropriately trained (by modality and level of educational attainment), appropriately qualified, insured and competent to provide the service you have oversight for, including sight of their annual audit, appraisal and patient satisfaction questionnaires

- ensure the practitioner fulfils their responsibilities as set out in this guidance and as required by law and by their professional, statutory regulator, as appropriate

- report concerns about poor, harmful, dangerous practice or problems with probity or health problems which may put the public at risk to the relevant authorities

- have policies and plans in place for remediation of poor performance

- only delegate tasks and duties that are within the other person's competence, making sure they fully understand your instructions and ensure the outcomes of those tasks are reported to yourself

- confirm the outcomes of any task delegated and follow professional guidelines and legal requirements on safe prescribing and dispensing, being particularly watchful for over or repeat prescribing; ensure also that you undertake a review of all repeat prescriptions after six prescriptions and/or a six month period.

If you have prescribing privileges you must also:

- ensure you are properly, trained, qualified, insured and registered with the appropriate competent authority for the prescriptions you issue

- ensure that you advise, prescribe, supply and/or administer medicines within the limits of your training and competence, the law and relevant policies, guidance and regulations

- ensure you only prescribe for patients who are under your direct care after a face-to-face consultation (not including via electronic communication or social media); you must ensure you have enough knowledge of the patient's health care history and needs to prescribe medicines/treatments appropriate for them and which will not compromise other aspects of their medical care or psychological wellbeing

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

- retain full responsibility and accountability for all prescriptions you authorise.

- inform the patient's GP, and receive their positive response to proceed, if any medication you wish to prescribe may interact with or alter an existing treatment in advance of providing the treatment yourself or by others for whom you have oversight

- Patients should also be encouraged to seek advice from their G.P. or pharmacist about potential interactions that might occur alongside the use of existing medication

- report poor prescribing or problems with probity to the relevant authorities

- fulfil all the responsibilities set out under the law of the country, in which you work, for the prescribing privileges you hold

- not allow any organisation for which you work, represent or own to advertise prescription only medications

- comply with the Advertising Standards Authority (ASA) guidance on advertising of prescription only medications.

If you provide training and/or assessment for other practitioners performing 'cosmetic interventions' you must also:

- ensure you are appropriately trained to the appropriate standard, qualified, insured and registered with the appropriate competent bodies to provide the level training you teach or assessments you perform

- ensure you instruct those you teach the responsibilities contained in this guidance and ensure the practitioner/s understand their responsibilities under this guidance

- audit the outcomes of your training and/or assessments.

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 and deal with any complications that may occur from the treatment e.g. by undergoing training or seeking opportunities for supervised practice,*

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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

4) You must follow, and comply with, all legal, clinical, professional and ethical guidelines and standards that apply to your work. You must follow the law, JCCP/CPSA guidance and other regulatory guidance 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. Reflection on the quality of your practice as shown by audit and appraisal of your work is mandatory to improving standards and minimising poor practice.

6) You must engage in annual appraisal/revalidation, which covers the whole scope of your practice and undertake regular continuous personal and professional development. If your your professional regulator applies more onerous criteria that that required by the JCCP/CPSA you must comply with your regulator's requirement. If such a period is not prescribed by your professional regulator, You must comply at least every three years when you apply to re-register your Membership with the JCCP.

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. 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, including those you have delegated and audit your practice annually and discuss the findings in your annual appraisal.
   d) report product safety concerns to the relevant regulator.*

8) You should share insights and information about outcomes with other people who offer similar interventions, to improve outcomes and patient safety.†

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

10) You have a 'duty of **candour'** to be open and honest with patients in your care if something goes wrong and the patient suffers or may suffer harm or distress as a result.‡

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

11) Prescribing practitioners must take a full medical history and carry out a face to face, physical examination of all patients before prescribing injectable cosmetic medicines or other invasive procedures. You must not, therefore, prescribe medicines by telephone, video link, social media, online or at the request of others for patients you have not examined in person. Repeat prescriptions must only be provided with the prescribers full knowledge of the patient's current medical and drug history and any change in any prescription you provide must only be made after a face to face consultation and examination in person.

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 must be satisfied that the environment in which you practice is safe, suitably equipped and staffed and complies with any relevant regulatory requirements.

You should also read Annex paragraphs - Good Practice; Raising Concerns

* Medicines and medical devices in the UK are regulated by the Medicines and Healthcare products Regulatory Agency. See www.gov.uk/government/organisations/medicines-and- healthcare-products-regulatory-agency (accessed 7 March 2016).

† The Private Healthcare Information Network (PHIN) collects and publishes surgical information about independent healthcare to help patients make informed choices. See www.phin.org.uk (accessed 7 March 2016).

‡ See the GMC/NMC guidance, Openness and honesty when things go wrong, available at: *www.gmc-uk.org/guidance/ethical_guidance/27233.asp* - April, 2017

Communication, partnership and teamwork*

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.

You should also read Annex paragraphs - Leadership and management for all practitioners

Seeking **patients'** consent

15) You must be familiar with the guidance on 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.

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You should also read Annex paragraphs - Consent; Patients and Practitioners making decisions together.

Responsibility for seeking consent for cosmetic interventions

16) If you are the practitioner 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 non-surgical cosmetic intervention is sought by the practitioner who will perform it, or supervise its performance by another practitioner. If you were not present when consent was gained by the person supervising you, you must reconfirm with the patient that the treatment you are about to deliver is that which the patient is expecting and they have consented to and confirm they wish to proceed. Where clinical oversight is required, patients must be informed in writing of the name and business address of the clinician providing the oversight. If you are performing procedures at level 6+ under supervision you must check the consent is completed correctly. If you were not present when consent was gained by the person supervising you, you must reconfirm with the patient that the treatment you are about deliver is that which the patient is expecting and they have consented to.

Responding to requests for cosmetic interventions

17) If a patient requests an intervention, you must follow the guidance on 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. Your discussions must be recorded contemporaneously in your clinical notes.

19) When you discuss interventions and options with a patient, you must consider their vulnerabilities, psychological and emotional needs. You must satisfy yourself that the patient's request for the cosmetic intervention is voluntary. If you have any concerns that the patient may suffer psychological or physical harm if their requested treatment is delivered, your duty of care is not to treat the patient but to advise they must consult

their GP and/or a psychologist with appropriate expertise for assessment before embarking on treatment.

20) You must explain any monitoring or follow-up care requirements, and potential costs involved, from 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 you do not have the skills to deliver the treatment they require.

22) You must discuss and have knowledge of all alternative interventions that could meet their needs or reduce risk, including referral to other practitioners.

Discussing side effects, complications and other risks

23) You must give patients clear, accurate information about the risks of the proposed intervention and any associated procedures appropriate to your level of training, including the use of any form of anaesthesia or sedation, as well as any other medication you recommend or use in their treatment

24) 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.† You must talk about the potential adverse physical and psychological impact of the intervention going wrong or failing to meet the patient's expectations.

* See the Royal College of *Anaesthetists'* Safe Sedation Practice for Healthcare Procedures: Standards and Guidance, available at: www.rcoa.ac.uk/document-store/safe-sedation- practice-healthcare-procedures-standards-and-guidance (accessed 7 March 2016).
† See Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11.

Giving patients time for reflection **('Cooling Off')**

25) 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.

26) 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.

27) You must tell the patient they can change their mind at any point.

28) 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. Irrespective of the patient's decision to allow or deny access to their GP record, practitioners should only prescribe medicines or provide treatment if they are assured that have adequate knowledge of the patient's medical and drug history.

Being clear about fees and charges

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

30) 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

31) 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 the GMC 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.

32) 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 the GMC Consent guidance.

You should also read Annex paragraphs - Capacity Issues; Confidentiality

Treating young people*

33) It is not appropriate to provide non-surgical cosmetic interventions to children up to 16 years of age unless there are specific, medical indications. You may, however give non-

surgical treatments to young persons between the ages of 16-18 with their consent (if they are competent to give it, or with the consent of a parent or the Court).

34) If indicated, you must only provide interventions that are in the best interests† of the 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.

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

You should also read Annex paragraphs - Making Decisions

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 is aware of the medicines or equipment they may need to care for themselves after an intervention.

38) You must make sure that your patients know how to contact you or another named, suitably qualified person if they experience complications outside your normal working hours

39) You should give patients verbal and/or written information that explains the intervention they have received in enough detail to enable another practitioner to take over the patient's care. This should include relevant information about the medicines, devices or products 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 (see also paragraph 28 of this guidance).

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) data protection requirements
b) JCCP/CPSA Confidentiality guidance
c) guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.

* See the GMC 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.
† See paragraphs 12 and 13 of 0–18 years: guidance for all doctors for guidance on assessing best interests.
‡ *'Parents'* are people with parental responsibility.
§ See the GMC Guidance for doctors acting as responsible consultants or clinicians.

Working with colleagues*

42) You must make sure that anyone you delegate† 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.

* *'Colleagues'* include anyone a practitioner works with, in and outside their team.
* † See GMC guidance on Delegation and referral, available at: www.gmc-uk.org/guidance/ethical_guidance/21187.asp.

44) You must ask for advice from colleagues if the patient has a health condition that lies outside your 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 advise and support you.

46) You should ask for advice when you treat patients who may need psychological or other expert assessment or support. You must recognise the training and skills of all colleagues, accepting and supporting them to achieve good patient care.

Non-medical aesthetic practitioners and provisionally registered clinical professionals (or trainees) must ensure they are supervised when performing treatments at level 6+.

Maintaining trust and probity

Honesty

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

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Communicating information about your services

48) When advertising your services, you must follow the regulatory codes and guidelines set by the Committee of Advertising Practice and administered by the Advertising Standards Authority* and you must follow any guidelines issued by the JCCP/CPSA. It is illegal to advertise prescription only medications.

49) You must make sure the information you publish is factual, verifiable and does not exploit patients' vulnerability or lack of medical knowledge.

50) Your marketing must be responsible.† 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.

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

52) 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.

53) You must not use promotional tactics in ways that could encourage people to make an ill-considered decision, such as "Buy one, get one free" or time limited offers.

54) You must not provide your services as a prize.

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

You should also read Annex paragraphs - Resolving disagreements

* The Committee of Advertising Practice (2013) Marketing of Cosmetic Interventions, available at: bit.ly/CAP_cosmeticmarketing (accessed 7 March 2016).
† 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, available at: www.treatmentsyoucantrust.org.uk/95-tyct-policy-statement-advertising- non-surgical-cosmetic-treatments-2015?lang=en (accessed 7 March 2016).

Honesty in financial dealings

56) 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, advise, treat, refer or commission services for them, especially if you are owner of the business or the premises in which the patient will be treated.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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

58) You should also act in the best interests of patients at all times in line with best available evidence. Practice and decision making should therefore be impartial, evidence based and centered on the best interests and health and wellbeing of the individual. Financial or other interests should not detract from this duty of care.

59) Offers of any gift from a patient must be appropriate and proportionate. The acceptance of any gift, hospitality or favour could be interpreted as an attempt to gain preferential treatment.

Other resources

References and links to other sources of information and guidance, which complement our guidance for practitioners, are included below. A number of organisations, including the GMC, Royal College of Surgeon of England , BAAPS, BAPRAS, the BAD, the BACN, the BACD, the General Pharmaceutical Council (GPC), Health Education England (HEE) have produced guidance on the professional standards, skills, experience needed to carry out cosmetic interventions. The Committee of Advertising Practice (CAP) has developed guidance on the advertising and marketing of cosmetic interventions.

■ Professional Standards for Cosmetic Surgery Published by the Royal College of Surgeons (2016), available at: bit.ly/RCScosmeticstandards.

■ 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.

A Competency Framework for All Prescribers is available at https://www.rpharms.com/resources/frameworks/prescribers-competency-framework

■ Marketing of Cosmetic Interventions Published by Committee of Advertising Practice (2013), available at: bit.ly/CAP_cosmeticmarketing.

* 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).

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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Annex

The following are extracts from our other pieces of selected guidance, which you are recommended to read alongside this document. Healthcare professionals, especially those prescribing, training, overseeing or assessing others, should also refer to profession-specific guidance provided by their respective professional body and/or professional associations. Our thanks to the General Medical Council for allowing us to base this guidance on their document on Good Cosmetic Surgical Practice.

"Good practice"

You must provide a good standard of practice and care. If you assess and 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.

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 and encourage 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.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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.

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 patient's confidentiality.

Good practice in prescribing and managing medicines and devices

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.

You must inform the Medicines and Healthcare Products Regulatory Agency (MHRA) about any 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. You should provide patients with information about how they can report suspected side effects directly to the MHRA.

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.

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.

Raising and acting on concerns about patient safety

Duty to raise concerns

All practitioners 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.

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.

Obstacles to sharing information

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.

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.

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 the GMC Good Medical Practice and the explanatory guidance Raising and Acting on Concerns About Patient Safety.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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Overcoming obstacles to reporting

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.

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. Advice on such channels if provided in the following website:

https://www.nmc.org.uk/standards/guidance/raising-concerns-guidance-for-nurses-and-midwives/whistleblowing/

Leadership and management for all practitioners.

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

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.

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.

You must be conversant with all relevant national and local guidance set down by employers, professional bodies and professional associations that relate to 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.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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Practitioners with extra responsibilities

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.

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.

Consent: patients and practitioners making decisions together

Sharing information

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.

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.

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.

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

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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

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.

Discussing side effects, complications and other risks

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.

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.

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.

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.

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.

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.

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.

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.

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

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 (e.g. Female Genital Mutilation – please see https://www.nmc.org.uk/standards/code/female-genital-mutilation-cases/).
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.

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

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.

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.

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

Before beginning treatment, you or a member of the 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.

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.

Capacity issues (see Paragraph 30)

The legal framework

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. There is more information about legislation and case law in the legal annex to this guidance.

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.

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Presumption of capacity

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.

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

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.

If a patient's capacity is affected in this way, you must follow the guidance in paragraphs 18–21 of GMP, 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.

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) peak 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.

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.

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

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

treatment may need to be recorded, signed and witnessed. Other information and guidance on these matters may be found at:

http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

OR

http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_part3_capacity_issues.asp

Assessing capacity

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.

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.

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.

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

You must avoid treating patients who lack capacity

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.

Confidentiality (see paragraph 31)

Protecting information

You must make sure that any personal information about patients that you hold or control is effectively protected at all times against improper disclosure. The UK health departments publish guidance on how long health records should be kept and how they should be disposed of. You should follow the guidance whether or not you work in the NHS. You must be registered with the Information Commissioners Office if you hold patient identifiable information in any form.

Many improper disclosures are unintentional. You should not share identifiable information about patients where you can be overheard, for example in a public place or in an internet chat forum. You should not share passwords or leave patients' records, either on paper or on screen, unattended or where they can be seen by other patients, unauthorised healthcare staff, or the public.

Unless they have a relevant management role, practitioners are not expected to assess the security standards of large-scale computer systems provided for their use in the NHS or in other managed healthcare environments. You should familiarise yourself with and follow policies and procedures designed to protect patients' privacy where you work and when using computer systems provided for your use. This includes policies on the use of laptops and portable media storage devices. You must not abuse your access privileges and must limit your access to information you have a legitimate reason to view.

If you are responsible for the management of patient records or other patient information, you should make sure that they are held securely and that any staff you manage are trained and understand their responsibilities. You should make use of professional expertise when selecting and developing systems to record, access and send electronic data. You should make sure that administrative information, such as names and addresses, can be accessed separately from clinical information so that sensitive information is not displayed automatically.

If you are concerned about the security of personal information in premises or systems provided for your use, you should follow the advice in Good medical practice on raising concerns about patient safety, including concerns about confidentiality and information governance.

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Sharing information with a **patient's** partner, carers, relatives or friends

You should establish with the patient what information they want you to share, who with, 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. Early discussions of this nature can help to avoid disclosures that patients would object to. They can also help to avoid misunderstandings with, or causing offence to, anyone the patient would want information to be shared with.

If anyone close to the patient wants to discuss their concerns about the patient's health, you should make it clear to them that, while it is not a breach of confidentiality to listen to their concerns, you cannot guarantee that you will not tell the patient about the conversation. You might need to share with a patient information you have received from others, for example, if it has influenced your assessment and treatment of the patient. You should not refuse to listen to a patient's partner, carers or others on the basis of confidentiality. Their views or the information they provide might be helpful in your care of the patient. You will, though, need to consider whether your patient would consider you listening to the concerns of others about your patient's health or care to be a breach of trust, particularly if they have asked you not to listen to particular people.

Making decisions (See paragraph 34)

You can provide non-surgical cosmetic treatment to a young person aged 16-18 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 young person.

Resolving disagreements (see paragraph 53)

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.

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.

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk

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Further resources

British Association of Aesthetic Plastic Surgeons (2012) Code of conduct
British Association of Plastic Reconstructive and Aesthetic Surgeons (2013) Code of Practice
Committee of Advertising Practice (2013)
Marketing of cosmetic interventions
Department of Health (2013) Review of the regulation of cosmetic interventions
Health Education England (2016) Qualifcation requirements for cosmetic procedures
Royal College of Anesthetists (2013) Safe Sedation Practice for Healthcare Procedures: Standards and Guidance
Royal College of Surgeons Professional Standards for Cosmetic Surgery (2016)
Scottish Cosmetic Interventions Expert Group (2015) Scottish Cosmetic Interventions Expert Group report
Treatments You Can Trust (2015) Policy statement on advertising and promotion of Non-Surgical Cosmetic Injectable Treatments by providers on the Treatments You Can Trust Register
General Medical Council (2007) 0–18 years: guidance for all doctors
General Medical Council (2009) Confidentiality General Medical Council (2008) Consent: patients and doctors making decisions together
General Medical Council (2013) Delegation and referral
General Medical Council (2013) Financial and commercial arrangements and conflicts of interests
General Medical Council (2013) Good medical practice
General Medical Council (2013) Good practice in prescribing and managing medicines and devices
General Medical Council (2014) Guidance for doctors acting as responsible consultants or clinicians
General Medical Council (2012) Leadership and management for all doctors
General Medical Council (2015) Openness and honesty when things go wrong: the professional duty of candour
General Medical Council (2012) Raising and acting on concerns about patient safety

Professor David Sines, Interim CEO david.sines@jccp.org.uk
Paul Burgess, Interim Executive Support paul.burgess@jccp.org.uk