General Medical Council

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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. You must be prepared to explain and justify your decisions and actions. Only serious or persistent failure to follow our guidance that poses a risk to patient safety or public trust in doctors 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.

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 *Decision making and consent*. 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 *Decision making and 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.

You must read paragraph 17 alongside:

- *Good medical practice, paragraphs 15 and 16*
- *Decision making and consent, paragraphs 6, 9, 30, 54–55.*

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 19 alongside:

- *Decision making and consent, paragraphs 69–73.*

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 *Decision making and consent* (paragraphs 11–12, 17–24, 27–30, 58f and 66–67).

You must read paragraph 22 alongside:

- *Decision making and consent (paragraphs 11–12, 17–24, 27–30, 58f and 66–67).*

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.

You must read paragraph 25 alongside:

- *Decision making and consent, paragraphs 56–59.*

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

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 87–93 of our *Decision making and 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.

You must read paragraph 30 alongside:

- *Decision making and consent, paragraphs 87–93.*

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 8–30 of our *Decision making and consent* guidance.

You must read paragraph 31 alongside:

- *Decision making and consent, paragraphs 8–30 of our Decision making and consent guidance.*

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.

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.

You must read paragraph 32 alongside:

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

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.

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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.

Decision making and consent

The dialogue leading to a decision

1 You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.

13 Other examples of information that might be relevant and, if so, should be shared with patients include:

- **b** whether there is a time limit on making their decision and what the implications of delaying might be

Discussing benefits and harms

21 You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

24 You should consider using visual or other explanatory aids to support patients to understand their personalised risk, taking account of their individual clinical and personal circumstances, compared with population level risk.

Supporting patients' decision making

27 Patients need relevant information (see paragraph 10) to be shared in a way they can understand and retain, so they can use it to make a decision. To help patients understand and retain relevant information you should:

- **a** share it in a place and at a time when they are most likely to understand and retain it
- **b** anticipate whether they are likely to find any of it distressing and, if so, be considerate when sharing it
- **c** accommodate a patient's wishes if they would like to record the discussion
- **d** accommodate a patient's wishes if they would like anyone else – a relative, partner, friend, carer or advocate – to be involved in discussions and/or help them make decisions
- **e** use an interpreter or translation[1] service if they have difficulty understanding spoken English
- **f** share it in a format they prefer - written, audio, translated, pictures or other media or methods
- **g** give them time and opportunity to consider it before and after making a decision.

28 You should be alert to signs that patients may need support to understand and retain the relevant information, use it to make a decision, or communicate that decision to you.

29 You should make sure that reasonable adjustments[2] are made so that patients with additional needs have enough time and support to understand relevant information and make a decision. In all cases, you must treat patients fairly and not discriminate against them.

41 There may be members of your healthcare team who are expert in certain conditions and their treatment, who are skilled communicators, or who have developed a trusting relationship with the patient. You should consider the role these team members could play in contributing to the dialogue that leads to a decision, while following paragraphs 42–47 on responsibility and delegation.

Time and resource constraints

60 Being able to meet a patient's individual needs for information and support depends, in part, on the time and resources available to you and your colleagues in the organisations where you work. Where there are pressures on your time or resources are limited, you should consider:

- **a** the role other members of the health and care team might play
- **b** what other sources of information and support are available to the patient, such as patient information leaflets, advocacy services, expert patient programmes, or support groups for people with specific conditions.

61 If factors outside your control mean that patients aren't given the time or support they need to understand relevant information (see paragraph 10), and this seriously compromises their ability to make informed decisions, you must consider raising a concern.[4] You should also consider if it is appropriate to proceed, bearing in mind that you must be satisfied that you have a patient's consent or other valid authority before providing treatment or care.

The information you give patients

11 You must try to make sure the information you share with patients about the options is objective. You should be aware of how your own preferences might influence the advice you give and the language you use. When recommending an option for treatment or care to a patient you must explain your reasons for doing so, and share information about reasonable alternatives, including the option to take no action. You must not put pressure on a patient to accept your advice.

12 You should not rely on assumptions about:

- **a** the information a patient might want or need
- **b** the factors a patient might consider significant
- **c** the importance a patient might attach to different outcomes.

Finding out what matters to a patient

17 You should try to find out what matters to patients about their health – their wishes and fears, what activities are important to their quality of life, both personally and professionally – so you can support them to assess the likely impact of the potential outcomes for each option.

18 You must seek to explore your patient's needs, values and priorities that influence their decision making, their concerns and preferences about the options and their expectations about what treatment or care could achieve.

19 You should ask questions to encourage patients to express what matters to them, so you can identify what information about the options might influence their choice. If you need more information to help you decide what options would serve the patient's needs, you must ask for it before recommending an option or proceeding with treatment.

20 You should explore with patients what risks they would and wouldn't be prepared to take to achieve a desired outcome, and how the likelihood of a particular outcome might influence their choice.

Discussing benefits and harms

21 You must give patients clear, accurate and up-to-date information, based on the best available evidence, about the potential benefits and risks of harm of each option, including the option to take no action.

22 It wouldn't be reasonable to share every possible risk of harm, potential complication or side effect. Instead, you should tailor the discussion to each individual patient, guided by what matters to them, and share information in a way they can understand.

23 You should usually include the following information when discussing benefits and harms.

- **a** Recognised risks of harm that you believe anyone in the patient's position would want to know. You'll know these already from your professional knowledge and experience.
- **b** The effect of the patient's individual clinical circumstances on the probability of a benefit or harm occurring. If you know the patient's medical history, you'll know some of what you need to share already, but the dialogue could reveal more.
- **c** Risks of harm and potential benefits that the patient would consider significant for any reason. These will be revealed during your discussion with the patient about what matters to them.
- **d** Any risk of serious harm, however unlikely it is to occur.
- **e** Expected harms, including common side effects and what to do if they occur.

24 You should consider using visual or other explanatory aids to support patients to understand their personalised risk, taking account of their individual clinical and personal circumstances, compared with population level risk.

30 You must check whether patients have understood the information they have been given, and if they would like more information before making a decision.

58 Reviewing a decision is particularly important:

- **f** if new information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently.

66 If a patient has chosen an option but doesn't want to discuss the details, you should explain they will need to have some information about what it would involve before you can proceed, such as:

- **a** whether the procedure is invasive
- **b** what level of pain or discomfort they might experience and what can be done to minimise this
- **c** anything they should do to prepare for the intervention
- **d** if it involves any risk of serious harm.

67 You should try to find out why they don't want to be involved in decision making and explore whether you can do anything to reassure and support them. They might be anxious about the decision or overwhelmed by the information and need time or support to process it.

If you're concerned a patient can't make a decision freely

69 Many factors influence patients' decision making, but it's important that nothing influences a patient to such an extent that they can't exercise free will. If a patient can't make a decision freely, they won't be able to consent.

70 Patients may feel pressure to have particular treatment or care. Pressure can come from others – partners, relatives or carers, employers or insurers – or from patients' beliefs about themselves and society's expectations.

71 You should be aware of this possibility and of other situations in which patients may be particularly vulnerable or susceptible to pressure, for example, if they are:

- **a** experiencing domestic or other forms of abuse
- **b** resident in a care home
- **c** cared for or supported by others because of a disability
- **d** detained by the police or immigration services, or in prison
- **e** subject to compulsory treatment or assessment orders, or at risk of becoming so.

72 If you suspect a patient's rights have been abused or denied, you must follow local safeguarding procedures and consider raising a concern.

73 You should do your best to make sure patients reach their own decision, having considered relevant information (see paragraph 10) about the available options, including the option to take no action. You should support them to make a decision, following the steps in paragraphs 27–30 as well as:

- **a** giving them more time and a safe, quiet space to consider the options
- **b** making sure you have an opportunity to talk to them on their own
- **c** signposting them to specialist support services.

Expressions of consent

6 Obtaining a patient's consent needn't always be a formal, time-consuming process. While some interventions require a patient's signature on a form, for most healthcare decisions you can rely on a patient's verbal consent, as long as you are satisfied they've had the opportunity to consider any relevant information (see paragraph 10) and decided to go ahead.

9 The purpose of the dialogue is:

- **a** to help the patient understand their role in the process, and their right to choose whether or not to have treatment or care
- **b** to make sure the patient has the opportunity to consider relevant information that might influence their choice between the available options
- **c** to try and reach a shared understanding of the expectations and limitations of the available options.

30 You must check whether patients have understood the information they have been given, and if they would like more information before making a decision.

Reviewing decisions

56 Unless treatment or care begins immediately after a patient has given consent, there will be opportunity for a decision to be reviewed.

57 You should review a patient's decision immediately before providing treatment or care and, if treatment is ongoing, make sure there are clear arrangements in place to review decisions regularly, allowing patients opportunity to ask questions and discuss any concerns. You should also consider regularly reviewing a decision to take no action.

58 Reviewing a decision is particularly important:

- **a** if you haven't personally had a discussion with the patient because they were initially seen by a colleague
- **b** if significant time has passed since the decision was made
- **c** if the patient's condition has changed
- **d** if you have reason to believe the patient might have changed their mind
- **e** if any aspect of the chosen treatment or care has changed
- **f** if new information has become available about the potential benefits or risks of harm of any of the options that might make the patient choose differently.

59 You must make sure that patients are kept informed about the progress of their treatment, and you should let patients know that they can change their mind at any time.

Making a decision when the patient *lacks capacity: overall benefit*

The legal framework

87 We use the term 'overall benefit' to describe the ethical basis on which decisions are made about treatment and care for adult patients who lack capacity to decide for themselves. This involves weighing up the risks of harm and potential benefits for the individual patient of each of the available options, including the option of taking no action. The concept of overall benefit is consistent with the legal requirements to consider whether treatment 'benefits' a patient (Scotland), or is in the patient's 'best interests' (England, Wales and Northern Ireland).

88 If you are the treating doctor, before concluding that it is your responsibility to decide which option(s) would be of overall benefit to a patient who lacks capacity, you should take reasonable steps to find out:

- **a** whether there's evidence of the patient's previously expressed values and preferences that may be legally binding, such as an advance statement or decision
- **b** whether someone else has the legal authority to make the decision on the patient's behalf or has been appointed to represent them.

89 If there is no evidence of a legally binding advance refusal of treatment, and no one has legal authority to make this decision for them, then you are responsible for deciding what would be of overall benefit to your patient.

In doing this you must:

- **a** a consult with those close to the patient and other members of the healthcare team, take account of their views about what the patient would want, and aim to reach agreement with them
- **a** b consider which option aligns most closely with the patient's needs, preferences, values and priorities
- **a** c consider which option would be the least restrictive of the patient's future options.

90 If a proposed option for treatment or care will restrict a patient's right to personal freedom, you must consider whether you need legal authorisation to proceed with it in the circumstances.

91 You should allow enough time, if possible, for discussions with those who have an interest in the patient's welfare, and you should aim to reach agreement about how to proceed.

Resolving disagreements

92 Sometimes members of the healthcare team disagree about what would be of overall benefit to the patient, or those close to the patient disagree with you and the healthcare team. It is preferable, and usually possible, to resolve disagreements about a patient's treatment and care through local processes.

For example, by:

- **a** involving an independent advocate or local mediation service
- **b** consulting a more experienced colleague and/or an independent expert
- **c** holding a case conference or seeking advice from a clinical ethics committee.

93 If, having taken these steps, there is still disagreement about a significant decision, you must follow any formal steps to resolve the disagreement that are required by law or set out in the relevant code of practice. You must make sure you are aware of the different people you must consult, their different decision-making roles and the weight you must attach to their views. You should consider seeking legal advice and may need to apply to an appropriate court or statutory body for review or for an independent ruling. Your patient, those close to them and anyone appointed to act for them should be informed as early as possible of any decision to start legal proceedings, so they have the opportunity to participate or be represented.

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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.

Endnotes

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).

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).