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General Medical Council

Guidance for doctors who offer cosmetic interventions

How this guidance applies to you

This guidance is for all doctors who offer cosmetic interventions.

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

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

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

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

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

* 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 www.gov.uk/government/uploads/system/uploads/attachment_data/file/472691/FGM_guidance.pdf (accessed 7 March 2016).

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*.*

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

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

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

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

Other sources of guidance

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

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

* 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).

† You can read all of our existing guidance at www.gmc-uk.org/guidance/ethical_guidance.asp.

- **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.*

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

* You can get advice on effective clinical supervision from sources such as the Care Quality Commission's *Supporting effective clinical supervision*, available at: www.cqc.org.uk/sites/default/files/documents/20130625_800734_v1_00_supporting_information-effective_clinical_supervision_for_publication.pdf (accessed 7 March 2016).

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.*

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 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.‡

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.*

* 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 our guidance *Openness and honesty when things go wrong*, available at: www.gmc-uk.org/guidance/ethical_guidance/27233.asp.

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.

Seeking patients' consent

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

Responsibility for seeking consent for cosmetic interventions

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

Responding to requests for cosmetic interventions

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

You must read paragraph 17 alongside:

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

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:

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

* See our *Guidance for doctors acting as responsible consultants or clinicians,* available at: www.gmc-uk.org/guidance/ethical_guidance/25335.asp.

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,* following the guidance in *Consent* (paragraphs 28–36).

You must read paragraph 22 alongside:

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

23 You must talk to the patient about any adverse outcomes that may result from the proposed intervention, paying particular attention to those the patient is most concerned about.† 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:

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

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

* 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.

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

Being clear about fees and charges

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

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

Treating adult patients who lack capacity

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

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

You must read paragraph 30 alongside:

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

You must read paragraph 31 alongside:

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

Treating children and young people*

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† 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‡ 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§ 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.*

* 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.

† 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 our *Guidance for doctors acting as responsible consultants or clinicians*.

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 requirements
- **b** our *Confidentiality* 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, paragraphs 12–16 and 64–66.*

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 doctor works with, in and outside their team, whether or not they are also doctors.

† See our guidance *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 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.*

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.† 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.

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* 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).

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.

Consent: patients and doctors making decisions together

Sharing information

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

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

b give information that the patient may find distressing in a considerate way

c involve other members of the healthcare team in discussions with the patient, if appropriate

d give the patient time to reflect, before and after they make a decision, especially if the information is complex or what you are proposing involves significant risks

e make sure the patient knows if there is a time limit on making their decision, and who they can contact in the healthcare team if they have any questions or concerns.

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

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

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

Involving families, carers and advocates

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

Obstacles to sharing information

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

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

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

Discussing side effects, complications and other risks

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

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

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

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

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

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

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

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

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

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

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

Ensuring that decisions are voluntary

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

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

Expressions of consent

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

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

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

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

Reviewing decisions

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

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

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

Part 3: Capacity issues

The legal framework

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

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

Presumption of capacity

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

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

Maximising a patient's ability to make decisions

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

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

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

- **a** discuss treatment options in a place and at a time when the patient is best able to understand and retain the information

b ask the patient if there is anything that would help them remember information, or make it easier to make a decision; such as bringing a relative, partner, friend, carer or advocate to consultations, or having written or audio information about their condition or the proposed investigation or treatment

c speak to those close to the patient and to other healthcare staff about the best ways of communicating with the patient, taking account of confidentiality issues.

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

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

Assessing capacity

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

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

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

a nursing staff or others involved in the patient's care, or those close to the patient, who may be aware of the patient's usual ability to make decisions and their particular communication needs

b colleagues with relevant specialist experience, such as psychiatrists, neurologists, or speech and language therapists.

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

Making decisions when a patient lacks capacity

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

a make the care of your patient your first concern

b treat patients as individuals and respect their dignity

c support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care

d treat patients with respect and not discriminate against them.

76 You must also consider:

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

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

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

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

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

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

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

Resolving disagreements

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

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

The scope of treatment in emergencies

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

0–18 years: guidance for all doctors

Assessing best interests

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

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

b the views of parents

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

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

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

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

Making decisions

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

Confidentiality

Protecting information

12 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.

13 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.

14 Unless they have a relevant management role, doctors 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.

15 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.

16 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.

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

64 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.

65 If a patient lacks capacity, you should share relevant information in accordance with the advice in paragraphs 57 to 63. Unless they indicate otherwise, it is reasonable to assume that patients would want those closest to them to be kept informed of their general condition and prognosis.

66 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.

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