

Agenda item:	12
Report title:	Consultation on cosmetic interventions guidance
Report by:	Mary Agnew , Assistant Director, Standards, Ethics and Education Policy magnew@gmc-uk.org , 020 7189 5325
Considered by:	Strategy and Policy Board
Action:	To consider

Executive summary

We have developed draft guidance for doctors who offer cosmetic interventions. This project forms part of the Government's response to Sir Bruce Keogh's review of cosmetic interventions.

The draft guidance draws together principles from existing GMC guidance that are relevant to cosmetic practice and introduces new principles that our group of expert advisers considered were necessary to address specific concerns about cosmetic interventions.

We would now like to launch a public consultation on the draft guidance.

Recommendations

Council is asked to:

- a** Agree to launch a 12 week public consultation on the draft guidance for doctors who offer cosmetic interventions.
- b** Note the draft guidance at [Annex A](#).

About the draft guidance

- 1 After the manufacturer Poly Implant Prosthèse was found to have supplied breast implants filled with industrial rather than medical grade silicon, the Government commissioned a review of cosmetic interventions by Sir Bruce Keogh ('the Keogh Review'). The Keogh Review recommended that the GMC develop a 'code of ethical conduct for cosmetic surgery' in collaboration with the Royal College of Surgeons of England. We undertook to lead this work and are accountable to the Department of Health for England for delivering it.
- 2 Our guidance will apply throughout the UK and to all cosmetic interventions, both surgical and non-surgical. The draft guidance ([Annex A](#)) was developed by an expert task and finish group with clinical, legal and lay representation, chaired by Judith Hulf. See [Annex B](#) for a list of members.
- 3 The draft guidance incorporates and builds on existing GMC guidance, and is framed around the domains of *Good medical practice*. It proposes new or more demanding standards where the Task and Finish Group believed these were necessary to address specific concerns about cosmetic interventions. For example:
 - a The guidance advises that, while doctors can normally delegate responsibility for seeking consent, it is essential to a shared understanding of expectations and risks that consent to a cosmetic intervention is sought by the doctor who will perform it.
 - b We say doctors must tell patients how long implanted medical devices are expected to last before they need to be removed or replaced.
 - c We have included more detail on responsible marketing practices.
- 4 As well as the topics highlighted by the Keogh Review Committee, we have also sought to address topics raised by stakeholders during our early engagement process or suggested by our research, such as concerns about:
 - a Doctors offering interventions to the public after taking short courses (for example, two-day courses in liposuction), without practising the interventions under supervision.
 - b Doctors who develop innovative techniques, including 'trademark' techniques that only they perform, who may not be seeking or acting on evidence about the effectiveness of the interventions they offer.

- c** Doctors who work as sole practitioners lacking access to colleagues who can advise them on best practice in cosmetic interventions or give specialist advice such as psychological assessment.

Collaborative working

- 5** Members of the Royal College of Surgeons (RCS) (England)'s Cosmetic Surgery Inter-specialty Committee sat on our Task and Finish Group. The RCS (England) presented draft wording to the Task and Finish Group, which has been incorporated into the draft guidance so far as it is applicable to all doctors.
- 6** The RCS (England) is very supportive of the guidance. It will publish complementary guidance for surgeons on its website and we will include a link to it within our guidance.
- 7** We also plan to include links to guidance published by other bodies that might be relevant to doctors who offer cosmetic interventions, including Health Education England.

Equality and diversity

- 8** The draft guidance recommends that doctors take different approach when people with the following protected characteristics ask for cosmetic interventions:
 - a** Children and young people.
 - b** People with mental health conditions that affect their requests for interventions.
- 9** As part of the consultation, we are asking for more information about differential impacts on groups who share protected characteristics.

Internal review

- 10** The draft guidance has been reviewed by the GMC's Fitness to Practise, Legal, Equality and Diversity and Publications teams, and cleared for publication by the Strategy and Policy Board.

About the consultation

- 11** We propose a 12 week consultation, which will involve a wide range of key interests across the UK and will also be publicised and promoted through members of the Task and Finish Group, including the RCS (England).

- 12** Given that this is quite a specialised field, we will conduct more limited engagement events to support it than we would for guidance that applies to all doctors. We will host targeted meetings with key interests and a listening event at the London office for those who have a strong interest in the subject. This group includes the other health professional regulators and bodies that represent practitioners who offer cosmetic interventions.
- 13** We are seeking Council's agreement to launch the consultation on 8 June 2015.
- 14** Following the consultation, we will work with the Task and Finish Group to develop final guidance, which we will launch early in 2016 following approval by the Strategy and Policy Board. We will report the final guidance to Council for noting at its meeting on 25 February 2016.

12 – Consultation on cosmetic interventions guidance

12 – Annex A

Draft: Guidance for all doctors who offer cosmetic interventions

Guidance for all doctors who offer cosmetic interventions

Who is this guidance for?

This guidance is for all doctors who offer cosmetic interventions wherever they practice in the UK.

The cosmetic interventions industry is a rapidly expanding area of practice that has gone from being a niche market to a popular area that is now widely available. Cosmetic interventions can have a profound impact on the health and well-being of patients. There have been particular concerns about patient safety and experience in the cosmetic sector, and whether it operates in an ethical manner. It is important that doctors have the right skills, the products being used are safe, and that patients are getting accurate information and support before any decision to undergo a procedure.

By cosmetic interventions, we mean any interventions, procedures or treatments carried out at the request of the patient¹ that have the primary objective of improving the patient's appearance.

This guidance builds on and incorporates our existing guidance,² and is structured under the four domains of *Good medical practice*. It applies and expands on our guidance to address the specific safety issues and ethical concerns particular to the cosmetic sector, as recommended by Sir Bruce Keogh's review, *Review of the regulation of cosmetic interventions*.

Other bodies have also produced guidance on the professional standards or the skills and experience needed for certain cosmetic interventions. We have included links to these other sources of guidance, which complement this guidance for all doctors.

As with all of our 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.

¹ When we say patient we also mean a person with legal authority to make a request on the patient's behalf.

² All of our existing guidance is available at www.gmc-uk.org/guidance/ethical_guidance.asp

You must use your judgement in applying the principles to the various situations you will face as a doctor, whether or not you hold a licence to practise, whatever field of medicine you work in, and whether or not you routinely see patients. You must be prepared to explain and justify your decisions and actions.

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.

Key points

We expect doctors offering cosmetic interventions to:

- Seek their patient's consent themselves rather than delegate
- Make sure patients are given enough time before they decide whether to go ahead with an intervention
- Consider their patients' psychological needs and seek expert advice from colleagues
- Make sure patients have the information they want or need, including a discharge letter that supports continuity of care and includes relevant information about the medicines or devices used
- Never prescribe non-surgical injectable medicines without seeing the patient
- Take particular care when they consider requests for interventions on children and young people, ensuring their best interests are fully considered
- Market their services responsibly, without making unjustifiable claims for the results of their 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, we also expect them to:

- 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, and within the limits of their competence
- Keep up to date with relevant law and guidance
- Be open and honest about their 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 patients to other practitioners where this serves the patient's needs.
- 2 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.
- 3 You should seek opportunities for supervised practice³ before you carry out interventions on your own or as a team leader or offer to supervise others.
- 4 You must take part in activities to maintain and develop your competence and performance across the full range of your practice.
- 5 You should seek and act on feedback from patients and use it to inform your practice. You should ask about the physical and psychological impact on the patient and about their overall satisfaction with the outcome of the intervention.
- 6 You must make sure that your annual appraisal covers the whole of your practice.

Safety and quality

- 7 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 that monitor public health.
 - f. You must contribute to clinical audit, adverse event reporting and national programmes to monitor quality and outcomes, including any relevant device registries and National Confidential Enquiry into Patient Outcome and Death

³ For more information about supervision, see our guidance on *Leadership and management for all doctors*

(NCEPOD) enquiries. You must report product safety concerns to the relevant regulator⁴.

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

- 8 You should share insights and information about outcomes with other people who offer similar interventions, where this is likely to improve outcomes or patient safety.
- 9 You must tell patients how to report complications and adverse reactions. You must make sure that your patients know how to contact you or another suitably-qualified person if they experience complications outside your normal working hours.
- 10 You must carry out a physical examination of patients before prescribing non-surgical cosmetic medicinal products such as Botox, Dysport or Vistabel or other injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video-link, or online.
- 11 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 treatments based on the best available up-to-date evidence about effectiveness, side effects and other risks.
- 12 You should be satisfied that the environment for practice is safe, suitably equipped and staffed.

Communication, partnership and teamwork

- 13 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.
- 14 When you discuss interventions and options with patients, you should consider their vulnerabilities and psychological needs to help you understand their requests for the intervention.

Consent

- 15 If you have overall responsibility for a patient's care, you must make your own assessment of their request for an intervention. You must ask them for relevant

⁴ Medicines and medical devices in the UK are regulated by the Medicines and Healthcare Products Regulatory Agency (<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>)

information about their medical history, why they have requested an intervention and the outcome they hope for.

- 16** In the case of cosmetic interventions, if a patient asks you for an intervention that you think is unlikely to be of overall benefit to them, you must explain why. You should talk to the patient to ask why they asked for the intervention. But, if you still think it is unlikely to be of overall benefit, you should not provide it. You should discuss other intervention options and respect the patient's right to seek a second opinion.
- 17** It is essential to a shared understanding of expectations and limitations that consent to cosmetic interventions is sought by the doctor who will perform it. Seeking consent should not be delegated.
- 18** When you discuss intervention options with patients, you must explain any monitoring or follow-up care requirements. For example, you must tell them how long implanted medical devices are expected to last before they need to be removed or replaced.
- 19** You should discuss what action the patient would like you to take if you find out, during the intervention and whilst the patient is unable to give consent to varying it, that you are unable to perform the intended intervention or would need to perform it differently.
- 20** You must make clear to prospective patients that alternative interventions may be available from other practitioners.
- 21** You must give the patient enough time and information to reach a voluntary and informed decision about whether to go ahead with an intervention.
- 22** The amount of time patients need for reflection and the amount and type of information they will need depends 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.
- 23** You must give patients the information they want or need about:
 - a** options for treating or managing the patient's condition or the physical feature about which they have concerns, including the option not to treat
 - b** the purpose of any proposed intervention and what it will involve
 - c** the potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or practitioner they choose to provide the intervention

- d** whether a proposed intervention is an innovative intervention and, if so, what arrangements exist to protect the patient's safety
 - e** the people who will be mainly responsible for and involved in their care and what their roles are
 - f** their right to seek a second opinion
 - g** any bills they will have to pay
 - h** any conflicts of interest that you, or your organisation, may have
 - i** any interventions that you believe have greater potential benefit for the patient than those you or your organisation can offer.
- 24** You should explore these matters with patients, listen to their concerns, ask for and respect their views, provide information on risks, including risks that are material⁵ and any risks they may be particularly concerned about, and encourage them to ask questions.
- 25** You should check that patients have understood the information you have given them and answer any questions they might have.
- 26** You should consider whether you or a colleague needs to review the patient's response to the intervention and make sure the patient understands whether you recommend a follow-up appointment.
- 27** 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.
- 28** You must tell the patient they can change their mind at any point. Explain your charges clearly from the outset, so that patients know the financial implications of any decision to proceed to the next stage or to withdraw.

⁵ See [Lanarkshire Montgomery]

Children and young people⁶

- 29 You should take particular care when you consider providing interventions for children or young people and, wherever possible, should work with multi-disciplinary teams that provide expertise in treating children and young people.
- 30 Interventions must be in the best interests of the child or young person and performed with consent. A parent⁷ can consent to an intervention for a child or young person who does not have the maturity and decision making capacity to consent, but you must not perform an intervention on a child or young person on the basis of consent having been given by a parent when it is clear that the child or young person has refused to agree to the cosmetic intervention.
- 31 Your marketing activities must not target children or young people through their content or placement.

Continuity of care

- 32 You must make sure the patient has the medicines or equipment they need to care for themselves after an intervention.
- 33 You should give patients a discharge letter that explains the intervention they have received in enough detail to let 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 to the patient's GP and any other doctors treating them, provided the patient consents to you sharing this information, if it is likely to affect their healthcare in future.
- 34 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.
- 35 You must keep records that contain personal information about patients securely and in line with:
 - a any data protection requirements
 - b guidance published by the UK health departments, even when the interventions are provided outside the National Health Service.

⁶ Children and young people are people aged between 0 and 18. Please see our guidance *0-18 years: guidance for all doctors* for more information about the general principles that you should follow, in addition to this guidance, when you treat children and young people.

⁷ 'Parents' are people with parental responsibility

Working with colleagues

- 36** You must make sure that anyone you delegate care to has the necessary knowledge, skills and training and is appropriately supervised.
- 37** You must work effectively with healthcare professionals and others involved in providing care. You must respect the skills of colleagues within multi-disciplinary teams and support them to deliver good patient care.
- 38** 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
- 39** You must make sure you have access to other professionals who can support and advise you, and you should seek their advice for patients who may need psychological or other expert support.

Maintaining trust

- 40** 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.
- 41** You must not allow your own financial or commercial interests to affect your intervention recommendations.
- 42** When advertising your services, 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.
- 43** Your marketing must be responsible⁸. It must not minimise or trivialise the risks of interventions and must not exploit patients' vulnerability.
- 44** You must always be honest and must not mislead about your skills, experience, qualifications, professional status and current role.
- 45** You must not mislead about the results you are likely to achieve.
- 46** You must not claim that interventions are risk-free.

⁸ Committee of Advertising Practice/Broadcast Committee of Advertising practice have guidance on the Marketing of cosmetic interventions which covers the marketing of both surgical and non-surgical cosmetic interventions.

(<http://cap.org.uk/~media/Files/CAP/Help%20notes%20new/CosmeticSurgeryMarketingHelpNote.ashx>)

- 47 You must not falsely claim or imply that certain results are guaranteed. If a medical assessment is required, your marketing must make that clear.
- 48 You must not use promotional tactics (for example, but not limited to, discounts, time-limited deals, refer a friend offers, gift vouchers or loyalty cards) in ways that could encourage people to make an untimely or ill-considered decision.
- 49 You must not provide your services as a prize.

References

- 1 General Medical Council (2013) *Good medical practice*
- 2 General Medical Council (2012) *Leadership and management for all doctors*
- 3 General Medical Council (2012) *Raising and acting on concerns about patient safety*
- 4 General Medical Council (2009) *Confidentiality*
- 5 General Medical Council (2008) *Consent: patients and doctors making decisions together*
- 6 General Medical Council (2007) *0-18 years: guidance for all doctors*
- 7 General Medical Council (2013) *Financial and commercial arrangements and conflicts of interests*
- 8 General Medical Council (2013) *Good practice in prescribing and managing devices*
- 9 Royal College Surgeons guidance, *Cosmetic Surgery Code of Professional Standards and Ethics*
- 10 Health Education England, *Qualification requirements for cosmetic procedures*

12 – Consultation on cosmetic interventions guidance

12 – Annex B

List of Task and Finish Group members

- 1 Set out below is a list of the Task and Finish Group members who helped to develop our draft guidance for doctors who offer cosmetic interventions.
- 2 The Group is chaired by Dr Judith Hulf, Senior Medical Adviser to the GMC.

The other members of the Group are:

Name	Organisation
Michael Cadier	British Association of Aesthetic Plastic Surgeons
Steve Cannon	Royal College of Surgeons (England)
Claire Grainger	Independent nurse practitioner
Mark Henley	British Association of Plastic Reconstructive and Aesthetic Surgeons
Carol Jollie	Health Education England
Nicholas Lowe	British Cosmetic Dermatology Group
Jose Miola	University of Leicester, Academic in Law
Sally Taber	Independent Health Advisory Services
Simon Withey	Professional and clinical standards sub group
Geoff Wykurz	GMC lay associate