To consider

Developing guidance for doctors who offer cosmetic interventions

Issue

1. In response to recommendations arising from Sir Bruce Keogh’s review of cosmetic interventions, we have developed draft guidance for doctors who offer cosmetic interventions and plan to conduct a consultation over the summer.

Recommendations

2. The Strategy and Policy Board is asked to:
   a. Agree to launch a 12 week public consultation on the draft guidance.
   b. Approve the draft guidance, at Annex A.
   c. Note our proposals for Council involvement.
   d. Agree that following consultation, the guidance will be submitted to the Strategy and Policy Board for approval.
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Issue

3 Sir Bruce Keogh’s review of cosmetic interventions (‘the Keogh review’) recommended that we develop a ‘code of ethical conduct for cosmetic surgery’ in collaboration with the Royal College of Surgeons of England (RCS). A list of the Keogh review recommendations relevant to our guidance is at Annex B.

Scope and content

4 Our guidance will apply throughout the UK and to doctors in all specialties, not just surgeons in England.

5 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.

6 The guidance builds on existing guidance, expanding this to apply to particular concerns around the cosmetic sector. 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.

7 On some topics, we have not adopted the recommendations of the Keogh review:

a The Keogh review asked us to develop guidance on insurance and indemnity requirements in the guidance. Because we already require doctors to hold
adequate insurance or indemnity, we have not added any new requirements in this guidance.

b The Keogh review said promotions should be banned. We understand that some providers offer discounts to patients who have already reached a decision about an intervention, for example to encourage them to attend during the less popular times of year or at short notice when another patient cancels. We think the guidance should allow these promotions, provided they do not affect patient’s decisions about whether to undergo an intervention.

Task and finish group

8 A task and finish group developed the draft guidance. A list of members is at Annex C.

9 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. The task and finish group included members of the RCS (England)’s cosmetic surgery inter-specialty committee and we have liaised with them throughout the guidance development process. The RCS (England) will publish their guidance for surgeons on their website towards the end of this year and we will include a link to it within our guidance.

10 We were unable to recruit task and finish group members from all four countries of the UK. The Devolved Offices have told us the market for cosmetic interventions is concentrated in England.

Supporting materials

11 We will also include links to relevant materials published by other bodies including Health Education England, which has developed a skills framework in response to another recommendation of the Keogh Review, and systems regulators including the Care Quality Commission (CQC).

12 We plan to develop supporting materials for this guidance, which may include case studies, Good medical practice in action scenarios or decision tools. This will allow us to present specialty- or procedure-specific recommendations from the Keogh review and other key interests as illustrative examples of good practice, whilst preserving the principle that standards guidance applies to all doctors in all specialties.

Developing the guidance

13 The draft has had input from colleagues in Fitness to Practise directorate and been edited for tone of voice. Input has been sought from colleagues in the legal team.
We will ask Council to note the draft guidance and to consider the process by which we have arrived at the draft guidance at its meeting on 2 June 2015.

Consultation

We propose a consultation of 12 weeks, currently planned for launch on 8 June 2015. If we need more time to address points made during Council’s discussion, we are able to delay launch until the first week of July.

We are considering whether to run engagement events to support the consultation.

We are working with colleagues in the Strategy and Communication directorate and the Devolved Offices to prepare a one-day programme to cover three consultations (the other two are credentialing and publications and disclosure). The Devolved Offices have advised that the cosmetic sector is much smaller outside England and that we might not attract enough interest in Wales, Scotland or Northern Ireland to run the session on cosmetic interventions.

We are also considering a low-cost event at the London office, for key interests 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.

After consultation

The Task and Finish group will meet again to draft amendments to the guidance in light of the consultation responses.

The Strategy and Policy Board will be invited to approve the amended guidance for at its meeting on 1 December 2015.

The publication date depends on the governance process for approving the final guidance. Under the current arrangements, Council would consider the guidance at its meeting on 25 February 2016, and publication would be in March 2016.
Supporting information

How this issue relates to the corporate strategy and business plan

22  Strategic Aim 2: to help raise standards in medical education and practice.

What equality and diversity considerations relate to this issue

23  We will undertake equality analyses throughout all our guidance development projects. Our engagement strategies will ensure we hear from diverse groups of patients, doctors and the public.

If you have any questions about this paper please contact: Mary Agnew, Assistant Director - Standards, magnew@gmc-uk.org, 0207 189 5325.
Guidance for all doctors who offer cosmetic interventions

Who is this guidance for?

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 well-being 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.

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

This guidance builds on and incorporates principles from our existing guidance, and is structured under the four domains of Good medical practice. It applies and in some cases sets a higher standard than in our current 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. It should be read alongside our other guidance†.

Other bodies have also produced guidance on 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.

* When we say patient we also mean a person with legal authority to make a request on the patient’s behalf.
† All of our existing guidance is available at www.gmc-uk.org/guidance/ethical_guidance.asp
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 and information before they decide whether to have an intervention
- Consider their patients’ psychological needs and if necessary 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
- Take particular care when considering requests for interventions on children and young people
- Market their 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, 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

www.gmc-uk.org
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 practice* 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, including the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) enquiries
   b. contribute to adverse event recognition and reporting
   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. contribute to clinical audit and national programmes to monitor quality and outcomes, including any relevant device registries
   g. report product safety concerns to the relevant regulator*.

* For more information about supervision, see our guidance on Leadership and management for all doctors
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, if this is likely to improve outcomes or patient safety.

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

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 or at the request of others for patients you have not examined.

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 interventions 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 a patient, you should consider their vulnerabilities and psychological needs (see also paragraph 39)

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


† Please also see our Guidance for doctors who are acting as responsible consultants or clinicians.

‡ Please see Consent: patients and doctors making decisions together for more guidance on the consent process.
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 options and respect the patient’s right to seek a second opinion.

It is essential to a shared understanding of expectations and limitations that consent to interventions is sought by the doctor who will perform it or supervise its performance by another practitioner. Seeking consent for interventions must not be delegated.

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.

You must make clear to prospective patients that alternative interventions may be available from other practitioners.

You must give the patient enough time and information to reach a voluntary and informed decision about whether to go ahead with an intervention.

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.

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.

23 You should explore these matters with patients, listen to their concerns, ask for and respect their views, provide information on risks, including risks the patient may see as material* to their decision and encourage them to ask questions.

24 You should check that patients have understood the information you have given them and answer any questions they might have.

25 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.

26 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.

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.

Children and young people†

28 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.

29 Interventions must be in the best interests‡ of the child or young person and performed with consent. A parent§ 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 being given by a parent if it is clear that the child or young person has refused to agree to the intervention.

* See Montgomery v Lanarkshire Health Board (Scotland) [2015] UKSC 11
† Please see our guidance 0-18 years: guidance for all doctors for more information about the general principles that you should follow, 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
30 Your marketing activities must not target children or young people through their content or placement.

**Continuity of care**

31 You must make sure the patient has the medicines or equipment they need to care for themselves after an intervention.

32 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.

33 You should give patients a discharge letter 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 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.

**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.

* Please also see our Guidance for doctors who are acting as responsible consultants or clinicians.
39 You must make sure you have access to other professionals 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**

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 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 responsible*. 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.

47 You must not falsely claim or imply that certain results are guaranteed from an intervention. 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 ill-considered decision.

49 You must not provide your services as a prize.

* 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)
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. General Medical Council (2014) *Guidance for doctors who are acting as responsible consultants or clinicians*
10. Royal College Surgeons guidance, *Cosmetic Surgery Code of Professional Standards and Ethics*
11. Health Education England, *Qualification requirements for cosmetic procedures*
List of the Keogh review recommendations relevant to our guidance for doctors who offer cosmetic interventions

Set out below is a list of the Keogh review recommendations relevant to our guidance for doctors who offer cosmetic interventions.

**Recommendation 1(f)**
The Royal College of Surgeons (RCS) should establish a Cosmetic Surgery Interspecialty Committee. This should consist of representatives from all the relevant specialty associations and professional associations and societies, including plastic surgery, ENT surgery, maxillofacial surgery, ophthalmology, breast surgery and gynaecology. Its task should be to: […]

- develop a specific code of ethical practice for cosmetic surgery, in collaboration with the GMC, to include guidance on advertising, insurance requirements and the psychological assessment for patients.

**Recommendation 14**
Those training to be non-surgical practitioners should have a clear understanding of the requirement to operate from a safe premises, and the responsibilities involved.

**Recommendation 24**
Adverse incident reporting should be a standard component of professional appraisals and revalidation.

**Recommendation 27**
The RCS Interspecialty Committee on Cosmetic Surgery should develop and describe a multi-stage consent process for operations. This consent process should be undertaken by the operating surgeon and its use should be mandated as part of the Code of Practice.
In due course, CQC will ensure that guidance that they publish about meeting national standards signposts where appropriate to GMC guidance.

All providers must keep full patient records, including clear operative records and precise details of any implant or device used. Providers should also be able to access data of implant cohorts readily and this should be available to regulatory authorities. Details of the surgery and implant used must be sent to the patient and to the patient’s GP.

**Recommendation 29**
The RCS Interspecialty Committee should develop a code of ethical practice developed for all practitioners of cosmetic interventions, and this should include standards to ensure that any advertising is conducted in a socially responsible manner.

**Recommendation 31**
The Review Committee considers that the following advertising practices are socially irresponsible and should be prohibited by the professional registers’ codes of practice:

- Time-limited deals
- Financial inducements
- Package deals, such as ‘buy one get one free’ or reduced prices for two people such as mother and daughter deals, or refer a friend
- Offering cosmetic procedures as competition prizes.

**Recommendation 32**
Providers and practitioners should provide continuity of care. Patients should be offered appropriate follow-up and after-care, rather than stand-alone procedures.

**Recommendation 36**
All individuals performing cosmetic procedures must possess adequate professional indemnity cover that is commensurate with the type of the operations being performed.

**Recommendation 38**
Patients’ rights should be protected even when a provider goes out of business. Providers of cosmetic surgery must either enter a risk pool or have appropriate insurance/financial arrangements to provide treatment following certain complications. The NHS should be able to recoup costs for management of certain complications following cosmetic procedures if the provider has been found to have failed the patient following surgery. A similar arrangement already exists following motor vehicle accidents.
Recommendation 39

The insurance status of all practitioners should be displayed on the practitioner register.
## 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:

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