Expert Group on the Regulation of Cosmetic Surgery

Report to the Chief Medical Officer

January 2005

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Foreword by Harry Cayton

I am pleased to submit the report of the Expert Group on the Regulation of Cosmetic Surgery. We were asked to report on whether the current system for regulation of cosmetic surgery was sufficient to ensure patient safety and to make recommendations.

The Group has considered evidence from a wide range of bodies and individuals. We have also had the benefit of input from the Healthcare Commission and have taken its report *An analysis of private cosmetic surgery provision in England for the Chief Medical Officer Sir Liam Donaldson* into consideration. The evidence that we reviewed suggested that avoidable harm is done to some patients.

The Group makes no judgement as to whether or not the current demand for cosmetic surgery and treatments is desirable. We note, however, that demand is considerable, that it is growing, and that cosmetic surgery and procedures are widely advertised and promoted in ways which would be quite unacceptable to the public or to professional ethics if they were used in relation to other surgical interventions.

People should be confident that their treatment will be safe, that the medical and nurse practitioners who treat them are qualified and competent, and that they have the information they need to make informed decisions. Further than that, it must be the responsibility of individuals to protect themselves by checking on the qualifications, experience and commitment to good practice of the providers they use.

Our recommendations fall into three broad groups; recommendations about clinical training, qualifications and accountability, recommendations about cosmetic procedures, and finally, recommendations about public information and education.

I am very grateful to all the members of the Expert Group who have given freely of their time and knowledge. We have had some challenging discussions and occasional disagreements but I am pleased that the recommendations in this report are unanimous. The written and verbal evidence we have received has also been important and I am particularly grateful to Professor Sir John Temple and the Cosmetic Surgery Inter-Specialty Group for sharing their work with us. We have been well served by our officials and I am grateful to them also.

Harry Cayton
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Introduction

1. The Expert Group on the Regulation of Cosmetic Surgery was established to advise the Chief Medical Officer on whether or not the current regulation of cosmetic surgery was sufficient to ensure patient safety and to make recommendations.

2. The Group has considered:

   - the available evidence of reported harm and risk of harm to patients and the public;
   - evidence relating to the quality and standards of care provided to patients undergoing cosmetic surgery and cosmetic procedures;
   - the levels of training and qualifications held by cosmetic surgeons, and associated professionals; and
   - the current regulation and inspection regimes.

3. The recommendations in this report are intended to reduce the risk of harm to patients and the public when considering or undergoing cosmetic surgery.

4. The full Terms of Reference for the Group are at Annex A. Membership of the Expert Group is at Annex B.

Definitions

5. For the purposes of this report, cosmetic surgery is defined as:

   Operations and other procedures that revise or change the appearance, colour, texture, structure, or position of bodily features, which most would consider otherwise to be within the broad range of "normal" for that person.[1]

6. This definition therefore includes invasive cosmetic surgery (carried out in an operating theatre under anaesthetic) as well as cosmetic procedures such as botulinum toxin injections, aesthetic fillers and laser treatment. This report does not consider beauty or grooming activities that have no structural impact on body tissue, nor ear and body piercing, or tattooing. The former is covered by The Cosmetic Products (safety) Regulations 2004, and the latter by a range of local authority health and safety Acts.

1 Good Medical Practice in Cosmetic Surgery – Independent Healthcare Association 2003 based on proposals from the Cosmetic Surgery Inter-Specialty Group.

Regulation of Cosmetic Surgery

7. The above definition of cosmetic surgery is wider than that covered by current regulations. The following table sets out the types of cosmetic surgery included in this report and whether they are currently regulated.

	Regulations
Invasive cosmetic surgery	Yes – Regulated by the Care Standards Act 2000. Responsibility of the Healthcare Commission since April 2004
Laser treatment	Yes – Practitioners are required to register with the Healthcare Commission. Regulated using Independent Healthcare Standards P1-P3 of the Care Standards Act 2000.
Botulinum toxins injections	The prescription of botulinum toxins is regulated and they should only be prescribed by a doctor for a named patient. However, botulinum toxins are not licensed for cosmetic use and are therefore only used for this purpose on an off-licence basis.
Aesthetic fillers	The injection of cosmetic fillers is not regulated. The regulation of filler products is very unclear. Some fillers are classified as drugs or medical devices and therefore are regulated by the Medical Healthcare Products Regulatory Agency (MHRA). Those which contain human tissue are not classified as a medical device and are covered under the General Product Safety Regulations 1994.

8. ***Regulation for invasive cosmetic surgery*** – The Healthcare Commission regulates and inspects all registered establishments in England carrying out invasive cosmetic surgery. The Healthcare Commission has no obligation to seek out unregistered establishments. However, it does review unregistered facilities when their operations are drawn to the Healthcare Commission's attention. Independent hospitals, where the majority of cosmetic surgery is carried out, are required to meet service-specific standards for acute hospitals.

9. The Group found no reason to consider the current inspection regime for invasive cosmetic surgery conducted by the Healthcare Commission to be inadequate. The Healthcare Commission's review reported compliance with the standards (particularly to the service specific standards relating to cosmetic surgery and laser use) which could imply that the inspection regime is effective. The Healthcare Commission in its review proposes to move away from yearly inspections to a system

of inspection by exception. The Group supports this proposal, on the condition that the exception determinants are based on risk and need not on available resources.

10. The Healthcare Commission has powers to undertake enforcement action and to seek orders to revoke licences to practice. If there are demonstrations of serious breeches of regulations and standards both the public benefit and the cost of legal action has to be considered. The Healthcare Commission is currently conducting a review of powers across all regulation to examine any appropriate opportunities for new ways of augmenting regulatory powers without always having to enforce them through the courts. Recommendations will be made to the Department of Health in due course. The Healthcare Commission is also working on the development of a prosecution policy.

11. Surgeons generally have to enrol on the Specialist Register of the General Medical Council (GMC). However, there are major difficulties for cosmetic surgeons currently in private practice being able to register. The first of these is that there is no such register for cosmetic surgery. The second is that to get on the specialist register they would have to give up their private practice, find a job in the NHS and then work for 5–6 years in order to gain the necessary experience to be placed on the specialist register in some other specialty (for example plastic surgery). This is further compounded by the limited training places for cosmetic surgery. In view of these difficulties standard A4.2 of the Care Standards Act 2000 allows surgeons who were practicing cosmetic surgery before April 2002, (i.e. before the Act came into effect), to continue practicing without being on the specialist register as long as certain criteria (set out below) are met.

12. The Care Standards Act 2000, standard A4.2, requires that all practitioners who work independently in private practice (except General Practitioners):

- are on the specialist register of the General Medical Council; or
- where they were undertaking cosmetic surgery in the independent healthcare sector before 1 April 2002 and are not on the specialist register, satisfy the following conditions:
  - To have completed basic surgical or medical training
  - To have undertaken specialist training in the specialty relevant to the procedures they provide
  - To maintain a record of patients to whom they have provided treatment or services in the establishment, which is made available to the registered person and the Healthcare Commission
  - To undertake regular patient satisfaction surveys, a record of which is made available to the registered person and to the Healthcare Commission at least annually.

13. The Healthcare Commission estimates that, in those practices registered to undertake cosmetic surgery, the number of surgeons currently practising who are not on the Specialist Register is approximately 63 (out of a total of 784). The number of these unregistered doctors will diminish over time as there can be no new entrants to this group.

14. Solicitors have advised that to change the standard A4.2 to require all doctors working independently in private practice be on the specialist register, without evidence of malpractice or harm by the unregistered doctors, would contravene the Human Rights Act 1998 Article 1 Protocol 1 – peaceful enjoyment of possessions. A person's livelihood is considered to be a possession. Surgeons would have to give up their private practice to meet the requirements to register and thus be denied their livelihood.

15. Training for cosmetic surgery in England is limited in availability because surgery in the NHS is carried out for clinical rather than cosmetic reasons. Training for cosmetic surgery in the NHS is provided within surgical specialties such as plastic surgery, and dermatology. Some training is provided in other countries and there are also a small number of cosmetic surgery fellowships in the independent sector.

16. Therefore, in summary:

- There is a group of doctors who are exempt from the requirement to enrol on the Specialist Register of the GMC who can legally practice cosmetic surgery with limited specialist training and/or no supervision.
- As there is no specialty for cosmetic surgery to which doctors can be registered, doctors can practice outside the area of competence for which they are registered.
- Independent sector facilities may enable surgeons to provide services to patients where those surgeons do not have the equivalent standing as a consultant in the NHS. The National Minimum Standards provide a number of requirements on independent providers to ensure patients receive treatment from an appropriately trained, qualified and insured surgeon. Standard A4 requires that medical practitioners who work independently in private practice clearly demonstrate that they have the necessary qualifications, expertise and experience to undertake competently and safely the treatment and services that they propose to provide. The Standards also require that hospitals have medical advisory committees to advise the provider on issues of eligibility and application of practicing privileges of medical practitioners.

17. The Expert Group considers the situation described to be unsatisfactory because it is virtually impossible for a person seeking cosmetic surgery to understand or evaluate the precise qualifications and supervisory framework in which their surgeon is practising.

18. There are no comparative data on the performance of surgeons on the specialist register, not on the specialist register or those who are NHS consultants or equivalent and specialist registrars working unsupervised in the independent sector.

19. One approach to this problem is to ensure that patients and the public are aware of a surgeon's qualifications, registration and training. Recommendation two (page 17) will apply to all surgeons and therefore ensure that the public and patients know as much information as possible about their surgeon. This will be further supported by public education (recommendations 15 – 20).

20. ***Regulation for laser treatment*** – All facilities providing laser treatment are required to register with the Healthcare Commission. Laser treatments and procedures are assessed using the Independent Healthcare National Minimum Standards P1 to P3 of the Care Standards Act 2000. This includes the requirement that practitioners should have completed a laser safety course and other appropriate training. However, no other clinical qualifications are required.

21. Manufacturers of the laser equipment do not necessarily inform their customers of the need to register with the Healthcare Commission and have no obligation to do so. The Healthcare Commission estimates that there may be a significant number of laser treatment practitioners whose facilities are not registered (based on estimates reported from practitioners and equipment distributors). The Expert Group does not consider this to be satisfactory and endorses the recommendation in the Healthcare Commission's review that the Healthcare Commission carry out a risk based review of the regulation of the provision of laser services.

22. ***Regulation for botulinum toxin injections*** – Botulinum toxin is a prescription drug and should therefore only be prescribed by a doctor and administered by a doctor, or a nurse under the direction of the doctor, for a named patient. This should follow discussion between the patient and doctor. Botulinum toxins are not licensed for cosmetic use but can be prescribed off-licence by a doctor (i.e. the drug is used for a different purpose than that for which it is licensed). The prescriber then accepts liability normally assumed by the product licence holder when the drug is used outside the licence. A nurse or other person who administers botulinum toxins for cosmetic purposes without the directions of a doctor relating to the patient in question will not be complying with the law.

23. From advertisements, it is known that 'Botox Parties' are arranged, often in hotel rooms, where the prescribing and administering of these injections to the public may be without medical supervision. It is illegal to advertise 'Botox' for sale (under the Advertising regulations 1994 SI 1994/1932, as amended) because it is a prescription drug.

24. ***Aesthetic fillers*** – The subcutaneous injection of filling agents – 'fillers' – is not regulated. The classification of fillers as medical devices is very unclear. Fillers containing human tissue are generally not classed as medical devices, although this

can depend on the source and process the tissue has been subjected to. Fillers which are classed as medical devices are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). Other filler products are covered by The General Product Safety Regulations 1994 of the Department of Trade and Industry (DTI). The DTI's Cosmetic Products (safety) regulations 2004 do not include aesthetic fillers. These regulations apply to cosmetic products which are used on the surface of the skin, hair and nails.

25. The lack of clarity over the classification of fillers, and therefore the regulation which applies to them, is unsatisfactory. We consider the DTI General Product Safety Regulations 1994 to be insufficient in regulating relevant aesthetic filler products. The Group received conflicting advice from the MHRA on the classification of filler products and they were unable to provide us with product lists. This is of concern as this information should be accessible to patients.

26. Fillers fall into two groups: fully biodegradable, and semi-permanent or permanent. Fully biodegradable fillers have a good safety record. However semi-permanent and permanent fillers have been reported to produce significant longer-term inflammatory reactions in the skin, leading to discomfort, scarring and disfigurement. These reactions may not appear for many years after the original implantation. The problems can be permanent and can often only be partially controlled. Given that new filling agents are regularly entering the market, better regulation and licensing of fillers in needed.

27. We are concerned that there is a risk of the transmission of blood-borne viruses and vCJD from the human tissue component of some filler products. The level of risk, if any, based on the type of tissue used and the processes undertaken, whether it is allogeneic (i.e. dead tissue) or autologous (i.e. grown from skin biopsy of the patient) needs to be investigated. If there is a risk, and there may be none, action should be taken to protect patient safety through regulation.

28. ***General Practitioners*** – The Group noted that there may be a small number of GPs who hold an NHS contract and who may be conducting cosmetic surgery procedures as private practice. This was of concern to the Group because the GPs will not be on the Specialist Register, and are not regulated by the Care Standards Act 2000 (see para 11). The number of GPs in this category is likely to be small.

29. ***Nurses*** – There are no specific qualification requirements for nurses advising on and carrying out aesthetic procedures. However, nurses undertaking cosmetic surgery procedures should work within the Nursing and Midwifery Council's code of professional conduct. This means they must work within the limits of their skills, knowledge and competence. The Aesthetic Nurse Forum of the Royal College of Nursing (RCN) is consulting on a Career and Competency framework. If this is accredited by the RCN, it may be useful for nurses and employers.

30. ***Dentists*** – Some dentists carry out cosmetic procedures, such as the injection of fillers. The Group considers that these dental practices should be registered with the Healthcare Commission in the same way as other facilities providing similar procedures.

Approach

31. In the time available to the Group we were not able to initiate substantial new research. We did have access to information collected by the Healthcare Commission and to the full text of its report, *An analysis of private cosmetic surgery provision in England for the Chief Medical Officer Sir Liam Donaldson*, dated May 2004, which was delivered to the Chief Medical Officer on 2 September 2004. The Group also benefitted from having senior representation from the Healthcare Commission in its membership. The Group is also grateful to Professor Sir John Temple, chairman of the Cosmetic Surgery Inter-Specialty Group of the Senate of Surgery of Great Britain and Ireland, for sharing the deliberations of his Group with us.

32. The Group also had the benefit of a number of expert witnesses who met the working group and contributed their knowledge and views. Those who gave evidence in person or in writing are listed at Annex C.

33. We wrote to thirty three organisations and invited them to share with the Group any information or evidence that they had, if they wished to do so. Many of these organisations had already contributed to the Healthcare Commission Report and may have had nothing further to add. Those who we contacted are also listed at Annex C. One hundred and seventy six establishments offering cosmetic surgery who are registered with the Healthcare Commission were also contacted.

34. We were restricted in our remit by both the Terms of Reference and the time available to us but we believe, as a Group, that the conclusions and recommendations we have drawn are reasonable and that the evidence we have used was adequate as a basis for those recommendations.

Values and Principles

35. The Group makes no judgement as to whether or not the current demand for cosmetic surgery and treatments is desirable. We note, however, that demand is considerable, that it is growing and that cosmetic surgery and procedures are widely advertised and promoted in ways which would be quite unacceptable to the public or to professional ethics if they were used in relation to other surgical interventions. A casual look in popular beauty and lifestyle magazines will reveal several pages of advertisements and a simple search of the internet will identify over 200,000 websites promoting cosmetic surgery, as well as recording the unhappy experiences and concerns of many people around the world.

36. We asked ourselves therefore whether the information that the public in general and patients in particular receive about cosmetic surgery and procedures was adequate for them to make an informed choice.

37. We also wanted to know if the public and patients were aware which parts of the cosmetic surgery industry were regulated and how, and if they knew which parts were unregulated. We sought some understanding of what the public would expect through a MORI survey. High-level results of this survey are set out at Annex D.

38. We took the view as a Group that regulation by Government in this context should exist to reduce risk, promote standards and to protect the public from harm, from dishonesty and malpractice, and from professional incompetence. Regulation should be proportionate to the problem it is trying to manage. Regulation cannot deal with whether or not patients have realistic expectations or are satisfied with the aesthetic outcomes of the procedures they have undergone, or whether or not they have made adequate enquiries on their own behalf in advance. Regulation can assist in ensuring that the information the public needs to make such enquiries and to come to judgements is reliable and readily available.

Summary of Evidence

39. The Group found that there is no one authoritative source of evidence to show that significant harm is caused to patients by cosmetic surgery. However, opinions of experts, the findings of the Healthcare Commission review and the proportion of complaints to it, and the evidence from the Medical Protection Society all point to some harm to some patients. Where that harm is avoidable, some harm is too much harm. Other areas of concern which affect the quality of patient care were also noted. The following section of this report sets these out.

General Medical Council (GMC)

40. Evidence from the GMC about whether cosmetic surgery was of particular concern in regard to patient safety was inconclusive. The GMC reported to us a small number of cases which were considered to be 'serious misconduct'. In the past four years, four cases had been passed to the Professional Conduct Committee and one to the GMC Committee on Professional Performance. One cosmetic surgeon had been struck off as a result. The GMC was not able to give us comparative information as to the number of complaints in other areas of surgical speciality because of the limitations in the way they record complaints. The Group considered this to be unsatisfactory.

41. The GMC was aware of the problems of delegation of clinical responsibility to unqualified people (for example where botulinum toxins were administered by people who were not doctors or nurses), and of aggressive marketing techniques. The former could affect a doctor's registration but the GMC had no data on this, nor were they aware of any action being taken towards doctors for inappropriate delegation in cosmetic clinics. The latter is an issue that would be unlikely to affect a doctor's registration with the GMC or lead to disciplinary action by the GMC.

Consumers Association

42. The Consumers Association presented to the Group the three investigations of cosmetic surgery which had been conducted in 1997, 2002 and in 2004. The investigations used actors as potential patients to test out how people were advised by different providers of cosmetic surgery. They were not set up to identify actual harm as the actors involved did not undergo treatment. The Consumers Association reported that only a very small number of people had contacted Health Which? subsequently to report harm as a result of cosmetic surgery. Important areas of concern for patients that arose from the studies are listed below.

Patient information

- There was insufficient information provided to patients on the choices available and the risks.
- Direct injection of botulinum toxin at some 'botox parties' was accompanied by the consumption of alcohol.
- Inadequate information was given about how to complain.

Professionals

- Initial consultations with patients about whether to undergo cosmetic surgery were often with a patient adviser or co-ordinator. Their professional training and qualifications to be able to give advice of this nature was uncertain.
- Risks in surgery were often discussed with the patient advisor, not the surgeon, and risks were also often played down.
- Some beauty therapists were carrying out treatments, possibly without necessary qualifications, particularly for botulinum toxin injections and acid peels.

Sales techniques

- High pressure sales techniques were often used, such as offering financial incentives to influence potential patients' decisions.
- Some clinics pressed for commitment to the treatment on the day of the consultation, giving patients no cooling-off period or time to reflect.
- Botulinum toxin injections were sometimes offered at parties on a 'buy one get one free' basis.

Healthcare Commission

43. We had access to the Healthcare Commission's review entitled *An analysis of private cosmetic surgery provision in England for the Chief Medical Officer Sir Liam Donaldson May 2004*. This was submitted to CMO on 2 September 2004. The remit of the review by the Healthcare Commission overlaps with the Terms of Reference of the Expert Group and it was helpful that a senior member of the Healthcare Commission sat on the Group. The Group benefited from the full text of the Healthcare Commission's review and relevant evidence from the review is included in this report. The main points are listed below:

- Cosmetic surgery lacks a contemporary definition. A more comprehensive definition would help regulate cosmetic surgery. More structured and dedicated training in cosmetic surgery as part of specialist training with enhanced accreditation arrangements is indicated. Current regulations exclude some cosmetic procedures such as botulinum toxin injections and remodelling fillers which do not require a surgical intervention.

- Compliance with specialty specific National Minimum Standards relating to cosmetic surgery and laser and intense pulsed light is extremely high across all service provider types (in the 2002-2004 review). However, the latter was only reviewed at larger acute hospitals as laser specific establishments were excluded from the Healthcare Commission's study report.
- Ninety-four percent of doctors in England, as identified by the Healthcare Commission, practicing cosmetic surgery as independent practitioners are on the GMC's specialist register. According to the information available, 72% are entered in the register in the specialty of plastic surgery. The remaining 22% are entered in other specialties, for instance general surgery. Independent facilities report that 6% of doctors are not on the specialist register (although they are on the GMC's ordinary register). It appears that facilities which only provide cosmetic surgery represent the lowest compliance in terms of doctors listed in the specialist register.
- Brokering (i.e. a person who acts on behalf of the consumer to match up price and types of service with the consumer's requirements) of service provided both within and outside the UK was an issue of concern. Such practices introduce a strong commercial element into the clinical relationship and would be considered unethical in any other area of clinical practice.
- There was insufficient regulation of cosmetic surgery advertising. Despite the manner in which the Advertising Standards Authority deals with complaints it receives, advertisements continue to be in breach of its code.
- In 2003/04 twenty-two complaints were received by the Healthcare Commission about cosmetic surgery and 16 of these related to laser treatments. Cosmetic surgery complaints accounted for 34% of all acute (private and voluntary healthcare) service complaints received (64 in total). Laser related complaints account for 25% of the total acute service complaints received. We considered that, given circumstances in which people might decide to complain to the Healthcare Commission, these figures were high and indicated cause for concern.

44. From the Healthcare Commission's review, the Expert Group particularly supports the recommendation for a risk based review of the provision of laser services (see para 20), and also that recognised specialist training in cosmetic surgery within specialist training should be established.

Medical Protection Society (MPS)

45. The Medical Protection Society (MPS) offers an indemnity for costs and damages to members for claims arising out of independent specialist practice. MPS has no data on claims against NHS employees which are managed through the NHS indemnity scheme.

46. MPS data can be used to calculate a relative reported claim frequency per member. If a general surgeon has a relative reported frequency of 1, a cosmetic surgeon has a

reported claim frequency relative to general surgery of 8.2. However, this must be considered with caution, as it does not take into account the differing amount of time devoted to private practice within respective specialties.

47. The MPS received over twice as many claims for cosmetic surgery as it did for general surgery, of which 70% were settled out of court.

Action Against Medical Accidents (AvMA)

48. AvMA did not provide any evidence of harm to patients but expressed concern in the following areas:

- Clarity of definition for what is included in the term 'cosmetic surgery', and better regulation of cosmetic treatments which may not be deemed to be 'surgery';
- Specific accreditation of surgeons specialising in cosmetic surgery;
- Clarity over who is regulating cosmetic surgery and their ability to prevent unregistered doctors from practising cosmetic surgery;
- Strict rules about advertising cosmetic surgery so that potential patients are not given false expectations; and
- Better patient information and support for potential and past cosmetic surgery patients.

Advertising Standards Authority (ASA)

49. The ASA only deals with advertising. Issues that relate to trading are outside its remit. The ASA reported that it receives complaints about advertising for cosmetic surgery on a fairly regular basis – to date this year nine complaints have been received on cosmetic surgery by the Authority.

50. Most complaints were about 'Botox' being advertised, which is illegal as it is a prescription drug (see para 17). Immediate action was taken by the ASA as a result of these complaints to prevent the advertisements re-appearing.

Public Attitudes

51. We wanted to know how aware the public was of the regulations applying to cosmetic surgery and what the public's view was of the need for regulation. The public's ability and willingness to protect itself from harm and the trust patients have in those providing treatment depend on their understanding of both professional self-regulation and standards, and the role of public institutions in protecting their interests.

52. We commissioned MORI to ask five questions as part of its regular omnibus survey to provide a snapshot of public awareness and attitudes. Results are based on interviews with 1,002 adults across Great Britain and are weighted to the known population profile. A summary of the results appears at Annex D.

53. The survey tells us that people are not particularly aware of the extent of regulation; 19% thought wrongly for instance that 'Botox' was regulated, while 41% thought wrongly that invasive cosmetic surgery was not. Over three quarters (78%) of respondents thought that invasive cosmetic surgery should be regulated. When asked about the level of regulation appropriate for invasive cosmetic surgery 64% thought it should be the same as other surgery for medical purposes, 24% more tightly regulated and 9% less tightly regulated.

54. Over half those interviewed (56%) thought that it should be the responsibility of those seeking cosmetic surgery to find out about the qualifications and experience of the surgeon but others thought it was the responsibility, variously, of the hospital or clinic, the Department of Health, or the British Medical Association (BMA). Only 1% thought it was the responsibility of the Healthcare Commission.

55. We also wanted to know how knowledgeable people were about how and to whom they could complain in the event of problem with invasive cosmetic surgery or cosmetic procedure. There was wide variation in the response to this question. Nearly half (49%) would complain to either the hospital or clinic, the GMC, the Healthcare Commission, the surgeon who performed the surgery and/or the regulating body responsible. The remainder (51%) either did not know where to complain (23%), or gave another answer (28%). Other answers included a wide range of possible bodies or individuals, including the Department of Health, their General Practitioner, their local authority and their Member of Parliament.

56. Data from the MORI survey suggested that there is a need to raise awareness and understanding of how cosmetic surgery is currently regulated. There is low awareness that invasive cosmetic surgery is currently regulated, and a widespread feeling that the patient should be responsible for checking the qualifications of cosmetic surgeons. The Group has made recommendations for public education about the qualifications and experience of those providing cosmetic surgery and the regulation of it.

Recommendations

Our recommendations fall into three categories:

- Professional training, development and accountability
- Non-surgical cosmetic procedures
- Public education

Professional training, development and accountability

Recommendation 1
That cosmetic surgeons working in private practice and undertaking cosmetic surgery, with exemption from being on the Specialist Register by virtue of working in the sector prior to April 2002, ensure that their independent professional appraisal and validation process includes a strong demonstrable component of peer review of their clinical procedures case work. This would be in addition to the requirements on them under National Minimum Standard A4.2.

Recommendation 2
That all cosmetic surgeons and nurses provide to potential and actual patients details of their qualifications, registration, membership of professional organisations, and other medical training and education. The Certificate of Completion of Specialist Training (or equivalent) and to be enrolled on the Specialist Register of the GMC is the minimum qualification for surgical practice for surgeons who are not exempt under standard A4.2 of the Care Standards Act.

Recommendation 3
That training programmes for cosmetic surgery are evolved by each of the Specialist Advisory Committees (SAC) of the relevant medical and surgical specialities.

Recommendation 4
That the Healthcare Commission look at whether the standards relating to practising privileges for surgeons are adequate for contemporary clinical practice in cosmetic surgery.

Recommendation 5
That all persons who advise patients about cosmetic surgery should be doctors or nurses.

Non-surgical cosmetic procedures

Recommendation 6
That steps are taken to ensure that the law pertaining to the injection of botulinum toxins is more consistently adhered to; that is that the botulinum toxins are prescribed by a doctor, and administered by a doctor (or a nurse under direction of a doctor) for a specific patient.

Recommendation 7
That the facilities where botulinum toxins are injected be licensed with the Healthcare Commission and therefore subject to its regulations.

Recommendation 8
That dental practices undertaking private cosmetic dentistry[2], and other non-dental aesthetic procedures be brought within the remit of the Healthcare Commission.

Recommendation 9
That current legislation and regulation governing the use of lasers – that every facility defined in the legislation should be registered with the Healthcare Commission – are more consistently enforced. That laser procedures are overseen by a doctor and conducted by appropriately trained and qualified practitioners.

Recommendation 10
That the recommendation in the Healthcare Commission's report to carry out a risk based review of the approach to regulation of the provision of laser services is implemented.

Recommendation 11
That the classification of aesthetic fillers, whether they are medical devices or not, be reviewed to ensure that the regulations applying to filler products are clear and easily understood by patients and the public and bring all filler products within a consistent regulatory framework. Classification of fillers should include whether the fillers are permanent, semi-permanent or temporary.

Recommendation 12
That an investigation into the risks of transmission of blood-borne viruses and vCJD in filler products containing human tissue be conducted. If a risk is identified patient safety must be protected through licensing and regulation of products.

Recommendation 13
That temporary aesthetic fillers are only injected by a doctor or nurse, and that permanent and semi-permanent fillers are only injected by a doctor.

Recommendation 14
That the facilities where aesthetic fillers are injected be licensed with the Healthcare Commission and therefore subject to its regulations.

2 Cosmetic dentistry is defined as treatment that is not clinically necessary to secure oral health.

Public Education

Recommendation 15
That the information referred to in Recommendation 2 be published by the responsible practitioner and made openly available for patients and the public. This should be monitored by the Healthcare Commission, where practitioners fall within its regulatory framework.

Recommendation 16
That the Department of Health ensures that accredited, detailed advice and educational materials are available for patients and the public setting out what standards, registration and qualifications to expect and what questions to ask when considering cosmetic surgery.

Recommendation 17
That all organisations providing cosmetic surgery and procedures publish information for patients on treatments available, details of how to complain, their rights as a consumer and of other organisations which can provide help and advice. The monitoring of this should be included within the Healthcare Commission's regulatory framework for all registered organisations.

Recommendation 18
That all advertising for cosmetic surgery and publications by providers of cosmetic surgery include the provider's registration number with the Healthcare Commission.

Recommendation 19
That the General Medical Council improves the recording and classification of data about complaints so that comparisons can be made between different medical specialties and procedures.

Recommendation 20
That the GMC make information about specialty registration and qualifications held by doctors more clearly available to the public on its website.

Conclusion

58. Although there is no one authoritative source of evidence to show that significant harm is caused to patients by cosmetic surgery, evidence from numerous bodies, as related in this report, suggests that there are grounds for concern. Nearly all the consumer and professional bodies who contributed to our review expressed strong concerns and we were persuaded by the argument that those damaged by cosmetic surgery were often reluctant to complain. It is clear to us that greater openness on the part of doctors and other health professionals involved in cosmetic surgery about their qualifications and experience would help potential patients make informed choices. Furthermore, we felt that the Department of Health and the Healthcare Commission should take responsibility for ensuring that the regulatory framework and complaints procedures were widely advertised and understood.

59. We were particularly concerned about the off-licence use of botulinum toxins and their apparent use outwith the Medicines Act. We were also concerned about the apparent lack of regulation for permanent and semi-permanent aesthetic fillers and the extent to which laser treatments were performed in unregistered premises by practitioners who needed no qualifications.

60. We believe that the changes in practice and regulations which we recommend, while not onerous or excessive, will:

- raise standards in cosmetic surgery;
- improve patient safety;
- increase public awareness of regulation, treatments and their risks, and of how to complain; and
- enable potential patients to make more informed choices and better protect themselves from harm.

Annex A – Terms of Reference

To consider the appropriateness of the National Minimum Standards as they currently apply to those practising invasive cosmetic surgery in England and who were doing so before April 2002 and who are not on the specialist register; and to report to the Chief Medical Officer with proposals for administrative and/or legislative action necessary to ensure that arrangements are in place which can assure reasonable levels of safety and efficacy in cosmetic surgery and allied cosmetic practice.

In particular the group should:

1. examine the available evidence on the standard of care provided to patients undergoing cosmetic surgery;
2. advise on the acceptability or otherwise of outcomes in terms of the clinical quality of cosmetic surgery undertaken;
3. consider the quality of training available and the range of qualifications held by cosmetic surgeons;
4. advise on the strengths and weaknesses of the current inspection regime, including powers to take steps against establishments which are considered to be inadequate;
5. consider the available evidence in respect of the quality of care provided in cosmetic practice other than invasive surgery involving treatment of patients for cosmetic purposes (e.g. the small number of wholly private GPs currently regulated under the NMS);
6. consider the training and qualifications of clinicians involved in practices outlined at 5 above; and
7. make recommendations to the Chief Medical Officer by 30 July 2004 on whether the current regulatory framework is sufficiently robust to ensure satisfactory clinical outcomes in cosmetic surgery.

In undertaking this review it is important to recognise that the scope of the group is confined to ensuring satisfactory clinical outcomes and is not concerned with issues of value for money nor of qualitative complaints (i.e. about aesthetic perceptions of outcome). The Group must also take account of the views of the major stakeholders.

Annex B – Group Membership

Harry Cayton (Chair, Director for Patients and the Public, Department of Health)

Dr Andrew Vallance-Owen (Group Medical Director, BUPA)

James Partridge (Chief Executive, Changing Faces)

Marie Duckett (Fiona & Marie Aesthetics Ltd)

Mark Avery (Healthcare Commission, and formerly National Care Standards Commission)

Norman Waterhouse (President, British Association of Aesthetic Plastic Surgeons)

Dr Wendy Denning (GP, Integrated Medical Centre)

Dr Andrew Markey (Consultant Dermatological Surgeon, The Lister Hospital)

Zoë Lawrence (Department of Health)

Secretariat provided by Julian Oliver and Sarah Fisher-Mackey, Department of Health

Annex C – List of those who gave written or verbal evidence and a list of those consulted

Those who provided written or verbal evidence:

Professor Sir J G Temple – Chair, Cosmetic Surgery Inter-Specialty Group

Sue Freeman – Managing Editor, *Health Which?* Magazine

Jane O'Brien – General Medical Council

Danny Walsh – General Medical Council

Michael Polakov – Medi-Build Consulting International

Peter Walsh – Action Against Medical Accidents (AvMA)

Melanie Luzet – Policy Executive, Advertising Standards Authority

Dr Gerard Panting – Medical Protection Society

Valerie Smith – Royal College of Nursing

The following were contacted and invited to comment, as well as the 175 cosmetic surgery providers registered with the Healthcare Commission:

Ian Richardson and David Mills – Transform

The Executive/President – British Association of Cosmetic Surgeons (BACS)

Paul Philip – Fitness to Practice

A E B Giddings – The Federation of Surgical Specialty Associations

Greg Machin – Private Practical Group – British Medical Association

Prof Roland Blackwell – UCL Hospitals NHS Trust

Jeremy Strachan – Private Practical Group – British Medical Association

Stephen F Wall – British Association of Oral and Maxillofacial Surgeons

A F Marcus – British Association of Oral and Maxillofacial Surgeons

Jan Bamberry – Harley Medical Group

Val Gooding – BUPA

David Mobbs – Nuffield Hospitals

Angela Pyne – The Health Quality Services

Mr Stephen Collier – General Healthcare Group

Mary-Lou Nesbitt – Medical Defence Union

Dr David Costane – PPP Healthcare Group

Michael Earley – The Royal College of Surgeons

Michael A Hall – Prime Health Ltd

Prof Carol Black – Royal College of Physicians

Michael Ore – Surgicare

Lesley Murphy – The Association of Anaesthetists of Great Britain and Ireland

Sir Peter Morris – The Royal College of Surgeons of England

Finlay Scott – General Medical Council

Nick Stace – Consumers Association

Roger Goss – Patient Concern

Gareth Davies – Cleft Lip and Palate Association

Christine Piff – Let's Face It

Paula Leddy – National Centre from Cosmetic Surgery

The President – British Association of Dermatologists

Prof Nicola Rumsey – Centre of Appearance Research

Charles Auld – BMI Healthcare

British Association of Plastic Surgeons

Capio Healthcare UK

Annex D – MORI survey results

Q1. **I am going to read out some types of invasive cosmetic surgery and cosmetic procedures and for each one I'd like you to tell me whether or not it is currently regulated, as far as you know.**

Q2. **And now I'd like to ask you whether or not you feel each of those same things should be regulated, regardless of whether or not they are at the moment.**

	Q1. Currently Regulated			Q2. Should be Regulated		
	Yes %	No %	Don't Know/ No Opinion %	Yes %	No %	Don't Know/ No Opinion %
A) Botox injections – that is, injections under the skin's surface for reducing or removing wrinkles	19	57	23	69	25	6
B) Body changes involving surgery, such as cosmetic nose operations, breast enlargements or reductions	40	41	20	78	17	5
C) Removal of small skin blemishes and hair, by laser	34	41	25	73	22	5

Q3 **Now focusing on 'invasive cosmetic surgery' only, if you were to undergo invasive cosmetic surgery whose job, if anyone's, do you feel it should be to find out about the qualifications and experience of the surgeon who would perform the operation?**

Ranked	%
Patient	56
GP	16
Government/Dept of Health	12
The hospital/establishment where surgery taking place	10
The BMA (British Medical Association)	7
The GMC (General Medical Council)	3
The Royal College of Surgeons	1
The Healthcare Commission/CHAI	1
The surgeon	1
The consultant who makes the referral	*
Other	3
Don't know	7

Q4. **Do you feel that 'invasive cosmetic surgery' should be more tightly or less tightly regulated than surgery undertaken for medical purposes, or do you think the two should be regulated equally?**

	%
…Much more tightly regulated (than surgery for medical purposes)	18
…A little more tightly regulated (than surgery for medical purposes)	6
…Regulated equally (with surgery for medical purposes)	64
…A little less tightly regulated than surgery for medical purposes)	6
…Much less tightly regulated (than surgery for medical purposes)	4
More tightly regulated	24
Less tightly regulated	9
None of these	1
Don't know	3

Q5 **Now thinking about both 'invasive cosmetic surgery' and 'cosmetic procedures', if you were to undergo cosmetic surgery or cosmetic procedures and wanted to make a formal complaint following it, who, if anyone, would you complain to?**

Ranked	%
The hospital/establishment where you had the surgery	35
The BMA (British Medical Association)	14
The GMC (General Medical Council)	11
GP	7
Government/Dept of Health	7
The surgeon who performed the surgery	3
The Council/Local Authority	3
The Healthcare Commission/CHAI	2
My MP	2
Solicitor/Would seek legal advice	2
The Royal College of Surgeons	1
The regulating body responsible	1
Ombudsman	1
Trading Standards	1
Citizens Advice Bureau	*
Other	3
Don't know	23

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265816 *Expert group on the regulation of cosmetic surgery: report to the Chief Medical Officer* can also be made available on request in Braille, on audio cassette tape, on disk and in large print.

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