



Review of the Regulations of Cosmetic Interventions

*Summary of the responses to the Call for
Evidence*

Review of the Regulations of Cosmetic Interventions Summary of the Responses to the Call for Evidence

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Summary of the responses to the Call for Evidence

Prepared by the Department for Health

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Foreword

I was asked to lead the Review of the Regulation of Cosmetic Interventions in the aftermath of the problems with Poly Implant Prothèse (PIP) breast implants. The PIP scandal exposed some serious concerns about the products used in cosmetic procedures, the training of those performing them and the way in which people were treated when complications occur.

To help us gather data, views and experiences of how the current system works, we launched a Call for Evidence in August. The Review Committee and I have been delighted by the huge number of responses we received from the public, practitioners, providers and industry. The volume of responses indicates just how much interest and enthusiasm there is in ensuring that people are better protected when they choose to undergo a cosmetic procedure.

It's not always acknowledged that people undergoing cosmetic interventions are not only consumers but also patients. They are taking decisions about medical procedures that can have a profound impact on their health and wellbeing. The responses to the Call for Evidence send a clear message that the current regulatory framework doesn't do enough to support consumer rights or patient safety. The supply and demand for procedures in this fast-growing sector has outgrown the existing legislation around the products used, the people providing treatments, and the information and advice available to the public.

Over the next few months we'll be using information gathered from the Call for Evidence alongside our engagement with the sector to formulate our recommendations. I hope what we propose will deliver a cosmetic interventions industry that will lead the world in terms of patient care without stifling consumer choice.

A handwritten signature in black ink that reads "Bruce Keogh". The signature is written in a cursive style with a long horizontal line extending from the bottom of the 'g'.

Sir Bruce Keogh

NHS Medical Director

Executive summary

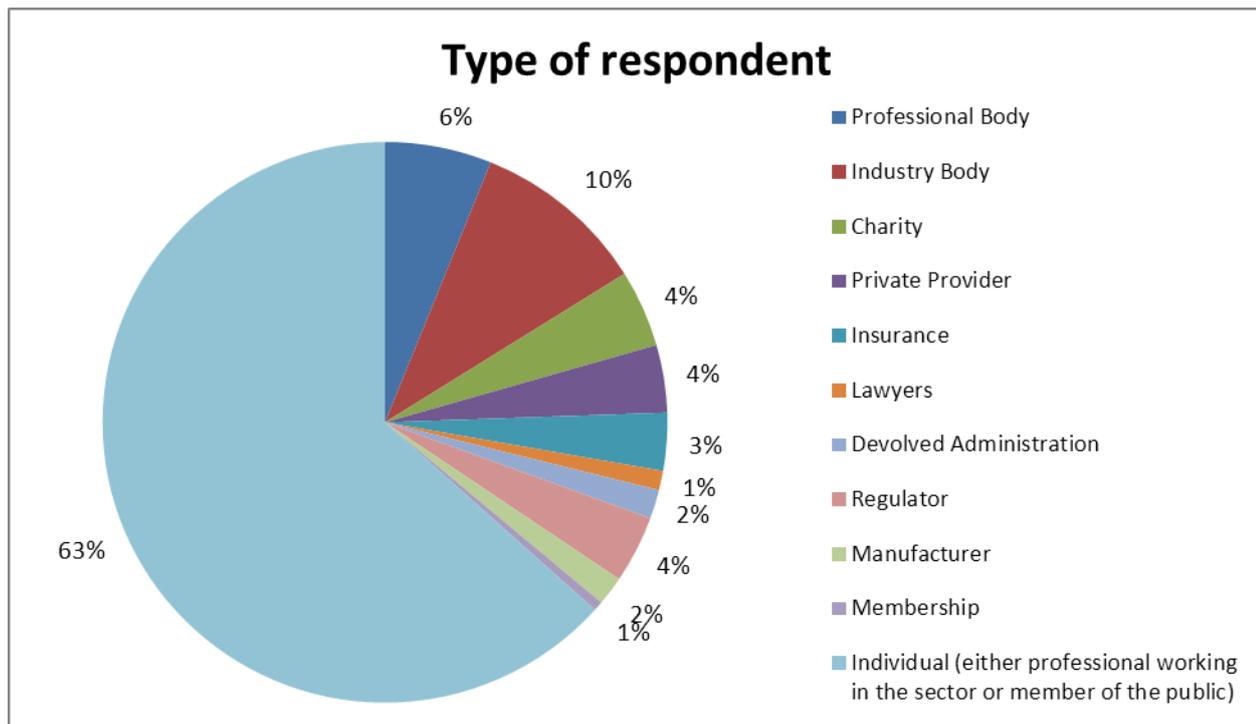
This report summarises the responses submitted to the Call for Evidence.

We conducted the Call for Evidence to help us gather the views, expertise and insights of those involved in the cosmetic interventions sector and the public. We asked a series of questions about the way the current regulatory system functions - these are available at Annex A. The Call for Evidence was launched on August 15th 2012 and closed on October 15th 2012.

We received over 180 responses to the Call for Evidence from a wide range of individuals and organisations.

A full list of all the organisations who responded is at Annex B.

Figure 1: Type of Respondent



The report

We have analysed the responses and this report presents the key messages from respondents thematically.

The summary of responses is not intended to present an indication of the Review Committee's emerging recommendations; it is a summary of external views that feeds into the committee work.

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This report cannot cover in detail all the responses to the questions we asked or reflect all the perspectives put forward. However, all responses have been analysed in depth and the data and evidence supplied will be used to inform our recommendations.

Key messages

While we had a wide range of responses and heard a variety of views on the future regulation of cosmetic interventions, some consistent key messages emerged from respondents:

- Respondents felt that the review was timely and an important part of restoring public trust in the cosmetic interventions sector following the issues with PIP breast implants
- Many felt that the current regulatory framework was inconsistent and did not reflect the many changes and innovations in such a fast-growing and dynamic sector
- Training requirements were felt by many to be disproportionately weak compared to the potential risks of a procedure and more specialised training was welcomed
- Dermal fillers and Intense Pulsed Light (IPL) and laser procedures were highlighted by many as an area where there was insufficient legislation to protect the public
- Respondents were concerned about the lack of data being collected on implants, procedures, adverse incidents and outcomes

There were also some consistent themes or principles that respondents highlighted as being essential components of any new regulatory system. These were:

- Information and advice;
- Safety and quality; and
- Transparency and accountability.

Next steps

The Review Committee Secretariat has been meeting with a range of individuals, practitioners, providers and organisations to gather further evidence and explore in depth some of the issues around regulation in this area.

We have also conducted research into public attitudes towards the regulation of the industry.

We will use all the information, data and evidence gathered over the last few months to help develop recommendations for the final report.

1. Information, consent and advertising

Key messages

- A large number of responses suggested that standardised, evidence-based patient information should be provided to anyone undergoing a cosmetic procedure
- Respondents indicated that consultations should be with the person performing the procedure, or at the very least should be with a medical professional rather than a sales adviser
- Almost all responses submitted supported a two-stage consent process for surgical procedures
- Most respondents felt the current use of psychological assessments to be sufficient
- The majority were in favour of tighter restrictions on the advertising of cosmetic interventions
- There was very strong support for the banning of financial inducements or time-limited deals promoting the sale of cosmetic interventions

Information

- 1.1. There was strong support amongst responses for written, standardised information to be given to patients to support a personalised discussion about the procedure between the patient and the practitioner. It was suggested that this material should contain evidence-based data on recovery times, products used, risks and outcomes. Some thought that photos could be included to demonstrate likely outcomes, for example the extent of bruising that should be expected. Some respondents also wanted standardised information to include details of the professional standards their surgeon or practitioner was expected to meet, and therefore what standard of service the patient was entitled to and should expect, and whether the practitioner had insurance or indemnity cover. It was suggested that the patient should receive a copy of this information to take home, as well as a copy being retained by the provider, as a record of what was covered in the patient consultation and what was agreed between the patient and practitioner. Generally, it was felt that the Department of Health or a similar body should oversee the production of this standardised information, working with appropriate professional bodies, and helping ensure it is made available to the public and providers.

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- 1.2. Patient consultations provoked a lot of comment. There was a strong sense that consultations should be with the person performing the procedure, or at the very least should be with a medical professional rather than a sales adviser. Some respondents suggested there should be a set duration for patient consultations, to allow for a thorough discussion of the risks and likely outcome, and including an exploration of the patient's motivation for surgery and their expectations from it. Brief consultations with sales staff that may be driven by the need to meet sales targets were generally considered to be unacceptable and not in the patient's interests.
- 1.3. Some respondents were in favour of banning free consultations on the ground that these are used as enticements for patients who will then be overly encouraged to book a surgical procedure. It is important that the consultation process is considered as an opportunity to explore the pro and cons of surgery, without pressure or encouragement to proceed to surgery. Concerns were raised regarding the practice of providers who charge non-refundable deposits after the consultation, it was felt that this effectively "signed patients up" to their procedure without giving them the time to reflect on the consultation, and take the time required to make what is frequently a complex decision.

Consent

- 1.4. Nearly all respondents supported a requirement for a two-stage written consent process for surgical procedures. There was a high level of support for a standardised consent process supported by a standardised form. This was considered to be essential for patients to be fully informed of the risks and outcomes of a procedure, and have time to reflect before making a decision. The majority of respondents supported a two-stage process for non-surgical procedures too, although some felt this could take place over a shorter time period than for surgical procedures. A minority felt a two-stage process was not necessary for non-surgical procedures or in line with what consumers expected.
- 1.5. There were concerns that where consultations were carried out by sales advisers or non-health professionals, the patient could not be sufficiently informed to give proper consent, free of financial considerations.

Psychological assessment

- 1.6. Most respondents acknowledged the importance of the practitioner making an assessment of the patient's motivation for seeking a cosmetic procedure. However, the majority of respondents considered the current use of psychological assessments to be sufficient. Surgeons, doctors and nurses tended to feel that they receive sufficient training on this and would be able to identify any patient that needed to be referred on for a more formal psychological assessment. Some called for a standardised psychological assessment tool to be used by surgeons where they feel that a patient

may need to be referred on for a formal psychological assessment. Those in favour of a psychological assessment for every patient tended to be patient groups, charities, and some surgeons.

- 1.7. Many respondents felt that a formal psychological assessment should not be needed for patients seeking non-surgical or minimally-invasive procedures.

Advertising

- 1.8. The majority of respondents were in favour of tighter restrictions on the advertising of cosmetic interventions. The proliferation of advertising for cosmetic surgery and its use in TV make-over programmes was felt to trivialise surgery and its risks, while making excessive claims of its impact on people's emotional wellbeing. The fact that cost is the primary factor for people's choice of provider, rather than quality or safety, was seen as a direct consequence of this trivialisation. [Department of Health. *Major review into cosmetic procedures launched*. <http://mediacentre.dh.gov.uk/2012/08/15/major-review-into-cosmetic-procedures-launched/> (accessed 19 December 2012)].
- 1.9. A range of approaches to the regulation of advertising were suggested which addressed the amount, content and vehicle.
- 1.10. A range of options were favoured by respondents. Some supported an outright of all advertising of cosmetic interventions to bring their advertising in line with that of prescription medicines. They felt that there is inconsistency between the regulation of advertising of prescription medicines and medical devices or implants. For example, implants are surgically inserted into the body, therefore requiring an invasive surgical procedure, so they could be considered to pose a higher risk to the patient than many medicines. Others raised the inconsistency with regard to surgery, which, as a medical procedure requiring anaesthetic, and with inherent medical risks, should be subject to the same level of advertising controls as prescription medicines.
- 1.11. Others felt a 'co-regulatory' system to policy advertising practice was more appropriate. This would allow referral of non-compliant providers to a statutory regulator such as Ofcom. There was some confusion as to the status of current voluntary guidance or codes of practice for advertising cosmetic interventions, proposed by industry or professional bodies, indicating a possible need for a single set of clearer, sector-wide standards.
- 1.12. Some respondents raised concerns that the current restrictions are inadequately enforced, for example the ban on advertising of prescription-only medicines with regard to botulinum toxin injection products such as Botox®, and the requirement in the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP) help note on cosmetic surgery marketing for marketers to hold evidence of the professional's qualifications. Some suggested the need for sanctions

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for those providers, be they individuals or organisations, infringing these codes or other professional regulations. Many were concerned that online and social media advertising was very difficult to monitor or police but was increasingly widespread. Some respondents suggested that any new approach to advertising in this sector would need to find an enforceable way to address this area.

- 1.13. A small minority of respondents considered the current regulation of advertising to be sufficient but that the regulations were inadequately enforced. Some respondents felt that advertising is a legitimate and important source of information for the public on the range of cosmetic interventions available and were concerned that should all advertising be banned, the public would struggle to find sufficient, appropriate information.
- 1.14. There was very strong support for the banning of financial inducements or time-limited deals promoting the sale of cosmetic interventions. They were seen as unethical, placing undue pressure on the patient and emphasising price rather than quality, thereby reinforcing the image of cosmetic interventions as commodities rather than medical procedures with a cosmetic application.

2. Regulation of Practitioners

Key messages

- The majority of respondents felt there needed to be a change in the training, revalidation and accreditation of professionals to prevent them from operating outside of their area of expertise
- Some respondents felt that the title of 'surgeon' should be protected
- The issue of whether non-healthcare professionals should be able to administer injectables was split, but the majority of respondents felt that the key issue was training, for both healthcare and non-healthcare professionals
- A majority felt that the training of those who administer laser and IPL treatments needs to be looked at to ensure that it is appropriate
- Virtually all respondents felt that good record keeping was an essential part of patient care, and practitioners had a responsibility to ensure that this was done

Healthcare professionals

- 2.1. There were concerns that current requirements for practicing cosmetic surgery were insufficient. Many felt that the system allowed those with medical training but no experience in cosmetic interventions to conduct procedures in which specialist training should be required.
- 2.2. Some felt that such training should be offered as a part of Higher Specialist Training and be the responsibility of the relevant professional associations.
- 2.3. Providers highlighted the range of methods they used to assess whether someone currently had enough training. Several respondents pointed out that for those operating in smaller or independent set-ups there was not necessarily the same oversight of surgical training and outcomes partly due to a lack of clear national professional standards.

Surgical specialty register

- 2.4. The majority of respondents felt that the creation of a specialist register for cosmetic surgery, with the relevant training that it involves, was a good idea. However, some respondents felt that this was misleading and that the real issue revolved around making sure that the surgeon had the appropriate training and skills. Several respondents suggested that a Royal College or Specialty Association could be set up

to oversee the additional training. Some respondents also called for the title of 'Surgeon' to become protected.

- 2.5. Some respondents felt that the existing plastics specialty register did not offer guarantees of good practice, and that doctors not on the specialist register were still able to routinely offer patients a safe, effective and appropriate service in a primary care or non-specialist setting, for example vasectomy, carpal tunnel surgery and skin cancer surgery by GPs with a special interest (GPSIs).

Revalidation

- 2.6. Most respondents felt that the industry would benefit from the introduction of revalidation for medical professionals and that it had a role to play in creating a culture of better clinical governance and raising standards.
- 2.7. A few responses expressed concerns that the requirements around revalidation were not targeted or specific enough to ensure good practice so should not be seen as a solution to improving cosmetic interventions practice in isolation.

Administration of dermal fillers, botulin toxin injections, chemical peels and other non-surgical cosmetic interventions

- 2.8. Views on the required training for practitioners administering injectables and other non-surgical cosmetic interventions were highly divided. There was a pronounced split in respondents as to whether this should be open to anyone who had completed the necessary training, just healthcare professionals, or just doctors. This tended to be consistent with the respondents' own background or affiliation. Some of those who felt that injectable treatments should be restricted to healthcare professionals thought that additional training should still be required. There were concerns that not all healthcare professionals' training meant that they had a good understanding of facial anatomy and the possible complications of procedures. Therefore, further specialist training and experience was required.
- 2.9. Those respondents who felt that a medical qualification was not essential, thought that the training should be thorough, and the practitioner should be trained to deal with any complications which might arise.

Intense Pulsed Light (IPL) and laser treatments

- 2.10. Some respondents felt that these procedures should only be carried out by a medical professional unless the equipment was restricted to very low levels, although again this was a divisive issue.

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- 2.11. However, most respondents felt that the training and accreditation of professionals administering these treatments varied enormously and a minimum standard of training should be introduced for practitioners administering them.

Accredited training and registers

- 2.12. There was widespread support for accredited training courses for these procedures that any practitioner should be obliged to attend. Many felt that the courses on offer currently differed greatly in terms of quality and content.
- 2.13. Opinions on who should offer accredited training were mixed and again tended to be based upon the respondent's affiliation or background, although for some procedures there was a greater consensus on who the lead body should be.
- 2.14. Some respondents wanted to see registers introduced for those who had completed appropriate accredited training. Furthermore, some felt that this should be a compulsory register, with only those on it allowed to perform procedure.

3. Regulation of Providers

Key Messages

- Virtually all respondents believed private providers of cosmetic interventions should meet the quality and safety standards expected of the NHS
- The majority of respondents believed all providers should be keeping records of all devices and implants they use, with a large section seemingly surprised this is not common practice, or indeed mandated. The recording of key data was popularly seen as an important aspect of protecting patients and crucial in alerting the public to issues with devices and implants
- Most respondents believed providers should be required to audit their processes and ensure their practitioners take part in clinical audit. Audit was seen by the majority to be an efficient and necessary part of best practice that helps highlight problems earlier and enables provision to evolve and improve
- Most respondents believed there should be clearer legal requirements to place a duty on providers to provide aftercare where a patient is harmed as an unexpected consequence of a procedure

Standards

- 3.1. The majority of respondents believed standards of safety and quality in private practice should, at the very least, meet those expected of the NHS. This partly reflected a belief that patients expected standards to be higher in private practice because of the monetary value and financial connotations compared to treatment on the NHS.
- 3.2. There was a small group of respondents that did not think private providers should be required to meet NHS standards as they believed that there are currently higher standards in private cosmetic intervention providers.
- 3.3. A large section of respondents, generally members of the public, expressed the view that, irrespective of the type of provider, they expected procedures to be delivered to the same set of standards and protected by the same safeguards.
- 3.4. For the majority of respondents, the current Care Quality Commission (CQC) model was seen to be effective, with registration of the CQC seen to ensure providers and their practitioners adhere to clear standards. However, there were a number of respondents who held some reservations over the effectiveness of the CQC, noting that unannounced inspections needed to be carried out regularly and by those with the appropriate knowledge and training in cosmetic surgery.

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- 3.5. A small group of respondents also highlighted that CQC registration is not a guaranteed fix, stating the 'good', compliant, clinics would continue to perform well, but a section of 'rogue' providers would continue to put patients and the public at risk.
- 3.6. There were also concerns about the lack of provider regulation for those providing non surgical cosmetic interventions such as laser treatments and injectables, as these are no longer subject to CQC registration. Some respondents felt that registering with a regulator gives the provider and practitioner a certain level of credibility or trustworthiness and safeguards high standards and a high quality of care. There was a sizable section of respondents who felt these premises should be brought back under the auspices of the CQC.
- 3.7. However, others noted that the CQC is not as well placed to perform these inspections as some suggest, highlighting Local Authorities could, and indeed some stressed should, continue to monitor facilities offering laser and IPL treatments. These respondents believed that Local Authorities, whilst possibly needing more resources and impetus, could continue to monitor these providers through rolling out the Council Special Treatment Licence scheme or using the Local Government Miscellaneous Provisions Act (1982) which could provide an effective way of policing the non-surgical end of the industry.

Requirements to provide aftercare

- 3.8. A clear majority believed clearer legal requirements on the provision of aftercare were needed. These respondents noted that many of these procedures are medical procedures and not just beauty treatments; aftercare is therefore part of the practitioner's duty of care to the patient.
- 3.9. A large group of respondents also had concerns over the differing standards between the NHS and private providers and stressed the importance of ensuring the duty of care remains the same in both amid fears of creating a two-tier system. Some went further in stating the importance of matching standards in both private care and the NHS to stop the instances where the NHS acts as a safety net for the substandard practices of some private providers.
- 3.10. The timeframes suggested for the provision of aftercare varied dramatically. Overall, the majority believed it should be procedure specific with a general tendency to differentiate between non-surgical and surgical. The more popular suggestions for dermal fillers were for anything from 24hrs to 6 months. For surgical procedures, the majority suggested aftercare should last anything from 1 month to 5 years; the lifetime of the device inside a person's body; or for the period the patient is still at risk from complications and side effects resulting from the procedure.

- 3.11. Some respondents highlighted the possible difficulty in regulating aftercare in regards to out-patient and day care centres who would not be able to provide a 24hr service. A small number of responses also referred to the problem of 'fly in - fly out' surgeons who are not always available for follow up treatment, aftercare, or, in some instances, even a telephone call.

Clinical audit

- 3.12. The majority of respondents believed that private providers should be required to audit their processes and ensure their practitioners take part in clinical audit. A large amount of responses, mainly from healthcare professionals, seemed concerned that those in private settings did not audit to the extent of the NHS and were surprised the issue had not been addressed previously.
- 3.13. A number of respondents outlined audit as being a crucial part of best practice, and part of the health professional's obligation of duty of care to the patient. A number of responses highlighted the need for audits to be mandated and published, with several suggesting an industry body, royal college or newly founded independent body should be overseeing and assessing them as part of the revalidation process. One response emphasised the regulatory merits of including audit as a mandatory part of insurance compliance and the effect this may have in addressing levels of competency.
- 3.14. Overall, there was a consensus that regular audit would help providers to maintain standards, evaluate work, flag up reoccurring problems, help streamline work processes and highlight problems and issues earlier or, hopefully, before they occur.

Audit outside of clinical settings

- 3.15. The vast majority of respondents believed that providers of non-surgical cosmetic interventions delivered in non-healthcare settings should be required to audit their processes and ensure that all practitioners take part in clinical audit.
- 3.16. However, a large group of respondents, mainly from a medical or industry background, also stated that while they agree non-healthcare professionals working outside of healthcare settings should be required to audit their processes, they do not believe that non-healthcare professionals should be administering these procedures. The majority of these respondents also stated that these procedures, regardless of the level of training or qualifications of the person carrying it out, should not be administered outside healthcare settings.
- 3.17. Of the respondents who did not believe providers should be required to audit their processes, the main reasons revolved around the ability of non-healthcare

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professionals to perform a detailed audit as well as issues around what, if anything, can be taken from poorly executed audits.

- 3.18. In all, there was popular belief that engagement in audit encourages the evolution of best practice and should be routinely carried out in every aspect of healthcare and cosmetic interventions.

4. Medical devices, implants and other products

Key Messages

- The current regulation of fillers was felt to be inadequate and tighter regulations were needed in terms of both the safety and administration of the product
- Many felt that all implants and fillers should be classified as devices and subject to greater scrutiny
- The majority of respondents felt that greater regulation of lasers and light treatments was needed given the potential risks to consumers

Fillers

- 4.1. There was strong support for tighter regulation for fillers used in cosmetic interventions. Most respondents felt that those not currently treated as a medical device, because they only had cosmetic and not medical applications, should be reclassified as devices. It was suggested that this could be done through revisions to the EU Medical Devices Directive but some felt something needed to be done sooner and that the Government should act to reclassify them as prescription only medical devices.
- 4.2. Some respondents also called for manufacturers to be required to tell the Medicines and Healthcare products Regulatory Agency (MHRA) or Notified Body when they brought a new filler product to market in the UK to help ensure better surveillance of product safety. Some responses suggested that new devices should be subject to the same surveillance processes as new medicines through the MHRA 'Black Triangle Scheme'.
- 4.3. Responses all agreed that those administering fillers should be required to have some kind of accredited training but there were differing views about whether the administration of them should be restricted only to certain healthcare professionals, all healthcare professionals or all those who have undertaken accredited training.
- 4.4. There were concerns that any legislation in this area would need to keep pace with new and emerging procedures such as 'vampire facelifts' or injectable stem cell treatments.

Implants

- 4.5. Responses for the most part agreed that all implants should be regulated as medical devices. Some mentioned the use of decorative implants to create unusual body shapes or display jewels etc should also be regulated as they carried additional risks and were often overlooked.

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- 4.6. The existing regulation for medical implants was felt by most to be suitable but there were concerns over how the CE marking system was monitored. Some felt that post-market surveillance needed much greater emphasis.

Lasers and lights

- 4.7. The regulation of laser equipment was felt to be inconsistent and not in line with the possible risks of improper use. For many, the growing popularity of these treatments increased their concerns about unscrupulous or ill-trained providers springing up to take advantage of consumer demand.
- 4.8. There were concerns that laser and light treatment providers were no longer regulated by the CQC and some respondents felt that there had been an increase in adverse incidents (mainly burns) as a result. Trading Standards and Environmental Health officers do inspect some premises but resources make it very difficult for this to be a priority and some highlighted that the nature of such inspections were better suited to a healthcare regulator.
- 4.9. A large number of responses suggested that accredited training for practitioners should be made mandatory. Some noted that insurers had withdrawn cover for beauty and dental therapists due to concerns about risks. Most responses said that performing laser and light treatments didn't need to be restricted to medical professionals only.

5. Data and registries

Key messages

- Improving data collection and the reporting of adverse incidents should be a priority for the review
- There were concerns about the current standard of record keeping and the risks of patient records being lost or difficult to locate when there were problems
- Device registries were widely supported and most respondents felt that manufacturers and providers should share the cost of these. However, there were differing opinions on scope and administration

Data collection and adverse incident reporting

- 5.1. There was very strong agreement on the importance of proper records being kept on any cosmetic intervention performed. Many said that this was vital for insurance requirements. There were some who suggested that there needed to be clearer guidance on how long records were kept because adverse incidents could occur a long time after the initial procedure.
- 5.2. The lack of data on the number of procedures taking place was felt to be a crucial issue for many in establishing a 'denominator', which was needed to understand the scale and level of reported incidents.
- 5.3. Reporting of adverse incidents to the MHRA was seen as a weak spot for many in the current system. Some suggested that providers and practitioners were not aware of the process or the role of the MHRA. Possible solutions suggested were including information about adverse incident reporting in any practitioner training, and greater clinical engagement by the MHRA. Some responses suggested that new devices should be subject to the same surveillance processes as new medicines through the MHRA's 'Black Triangle Scheme'.

Device registries

- 5.4. The vast majority of respondents believed that providers should be required to ensure records of the implants and devices they use are kept. There was a broad section of respondents who seemed generally surprised this was not mandated, or, at the very least, a common part of best practice, and believed it to be not just desirable, but essential.

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- 5.5. A large group of respondents believed information on implants should be stored electronically as part of a register with track and trace capabilities, while other respondents suggested each patient should be issued with a 'device passport' containing all the relevant details of the implant or device and procedure.
- 5.6. The majority of respondents also felt that a breast implant registry should be re-established, with funding coming from a levy on each implant for manufacturers that may be partly shared by providers in purchasing these implants. Some acknowledged that these costs would be passed downstream to patients with some responses even suggesting that only the patient pay an additional sum to fund a registry. A number of respondents believed a breast implant register should be extended to all devices and implants, inclusive of fillers. There were differing views about whether providers or manufacturers should bear the cost and over who might manage and oversee them.
- 5.7. There was also a distinct trend in respondents stating concerns over some of the lower end clinics providing reliable and accurate data, and the issue of data being lost in the event of businesses closing down. Many of these respondents used this as further evidence for the need to set up an implant register.
- 5.8. Suggested periods for keeping device and implant records varied from 2 years to indefinite, with 10yrs and the projected lifetime of the implant or device being the most common responses. Others included the timeframe the patient is advised a replacement would be needed; the length of time the device or implant is in the person's body; or, the whole period where complications resulting from the procedure are still a risk to the patient.

Patient Records

- 5.9. Responses on this subject varied considerably, although most agreed that patients should be able to access any health records and records related to their cosmetic procedure. Some respondents, generally GP's and healthcare professionals, highlighted access to health records are in fact governed by the 'Access to Health Records Act (1990)' and the 'Data Protection Act (1998)' meaning access should not be, and is not, a problem.
- 5.10. Many responses pointed out that there are times when patients should be able to access their notes quickly and easily. The PIP crisis highlighted that certain clinics were slow to retrieve notes or had lost them altogether. A large number of respondents felt a written request for records with set time frames for responses, such as the 12 day standard, should be adopted. Other respondents believed the patient should be given a copy each time they see a practitioner and essentially hold and build their own complete medical records.

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- 5.11. The majority of respondents also stressed the importance of confidentiality and the need for any new systems introduced to ensure data is accessible but safe.

6. Indemnity and Insurance

Key points

- Very little scope in the current system for people who have had a procedure to seek financial redress when things go wrong
- Most responses suggested that all practitioners should have liability insurance that provided cover appropriate to the risks of any procedure
- Many felt that providers should also have cover, which included ensuring that patients could still claim if they went out of business
- There was support for the introduction of a bond-scheme for device manufacturers.

Protection

- 6.1. Many noted that currently there were very few avenues of financial redress for those who had encountered negligent treatment whilst undergoing a cosmetic intervention.
- 6.2. The example of the PIP breast implant scandal was frequently cited by respondents as an example of how difficult it was for patients to get compensation and the failure of existing liability arrangements to deliver.

Practitioners

- 6.3. The majority of respondents felt that anyone performing cosmetic interventions, including non-healthcare professionals, should have liability insurance. All medical professionals in the UK will be required to have insurance or other arrangements 'appropriate to the nature and extent of the risk' in place by October 2013 as part of the implementation of the EU Patients' Rights in Cross Border Healthcare Directive.
- 6.4. Some responses highlighted the difference between claims-made and occurrence based liability arrangements, noting that claims-made insurance only paid out if the policy was in place at the time of the incident and at the time of the claim. Individuals may need to purchase run-off cover to ensure that they still have insurance after the policy ends. Conversely, occurrence-made cover means that provided insurance was in place at the time of the incident, all future claims are covered, regardless of whether there is a policy in place at the time of the claim. This means that if an individual is no longer practicing or has taken a break in their insurance, an individual is still able to pursue them for a claim. However, occurrence-made cover was expensive to establish and some felt an unsustainable option.

- 6.5. Many suggested that if liability insurance for practitioners was to be made mandatory, the Government would need to specify the nature and extent of the cover to avoid confusion.

Providers

- 6.6. There were concerns that there were scenarios in which the nature and extent of practitioners cover would not cover the circumstances of a possible patient claim. These included:
- Problems with the product used in a procedure
 - Practitioner not having cover or adequate cover
 - Practitioner having retired, died or being untraceable
 - Incident being caused by problems with provider facilities, follow-up or advice
- 6.7. Some suggested that an ABTA type bond, taken out by insurers, might act as a safety-net in these situations and also enable patients to still pursue financial redress if a provider went out of business. There were mixed views on whether this type of provider cover should be bond or whether providers could be required simply to have in place sufficient financial arrangements to cover any liability claims. Equally, respondents were unsure whether this should be mandatory and linked to CQC registration or simply good practice.

Manufacturers

- 6.8. There was general support for manufacturers to set up a ABTA-type bond scheme to cover device failure. Many thought this could be funded through a small levy on each implant with the cost borne by the provider, although most accepted that this would be passed downstream to patients.

7. Conclusion

- 7.1. The Review Committee are grateful to all those who responded to the Call for Evidence. The amount and range of the responses received reflects both the broad scope of the review and the large number of interested parties in this area.
- 7.2. We will be using the responses to the Call for Evidence to help inform and develop recommendations. We will be considering how our emerging proposals can support the themes of information and advice; safety and quality; and, transparency and accountability that were identified by respondents.
- 7.3. We're keen to keep engaging with all those who contributed and continue to welcome evidence. We're particularly keen to get quantitative data from providers, insurers, manufacturers and professional organisations. We'd also welcome any personal experiences of cosmetic interventions. You can contact the Review via cosmeticinterventionsreview@dh.gsi.gov.uk
- 7.4. The Review will report in March with recommendations.

8. Annex A

List of Call for Evidence Questions

1. What are the risks and benefits presented by dermal fillers?
2. What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?
3. Are any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out in section two of the call for evidence?
4. Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?
5. Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can health providers, professional bodies, regulators and patient groups promote the best possible understanding of the role of the incident reporting system and ensure that professionals in particular understand what they have a duty to report?
6. Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, i.e. be on the Specialist Register?
7. Currently 'cosmetic surgery' is not recognised as a specialty for which doctors can train and achieve a Certificate of Completion of Training (CCT) leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for 'Cosmetic Surgery' or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?
8. Do people who deliver cosmetic interventions like fillers, Botox®, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?
9. Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can medical revalidation be used to promote this?

**Review of the Regulations of Cosmetic Interventions
Summary of the Responses to the Call for Evidence**

10. Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?
11. Is it right that private providers of cosmetic surgery meet the standards expected of the NHS?
12. The CQC registration requirements place a duty on providers to protect their patients from unsafe treatment, but it is not clear how far this extends in the private sector to providing appropriate after-care where a patient has suffered harm as an unexpected consequence of treatment. Do we need to impose a clearer legal requirement on registered organisations to provide after-care to their patients? If so, for how long after the original treatment?
13. Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?
14. Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?
15. Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?
16. Should providers be required to ensure that records are kept on the implants and devices they implant? If so, for how long?
17. Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?
18. How could cosmetic surgery organisations make it easier for patients to access their health records?
19. What can be done to protect patients if their provider goes out of business?
20. What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?
21. Should providers be required to carry out a two-stage consent process (i.e. allowing a 'cooling-off' period between consultation and surgery)?
22. Do you think the existing regulation of the advertising of cosmetic interventions is proportionate?

**Review of the Regulations of Cosmetic Interventions
Summary of the Responses to the Call for Evidence**

- 23.** Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?
- 24.** What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?
- 25.** How could a national implant registry be set up and funded? Which treatments should it cover? Should participation be a statutory requirement for providers? Should patients have the right to opt out of having their information recorded?
- 26.** Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification eg tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

9. Annex B

Call for Evidence respondents

- 9.1. Due to confidentiality, this list of respondents is not exhaustive and only includes responses clearly submitted on behalf of an organisation, company or charity. All responses from individuals and members of the public will not be published but will be fed into the review.

Organisations

Academy of Aesthetic Excellence (AAE)
Academy of British Cosmetic Practice (ABCP)
Advertising Association (ADASSOC)
Advertising Standards Association (ASA)
Association of Aesthetic Healthcare Professionals (AAHP)
Association of Aesthetics, Injectables and Cosmetics (AAIC)
Association of Breast Surgery (ABS)
Association of British Healthcare Industries (ABHI)
Association of Dental Implantology (ADI)
Association of Laser Safety Protection (ALSP)
British Association of Aesthetic Plastic Surgeons (BAAPS)
British Association of Beauty Therapy and Cosmetology (BABTAC)
British Association of Cosmetic Nurses (BACN)
British Association of Dermatologists (BAD)
British Association of Oral and Maxillofacial Surgeons (BAOMS)
British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS)
British College of Aesthetic Medicine (BCAM)
British Dental Association (BDA)
British Medical Laser Association (BMLA)
British Standards Institute (BSI)
Care Quality Commission (CQC)
Chartered Institute of Environmental Health (CIEH)
Cosmetic, Dermal, Botulinum, Aesthetic & Fillers Inspectorate (cdBAFI)
Professional Standards Authority (PSA), formerly the Council for Healthcare Regulatory Excellence (CHRE)
General Dental Council (GDC)
General Medical Council (GMC)
Hair and Beauty Industry Authority (HABIA)
Health and Care Professions Council (HCPC)
Independent Healthcare Advisory Services (IHAS)
Institute of Physics and Engineering in Medicine (IPEM)
Nursing Midwifery Council (NMC)
Royal College of Gynaecologists (RCOG)
Royal College of Nurses (RCN)
Royal College of Ophthalmologists (RCOph)
Royal College of Surgeons (RCS)
Society for Radiological Protection (SRP)

Review of the Regulations of Cosmetic Interventions Summary of the Responses to the Call for Evidence

UK Feminista
United Kingdom Accreditation Service (UKAS)

Devolved Administrations

Welsh Devolved Administration
Chief Dental Officer, Wales
Chief Medical Officer, Scotland

Providers

Head2Toe Holistic
Make Yourself Amazing (MYA)
Mapperley Park Clinic
Nuffield Helath
Oris Medical
The Hospital Group
Transform

Pharmaceuticals

Healthxchange

Legal

Claimant Product Liability Solicitors' Group
The Dental Law Partnership Solicitors Ltd
Freethcartwright
Radcliffes Le Brasseur

Insurers

BUPA
Medical and Dental Defence Union of Scotland (MDDUS)
Medical Protection Society (MPS)
Willis Group Limited

Manufacturers

Aesthetika
Allergan
Lynton Lasers

Charities

Action Against Medical Accidents (AvMA)
BEAT
British Heart Foundation
Changing Faces
Endangered Bodies UK
The Health Advocacy Project (FMG Forum)