Department of Health

Review of the Regulation of Cosmetic Interventions

Final Report

April 2013

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Review of the Regulation of Cosmetic Interventions

Final Report

Prepared by the Review Committee

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Foreword

This group was asked to review regulation in the cosmetic interventions sector following the PIP implant scandal which exposed woeful lapses in product quality, after care and record keeping. It also drew attention to widespread use of misleading advertising, inappropriate marketing and unsafe practices right across the sector. Cosmetic interventions are a booming business in the UK, worth £2.3 billion in 2010, and estimated to rise to £3.6 billion by 2015. They can either be surgical – such as face-lifts, tummy tucks and breast implants – or non-surgical – typically dermal fillers, Botox® or the use of laser or intense pulsed light (IPL). These latter account for nine out of ten procedures and 75% of the market value. We were surprised to discover that non-surgical interventions, which can have major and irreversible adverse impacts on health and wellbeing, are almost entirely unregulated.

In fact, a person having a non-surgical cosmetic intervention has no more protection and redress than someone buying a ballpoint pen or a toothbrush.

Dermal fillers are a particular cause for concern as anyone can set themselves up as a practitioner, with no requirement for knowledge, training or previous experience. Nor are there sufficient checks in place with regard to product quality – most dermal fillers have no more controls than a bottle of floor cleaner. There has been explosive growth in this market, driven by a combination of high demand and high profits in an era when all other commercial income is stalling.

It is our view that dermal fillers are a crisis waiting to happen.

Previous attempts at self-regulation in the industry have failed, largely because voluntary codes have meant that only the best in this disparate sector commit themselves to better practice, whilst the unscrupulous and unsafe carry on as before.

Throughout our meetings, discussions and correspondence with stakeholders from all groups, professions and experts, the call has been for a new legislative framework. Taken together, our recommendations provide that framework for both surgical and non-surgical interventions. They set out a range of actions to ensure practitioners have the right skills, the products used are safe, providers are responsible, people get accurate information and support is available if things go wrong.

These recommendations are not about increasing bureaucracy but about putting the everyone's safety and wellbeing first.

Those having cosmetic interventions are often vulnerable. They take their safety as a given and assume regulation is already in place to protect them. We urge the government, regulators, provider organisations and professionals to help implement these recommendations and to make sure that individuals' health and safety is prioritised ahead of commercial interest, so maintaining the trust and safety of the public and the future viability of this industry.

Professor Sir Bruce Keogh KBE

On behalf of the Review Committee members:

Ms Trish Halpin	**Dr Rosemary Leonard**	**Dr Andrew Vallance-Owen**
Prof. Sir Ian Kennedy	**Mrs Vivienne Parry**	**Mr Simon Withey**
Ms Catherine Kydd	**Prof. Shirley Pearce**	

Executive Summary

The cosmetic interventions sector is growing rapidly. The existing regulatory framework has not kept pace with changes and it does not provide enough protection against many of the potential risks from cosmetic procedures.

The Review Committee has gathered evidence from those in the sector, the public, academics and international policy makers and believes that better regulation is needed to bring the industry into line with those in other countries and align this sector with comparable public health and consumer practice in this country.

There are three key areas in which changes are needed: **high quality care** with safe products, skilled practitioners and responsible providers; an **informed and empowered public** to ensure people get accurate advice and that the vulnerable are protected; and, **accessible redress and resolution** in case things go wrong.

The Review Committee's recommendations aim to ensure these changes can occur. Taken together they form a new legislative framework that is proportionate to the potential risks of cosmetic interventions.

Key recommendations:

High quality care

- The scope of the EU Medical Devices Directive should be extended to include all cosmetic implants including dermal fillers, UK legislation should be introduced to enact the changes sooner. Legislation should be introduced to classify fillers as a prescription-only medical device.
- The Royal College of Surgeons (RCS) should establish an Interspecialty Committee on Cosmetic Surgery, made up of representatives of all the relevant specialty and professional associations. The purpose of this group is to set standards for cosmetic surgery practice and training, and make arrangements for formal certification of all surgeons regarded as competent to undertake cosmetic procedures, taking account of training and experience.
- All those performing cosmetic interventions must be registered.
- The Health Education England's (HEE's) mandate should include the development of appropriate accredited qualifications for providers of non-surgical interventions and it should determine accreditation requirements for the various professional groups. This work should be completed in 2013.
- Surgical providers should provide both the person undergoing a procedure and their GP with proper records.

- A breast implant registry should be established within the next 12 months and extended to other cosmetic devices as soon as possible, to provide better monitoring of patient outcomes and device safety.

An informed and empowered public

- The RCS Interspecialty Committee on Cosmetic Surgery should develop and describe a multi-stage consent process for operations. Consent must be taken by the surgeon performing the operation to ensure that the patient and practitioner have a shared understanding of the desired outcome and the limitations, implications and risks of the procedure.
- Evidence-based standardised patient information should be developed by the RCS Interspecialty Committee on Cosmetic Surgery, with input from patient organisations.
- For non-surgical procedures a record of consent must be held by the provider.
- Existing advertising recommendations and restrictions should be updated and better enforced.
- The use of financial inducements and time-limited deals to promote cosmetic interventions should be prohibited to avoid inappropriate influencing of vulnerable consumers.

Accessible resolution and redress

- The remit of the Parliamentary and Health Service Ombudsman (PHSO) should be extended to cover the whole private healthcare sector. This will de facto include cosmetic procedures of all kinds.
- All individuals performing cosmetic procedures must possess adequate professional indemnity cover that is commensurate with the type of operations being performed. For surgeons working in this country, but who are insured abroad, indemnity insurance must be commensurate with similar UK policies.
- The Review Committee supports the future development of insurance products such as risk pool arrangements, to cover product failure and certain complications of surgery.

1. Introduction

1.1. The events surrounding Poly Implant Prothèse (PIP) silicone breast implants raised specific issues regarding the safety and regulation of cosmetic surgery. The Department of Health convened an expert group to develop advice on PIP implants[1] and asked Earl Howe to review the response of the Department and MHRA[2].

1.2. This process exposed wider, serious concerns about the regulation of cosmetic interventions – for example, why were unsafe products on the market; why was it so difficult to reliably trace people who had received cosmetic implants; were vulnerable people put under inappropriate pressure to have cosmetic procedures; and were they properly informed about the risks?

1.3. Existing regulations were not designed to encompass the changes seen in the cosmetic interventions industry, which is evolving and expanding very rapidly. In 2005, the cosmetic sector was worth £720m, by 2010 it was valued at £2.3bn and by 2015 the sector is forecast to grow to a value of £3.6bn[3].

1.4. Demand has been driven by a wide range of social, economic and technological factors. Cosmetic interventions have been normalised[4]. Previously undertaken discretely, now people will admit to having had procedures and even celebrate them. Men are also increasingly likely to consider having a cosmetic intervention[5].

1.5. Advances in technology mean an ever-growing range of interventions or treatments are available, many of these are quicker and less invasive than past procedures. The majority of the market growth has been seen in the non-surgical interventions sector[3], which is lightly regulated, despite known risks to the consumer[6].

1.6. Technology has also changed how these procedures are marketed: social media have been cited as a key driver of market growth, particularly among younger people[4]. The pervasiveness and accessibility of images, advertising and celebrity endorsements through the internet have encouraged changing attitudes and growth of the industry.

1.7. In light of concerns about the whole cosmetic interventions industry, both surgical and non-surgical, the then Secretary of State for Health, the Rt Hon Andrew Lansley MP, asked Professor Sir Bruce Keogh, the NHS Medical Director, to review how the safety of people considering or undergoing cosmetic interventions might be better ensured[7]. To help achieve this goal, Sir Bruce set up a Review Committee with broad membership (see Appendix 1), to provide him with expert advice.

1.8. The Review's Terms of Reference asked it to consider in particular:

- whether the regulation of the products used in such interventions is appropriate;
- how best to assure patients and consumers that the people who carry out procedures have the skills to do so;
- how to ensure that the organisations which deliver such procedures have the clinical governance systems to assure the care and welfare of people who use their services;
- how to ensure that people considering such interventions are given the information, advice and time for reflection to make an informed choice;
- whether there should be a statutory requirement for such organisations to offer redress in the event of harm, and if so how this could be funded;
- what improvements are needed in systems for reporting patient outcomes, including adverse events, for central analysis and surveillance.

1.9. In examining these issues, the Review Committee has considered the findings of others who have looked at this area. In 2005, Sir Harry Cayton chaired an Expert Group on the Regulation of Cosmetic Surgery, which made recommendations to the Chief Medical Officer, focussed on improving safety through increasing specialist training and accountability[8]. The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) published the report *On the Face of It* in 2010, which exposed failings of many providers, including a lack of appropriate facilities, lack of clarity regarding surgeons' competence, and a lack of support to help patients understand the risks of procedures[9]. This year the Royal College of Surgeons brought together a range of existing standards into one document, *Professional Standards for Cosmetic Practice*[10].

1.10. The regulation of cosmetic interventions is not just a challenge for England; other governments are considering how best to ensure quality and safety in this rapidly expanding area and the Review Committee has considered their approaches. In 2010 the Australian Health Ministers' Advisory Council published its findings which proposed a National Framework including new training standards and tighter enforcement of advertising restrictions[11]. In Hong Kong, the government is conducting a review about where the line should be drawn between beauty therapy procedures and medical treatments[12]. Denmark has introduced new regulations addressing who can perform cosmetic procedures[13] and Sweden announced in December that it is considering similar proposals. At a European level, new voluntary standards are currently being developed for aesthetic surgery and non-surgical medical services which cover the required competencies, consent and complaints processes[14].

1.11. The Review Committee has considered these reports, their findings and their impact. In addition, a Call for Evidence[15] was issued to gather the views of the industry, public and wider stakeholders. The Committee and its Secretariat have met with many stakeholders from all sectors and have sought the advice of a wide range of experts.

1.12. In general, there is a concerning lack of data in this sector. There is also a limited knowledge of the views, understanding and attitudes of people undergoing these procedures. Therefore, the Review Committee commissioned additional research into public attitudes towards the regulation and safety of cosmetic interventions, and consulted experts regarding psychological assessment and aids to predictors and outcomes of cosmetic interventions.

1.13. The Review Committee has taken a broad view of cosmetic interventions. It has considered the issues relating to those procedures that are carried out for aesthetic and functional reasons. While not every procedure will be named in this report, the principles set out are intended to apply across the sector. The Review Committee intends that this approach will ensure that its recommendations will remain relevant as new procedures emerge.

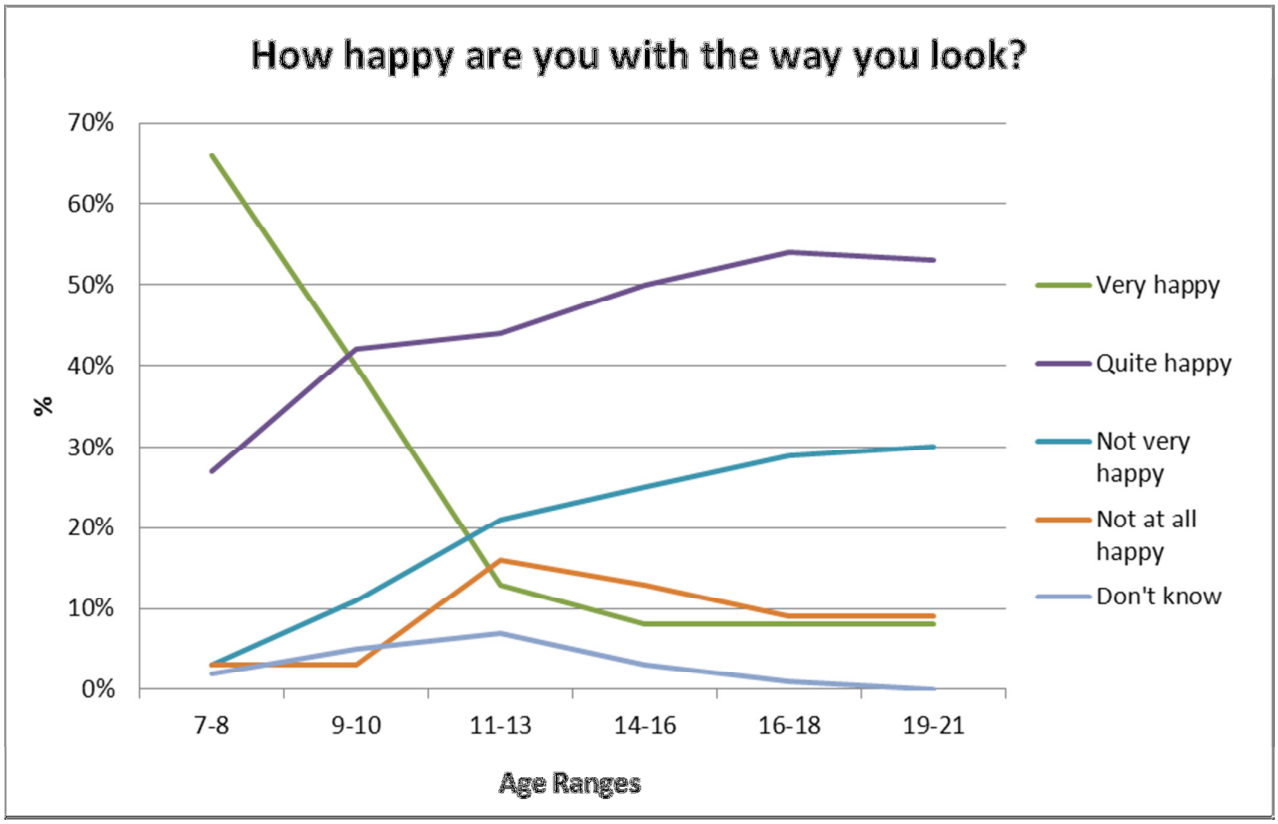
Our Approach

1.14. The cosmetic interventions sector is highly fragmented. It encompasses an enormous range of procedures, from relatively minor interventions to major surgery. There is a wide range of different interest groups, including product manufacturers, practitioners and those who provide premises and facilities, and there is no single professional or trade organisation that represents all these groups. The rapid growth and diversification of the sector is compounding the difficulties of quality control.

1.15. Existing legislation in this area has developed in a piecemeal fashion, addressing certain aspects of the sector but not taking a systematic approach. Attempts at self-regulation have largely failed because of the diversity of the sector and the lack of mandation.

1.16. Cosmetic interventions can have a profound impact on health and wellbeing[16]. In other areas of life where this is the case, regulation provides safeguards to reduce harm. However, in the case of dermal fillers, the treatments are almost entirely unregulated – anyone can perform them, anywhere and with any product – this is a crisis waiting to happen.

1.17. There is also a need for greater protection for vulnerable people. Cultural changes have placed much greater emphasis on physical perfection. Young people and girls in particular, are becoming more and more concerned with their appearance.



Source: The Girl Guides Association, *Girls' Attitudes,* 2012.

1.18. The Review Committee's attitudinal research suggested younger people see cosmetic procedures as a commodity – something they might 'get done'[4]. This can be attributed in part to the use of social media and the growth in celebrity culture: 41% of girls aged 7 to 10 and 62% aged 11 to 16 said they felt some pressure to look the way celebrities do[17].

1.19. The Review Committee has not made judgements about whether the growth in cosmetic interventions is good or bad. Its approach has been to ensure that there is a framework to protect patients and enable consumers to choose.

2. Overarching objectives

2.1. Having reviewed the evidence, the Committee believes the government needs to establish a regulatory framework that encompasses the whole sector, employing a clear, consistent and proportionate approach that is able to adapt to new developments. The Review Committee believes that any new regulations must meet certain overarching objectives.

High quality care

2.2. First and foremost, people should receive high quality care when they choose to undergo a cosmetic procedure. In England, the quality of healthcare is defined and assessed by its effectiveness, safety and patients' experience[18]. For cosmetic procedures, this means the products used should be safe, the practitioners should have the appropriate skills and training, the premises must be suitable, and those undergoing procedures must be treated with respect.

An informed and empowered public

2.3. People choosing to undergo cosmetic interventions are both patients and consumers. They are making purchasing decisions on procedures and products that may have a significant impact on their health and wellbeing. It is essential that people are helped to make informed decisions based on clear, easily accessible and unbiased information and data. Management of the expectation of individuals who are considering a cosmetic intervention must be part of the consent process.

Accessible resolution and redress

2.4. In the event of medical complications, or where poor clinical care leads to substandard outcomes, practitioners and providers should provide continuity of care. Where appropriate, insurance schemes should be in place to provide support and reassurance. Patients should have access to guidance and assistance in dispute resolution.

Current Regulation of Cosmetic Interventions 'At a Glance'

	Botulinum toxin (medicine)	Breast implants (devices)	Chemical peel	Dermal filler	Laser treatment	Intense Pulsed Light
Product	Regulated as a prescription Medicine	Regulated as a medical device	Regulated under General Product Safety Directive only if sold direct to consumer	Regulated as device only if it has explicit medical purpose – most don't	Equipment regulated as a medical device	Not regulated as a device. Safety covered by Health and Safety at Work (H&SW) rules
Practitioner	May only be prescribed but can be administered by non-health professional	Must be performed by qualified doctor	Can be performed by anyone	Can be performed by anyone	Can be performed by anyone	Can be performed by anyone
Premises	Anywhere. General H&SW rules apply	CQC registered	Anywhere. General H&SW rules apply	Anywhere. General H&SW rules apply	Anywhere. General H&SW rules apply Some LA's license	Anywhere. General H&SW rules apply Some LA's license
Risks and Complications	Bleeding, unintended muscle weakness, eyelid droop, double vision, speech and breathing difficulties, asymmetry, infection, allergic reaction. Not to be used in pregnancy.	Poor scarring, bleeding, infection, numbness, discomfort, implant palpability, implant visibility, asymmetry, implant rupture, capsular thickening/ contracture, failure to achieve aesthetic expectations.	Burns, infection, scarring, changes in pigmentation alteration of skin texture, persistent redness, asymmetry.	Infection, scarring, persistent inflammatory response (redness), thickening, pain, infection, asymmetry, tissue loss, poor aesthetic outcome, visual disturbance, blindness.	Burns, infection, changes in pigmentation scarring, asymmetry, visual disturbance, blindness.	Burns, infection, changes in pigmentation scarring.

3. High Quality Care

Skilled and responsible practitioners

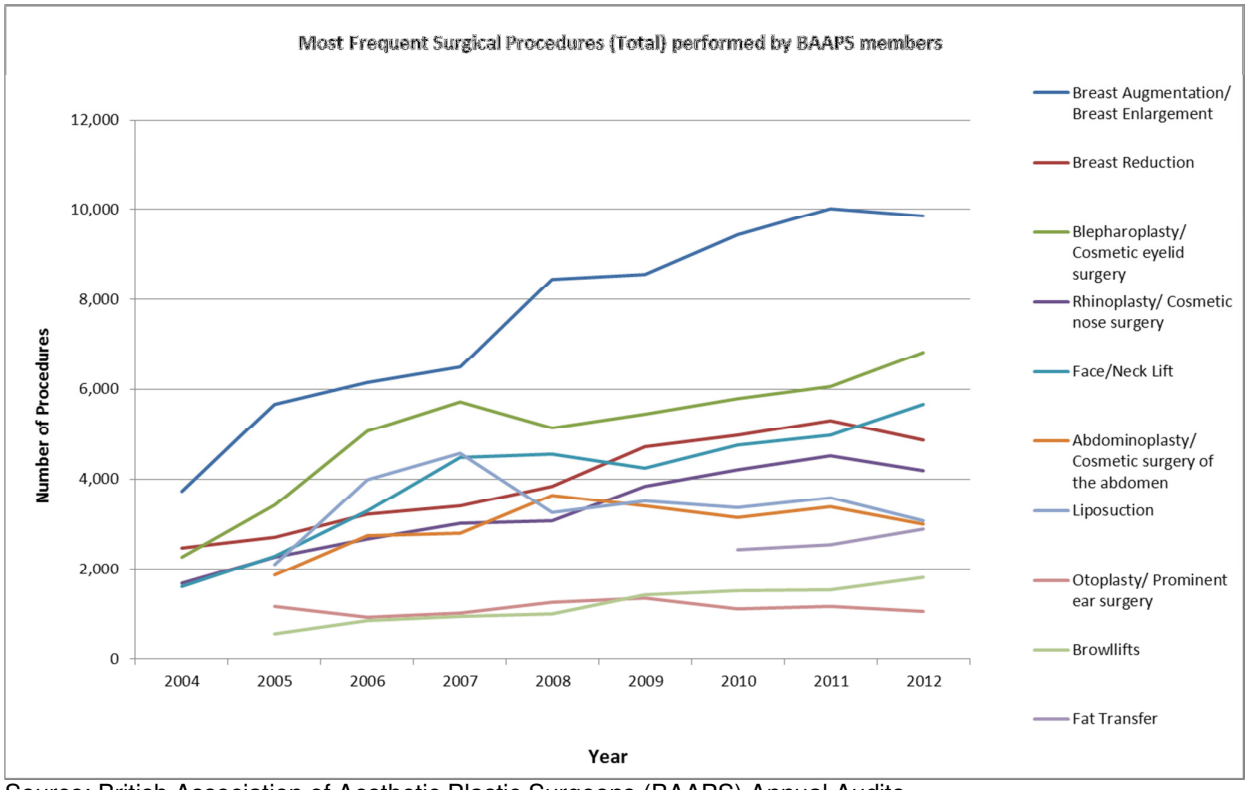
3.1. Any cosmetic procedure carries risks for an individual's health and wellbeing[19]. Known clinical risks include, for example, risks from general anaesthesia, infection of surgical wounds and injection sites. Similarly, there are risks that the procedure will not fulfil the patient's expectations[20]. No surgery can ever be risk free, but the risk can be considerably reduced with a skilled and experienced practitioner. People need to be able to identify and choose a practitioner with the appropriate qualifications and be able to ascertain in advance their skills and experience in performing a given procedure.

Shortcomings of the current regulatory approach:

Cosmetic surgery is not a defined and discrete area of medical practice

3.2. For those areas of medical practice that are defined as a specialty[21], there are rigorous training programmes leading to admission onto the relevant specialist register, held by the General Medical Council (GMC)[22]. Inclusion onto such a register is a prerequisite for consultant practice in the NHS and relevant information is publicly available as an annotation in the GMC's list of Medical Practitioners along with dates and details of other qualifications.

3.3. For a variety of reasons, cosmetic surgery is not a defined surgical specialty in its own right. The training within certain defined specialties, such as plastic surgery, ear nose and throat surgery and eye surgery includes an aspect of cosmetic training but there is no common qualification available for those performing cosmetic surgery. It is a tenet of the GMC guidance, "Good Medical Practice"[23], that all doctors including surgeons must act within their competence. Until the introduction of medical revalidation in December 2012, doctors have been able to deem themselves competent in a procedure[24]. A poll conducted by the Patient Liaison Group at the Royal College of Surgeons showed that most patients would not check the qualifications of a surgeon before consenting to an operation[25]. Furthermore, 91% of people asked would expect any doctor performing surgery to have qualified as a surgeon, and to be 'fully qualified' in the procedure.



Source: British Association of Aesthetic Plastic Surgeons (BAAPS) Annual Audits

3.4. Frequency of performing relevant surgical procedures can be an important component of maintaining competence[9]. Some procedures are less frequently performed than other more 'popular' operations. The NCEPOD report found that the majority of centres 'performed fewer than 20 of the offered procedures per year', and that some providers performed significantly fewer[9]. This suggests that some cosmetic surgical teams may be performing operations too infrequently to maintain competence, let alone excellence. Conversely the Review Committee noted that because an individual is carrying out a large number of procedures, it does not necessarily mean that a high quality service is being provided.

3.5. Revalidation is intended to ensure that all doctors demonstrate competence in all areas of their practice[24]. There is clearly also a responsibility on providers to ensure they are employing surgeons who are fully competent in the procedures that they are authorised to perform[26]. Provided that satisfactory results are achieved in yearly appraisals, a doctor will be 'revalidated' every five years – if not, their licence to practise may be withdrawn. Although not the complete solution, revalidation does provide an important opportunity to strengthen the regulation of cosmetic practice, and the Review Committee is convinced of its importance. From the end of 2012, doctors with a licence to practise in the UK must be linked to a 'Responsible Officer' (a senior doctor) who must have systems in place to ensure they are competent and fit to undertake the work they are undertaking. The Responsible Officer must hold them to account for their standards of practice and, based on this, has to make a revalidation recommendation to the GMC.

3.6. Historically, governance of standards of practice in cosmetic surgery has been limited. Under the new system, the Responsible Officers must demonstrate that they have systems in place to ensure that all the doctors engaged in cosmetic surgery are providing high standards of care. There is also a responsibility on providers to ensure they are employing surgeons who are fully competent in the procedures they will be expected to perform. While revalidation is to be welcomed, the Committee's view is that this alone will not help a prospective cosmetic surgery patient, or an NHS patient, assess a doctor's level of expertise and experience in a particular procedure.

3.7. As cosmetic surgery is not a discrete area of surgical practice, but a component of a number of surgical specialties, there is no individual professional organisation that is responsible for setting standards that could be used in training or to assess competence in cosmetic surgery as part of revalidation. The weakness of the professional regulatory oversight arises in part from the fact that cosmetic surgery is not a discrete defined specialty, in part from its provision in the private health sector, outside the framework of the NHS system, and in part from a lack of data. We do not know how many cosmetic procedures are carried out each year, by whom, or with what outcomes. The British Association of Aesthetic Plastic Surgeons (BAAPS) carries out an annual audit of its members' activity[27], but the data are not published at individual surgeon level. Furthermore, BAAPS estimates that its members only carry out around 30-40% of cosmetic surgery procedures conducted in the UK[3] so their data only provide a partial insight into activity in the sector. To make matters worse, some doctors performing these operations are not based in the UK – they fly in to perform the procedure and then fly out[28].

3.8. The Review Committee charged Mr Chris Munsch, Consultant Cardiothoracic Surgeon, formerly chair of the Joint Committee for Surgical Training in the UK and Ireland and now Clinical Adviser to Health Education England, with convening a working group to consider who should set standards for cosmetic surgery and the consequent issue of how training in cosmetic surgical procedures should be provided. The group confirmed that currently there is no single qualification that demonstrates whether surgeons are equipped with the skills and experience to carry out cosmetic procedures. The working group was not in favour of creating a dedicated specialty for cosmetic surgery because of the interdisciplinary nature of cosmetic practice. There are already specialty associations responsible for setting standards in their specific disciplines and they alone should be responsible for the standards of medical practice in their specialty specific area, irrespective of whether a particular procedure is generally performed for therapeutic or cosmetic purposes. Instead the working group recommended the establishment of an interdisciplinary oversight group to ensure that standards are developed, and consistently and appropriately applied across all areas of cosmetic surgical practice, the Review Committee accepts this recommendation. The full list of the working group's recommendations is included in Appendix 4.

3.9. The Committee noted similar concerns with cosmetic dentistry and Ministers may wish to consider a further review in this area.

Absence of any standards or accredited training for non-surgical cosmetic procedures

3.10. The current regulatory framework places no restrictions on who may perform non-surgical cosmetic procedures. No qualifications are required to carry out these procedures and, in the absence of accredited training courses, anyone can set up a training course purporting to offer a qualification. The committee was alarmed that a number of self-accredited training organisations have sprung up.

3.11. There question of “who should perform” non- surgical cosmetic procedures has provoked debate. Historically the argument over “who” has been adequately qualified has distracted from the question “ what should adequate training and accreditation involve?”. Once the requirements for training are identified and understood, it should be possible to identify, for each professional group, which parts of the curriculum have been covered with prior training and which are consequently required to complete training. This will mean that different professional groups will enter the training scheme at different points. Such a scheme could provide broad access, and may be able to provide professional training for those with no prior experience. The aim should be that, every practitioner, no matter what their starting point should attain the necessary skills and expertise to perform these varied procedures safely and to a high standard.

3.12. Some individual responses to the Review’s Call for Evidence suggested that these non-medical, non-dental and non-nursing practitioners were greatly valued by consumers for their perceived skill, accessibility and service[29]. However, without specific, accredited training in physiology, anatomy, infection control, treatment of anaphylaxis, or an understanding of any existing medical conditions, practitioners are unlikely to be aware of all the possible risks and complications of the procedures, or able to recognise and treat complications.

3.13. Other countries have also considered how to ensure that the practitioners performing the ever-increasing range of non-surgical aesthetic treatments are sufficiently trained.

International Example: Denmark

The Danish government introduced new regulations for surgical and non-surgical cosmetic procedures in 2007.

The cosmetics register

All those carrying out cosmetic interventions must be registered with the Danish Health Board. Practitioners pay 16,000DK (roughly £1850) a year for membership of the register. The Health Board carries out scheduled and announced, as well as unannounced, inspections performed by doctors. Where standards are breached, the Health Board can order clinics to suspend operations, cease operations, impose fines, strike professionals off the cosmetics register and refer cases to the police.

Cosmetic surgery

Cosmetic surgery may be performed by plastic surgeons. Surgeons qualified in other specialties may carry out cosmetic surgery but only if it is related to their anatomical area of expertise. For example, ear, nose and throat surgeons may carry out cosmetic surgery on the ears and the nose.

Non-surgical cosmetic procedures

Non-surgical cosmetic procedures such as botulinum toxin injections, dermal filler injections, laser or IPL treatments for smaller vein and fine wrinkle removal or hair removal, chemical peels and sclerotherapy, may be carried out by consultant dermatologists or plastic surgeons, and, in the case of botulinum toxin injections, ophthalmologists and neurologists. Specific qualifications are required for the practice of laser and IPL treatments.

Nurses and junior doctors
Botulinum toxin injections, dermal filler injections, laser or IPL treatments for smaller vein and fine wrinkle removal or hair removal, weaker chemical peels (with a pH value of 3 or over) and sclerotherapy in small blood vessels, can be delegated to nurses and junior doctors, including the pre-examination, taking consent and selection of treatment. The consultant retains overall responsibility for the patient.

Non-health care professionals

Non-health care professionals may perform dermal filler injections, weaker chemical peels and laser or IPL treatments to remove hair, smaller veins and fine wrinkles, if they hold a recognised beauty therapy qualification and can demonstrate that their qualification meets the relevant competences. The qualification must be recognised by the Danish Health Board but no accredited qualification currently exists. Non-health practitioners must also be deemed competent by the doctor who will be employing them. Non-health care professionals may not perform botulinum toxin injections, microdermabrasion or sclerotherapy.

Patient complaints and redress

In the event of complications, people can seek the help of the National Patient Complaints Board. A National Patient Insurance Scheme also exists which is open to patients of both state and private healthcare. This is independent of government, and is a public/private partnership funded by insurance companies and regional state boards.

The changes needed to improve the sector for the public:

3.14. There is a clear need for accredited training standards to be set for cosmetic procedures so that patients can be assured that the person carrying out an intervention has the appropriate training. The Review Committee wants to see an end to the possibility of an unscrupulous practitioner being able to mislead the public as to their skills and experience, and of training providers offering poor quality training courses for practitioners.

3.15. To achieve the above objective, the Review Committee recommends the creation of approved training schemes, accredited qualifications, and associated registers for both surgical and non-surgical cosmetic procedures. The register will make it easier for the public to identify a practitioner with the appropriate training.

The Review Committee recommends that:

Recommendation 1

- **The Royal College of Surgeons (RCS) should establish a Cosmetic Surgery Interspecialty Committee. This should consist of representatives from all the relevant specialty associations and professional associations and societies, including plastic surgery, ENT surgery, maxillofacial surgery, ophthalmology, breast surgery and gynaecology. Its task should be to:**
    - **set standards for the training and practice of cosmetic surgery.**
    - **make arrangements for the formal certification of all surgeons regarded as competent to undertake cosmetic procedures, taking account of training and experience.**
    - **establish and oversee a clinical audit database for cosmetic surgery, working with the Healthcare Quality Improvement Partnership (HQIP).**
    - **work with the Parliamentary and Health Service Ombudsman (PHSO) on dispute resolution (see recommendations regarding accessible resolution and redress).**
    - **meet the General Medical Council (GMC), Care Quality Commission (CQC), and the Medicines and Healthcare products Regulatory Agency (MHRA) regularly and, when appropriate, with provider representatives, to discuss current issues and share information and intelligence on the quality of care being provided.**
    - **develop a specific code of ethical practice for cosmetic surgery, in collaboration with the GMC, to include guidance on advertising, insurance requirements and the psychological assessment for patients.**

Recommendation 2

- **The RCS Interspecialty Committee should work with the CQC and the new Chief Inspector of Hospitals to ensure that providers follow the standards developed. In the meantime, the Review Committee recommend that only doctors on a GMC Specialist Register should perform cosmetic surgery, and that those doctors should work within the scope of their Specialty specific training.**

Recommendation 3

- **The RCS Interspecialty Committee should be responsible for developing clear, credible outcome measures for cosmetic surgery that are published at individual surgeon and provider level on the NHS Choices website.**

Non-surgical procedures

3.16. People undergoing non surgical treatments should be able to be confident that their practitioner has the required skill and expertise to undertake the procedure successfully and safely. The training and accreditation process should ensure that practitioners are able to identify and manage complications of treatment. The curriculum and training requirements should be regularly reviewed to ensure that all practitioners are adequately trained in emerging procedures, this will involve regular retraining for those who wish to perform the latest treatments.

3.17. The committee believes that anyone prescribing fillers, or performing other potentially harmful non surgical cosmetic procedures, should be accountable to a professional regulator. It believes that this recommendation is reasonable and proportionate, and aligned with the principles of Better Regulation[30], given the failure of self regulation and the potential for harm.

Recommendations 4

- **All non-surgical procedures must be performed under the responsibility of a clinical professional who has gained the accredited qualification to prescribe, administer and supervise aesthetic procedures.**

Recommendation 5

- **Non-healthcare practitioners who have achieved the required accredited qualification may perform these procedures under the supervision of an appropriate qualified clinical professional.**

Recommendation 6

- **The Government's mandate for Health Education England (HEE) should include the development of appropriate accredited qualifications for providers of non-**

surgical interventions and it should determine accreditation requirements for the various professional groups. This work should be completed in 2013.

Recommendation 7

- **All practitioners must be registered centrally. The register should be independent of particular professional groups or commercial bodies, and should be funded through registration fees.**

Recommendation 8

- **Entry to the register should be subject to:**
  - **achievement of accredited qualification**
  - **premises meeting certain requirements**
  - **adherence to a code of practice that covers handling complaints and redress, insurance requirements, responsible advertising practice and consent practices**
  - **continued demonstration of competence through an annual appraisal.**

Improving Quality of Care

3.18. There is a wide variety of provider business models in the cosmetic interventions sector: large private healthcare companies which provide cosmetic interventions as just one of many services; national chains dedicated to cosmetic procedures; individual surgeons; high street clinics; spas and beauty salons; mobile practitioners; and those who arrange for patients to receive treatments abroad. Those performing surgery have to be registered with the Care Quality Commission (CQC), and non-surgical premises are subject to inspection by Local Authorities.

Shortcomings of the current regulatory approach:

Not all providers take safety seriously

3.19. While some providers operate to extremely high standards of safety and quality, others do not. The NCEPOD report *On the face of it* found that too many surgical providers were offering procedures that they performed infrequently, while few were adequately equipped to deal with complications[9]. The report noted that some providers failed to meet their obligations to participate in confidential enquiries – only 32% responded to the questionnaire – suggesting that there is a general lack of understanding among some providers of the importance of such work in ensuring the patient's safety[9].

3.20. There is also a high turnover of providers. NCEPOD found that 11.5% of those registered had ceased trading in the 12-month data collection period[9] and Citizens Advice

highlighted that their Consumer Advice Service frequently took calls regarding problems with cosmetic interventions where individuals were not able to obtain redress because the provider no longer existed[31].

3.21. It can be argued that the business model of cosmetic surgery providers relies to some extent on the NHS being there to act as a safety net to treat clinical complications. In some cases it may be that the private provider does not have the competence or equipment required to treat a specific condition. In other cases, it may be that treatment of a particular complication, or indeed any aftercare was not covered by the contractual agreement between the private provider and the patient, and therefore the patient may choose to seek treatment from the NHS rather than incur further costs.

3.22. There are few data on the costs incurred by the NHS in dealing with the clinical problems caused by cosmetic surgery in the private sector, but data submitted to the Review by surgeons at the Chelsea & Westminster Hospital in London showed that, over a 15 month period, 12 patients presented to A&E needing treatment for complications from cosmetic procedures[32]. This resulted in 34 outpatient visits and 66 inpatient nights, costing a total of £43,000. The hospital has also reported on costs for dealing with adverse reactions to facial dermal fillers which for one individual resulted in a five-night hospital stay for the patient and a reported cost to the NHS of £4,028[32]. Estimates have also been published on the costs incurred by the NHS treating people with PIP breast implants[33].

3.23. The NHS does not routinely attempt to recover costs from these providers. The growth of the cosmetic interventions industry would suggest a growing burden on the NHS from such referrals. The attitudinal research showed respondents were unanimous in believing that the NHS should not have to bear responsibility for providing care for procedures conducted privately that have gone wrong[4].

Limitations of inspection regime for surgical providers

3.24. Surgical providers have to be registered with the Care Quality Commission (CQC). The CQC performs annual inspections and can perform responsive inspections based on complaints or concerns raised[34]. However, as highlighted by the NCEPOD report[9], given the lack of clear standards for the provision of cosmetic surgery services, the Review Committee believes that the CQC does not have the necessary precise criteria or expertise with which to assess cosmetic surgery providers.

Lack of data on outcomes

3.25. The Review identified a concerning lack of available data in all areas of cosmetic surgical practice. The Review Committee is determined that data should be available in a suitable

form to drive the required improvements in clinical practice, patient education, innovation and research. There are some examples of clinical audit processes, but the problems with PIP breast implants demonstrated that in many cases appropriate clinical audit data were not available when needed. There is a clear need for more widespread participation in good quality clinical audit in order to improve healthcare provision. There is also a need for greater transparency and greater data-sharing with the regulatory authorities and the public. Responses to the Call for Evidence were strongly in favour of making participation in clinical audit a condition of CQC registration for providers[29].

Poor protection for people undergoing procedures in non-surgical sector

3.26. The non-surgical end of the market is growing rapidly, and was estimated to account for more than nine in ten cosmetic procedures and almost three quarters of market value in 2010[3]. Non-surgical cosmetic procedures such as the injection of dermal fillers and treatments using lasers or intense pulsed light (IPL) are not classified as a regulated activity by the CQC. Non-surgical providers are not required to register with the CQC. Generally, these providers are not subject to any additional regulation beyond those of the wider service sector such as the requirements set down by the Health and Safety at Work Act (1974)[35]. These regulations are enforced by Local Authority bodies such as Trading Standards and Environmental Health. Local Authority Environmental Health Officers (EHOs) can inspect premises to ensure that they conform to health and safety requirements. EHOs do not have the training or expertise to determine whether staff are adequately trained and following best practice, and neither do EHOs possess the power of sanction.

Risks associated with the use of dermal fillers

The complications associated with the injection of dermal fillers include:

- ***Infection:*** *acute or chronic*
- ***Lumpiness:*** *firm, raised nodules*
- ***Granuloma formation:*** *a type of tissue reaction resulting in lumps and nodules in the skin which can be chronic and may be related to progressive destruction and deformity.*
- ***Ulcer formation:*** *break down of the overlying skin resulting in an open sore*
- ***Vascular occlusion:*** *blockage of a blood vessel*
- ***Tissue necrosis (tissue death):*** *occurs when the blood supply to the skin and tissues is compromised, and results in loss of the affected tissues*
- ***Allergic reaction:*** *redness, swelling and discomfort in the area injected or systemic allergic response*
- ***Prolonged swelling, bruising:*** *significant swelling and bruising of the tissue which can be difficult to disguise*
- ***Failure to meet the patient's expectations***
- ***Blindness:*** *this complication is rare but has been associated with a range of filler injections used in the periorbital area (area around the eyes)*

A full list of the risks and complications of dermal fillers is at ***Appendix 2.***

3.27. A recent survey undertaken by the Royal College of Nursing[36] found that 36% of nurses performed non surgical procedures, either from their homes, or within their clients homes. Other venues used include temporary "pop-up" shops, hairdressing salons and hotel rooms. The nature of the locations used to perform treatments and the fact that many practitioners are peripatetic leaves the local authorities largely unaware of the extent of practice in their areas. There are no national guidelines for the licensing of non surgical "outlets" by the local authorities, and the efficacy of those licenses issued is limited.

Risks associated with laser and Intense Pulsed Light (IPL) treatments

The complications associated with use of lasers and IPL in the treatment of skin conditions, including hair reduction, are:

- ***Damage to the eye and vision*** *such as corneal abrasions, retinal burns, damage to blood vessels in the eye, and macular damage (opaque spots on the cornea) which can result in total blindness.*
- ***Injury to the skin*** *such as scarring, hyperpigmentation (darkening of pigmentation), hypo and depigmentation (loss of pigment resulting in pale or white areas), burns and blisters, infection, bruising, prolonged redness, and milia (tiny cysts).*
- ***Worsening of pre-existing skin conditions*** *such as acne or rosacea*

A full description of the risks and complications associated with the use of lasers and IPL is at ***Appendix 3***

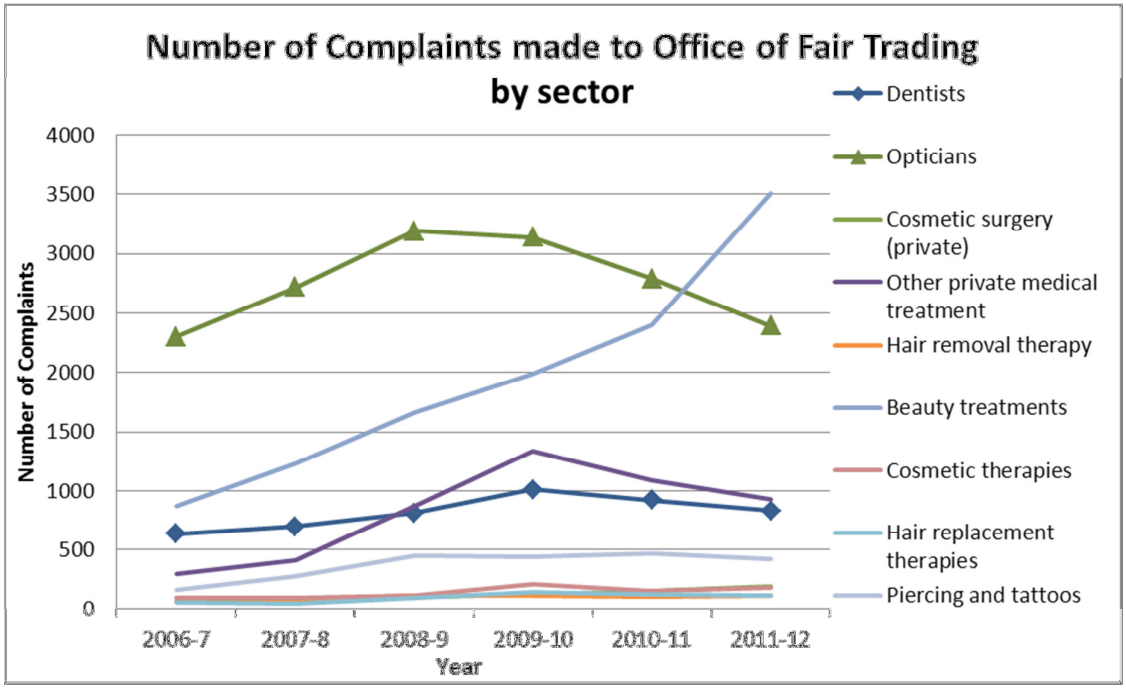
3.28. With the many demands on Local Authority (LA) resources, inspection of non-surgical cosmetic providers may be considered a relatively low priority. However some responses to the Call for Evidence argued that as these procedures can have profound medical consequences[29], Local Authorities were not the most appropriate monitor.

3.29. The data on rates of reported adverse reactions caused by dermal fillers and other non-surgical cosmetic interventions are poor because there are no formal reporting mechanisms in place for many of these products. People with adverse reactions may go to the original provider, an alternative provider, their GP, Trading Standards, Citizens Advice, the MHRA or a firm of solicitors. Some may choose not to report problems at all.

3.30. Attempts have been made to encourage providers to self-regulate in this area. A voluntary register for cosmetic injectable treatment providers was set up following the Department of Health's 2005 Cayton Review[8] with some Department of Health funding – *Treatments You Can Trust* (TYCT)[37] is operated by the Independent Healthcare Advisory Service (IHAS)[38], a trade association for private healthcare and cosmetic surgery providers. Despite efforts from IHAS, TYCT has attained limited support from the sector, and this may reflect the challenges of voluntary regulation in this diverse industry. There

are also concerns that, as a trade body, IHAS is not the appropriate organisation to run an independent register. From a consumer perspective, awareness of the register is low.

3.31. The failure of the sector to self-regulate may also partly reflect public attitudes which assume that there is already legislation. The attitudinal survey found that people believed that if premises were offering treatments then they must have been deemed safe – and most were shocked when they realised how few safeguards were in place[4]. Laser and light treatments were exempted from CQC regulation in 2010 as part of the Government's Better Regulation agenda. Since then there is evidence that the number of practitioners attending training courses has decreased and the number of insurance claims has increased. Data from the Office of Fair Trading also suggest that they have seen an increase over recent years in the number of complaints about beauty treatments[39].



Source: OFT Annual Report

The changes needed to improve the sector for the public:

3.32. The Review Committee believes that greater scrutiny of providers is required given the potential risks posed by cosmetic procedures. Outcomes data and complications data are required to enable regulators, professional organisations and the public to judge performance.

Cosmetic surgery

In order to achieve the above aim, the Review Committee recommends that:

Recommendation 9

- **The CQC should work with professional organisations to produce inspection guidelines for cosmetic surgery providers.**
- **Full participation in all clinical audit and data collection programmes that have been recommended by the RCS Interspecialty Committee should be part of CQC registration requirements and full participation by surgeons should be an essential component of their annual appraisal and revalidation. The CQC should use this data and clinical audit findings to analyse outcomes and assess risk, and this data should be used to guide inspection teams.**
- **Risk-based and unannounced CQC inspections should be performed.**
- **The inspection teams should have appropriate expertise and experience in this sector.**

Recommendation 10

- **Data on performance should be made publicly available at surgeon and provider level.**

Recommendation 11

- **Providers should be required to notify the public on their websites of any CQC inspection concerns or notices.**

Recommendation 12

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

Furthermore, the Review Committee accepts the recommendation made by the NCEPOD in its report *On the face of it*[9], that:

Recommendation 13

- **'Independent healthcare providers should only allow practising privileges to those cosmetic surgeons who can demonstrate that they have achieved and are able to maintain competence in the procedures which they offer'.**

Non-surgical procedures

3.33. The Review Committee finds that the current regulation of non-surgical providers is insufficient to adequately protect public health and safety. Given the known risks, it is not appropriate that the public has no more consumer rights when receiving a dermal filler injection than when buying a toothbrush. The Review Committee is alarmed by the casual use of some cosmetic interventions by unqualified individuals, and by reports of people buying injectable products over the internet and self-administering.

Recommendation 14

- **Those training to be non surgical practitioners should have a clear understanding of the requirement to operate from a safe premises, and the responsibilities involved. The training curriculum should include topics such as infection control, treatment room safety and adverse incident reporting. The code of conduct for those on the register should include an obligation to abide by certain clearly defined minimum standards for premises.**

4. Ensuring safe products

4.1. The products used in cosmetic interventions include implants, medicines such as botulinum toxin and injectable dermal fillers. As the issues around PIP breast implants highlighted, the safety of some products being used in cosmetic interventions is an area of serious concern and the existing regulations are not sufficient to protect the public.

Shortcomings of the current regulatory approach:

Only some of the products implanted or injected into the body are regulated as medical devices.

4.2. Breast implants are classified as "medical devices" and must carry a CE (Conformité Européenne) marking[40]. This denotes that the product has met certain essential safety requirements. Other kinds of cosmetic implants, such as calf or buttock implants, do not fall under the EU medical device regulations as they are not considered to have a medical purpose and hence do not require CE marking before being sold[41]. Similarly, dermal fillers that do not claim to have a medical purpose (i.e. they are purely for cosmetic use) are exempt for the same reason.

4.3. Implants falling outside the medical devices regulations are only covered by the general provisions of the EU General Product Safety Directive[42]. This maintains only a very general responsibility on distributors to place on the market (or supply) products that are safe in normal or reasonably foreseeable use. Products like toys, make-up and electrical equipment are subject to more stringent safety requirements.

4.4. Furthermore, when a product such as a filler is used as part of a 'professional service' it is currently exempt from the EU General Product Safety Directive[42]. This means that in effect some dermal fillers and some implants used in cosmetic interventions in the UK are exempt from any product safety regulations. While this does not necessarily mean that the products are unsafe, it does mean that consumers and patients are reliant on manufacturers' and providers' own assessment of the safety of the product.

4.5. These inconsistencies are not only irrational but they pose a risk to patients since all implants, solid or liquid, carry a risk to the recipient based on the material used and the standard of construction or manufacture.

4.6. Proposed revisions to the EU Medical Devices Directive are currently being discussed and may result in all dermal fillers and other implants for cosmetic use being classified as medical devices and therefore subject to the safety checks required for CE marking[43]. However, even if these changes to the EU Directive are agreed, they are unlikely to be

implemented before 2018. In the Review Committee's view, this leaves the public unprotected for too long.

The assessment of the safety of devices varies even within the system laid down by EU legislation

4.7. There are 76 Notified Bodies that are able to undertake the required conformity tests for medical devices placed on the EU market. While Notified Bodies work to standards, there have been accusations that some Notified Bodies are not working to the same high standards as others in the system[44].

4.8. There are also concerns about how manufacturers are inspected and whether these checks are sufficiently rigorous to identify safety problems. Both of these issues have been raised by the House of Commons Science and Technology Committee Report[45] and Earl Howe's review of the actions of the MHRA and the Department of Health in response to the events surrounding PIP breast implants[2].

There is a lack of information about what products are being sold

4.9. Manufacturers are not required to notify the MHRA that they are bringing medical devices or cosmetic implants to market in the UK and it is difficult therefore to get data on product use. As a rough estimate, there are between 140 and 190 dermal filler products available in the UK[46] (including CE marked and non-CE marked products), and no restrictions on who can purchase these products. In the US all dermal fillers are classified as medical devices and are regulated by the Food and Drug Administration (FDA) under a more restrictive system of regulation than in the EU. Only 14 different dermal fillers are permitted for sale and information about all of these products is publicly available on the FDA website[47].

Safety and performance data is not captured and shared transparently

4.10. The MHRA has a system in place for reporting adverse incidents relating to medical devices, but it is not used appropriately[29]. It has been estimated that 10% of adverse reactions to medical devices are reported to the MHRA[48]. The MHRA estimated that, following retrospective analysis, only about 15-18% of adverse incidents expected for PIP breast implants were reported[49]. In the case of products that are not classified as medical devices, no formal national reporting system exists. This poses a very significant risk.

Data on complications

There is no central collection of data on the complications following cosmetic interventions and hence no information on the type or frequency of complications. In order to get a better feel for the area, the Review carried out a small survey of professional groups working in the area.

Amongst the 86 GPs who replied, over 900 cases of complications were reported following cosmetic interventions. Those following botulinum toxin injections, laser/IPL treatment, and dermal fillers were the most common issues upon which patients consulted their GP. A similar pattern was reported by the 129 nurses who responded to the survey.

The 57 plastic surgeons who took part reported seeing 380 patients with complications of non-surgical treatments. These included problems following botulinum toxin injections, dermal fillers, chemical peels, and laser/IPL treatments. Complications following minor liposuction and autologous fat transfers were also reported. Plastic surgeons reported that nearly two-thirds of the complications reported were irreversible.

4.11. Furthermore, there is no mechanism to track and trace patients when there are concerns regarding product safety. For example, if a problem is reported with a particular cosmetic implant there is no systematic method of centrally identifying and notifying all those individuals affected. Instead people must rely on their provider or practitioner notifying them that there is a problem.

4.12. Amongst the concerns following the PIP episode was the inability of certain providers to track and trace patients with potentially faulty implants. We are convinced that it is critically important to be able to trace patients in the event of product recall, all providers should keep the data required to do so. Implant and device data should be linked to patient data in such a fashion that they can be recalled easily and completely. Compliance with such collection of data should be seen as part of good medical practice.

4.13. There have been attempts in the past to address this kind of problem through the establishment of a register for breast implants. However, concerns over cost, patient consent and the low participation rate meant that this was abandoned. Following events around PIP, there is renewed interest in this area both within the UK and internationally, particularly with the development of Unique Device Identifier codes for each medical device. Respondents to the Call for Evidence were strongly in favour of establishing registries for implants and some suggested that this should be extended to all devices used in cosmetic interventions, including dermal fillers[29].

The changes needed to improve the sector for the public:

Product safety

4.14. The Review Committee concludes that there should be a consistent regulatory approach to ensure the safety of all products that are inserted into the human body, whether by

surgery or other means. This means all substances used in the cosmetic interventions industry whether solid or liquid, with or without pharmacological action. It is inconsistent that, while breast implants are regulated as medical devices, other kinds of implants and fillers are not. The quality and safety of some of these products are not subject to standards that are proportionate to the risks associated with their use.

4.15. The Review Committee welcomes the proposed changes to the EU Medical Devices Directive that should bring all cosmetic implantable devices within the scope of the new Directive. However, the Committee is concerned that these changes will take time to implement while, in the meantime, the public are being exposed to unnecessary risk. The massive growth in demand for these treatments means more people are being exposed to these risks and the Committee is concerned that a major safety problem may arise. The Review Committee is also of the view that the supply of dermal fillers should be restricted by making them prescription only products. This would bring their supply in line with injectable medicines. In order to meet the Committee's concerns, it recommends that:

Recommendation 15

- **The scope of the EU Medical Devices Directive should be extended to cover all cosmetic implants, including all dermal fillers. UK legislation should be introduced to make fillers a prescription only medical device.**

Recommendation 16

- **The EU General Product Safety Directive (GPSD) should be revised so that products used as part of a professional service are no longer exempt from product safety legislation.**

Product and device scrutiny

4.16. The system for monitoring the quality and safety of medical devices must be improved. There should not be any countries in which there are less stringent CE marking processes or it is possible to escape proper inspection. To achieve this, the Review Committee believes the UK should press for improved device scrutiny as part of the negotiations on the Medical Devices Directive and recommends that:

Recommendation 17

- **All European Notified Bodies should be regularly and rigorously assessed and audited, to ensure they all work to the same high international standards; and reports of these assessments should be made public.**

Recommendation 18

- **There needs to be unannounced inspections of manufacturers of class III and IIb medical devices to ensure production is compliant with the regulations. Reports of such inspections should be made public where possible.**

4.17. Within the UK, we must know what products are being marketed and used in cosmetic interventions to enable better post-market surveillance.

Recommendation 19

- **Manufacturers should inform the MHRA when bringing a new product to the UK market and the MHRA should publish a list of the cosmetic devices available in the UK.**

Device registries

4.18. Following lessons learnt from problems with PIP breast implants, the Review Committee places particular importance on systems that can precisely identify the complete cohort of patients in which a specific implant has been used. Such data are currently recorded and held at provider and hospital level, and linking them together nationally would provide a better knowledge of the products currently being used; enabling product performance to be monitored; and alerts of possible product failure to be recognised at an early stage.

4.19. Details of all products that are implanted or injected into a person must be recorded, these should be linked to details of the practitioner and the centre. Patients and consumers should be informed of the specific details of the product or device used in their care.

4.20. Monitoring of device implantation and performance for clinical outcomes and tracing of patients at risk of device failure is an important safety issue. We have had examples of heart valve failure and prosthetic joint failure where such a facility would have been of benefit to patients. So, this is not just an issue for cosmetic implants it is an issue for the NHS and private sector alike.

4.21. The MHRA are developing a Unique Device Identifier so that all implantable devices can be tracked. In order to prepare for this:

Recommendation 20

- **A system should be developed by the MHRA to link the Unique Device Identifier for all implants to the patient's electronic record, enabling routine collection through Hospital Episode Statistic (HES) data. This information would enable assessment of implant performance, and the tracking and tracing of patients in case of a safety alert. The use of HES in the private sector hospitals which implant devices into people should be a CQC registration requirement.**

Recommendation 21

- **Until such a system is developed, a National Breast and Cosmetic Implant Registry should be established and operational within 12 months. All cosmetic surgery providers need to keep a minimum data set that should be defined by the RCS Interspecialty Group. This should include details of the implant, the surgeon, the hospital and appropriate outcomes, and these data need to be held in electronic format until the registry is operational. These data should be easily accessible in the case of a product recall.**

Adverse incident reporting

4.22. The reporting of adverse incidents related to implantable devices is not embedded adequately in the culture of the NHS or the private sector. The reporting of adverse incidents needs to become standard practice to help identify problems early and to reduce risks to patients. Following the issues around PIP breast implants, it is clear that the role and practice of the adverse event reporting system, and the duty on health professionals to report, needs to be better understood[2]. Those who need to be engaged are the surgeons and physicians who have to assess and deal with the consequences of failed or faulty devices. In order to achieve this the Review Committee recommends:

Recommendation 22

- **The Director of Patient Safety for NHS England should develop a framework to encourage and support the reporting of suspected device failures to the MHRA.**

Recommendation 23

- **Formal relationships need to be developed between the MHRA, and professional organisations such as the Academy of Medical Royal Colleges and the Specialist Associations whose members implant medical and cosmetic devices and deal with the consequences of failure.**

Recommendation 24

- **Assessment of systems for reporting adverse events should be part of CQC's registration and assessment of providers. Adverse incident reporting should be a standard component of professional appraisals and revalidation.**

5. Informed and Empowered Public

Improving the quality and accessibility of information and advice

5.1. When choosing to have a cosmetic intervention people need access to independent and evidence-based information to help inform their decisions. Many of these procedures are considered by both purchaser and provider to be little different from 'consumer goods' and it is important that people are informed of potential risks.

Shortcomings of the current regulatory approach

Lack of independent, evidence-based advice

5.2. Research carried out for the Review suggested that, in general, people think long and hard about cosmetic procedures, usually opting for them to resolve a long-standing issue that they perceive to be a problem[4].

5.3. However people considering these procedures are frequently overwhelmed with information and have considerable difficulty assessing its quality.

5.4. There is little reliable data to assist patients in making assessments of the efficacy and risks of treatments, or of the expertise and experience of the practitioner. Inflated claims can be made with little or no evidence and new procedures can be devised and promoted with the primary aim of gaining commercial advantage.

Poor consent practices

5.5. People considering cosmetic surgical procedures have a natural tendency to focus on outcome and unless guided may not pay enough attention to limitations and risks. This differs significantly from most surgery where patients may have no knowledge of the procedure but are acutely aware of, and alert to, the risks. Those actively seeking an aesthetic procedure may have a tendency to underplay the risk, in contrast to the apprehensive patient required to undergo a significant medical procedure.

5.6. Under these circumstances it is very important that practitioners taking cosmetic procedures and operations manage people as patients and not consumers when marketing to them, considering their suitability for the surgery, and when undertaking consent.

5.7. While there is some good provider practice, too often insufficient emphasis is given to explaining the risks of a procedure. The 2010 NCEPOD report *On the face of it* found

that 32% of sites were not performing the two-stage consent process for surgery[9] as recommended by the GMC[23]. This important recommendation is made to encourage a period of reflection during which the patient has the opportunity to consider the full implications of surgery.

5.8. The Review Committee was concerned about reports of patients being offered discounts for surgery if they sign a binding contract at the end of the first consultation. There were similar concerns following reports of enticements using 'last minute' and 'late space' deals whereby the patient was offered a discount to fill a 'free slot' a matter of days after the initial consultation. A patient cannot give informed consent if they are not provided with time to reflect. It is not acceptable that patients are encouraged to commit to such a significant decision without the opportunity for careful consideration. By comparison, the Distance Selling Regulations ensure that anyone buying a product via the internet has a 7-day cooling off period[50].The Committee believes that offers to fill such 'gaps' at a discounted price displays greater concern for commercial gain than patient wellbeing.

5.9. For non-surgical procedures, people are often seeking convenience and affordability and a two-stage consent process may add to the costs and inconvenience. While a two-stage consent process is less likely to be necessary for some non-surgical procedures, people still need to be made aware of the risks.

Insufficient focus on patients' expectations

5.10. Research commissioned for this review identified psychosocial and behavioural[51] factors as being more influential than demographic variables on people's enthusiasm for cosmetic surgery. Patients and practitioners should be aware that people considering cosmetic surgery at times of considerable change in their lives, such as separation or bereavement, are frequently more vulnerable than others.

5.11. Factors found to be associated with poor psychological outcomes following a cosmetic procedure included having a procedure to address relationship problems; unrealistic expectations of outcome and dissatisfaction with previous cosmetic surgery. Having a violent partner and dieting were also strongly associated with a decision to have cosmetic surgery, and moderate associations were found with being verbally abused; taking medication for sleep or anxiety; higher levels of stress and other forms of poorer mental health[51].

5.12. If a patient's motivation for seeking cosmetic surgery is not fully explored there is a risk that indications of underlying psychological issues, such as Body Dysmorphic Disorder (BDD) may not be picked up, and a patient may end up having surgery that is

unnecessary or is unlikely to bring them the result they seek. It is unlikely that cosmetic surgery alone will resolve their psychological problems[51].

5.13. The NCEPOD report *On the Face of It* found that of the 87% of those who responded, only a third (119 sites) carried out routine psychological evaluation of patients prior to surgery, and in only 4% of those sites were assessments routinely performed by a clinical psychologist[9].

Female Genital Cosmetic Surgery

5.14. Studies have suggested an increase in demand for female genital cosmetic surgery[52, 53], such as labiaplasty, driven in part by a combination of the influence of pornography but also by the lack of people's awareness of the normal range of size and shape of genitalia.

5.15. As with all other cosmetic surgical procedures, standards will be drawn up by the RCS Interspecialty Committee to cover this area, building on guidance recently developed by the Royal College of Obstetricians and Gynaecologists. Particular emphasis needs to be placed on the psychological assessment of the patient, the management of patient expectation, and ensuring that practitioners have a clear understanding of the Female Genital Mutilation Act[54].

The changes needed to improve the sector for the public:

5.16. People considering cosmetic interventions should be able to access clear, independent and evidence-based information to help inform their decisions. This should include information about the risks and possible outcomes from any procedure, what to expect, what questions to ask about a procedure and what happens in the event of complications or corrections. The information should be available freely before people decide to choose a procedure and available at consultations.

5.17. There is insufficient research and data on the effectiveness and risks of many cosmetic procedures on which to base patient information materials. More research and reviews of the available evidence for both existing and emerging procedures should be encouraged. The Committee welcomes the joint initiative by The Healing Foundation and BAAPS to establish an Aesthetic Research Institute as a potential model for boosting research in this area.

Recommendation 25

- **Evidence-based standardised patient information should be developed by the RCS Interspecialty Committee on Cosmetic Surgery. This should be done with input from patient organisations. This information should be available on NHS Choices and the Parliamentary Health Service Ombudsman (PHSO) website.**

Recommendation 26

- **Patient Decision Aids (PDAs) should be developed for cosmetic procedures and these should be piloted by the RCS Interspecialty Committee on Cosmetic Surgery.**

Consent

5.18. Obtaining proper informed consent is part of a practitioner's duty of care[23], and it is also a requirement for provider's registration with the CQC[55].

5.19. Patients should be aware of the implications of surgery, the limitations of the procedure and the potential complications. When the risks of surgery are discussed patients should be alerted to the risks of medical complications and also the possibility of an unsatisfactory aesthetic outcome. It is important that where appropriate the patient should be aware of the long term financial implications of surgery as well as the immediate costs of a procedure. For example, the Review Committee recommends that in the case of implants patients should be aware that there may be the need for future investigations, such as scans to check implant integrity, and treatment, such as the removal and/or replacement of an implant. Details of fees charged, including the possibility of any additional costs, should be provided, and the patient should be aware of the extent of aftercare.

5.20. Careful planning has a major influence on outcome in cosmetic surgery, and it is critical that the surgeon and patient have a shared understanding of expectations and limitations. It is the view of the Review Committee that this can only be achieved if the preoperative consultation is carried out by the surgeon planning to undertake the procedure. It is the Review Committee's view that the responsibility of obtaining consent should never be delegated by the operating surgeon to support staff.

Recommendation 27

- **The RCS Interspecialty Committee on Cosmetic Surgery should develop and describe a multi-stage consent process for operations. This consent process should be undertaken by the operating surgeon and its use should be mandated as part of the Code of Practice.**

Non-surgical interventions

The Review Committee is of the view that consent is an important issue for non-surgical interventions and recommends that:

Recommendation 28

- **For non-surgical procedures, a record of consent must be held by the provider.**

6. Responsible advertising and marketing

6.1. Providers use advertising and marketing to compete for consumers. A variety of media are being used, from traditional print media, radio and television advertising, "advertorials" (paid for editorials typically in magazines), through to digital social media advertising and marketing which has been growing in importance. Celebrity endorsements whether direct or indirect are especially important in this market. Advertising and marketing can have a legitimate role in that they provide information and raise awareness of the choice of providers available. However, they can also play a negative role particularly if they trivialise the risks of procedures, target vulnerable consumers, or mislead by portraying an outcome that may not be attainable for many.

Shortcomings of the current regulatory approach

Scope of current regulations doesn't reflect changing market

6.2. All advertising in the UK is controlled through a system of co-regulation and self-regulation, which is administered by the Advertising Standards Authority (ASA)[56]. This regulatory system is independent of government. The Committee of Advertising Practice (CAP)[57] and the Broadcast Committee of Advertising Practice (BCAP)[58] are responsible for writing and maintaining the advertising codes. The ASA regulates advertising in all media and ensures that advertisements, wherever they appear, comply with the requirements of the advertising codes – in particular that they are legal, decent, honest and truthful[59].

6.3. In addition, the CAP has issued a specific guidance note setting out good practice for the advertising of cosmetic surgery[60]. This clarifies the rules around issues like the use of the term 'specialist' or 'leading clinic'. Despite non-surgical procedures being the biggest area of growth for the industry, there are no specific guidelines around their advertising and marketing. These are currently regulated under the medicines, medical devices, health-related products and beauty products code[61].

6.4. Enforcement of these rules is largely reactive – breaches are normally investigated only in response to complaints. An advertisement may be withdrawn as a result of the investigation, but only after the advert has been in the public domain[62]. Moreover, much of the advertising of cosmetic interventions now takes place through social media[4], including direct messaging of potential consumers with marketing materials. Monitoring and enforcement can be more difficult in these areas and evidence suggests that there have been serious breaches that have not been picked up, including the targeting of minors.

Content of adverts does not reflect potential health consequences

6.5. There are no requirements for advertisements or marketing material to provide any information on the health risks of cosmetic procedures. Both surgical and non-surgical interventions can have a serious impact on an individual's health and wellbeing, yet much of the advertising trivialises the procedures and presents them as a desirable commodity.

6.6. The lack of regulation on risks seems inconsistent when considered in the context of other areas of advertising. Under medicines legislation prescription medicines cannot be advertised to avoid advertising practices conflicting with the health needs of patients. This means that botulinum toxin cannot be advertised[63]. In some other sectors, such as financial services, where there are potential risks to consumers, disclaimers are required and where there are potential public health risks, such as alcohol, tobacco or the advertising of food high in fat, salt and sugar to children, there are advertising bans in place. However, there are no specific restrictions on the advertising of medical devices, such as breast implants and dermal fillers.

Misleading and unethical practices

6.7. Some of the advertising and marketing practices used by the industry are highly misleading. 'Before' and 'after' photos may be digitally altered and may not show a typical or realistic result[64]. Claims are frequently made about 'creating a new you' or that a procedure will make you 'feel great' without any supporting evidence creating potentially unrealistic expectations, particularly among vulnerable consumers[4]. An area of concern to the Review Committee is the many TV makeover programmes where participants have procedures financed by providers. These programmes are the equivalent of magazine advertorials and often give a false impression of the transformative powers of cosmetic surgery. Of particular concern are TV reality/drama shows in which in which its young stars glamorise cosmetic procedures. It is not always made clear that these celebrities have contracts with particular providers.

6.8. Both financial inducements and time-limited deals are permitted under the current regulations. Cost is the key deciding factor for most people choosing a procedure or provider[65], so offers are likely to have an impact on purchasing behaviour. However, discounts for a package of procedures or offering cosmetic procedures as competition prizes may impair an individual's ability to give proper thought to what is being offered. Time-limited deals, which offer discounts within a certain timeframe, allow little or no opportunity for proper consideration of the risks involved.

International Example: Australia

In November 2010, the Australian Health Ministers' Advisory Council published its report Cosmetic Medical and Surgical Procedures – a National Framework. It made recommendations to Ministers for improved regulation across five areas of the cosmetic medical and surgical industry: the procedures, the promotion of the procedures, the practitioner, the patient and the place. The Council's proposals included:

- *Tighter restrictions on advertising, including prohibiting cosmetic procedures being offered as prizes and financial incentive schemes*
- *The introduction of minimum training and accredited standards for practitioners*
- *A public consultation on regulating unregistered practitioners*
- *Developing guidelines on consent and follow-up care*
- *Improved, accessible information for people considering procedures*
- *Clear avenues for redress, regardless of status of practitioner*

The changes needed to improve the sector for the public:

6.9. The current regulatory system needs to be updated to provide clearer rules through which to hold advertisers to account and which reflect the changing market, particularly the huge growth in non-surgical procedures and the increasing use of digital marketing. The Review Committee encourages the ASA to take a more proactive stance and monitor the industry more closely but professional organisations should also ensure that their members act responsibly when marketing their services. The ASA is also encouraged to look more closely at "hidden" advertising in reality TV shows.

Recommendation 29

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

Recommendation 30

- **CAP should extend its guidance note on cosmetic surgery advertising to cover non-surgical cosmetic procedures, and the sponsoring of TV and other programmes**

6.10. The Committee believes that advertising and marketing practices should not trivialise the seriousness of procedures or encourage people to undergo them hastily. Any claims must be based on high quality evidence and should not raise unrealistic expectations. The use of body images in advertising is an issue of particular concern, and it is an area that the Committee would like to see researched more fully to understand the impact it has on vulnerable consumers.

Recommendation 31

- **The Review Committee considers that the following advertising practices are socially irresponsible and should be prohibited by the professional registers' codes of practice:**
    - **Time-limited deals**
    - **Financial inducements**
    - **Package deals, such as 'buy one get one free' or reduced prices for two people such mother and daughter deals, or refer a friend**
    - **Offering cosmetic procedures as competition prizes.**

7. Accessible resolution and redress

Better support for people when problems occur

7.1. Sometimes cosmetic procedures are affected by complications. Results may not meet practitioner, patient or consumer expectations.

Shortcomings of the current regulatory approach

Insurance and indemnity arrangements are limited

7.2. Where an individual has suffered loss or harm due to negligence they may be able to seek financial compensation via the healthcare practitioner's insurance. The GMC 'Good Medical Practice' places a professional duty on doctors to have indemnity arrangements to cover claims of negligence. From October 2013, all healthcare practitioners will need to have appropriate cover as part of the EU Cross Border Healthcare Directive[66]. The scope of such insurance varies and it may not cover corrections or complications that are not directly due to practitioners' negligence – for example, for problems caused by faulty equipment or products.

7.3. Non-healthcare practitioners are not legally required to hold any insurance. Some choose to take out cover or are required to do so by the providers they work with.

7.4. There are no legal requirements for provider organisations to have insurance against patient claims. There is nothing to stop a provider who is facing claims from dissolving their business, thereby abdicating responsibilities to those patients, and then reopening as a new business offering similar services.

Concerns regarding continuity and complications are not always resolved

7.5. The extent to which complications of surgery are managed and patients are provided with continuity of care varies, and is dependent on the practitioner and the provider. Some will deal with certain complications without further costs, others may charge additional fees, and there have been examples of others who either refuse to help or are unable to due to lack of expertise. In these cases, the NHS often acts as the 'safety net', picking up where private providers have failed to offer safe and on-going care[32].

7.6. Difficulties may arise when the patient is dissatisfied with the cosmetic result of a procedure and believes that it does not meet the agreed expectation. The position can be particularly complicated if the practitioner feels that the clinical result is satisfactory. In

these cases, the patient is often unsure who to approach to try to seek redress. This applies equally to the non-surgical cosmetic interventions sector.

The redress systems available are unclear and hard to access

7.7. When patients have concerns over outcomes, many are unsure where to turn and there are few options available. While all organisations which provide goods or services directly to consumers on a commercial basis are required to comply with the general requirements of consumer protection legislation, the consumers and providers are not always aware of these requirements. Some providers have their own consumer codes of practice or schemes in place but these may not offer independent adjudication. Without avenues for informal dispute resolution people may only be left with the option of legal action. However, embarrassment, the cost and the level of commitment required may discourage them. There are a growing number of solicitors offering to take up cases, particularly for those who have had non-surgical procedures, on a 'no win, no fee' basis. But resorting to legal action may not always be in the best interests of the patient and consumer. Moreover, the lack of alternative dispute resolution options in this sector is out of step with wider consumer policy[67].

Cosmetic Tourism

The Review Committee was very concerned about the practice of cosmetic tourism[68], [69] with people travelling abroad for a procedure.

The following issues were felt to increase the risk, difficulties and costs

1. Lack of pre-operative screening and assessment

2. Typically patients only meet the surgeon and view the facility once fees have been paid and they have travelled abroad, at this stage they are financially and geographically committed. Any thoughts of pulling out are complicated by these commitments. There have been many reports of patients who describe feeling uncomfortable with the surgeon or facility and yet proceeded because of these pressures, only to experience problems later.

3. Difficulties arising on site, by the time the fee is paid they are hundreds of miles from home

4. Lack of cooling off periods

5. Difficulties of obtaining adequate consent in a foreign language

6. Difficulties of accessing after care and care of complications once home and hundreds, or thousands of miles from the surgeon

7. Difficulties of legal redress for patients in case of negligence

8. Risks of flying soon after surgery

The Review Committee recognises that people may consider cosmetic tourism in future but recommends that the individual considers all aspects of the offer very carefully, including limitations of remote care, and that they speak to their GP before committing to such an arrangement.

The changes needed to improve the sector for the public

7.8. The Review Committee believes that a practitioner's duty of care to a patient and consumer should go beyond the simple act of carrying out the procedure. This duty includes ensuing that a patient is appropriately informed of the risks of surgery, and has realistic expectations of outcome. The surgeon should provide appropriate follow up and aftercare. In the event of a complication and if the practitioner is not accessible, the Medical Director/Responsible Officer of the provider organisation, or the organisation providing admittance rights, should retain responsibility for the patient.

Recommendation 32

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

Recommendation 33

- **All organisations providing cosmetic surgery should have a doctor on the Board as Medical Director who is professionally accountable for all work carried out by the provider organisation and for its procedures, practices and wider activity.**

7.9. The Review Committee wants to see a transparent and accessible redress system in place across the industry covering both non-surgical and surgical procedures. Disputes should be resolved quickly and efficiently and wherever possible at the local level. The system should enable consumers to avoid resorting to legal recourse except in exceptional cases.

Recommendation 34

- **The remit of the Parliamentary and Health Service Ombudsman (PHSO) should be extended to cover the whole private healthcare sector, including cosmetic procedures and ophthalmology. Providers should offer advice on their complaints procedures to their patients, and where appropriate this advice should be available on their websites.**

Recommendation 35

- **Complaints against providers that are investigated and upheld by the Ombudsman should be publicly available.**

7.10. Patients should have recourse to financial compensation if they have been harmed by a practitioner, provider or product. The insolvency of the provider, practitioner or manufacturer should not leave patients unsupported financially.

7.11. Mechanisms need to be explored on how the NHS can recover costs[70] when it has to provide care for a patient in a situation where a practitioner, provider or manufacturer has been found to have failed the patient following surgery.

Recommendation 36

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

Recommendation 37

- **Device manufacturer risk pools should be established. The Department of Health should work with the EU and industry to help support this. This risk pool would meet the costs of complications or corrective surgery in the event of wholesale problems with a device.**

Recommendation 38

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

Recommendation 39

- **The insurance status of all practitioners should be displayed on the practitioner register.**

Recommendation 40

- **In order to ensure that all patients are adequately protected, overseas surgeons operating in this country should have the same level of professional indemnity as UK-based surgeons.**

What are insurance risk pools?

All insurance works on the basis of sharing the risk and cost between pools of people who have similar risks. Prices (premiums) may vary between payers, depending on their individual risk and the level of cover that they choose to buy. But insurance only works effectively if the members of the pool have similar risk profiles.

A bonding or risk pool arrangement is a type of insurance funding arrangement that pays money to an intermediary (typically, a trade association) when a triggering event occurs.

Bonding typically involves pooling, i.e. the members of a pool pay into a common fund and so directly co-insure each other. This is only possible where it is either imposed by law or the members of the pool enter voluntarily because they have sufficient common interest in co-insuring each other.

8. Appendix 1

MEMBERSHIP OF THE REVIEW COMMITTEE

Professor Sir Bruce Keogh, (Chair), NHS Medical Director
Ms Trish Halpin, Editor-in-Chief, Marie-Claire magazine
Professor Sir Ian Kennedy, Emeritus Professor of Health Law, Ethics and Policy at University College London
Ms Catherine Kydd, campaigner on PIP implants
Dr Rosemary Leonard, GP and media doctor
Mrs Vivienne Parry, writer and broadcaster.
Professor Shirley Pearce, clinical psychologist and former Vice Chancellor of Loughborough University
Dr Andrew Vallance-Owen, former Group Medical Director of BUPA
Mr Simon Withey, consultant plastic surgeon

SECRETARIAT

Dorian Kennedy, PhD
Kate Lawson
Stephen Mulgrew, MRCS
Jude Thorling

TERMS OF REFERENCE FOR SIR BRUCE KEOGH'S REVIEW

Taking into account the government's Better Regulation framework and the concurrent review by the EU of current arrangements for the regulation of medical devices:

1. To review the current arrangements for ensuring the quality and safety of cosmetic interventions posing a potential risk to physical or psychological health, and in particular to consider:

- whether the regulation of the products used in such interventions is appropriate;
- how best to assure patients and consumers that the people who carry out procedures have the skills to do so;
- how to ensure that the organisations which deliver such procedures have the clinical governance systems to assure the care and welfare of people who use their services;
- how to ensure that people considering such interventions are given the information, advice and time for reflection to make an informed choice;
- whether there should be a statutory requirement for such organisations to offer redress in the event of harm, and if so how this could be funded;
- what improvements are needed in systems for reporting patient outcomes, including adverse events, for central analysis and surveillance.

The review will consider issues of governance, data quality, record keeping and surveillance, as well as ensuring that sufficient information is provided to secure patients' informed consent. It will include consideration of the feasibility of an outcomes-based register of commonly implanted devices.

2. To make recommendations to ministers, including interim recommendations if appropriate, and to inform the UK contribution to the EU review.

The interventions to be considered for the purpose of this review could potentially include

- the surgical insertion of a medical device or prosthesis, or other surgery intended to change the appearance of the body
- injection with any product, whether medicinal or otherwise
- any other form of intervention at the discretion of the review team

  where the intervention is not clinically indicated to safeguard or improve the physical health of the recipient.

Appendix 2 – Risks of dermal fillers

Tamara Griffiths, MD FRCP – Consultant Dermatologist

On behalf of the British Association of Dermatologists

Loss of facial fat and volume loss is a hallmark of facial ageing, which results in a gaunt, haggard appearance. Dermal fillers can be used effectively to replace volume and restore a more youthful facial shape, as well as fill lines and wrinkles. Common areas treated are the nasolabial folds (lines between the nostril and corner of the mouth), marionette lines (lines between the corners of the mouth and side of the chin), glabella (between the eyebrows) and lips. More sophisticated practitioners can treat the midface/cheeks, temples and periorbital areas (areas around the eyes). Products have been developed to treat areas on the body such as the breast and buttocks to enhance volume and shape, which require injection of large volumes of product. Other products are used superficially in the skin to reduce the thin, crepe-like appearance for example on the backs of the hands and neck/anterior chest. Fillers can also be used to improve cosmetic appearance in defects which involve underlying disease (e.g., linear morphea, facial atrophy associated with HIV treatment)

Risk of **ALL** injectable fillers: Injection-related risks common to all fillers includes superficial infection, bruising, bleeding, under/over-correction and poor outcome. A more serious risk for **all** injectable fillers is: vascular occlusion either through embolisation or compression. This can result in ulceration, tissue necrosis and scarring. In the case of retinal artery occlusion, permanent blindness can occur. Retinal blindness due to all types of dermal fillers (autologous, permanent, semi-permanent and non-permanent) has been documented in the medical literature. In the case of large vessel embolism, pulmonary embolism and death has been reported (buttock injection). Nerve damage is another potential risk.

Injectable fillers can be classified as: autologous and non-autologous. The non-autologous category can be further classified as: permanent, semi-permanent and non-permanent (temporary).

Autologous fillers use the patient's own tissue to fill the volume defect, for example: autologous fat transplant and autologous fibroblast transplant (donor graft harvested from patient's own skin, cells cultured and reintroduced by injection). Autologous transplants carry little risk of allergic reaction or granuloma formation (which is an inflammatory response to a foreign body). There is also little risk of bio-film formation which is a chronic, low-grade bacterial encapsulation and colonisation around the implant. However with fibroblast transplant, there is a risk for error with mismatched tissue donors. A patient's skin cells are sent to an off-site laboratory to "grow" more cells in culture, and then sent back for injection into the same patient; samples can get confused with subsequent inherent infection and biohazard risk. The technique of autologous fat transplant is complex and there is higher risk for tissue damage and poor outcome. Fat tissue is harvested and prepared in real time on site, so there is little risk for donor mismatch. Both fat and fibroblast transplant carry risk of non-viability of transplanted cells and unsatisfactory results.

Non-autologous fillers are classified as permanent, semi-permanent and non-permanent (temporary). A potential risk for all of these is bio-film formation, as described above. The risks are mitigated with non-permanent fillers as the product is eventually resorbed by the body, resorption can be accelerated in the case of hyaluronic acid fillers with the use of hyaluronidase injection. Sterile technique and a clinical environment will reduce risk of bio-film.

A theoretical benefit of **permanent fillers** is that further treatment may not be needed as the effect is long-lasting. In reality, however, facial ageing is a dynamic process and permanent change may with time become aesthetically displeasing. Permanent fillers carry a very poor record in terms of safety and are the most common type of filler associated with granuloma formation. This is a chronic, debilitating foreign body reaction also seen in diseases such as sarcoidosis and tuberculosis. Chronic nodules develop which may require treatment with systemic immunosuppressive agents (e.g. Prednisolone) and recurrent surgical removal.

Figure 1: Chronic granuloma formation due to permanent filler injection

Semi-permanent fillers are those that potentially have a long-lasting effect through stimulating an autologous response, such as increased collagen production. Examples are poly-lactic acid (Sculptra®) and hyaluronic acid plus calcium hydroxyapetite (Radiesse®). These products, by definition are not “inert” and have an intentional biologic activity, i.e. stimulatory effect on cells with tissue response. Those which contain components that are permanent (calcium hydroxyapetite) can cause granuloma formation. Some semi-permanent filler (poly-lactic acid) have been associated with nodule formation which may be dependent on injector technique. Benefit from semi-permanent filler may be disappointingly short-lived if the tissue response is poor.

Non-permanent or temporary fillers are unlikely to elicit granuloma formation; however, other allergic reactions can occur, such as delayed-type hypersensitivity with bovine collagen. Bluish discoloration due to an optical phenomenon called the Tyndall effect can occur if the product is injected in the wrong plane. It may be possible to mitigate some adverse events caused by hyaluronic acid filler with hyaluronidase. There is evidence documented in the literature that even hyaluronic acid fillers are not “inert” and stimulate a tissue response through fibroblast proliferation and collagen production, though they were not designed with this intention. Some temporary fillers contain local anaesthetic (lignacaine) which can cause anaphylaxis and death.

Appendix 3 – Risks posed by laser treaments

COMPLICATIONS OF DERMATOLOGICAL LASER AND INTENSE PULSED LIGHT TREATMENTS

Dr Vishal Madan, MD, MRCP
Consultant dermatologist.
The British Association of Dermatologists

Lasers emit light with single wavelength and in order for the light to have an impact on human tissues; it must be absorbed by a target (chromophore) within the tissue. Laser light is usually fired at high energy or fluence, and its interaction with the specific target chromophore generates heat, which results in selective destruction of the target (selective photothermolysis). For skin lasers common targets include water, haemoglobin, melanin and tattoo ink. Despite being selective for the target chromophores, complications arise from collateral extension of heat to surrounding tissues and to competing targets. This results in injury to structures and tissues which were not the intended targets of the laser beam resulting in adverse events.

Complications arising from laser treatments are primarily due to: lack or deficiency of core knowledge of laser-tissue interaction on the part of laser operator, overzealous or inappropriate treatment, and very importantly improper patient selection. Notwithstanding, some side effects are common, expected and self-limiting and it is important that the laser operator is familiar with such phenomena in order to educate the patient of their expected occurrence.

Most medical lasers and indeed many used for treating “cosmetic” skin conditions belong to Class 4; the most dangerous class of lasers which have the potential to burn the skin and importantly to cause permanent eye damage and blindness. Such lasers may also represent a fire risk. Whilst most laser-tissue interaction is a result of the direct impact of the laser beam, indirect injury from reflections of the beam can also cause significant harm. For this reason, the setting and laser environment is critical and must comply with strict laser protection rules.

Intense pulsed light (IPL) differs from lasers by emitting a broad spectrum of light which is not coherent. Restrictive “cut off” filters are used to narrow the broad wavelength window in order to achieve a meaningful response to the skin condition being treated. IPL devices are extremely popular by virtue of their versatility in treating a range of dermatological indications. The common applications of IPL devices include laser hair reduction, treatment of vascular and pigmented lesions and skin rejuvenation. Unlike lasers, IPL does not identify a specific target chromophore. This can result in non-specific heating of the surrounding skin thus increasing the likelihood of adverse events, which confounds the widespread notion that they are actually “safer” than lasers.

Below are the complications associated with use of lasers and IPL in treatment of skin conditions, including hair reduction.

1. **Damage to the eye and vision**- direct or indirect ocular exposure to laser irradiation can result in injury to the cornea or retina. The chromophore is water in case of corneal injury, and with retinal injury it is the pigment melanin. Lasers which have water as a chromophore (carbon dioxide and Erbium: YAG, the two common ablative lasers) can result in corneal abrasions. Pigment specific lasers such as Nd: YAG, Ruby and Alexandrite can damage the retinal pigment resulting in retinal burns, and in the case of macular damage, total blindness. Vascular lasers such as the pulsed dye and KTP lasers can also cause injury to the retinal vasculature. Laser injury can also be caused by seemingly innocuous devices such as laser pointers and reports of blindness after

such injuries are not uncommon[71]. Protective eyewear should be worn by the patient and operator/s during all laser treatments. The author avoids treatment of periocular skin with 1064nm QS Nd:YAG laser and recommends appropriate intraocular shields for treatment of periocular skin. There is also risk of significant injury to the eye with IPL devices, necessitating appropriate eye protection for patient and operator.

2. **Fire hazard**- high intensity laser beams can ignite clothing, hair or oxygen tubes. It is therefore recommended that when operating in the vicinity of combustible material, saline soaked gauze is readily available.

3. **Injury to the skin**

   a. **Scarring**- All laser and IPL treatments have the potential to cause scarring. Overzealous fluence, incorrect patient selection and laser parameters, and post-operative infection are the common causes of scarring after laser and IPL treatments. Even the newer, low risk vascular lasers can result in scarring if recommended skin cooling techniques are not employed.

   b. **Hyperpigmentation (darkening of pigmentation)**- The skin pigment melanin is the desired laser target in certain conditions. However, sub-lethal energy to cells which produce melanin (melanocytes), can be innocent bystanders after any skin laser and IPL treatment. Both selective lasers such as Q switched laser treatments for tattoo removal and certain non-selective laser treatments such as ablative laser resurfacing and IPL can result in increased pigmentation (hyperpigmentation) and darkening which can be temporary to long-standing. This risk is highest in patients with darker skin types and for this reason, test patches are recommended before proceeding with laser and IPL treatments in these patient groups. Additionally sun avoidance and appropriate sun protection should be strictly enforced.

   c. **Hypo and depigmentation (loss of pigment resulting in pale or white areas)**- Stunning of the melanocytes by heat energy from various laser and IPL sources may result in hypopigmentation and lethal damage to these cells manifests as depigmentation. Such pigmentary alteration is more challenging to treat and can be permanent. Inability of the skin to acquire a tan on subsequent sun exposure means that damage to melanocytes has ensued. Test patches, whilst not confirmatory may guide and alert the practitioner of this potential complication.

   d. **Burns and Blisters**- This is usually a manifestation of high laser and IPL energy, missed tan or lack of protection of the epidermis by cooling or a combination of the above. Prolonged and painful blistering may be sign of incipient scarring.

   e. **Infection**- Broken skin after laser injury can be a portal of entry for infective organisms. Both bacterial and fungal skin infections have been reported after laser treatments. Patients undergoing laser and IPL treatments around the mouth may suffer from reactivation of cold sores.

   f. **Bruising**- is usually self-limiting and seen after vascular laser treatments such as the pulsed dye laser.

   g. **Prolonged redness-** is a rare complication of laser resurfacing and IPL procedures.

   h. **Milia-** these are tiny skin coloured cysts which may form after certain resurfacing procedures.

4. **Worsening of pre-existing skin condition/s**

   Patients undergoing laser and IPL treatments for acne or rosacea may experience a flare of their skin problems after treatment. Such patients should be warned of this risk and should be managed with appropriate therapies during the course of laser treatment.

   Darkening of tattoos is a phenomenon which is observed after treatments of certain coloured tattoos. This paradoxical darkening can be challenging to remove.

   Paradoxical hypertrichosis refers to increased hair growth following laser hair reduction procedures. The exact cause remains unknown.

5. **Infection risk for the operator**- Laser treatment generates splatter of tissue and laser plume (smoke generated during some laser treatments) has been found to contain viruses such as human papilloma virus. If the plume is inhaled, there is potential of development of respiratory or laryngeal warts. To avert this side effect, appropriate laser masks should be worn by the practitioner/s.

Appendix 4

RECOMMENDATIONS OF THE WORKING GROUP ON TRAINING AND EDUCATION IN COSMETIC SURGERY

Mr Chris Munsch, ChM, FRCS Consultant Cardiothoracic surgeon, Past Chairman of the Joint Committee on Surgical Training for the Royal College of Surgeons.

1. The only person who should carry out cosmetic surgery is a doctor, fully trained in the technical, professional and cognitive aspects of the practice, and competent to handle any complications that may arise
2. This person should have completed a full training programme in a recognized surgical specialty that has cosmetic and reconstructive elements in its curriculum. They should be on the specialist register in that specialty.
3. All surgeons carrying out cosmetic surgery must work within their defined scope of practice and expertise.
4. The term surgeon should be protected and defined by qualification and training.
5. Where cosmetic surgery forms part of the curriculum in a surgical specialty training programme, it is essential that the curricula requirements be delivered, including the practical and technical aspects of the curriculum.
6. It is appropriate that the NHS continues to fund training in cosmetic surgery. Surgical specialties, education commissioners and education providers need to develop effective partnerships and mechanisms to ensure that training in cosmetic surgery is delivered and quality managed. Effective local arrangements with private providers need to be developed, similar to the programme in the East Midlands. High-level support and resource for these arrangements is required.
7. The pre CCT fellowship programme in Cosmetic Surgery should be expanded to allow a greater number of surgeons in training to gain wider experience in aspects of cosmetic surgery prior to CCT.
8. Post CCT fellowships in cosmetic surgery should be created. These posts would be designed to bridge the gap between training and independent practice. They would be developed and quality managed by the specialty associations. It is suggested that healthcare providers might fund these posts as part of a ‘training levy’.
9. Specialty associations should consider establishing a mentorship network for surgeons new to independent practice.
10. Consideration should be given as to whether surgeons might be credentialed to undertake specific procedures, and if so how, either through local governance arrangements or through national standard setting.
11. All surgeons undertaking cosmetic surgery should undergo a preliminary appraisal by the provider institution, before undertaking independent practice.
12. All surgeons should undergo thorough annual appraisal, based on the production of evidence of good practice and satisfactory outcomes. Individual specialty associations should establish criteria and standards to apply to these appraisals.
13. Consideration should be given to the establishment of an interdisciplinary oversight group to ensure standards are consistently and appropriately applied across all areas of cosmetic surgical practice. However we do not recommend the establishment of a separate specialty of cosmetic surgery at this stage.
14. All surgeons undertaking cosmetic surgical practice in the UK should have medical indemnity cover with a UK MDO, with a cover level of £10m.

15. Provider institutions need to be subject to robust regulation through active inspection and enquiry. There should be an annual reporting mechanism to the regulator, who should at all times have the expertise and authority to act in the public interest.
16. A form of mandatory licensing should be introduced, applicable to all healthcare providers carrying out cosmetic surgery. This license should be dependent on the provider having effective systems of appraisal and assessment of doctors, and be subject to annual review.
17. There is a need for proper and rigorous regulation of Fly in/Fly out doctors, without the unintended consequence of disadvantaging UK based doctors
18. Fly In/Fly out doctors must be subject to the exactly the same standards and regulations as UK surgeons. Healthcare providers must demonstrate that they are using appropriate processes to ensure that this is the case
19. To summarise all surgeons wishing to undertake cosmetic surgery in the UK must:

- Be fully trained in the relevant surgical specialty
- Be on the UK specialist register in that surgical specialty
- Undergo a preliminary, pre-practice assessment/appraisal to determine competence before undertaking independent practice.
- Undergo a thorough annual appraisal and be able present evidence of consistent good practice
- Carry £10m of indemnity cover with a UK based MDO.

29 January 2013

Glossary

Abdominoplasty This is an operation also known as a 'tummy tuck', it involves removing excess fat and skin in order to make the abdomen more firm.

ABCP Academy of Cosmetic Practitioners

ASA The Advertising Standards Agency is the UK's independent regulator of advertising across media, including TV, internet, sales promotions and direct marketing.

AvMA Action against Medical Accidents (previously known as Action for the Victims of Medical Accidents)

BAD British Association of Dermatologists

BAAPS the British Association of Aesthetic Plastic Surgeons. Association ''established for the advancement of education in, and the practice of, Aesthetic Plastic Surgery for public benefit''

BABTAC British Association of Beauty Therapy and Cosmetology

BAPRAS British Association of Plastic, Reconstructive and Aesthetic Surgeons. Professional association that ''exists to promote the best evidence-based practice in plastic, reconstructive and aesthetic surgery in order to achieve the highest standard of patient care through professional support in education, research and the development of knowledge''.

Blepharoplasty This is a cosmetic procedure used to remove excess skin from the either the upper or lower eyelid.

BMA British Medical Association

Body Dysmorphic Disorder Defined as a preoccupation that causes significant distress with one or more defect in one's appearance for which most people can hardly notice or do not believe to be important.

Body lift A body lift is surgery performed to correct excess loose and sagging skin. Surgical body lifting improves the shape and tone of the underlying tissue that supports fat and skin.

Brachioplasty A brachioplasty, or arm lift, is a surgical procedure to remove loose skin and excess fat deposits in the upper arm.

Breast augmentation/reduction Breast augmentation involves surgically inserting an artificial implant to increase the size of the breast. Breast reduction involves removing excess tissue to reduce the size of the breasts.

Breast implant a medical prosthesis used in post–mastectomy breast reconstruction or for breast augmentation.

Breast Implant Registry a voluntary registry of breast implant usage in the UK which was operated from 1995 to 2005. It was shut down due to a high proportion of women not consenting to their details being recorded, meaning the information the registry contained was of inadequate quality for research purposes.

Browlift Also known as a forehead lift or browplasty, is a cosmetic surgery procedure used to elevate a drooping eyebrow that may obstruct vision and/or to remove the deep "worry" lines that run across the forehead.

Buttock lift/ implant A surgical procedure that removes excess skin and fat from the buttocks, and/or the insertion of an implant may enhance the appearance, size and definition of gluteal muscles in the buttock area.

CAP Committee of Advertising Practice

Cheek implant Also known as Malar augmentation, uses implants, usually made of synthetic material, to make cheek bones more prominent

CMO Chief Medical Officer

Competent Authority national body responsible for the compliance with and enforcement of the EU Medical Devices Directive as it applies to medical devices, device manufacturers and notified bodies in their Member State. In the UK this is the MHRA.

Cosmetic intervention operations or other procedures that revise or change the appearance, colour, texture, structure, or position of bodily features, which most would consider otherwise within the broad range of 'normal' for that person.

CQC Quality Care Commission is the regulatory body for all health and social care services in England.

CPSD Cosmetic Products (Safety) Regulations 2008

Facelift Also called rhytidectomy, facelift is a plastic surgery procedure used to remove facial wrinkles, sagging skin, fat deposits, or other visible signs of aging for cosmetic purposes

FDA Food and Drug Administration USA

GDC General Dental Council

GMC General Medical Council is the regulatory body for doctors in the UK.

GP General Practitioner

GPSR the General Product Safety Regulations 2005

Gynaecomastia is a common condition in teenage boys where firm tender breast tissue grows under the nipples. It is usually caused by an in balance if hormones during puberty and usually disappears in a couple of years.

IHAS Independent Healthcare Advisory Services is a representative organisation for the independent healthcare sector.

Labiaplasty A surgical procedure to reshape the inner lips of the vagina.

Laser liposuction A method of liposuction that utilizes a laser during surgery to assist in unwanted fat removal.

MAC Medical Advisory Committee

Mastopexy Plastic surgery in which the breasts are lifted or reshaped.

MDA Medical Devices Alert notice issued by MHRA with important safety information related to a medical device sent to key contacts across the healthcare system using the Central Alerting System with instructions for further cascading to relevant health care workers, as well as being posted on the MHRA website.

Medical Device defined in European law as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.

MDT Multi-disciplinary team

MDEG Medical Device Expert Group. Established by the EU Commission, MDEG is composed of delegates from member state competent authorities, industry and other stakeholder representatives in the area of medical devices and is the forum in which the implementation of the Medical Devices Directive is discussed. In closed session, MDEG consists of member state competent authorities only and is a forum to discuss all issues relating to the implementation of the medical device directives. MDEG is responsible for publishing guidance documents which reflect the consensus position of its members on interpretation of the Medical Devices Directive.

Medical Device Liaison Officers members of staff designated in all NHS trusts and primary care trusts in England who are responsible for encouraging effective and comprehensive adverse incident reporting and action on medical device safety publications through encouragement and training of healthcare and support staff and medical device users.

Medical Devices Directives European Union legislation which, when translated into national law in EU member states, provides the legal framework for regulation of medical devices in Europe.

MHRA the Medicines and Healthcare products Regulatory Agency, the UK competent authority responsible for regulation of medicines, medical devices, blood and blood

components. MHRA is an Executive Agency of the Department of Health.

NMC Nursing and Midwifery Council

Notified Body third-party private sector organisations designated by their national competent authority and commissioned by manufacturers to determine whether a particular medical device meets the relevant regulatory requirements and, whether, when used as intended, it works properly and is acceptably safe (the process known as conformity assessment).

Pinnaplasty Also known as otoplasty, a surgical procedure done to correct misshaped or prominent ears.

Post-market surveillance a systematic procedure to review experience gained from their devices after they are placed on the EU market, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of:

(a) any adverse incident which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;

(b) any field safety corrective action (e.g. systematic recall) undertaken by the manufacturer to reduce the risk of adverse incidents with the device.

RCN Royal College of Nurses

Rhinoplasty Aesthetic surgery of the nose where cartilage and bone are reshaped and reconstructed; excess bone or cartilage may be removed.

Thigh lift A thigh lift can be performed to tighten sagging

muscles and remove excess skin in the thigh area.

Thread/suture facelift Minimally-invasive facelift procedure involving the insertion of fine threads (sutures) through small incisions into deeper tissues. The threads are attached to soft tissues and are pulled upwards to tighten the deep tissues

SMR08 Supply of Machinery (Safety) Regulations 2008

TYCT Treatments You Can Trust A provider register run by IHAS. Registered Providers are fully qualified, trained and insured and will deliver treatments which comply with a minimum of standards and are delivered in facilities which are clean, hygienic and comfortable.

Vaginoplasty is a plastic surgery procedure used to construct or reconstruct a vaginal canal and mucous membrane.

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