

# **Scottish Cosmetic Interventions Expert Group**

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## **Scottish Cosmetic Interventions Expert Group**

### **FOREWORD**

The Scottish Cosmetic Interventions Expert Group (SCIEG) was set up in January 2014 to explore the need for introducing regulation to cosmetic procedures following the publication of the Keogh Review in April 2013. The Keogh Review noted that little regulation already exists, and that there was a call for this amongst those working within the sector.

The SCIEG was formed with representation from all those interested in ensuring that those delivering cosmetic interventions do so with an appropriate level of training and skill. The recommendations contained within this report have been designed to ensure those who choose to seek cosmetic interventions can do so with the knowledge that providers delivering services meet certain basic standards of training. Whilst any cosmetic intervention can have a poor outcome, this will be less likely if delivered by those with adequate training.

One of the problems encountered by the SCIEG in its work was the lack of information about the numbers of procedures being performed, and where they are taking place. As well as aiming to safeguard standards of practice, these recommendations should allow improved collection of data regarding levels of activity and therefore a greater insight into the sector.

There are a number of areas where decision making is reserved to the UK Government, and these are identified in the report. It is the areas which are devolved, and where in some cases there are no current parallels with existing mechanisms in England, that particular attention has been paid.

The Keogh review opened with the stark statement that “a person having a non-surgical cosmetic intervention has no more protection and redress than someone buying a ballpoint pen or a toothbrush”. It is hoped that adoption of these recommendations will end this situation.

**Andy Malyon**

**SCIEG Chair**

**Consultant Plastic Surgeon**

**Chief Medical Officer’s Speciality Adviser in Plastic Surgery**

## Abbreviations

ASA	Advertising Standards Authority
ASD	Analytical Services Division (Scottish Government)
BAAPS	British Association of Aesthetic Plastic Surgeons
BAPRAS	British Association of Plastic, Reconstructive and Aesthetic Surgeons
CAP	Committee of Advertising Practice
CSIC	Cosmetic Surgery Interspeciality Committee (Royal College of Surgeons)
DH	Department of Health
EU	European Union
HEE	Health Education England
HFS	Health Facilities Scotland
HIS	Healthcare Improvement Scotland
HQC	High Quality Care (subgroup)
IEP	Informed and Empowered Public (subgroup)
IRIC	Incident Reporting and Investigation Centre
ISCAS	Independent Sector Complaints Adjudication Service
MHRA	Medicines and Healthcare products Regulatory Agency
PHIN	Private Healthcare Information Network
PIP	Poly Implant Prothese
SCIEG	Scottish Cosmetic Interventions Expert Group
SGHSCD	Scottish Government Health and Social Care Directorate
SMASAC	Scottish Medical and Scientific Advisory Committee
UDI	Unique Device Identifier

## **1. Executive Summary**

This report summaries the work of a range of stakeholders with expertise in: different areas of health care (including dentistry, general practice, medicine, surgery, nursing, pharmacy), regulation of health care professionals, cosmetic industry provision and regulation, public engagement, data analysis, public health, higher education, and social marketing.

The deliberations of the SCIEG and its subgroups were aimed at improving the safety of the public who choose to have services in the independent cosmetic health care sector. The work revolved around four themes: improved and proportionate regulation; enhanced communication and care between patient and provider; increased knowledge and awareness of the risks and benefits among potential customers; and finally and crucially, the need for a monitoring framework to find out the impact of this work.

There is considerable diversity in the cosmetic interventions sector. People with a broad range of backgrounds provide rapidly changing interventions which are becoming increasingly popular. To better understand the most appropriate approach to improving quality in the cosmetic interventions sector, a range of evidence was considered. These included a literature review, Omnibus survey of the general population, survey of consumers, survey of providers and a series of focus groups with the public. To clarify current regulation of providers, the term 'regulated professional' means a health care professional who is required to register with a statutory regulatory body in order to practice in the UK, such as a dentist with the General Dental Council, or a nurse with the Nursing and Midwifery Council, a medical doctor with the General Medical Council.

The recommendations that the Group puts forward to the Scottish Government are:

### **1. REGULATION**

The SCIEG recommends a three phase approach to introducing regulation of cosmetic procedures. The rationale for this approach is outlined in chapter 6. Regulation should operate on a cost-recovery basis, based on fairness. The three phase approach combines proportionality and timeliness:

- a. Phase 1: Regulation of independent clinics (on the basis of services being provided by a doctor, dentist, dental care professional, nurse or midwife) with Healthcare Improvement Scotland. Statutory arrangements for independent clinics and the capacity for Healthcare Improvement Scotland to receive complaints from the public will foster improvement in the delivery of high quality care.
- b. Phase 2: Extending regulation through the use of one or more of the following options:
  - i) Certain high-risk procedures (and especially dermal fillers) should only be provided by, or on behalf of, regulated health care professionals who have an appropriate level of expertise. If at all possible, this should be introduced in a coordinated

manner across the UK, to reduce the chance of 'cross-border tourism'. When provided on behalf of a regulated health care professional, that professional should ensure that all reasonable steps have been taken to assure the training of those delivering the procedure and should have overall responsibility for the quality of care delivered.

ii) In addition, compulsory licensing by local authorities should be required for all cosmetic practitioners delivering specific cosmetic procedures (a broader range of procedures than covered by i).

c. Phase 3: A few individuals with health care professional training who are outwith the groups noted in phase one may provide specific cosmetic procedures now and in the future to consumers. The numbers are expected to be very small compared to the professional groups involved who would have acquired the necessary additional skills and expertise. This may include for example, any clinical scientists who are supervising and performing aesthetic laser procedures, whose services can be regulated as independent clinics in their own right if necessary. Progress on the regulation of independent clinics will be monitored and consideration given to a new accreditation scheme, voluntary or legislative, for specified health care professional groups who wish to join the regulatory process.

## **2. GOOD PRACTICE**

According to the data gathered, consent for surgical and non-surgical interventions is mainly taken in writing. Implied consent is used by a minority for non-surgical procedures. The main reason for health care professionals and cosmetic practitioners refusing treatment is that it will not meet the expectations of the clients. Ensuring the client / patient is fully informed about a procedure so that they are able to give genuinely informed consent is known to be difficult. Clients / patients are often unable to recollect information they have been given or misinterpret what they have been told, despite the best efforts of providers.

The new ruling from the recent Supreme Court (Montgomery vs Lanarkshire HB) dictates an explicit need to detail and record discussion around risk. Risk is 'material' if it is seen as of significance to a reasonable person in the patient's position.

A new concept developed from the plastic surgery speciality is a 'request for treatment' agreement between the provider and client. This allows the client to state what they are expecting to occur as a result of the treatment and an explicit discussion to be had on the likely outcomes. The first recommendation for good practice is:

a. 'Request for treatment'<sup>1</sup> should be used as the standard agreement between a provider and a consumer of cosmetic interventions to obtain informed consent.

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<sup>1</sup> <http://www.ncbi.nlm.nih.gov/pubmed/20353637>

Advertisements were seen as presenting an unrealistic image of cosmetic interventions by the participants in the focus groups. There are standards on what can and cannot be advertised, including restrictions on advertising prescription-only medicines and the need to present a fair portrayal of what outcomes are likely from treatments. Sales promotions should be guided by UK advisory bodies and must not pressurise consumers with time-limited offers. The SCIEG observed many instances in which existing guidance on the marketing of cosmetic procedures is ignored. In order to reduce problematic marketing, poor practice needs to be notified to the Advertising Standards Authority (ASA). The second recommendation is:

b. It should be the duty of regulated care professionals and cosmetic practitioners providing cosmetic interventions to report breaches of advertising guidelines to the Advertising Standards Authority

The training of all health care professionals and practitioners of cosmetic interventions must be kept up to date and linked to national standards (such as the Royal College of Nursing accredited competencies used by the British Association of Cosmetic Nurses). The developing certification for surgeons from the Royal College of Surgeons and the Health Education England (HEE) framework for qualifications accrediting individuals to carry out non-surgical procedures are helpful additions. Both reports are likely to be published by the middle of 2015. The third recommendation is:

c. Health care professionals and cosmetic practitioners undertaking cosmetic interventions must be aware of training standards in their sphere of practice and keep up to date. The HEE training framework for nonsurgical cosmetic interventions will need to be assessed for relevance to Scotland.

New procedures, medical devices and devices sold for cosmetic interventions without a medical purpose, can be introduced into independent health and beauty care without strict monitoring processes. The literature review carried out for SCIEG found major limitations in the evidence base for many procedures and this makes it difficult for health care professionals and cosmetic practitioners to accurately inform potential consumers about the risks and benefits of many cosmetic procedures. Regulated health care professionals are required to demonstrate through revalidation how they are examining and reflecting on their practice. It is vital that all adverse events are reported promptly and feedback given on the outcome of reports. The fourth recommendation is :

- d. Providers are expected to have clear governance processes (similar to those in the NHS) and pursue evidence-based practice by collecting, analysing and making available comparable data.

Focus group participants suggested that psychological assessment or group work would be beneficial to some people before having a cosmetic intervention. Patient/client group work has been used with success in certain other areas of surgery (e.g. bariatric surgery) where individuals provide support for each other. Therefore the fifth recommendation for good practice is:

- e. Providers of cosmetic services should always consider, and record the outcome of their assessment of the current and on-going psychological and emotional support requirements of their clients.

### **3. INFORMED AND EMPOWERED PUBLIC**

Evidence from the focus groups and questionnaires found understanding of the potential risks of cosmetic intervention treatments varied widely. The gap in knowledge tends to be partly filled after a poor experience of a family member or friend. The consequences of some procedures are also masked when offered in situations where clients are under time pressure (e.g. offer ends today) or when alcohol is available. The likelihood of a procedure having long-term adverse effects may not be clearly stated. The IEP subgroup identified a need to improve the public's knowledge so that the right questions can be asked by potential clients from their providers; they know what to reasonably expect from a provider; and know who to report any problems to if things go wrong. The first recommendation for informing and empowering the public is:

- a. Conduct a social marketing campaign, targeted at groups with specific need such as young people, to inform and empower the public so that they have a realistic understanding of the potential risks and benefits of treatments.

Cosmetic procedures are requested to change or improve an aspect of an individual's appearance. The change is usually enjoyed and the market for new and improved procedures expanding. There is concern among some providers and sections of the public that a false image of what is normal, age appropriate or can be realistically achieved may also be growing. Opportunities to teach and explore body image within personal development classes, young people's groups, older people's forums and elsewhere, could contribute to enhanced self-esteem and foster mental wellbeing. The second recommendation is:

- b. Consider ways of supporting positive views of body image through education, mental health and broader wellbeing initiatives amongst different population groups

### **4. ACCESSIBLE REDRESS AND RESOLUTION**

The consumer questionnaires and the focus groups found that sometimes clients are not aware of who is providing their cosmetic procedure, or of their relevant

qualifications. This is unprofessional and risks compromising follow-up with the provider should difficulties arise. The recommendation is:

- a. The client / patient must be given information on the name and the relevant qualification(s) of the person providing the procedure

The PiP silicone breast implant failure was followed by some independent providers indicating they had insufficient resources to respond to all those in need of care. This situation was unusual but the need for adequate indemnity is now a requirement for all health care professionals and must be a feature of the training and business management information for all those providing cosmetic interventions. The second recommendation is:

- b. All providers undertaking any cosmetic intervention must have sufficient indemnity for their services

While Healthcare Improvement Scotland receives complaints about those services which it inspects, it is where to complain when issues arise in different settings or after a course of treatment has finished may be unclear to clients and the general public. The Independent Sector Complaints Adjudication Service (ISCAS) requires all independent hospitals to have transparent complaints systems.

Follow-up needs to be clearly described for both clients and the general public for care in the independent health care sector. Local authorities may receive complaints either directly or through the Citizen Advice Bureau. However, there appears to be reluctance for members of the public to complain if they have experienced poor care or an adverse event. Clinicians have found people are often not willing to complain about poor care but will seek out another practitioner. Being aware of how to complain and providing support to complain, in a manner that is sensitive to different ethnic groups, is a key component of accessible redress and resolution. The third recommendation is:

- c. Transparent complaints systems must be visible for all services, enforced by Healthcare Improvement Scotland for the services they regulate, the Independent Sector Complaints Adjudication Service for independent hospitals and the Local Authorities for the services they monitor.

Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practice. The process is also being introduced for dentists, nurses and midwives. The formal system is supported by annual appraisal meetings at which the outcomes of their NHS work and any other work should be discussed and examined. Appraisals can be informed by reviewing compliments, complaints and any significant adverse events. The fourth recommendation is:

- d. Appraisal of health care professionals should include discussion about the entirety of their practice, including cosmetic procedures.

The PiP silicone breast implants and metal on metal hips device failures highlighted the need for people to know what implant they have in place and for their medical records to be easily examined to find out if they are potentially at risk of an adverse outcome. The Private Healthcare Information Network (PHIN) is mandated by the Competition and Market Authority to collect data from all organisations undertaking cosmetic surgery. Currently all implants must be recorded in operation notes and kept for life. Some patients receive an implant card with all details listed. However patients' paper records may become detached from the operation notes and searching through all records to find those that might be affected by a device failure is time-consuming and may be impractical. Therefore there is a concurrent project examining whether a unique device identifier (barcode) can be entered into the electronic patient record so in case of device issues, patient requests, needs for certain medical scans and death certification, the information can be easily retrieved. This project is exploring the feasibility of such an approach and the first report is likely to be at the end of 2015. To support this work the fifth recommendation is:

- e. Data including the UDI on all devices and implants must be included and easily extracted from electronic records of patients and clients and comply with any future / evolving UDI requirements.

## **5. MONITORING AND EVALUATION**

It is important to monitor and evaluate the impact of any actions taken forward by Scottish Government and other stakeholders as a result of the recommendations of SCIEG. Questions on cosmetic procedures have been added to the Scottish Health Survey and will provide a baseline picture, prior to the implementation of these recommendations. A draft logic model has been developed and will be revised once the policy response to this report is available. A basket of process and outcomes indicators will be selected to keep track of progress and evaluate the outcomes of policies. The recommendation is:

- a. A framework for monitoring and evaluation is expected to be developed by the Scottish Government to ensure monitoring of the implementation of the recommendations and evaluation of their impact.

## **2. Background**

### **Cosmetic procedures: An overview of the market**

There is currently a lack of internationally agreed terminology to describe what cosmetic procedures are and how they should be defined. The UK Cosmetic Surgery Interspecialty Committee (CSIC) previously defined cosmetic surgery as an area of practice involving:

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

Cosmetic surgery does not constitute a defined medical specialism, in contrast to for example, plastic surgery, maxilo-facial surgery and dermatology. As a result, some procedures may be performed by a range of specialist doctors (e.g. rhinoplasty<sup>2</sup>) and some could be performed by those with no specific mandatory specialist training.

Cosmetic procedures refer not only to surgery but also include a large variety of non-surgical procedures, such as injection of botulinum toxin (several different brands and an example is 'botox®') or dermal fillers. A commonly used distinction between invasive and non-invasive procedures is whether a surgical incision is required to carry out the procedure. Unfortunately, terminology remains highly variable and the proliferation of new treatments adds to the challenges in understanding the range of available procedures. In this report, the terms 'cosmetic procedures' and 'cosmetic interventions' will be used interchangeably to refer to both non-surgical and surgical procedures.

In addition to the diversity of procedures available, many different types of providers may offer services. For many non-surgical procedures no mandatory qualifications, skills or training are stipulated. There is anecdotal evidence that a huge variety of providers exists, often describing themselves using a range of terms. The diverse descriptions of providers makes assessments of their competence difficult for both the general public and even trained health care professionals & practitioners (see Box 1). In this report, the terms health care professional and cosmetic practitioner will be used to distinguish between two groups:

- Health care professional– providers of procedures subject to their code of practice who have received a formal health qualification and are subject to compulsory licensing with a regulatory professional body in order to practice within the UK. This includes doctors, dentists, dental care professionals, clinical scientists, nurses, pharmacists, physiotherapists, occupational therapists and others. The scope of practice for doctors, dentists, dental care professionals and nurses can include cosmetic procedures.
- Cosmetic practitioner– providers of cosmetic procedures who are not subject to a formal system of compulsory professional regulation. This includes beauty therapists, hairdressers and a range of other providers.

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<sup>2</sup> Operation on the nose

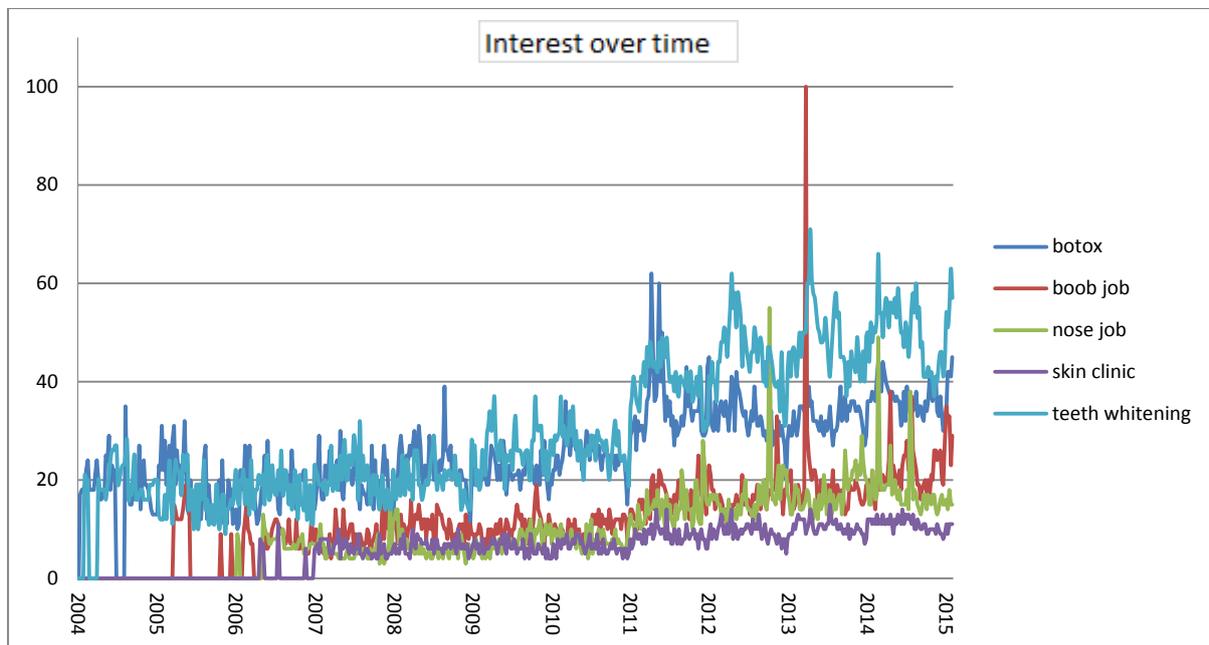
## Box 1: Examples of providers of non-surgical cosmetic procedures

Title	Meaning
Cosmetic/Aesthetic doctor/dentist/nurse	A registered health care professional who may or may not have additional relevant specialist training
Cosmetic surgeon	A medically trained health care professional who may or may not have expertise in surgery. There is no recognised training pathway to become a cosmetic surgeon.
Plastic surgeon	A surgeon who has received specialist training in the restoration of appearance and function of the human body following trauma or illness, as well as aesthetic surgery. They will have undergone a (minimum) six year training programme laid down by the Joint Committee on Surgical Training, the UK body which regulates all surgical training.
Beauty therapist	A person trained through a two or three year programme to improve or alter the appearance of a person's face, body or hair. The programme includes formal training on certain manual and electrical cosmetic procedures as well as health care risk and management, lifestyle advice and product knowledge
Beautician	A person who is trained to improve the appearance of a person's face, body or hair. They may have a range of practical skills including facials, makeup and nail treatment, with knowledge of and adherence of health and safety procedures, dealing with products and customer support in beauty activities. They may or may not have any formal training in delivery of cosmetic procedures.
Cosmetic/Aesthetic practitioner	A person providing cosmetic procedures who may or may not have any specific qualifications or training in this field.

Over the last decade, the uptake of cosmetic procedures appears to have soared. According to market research data, cosmetic procedures were worth £2.3 billion in 2010 and up to £3.6 billion in 2015 (Keogh Review<sup>3</sup>). The market rate of growth in the sector shows no signs of slowing. According to the British Association of Aesthetic Plastic Surgeons (BAAPS), the number of cosmetic surgical operations increased by an average of 17% between 2012 and 2013, with some procedures increasing far more quickly – for example, liposuction increased by 41%. The volume decreased in 2014 due to a reduction in the number of breast implant operations which had peaked during the PIP implant actions in 2012/13; other cosmetic procedures continue rising.

<sup>3</sup> <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>

While robust data are lacking, there are indications that the increase in non-surgical cosmetic procedures may be even greater. For example, Google searches in the UK for terms related to non-surgical procedures appear to have increased more rapidly than for surgical cosmetic procedures (see Figure 1).



**Figure 1 Trends in searches for four terms related to the use of cosmetic procedures on the Google search engine**

Source: Google trends. Purple = tooth whitening. Blue = botox®. Red = boob job. Green = skin clinic. Note: An improvement to Google’s geographical assignment was applied on 1/1/2011.

As cosmetic procedures have grown in popularity, the diversity of settings in which they are performed has increased. Historically, cosmetic surgery was almost exclusively performed within hospital settings. In contrast, the range of procedures currently available can be performed within many locations – including private clinics, dental surgeries, beauty parlours and client homes.

While there is a lack of robust data on the consumers of cosmetic procedures, the available evidence suggests that females have been the predominant consumers to date. However, the growing popularity of procedures more targeted at males (such as hair transplantation) may herald an increase in uptake amongst this population.

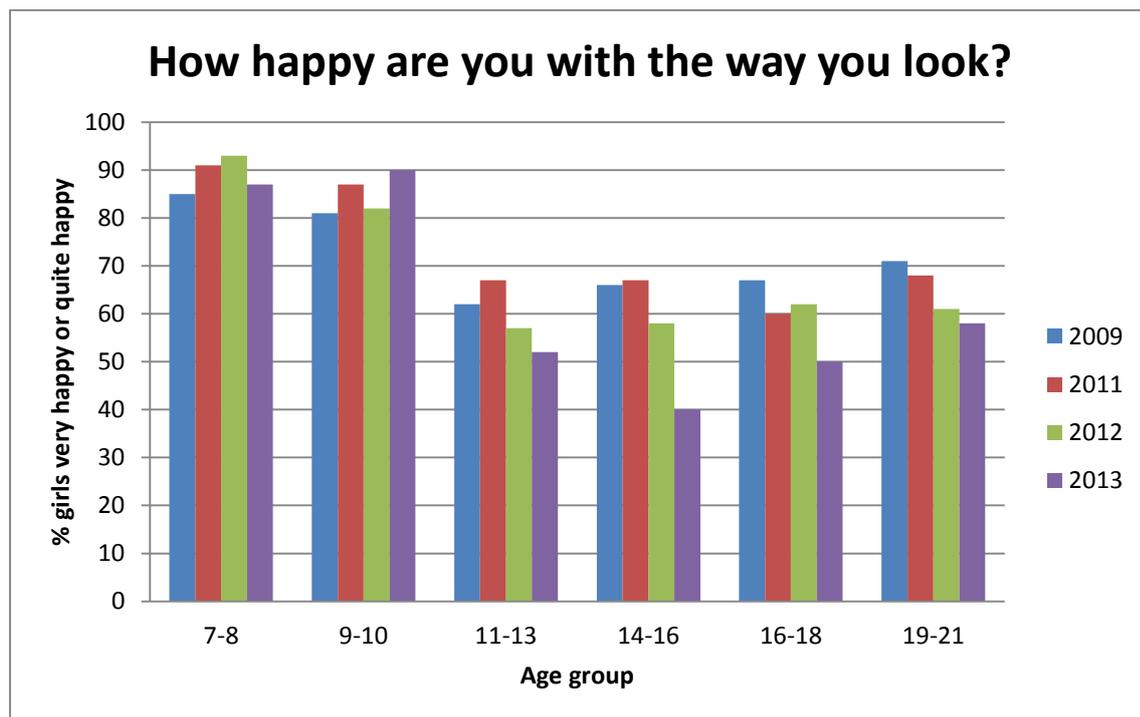
### Advertising and changing in social norms

Paralleling the growth in cosmetic procedures has been an emerging concern amongst health professionals and academics that aggressive marketing may be bringing about adverse changes in social norms. Breaches of the ASA voluntary code appear to be commonplace. In relation to the marketing of cosmetic procedures, the Committee of Advertising Practice (CAP) specifically cautions against the use of time-limited offers and that adverts should not encourage consumers to undergo unnecessary or unwanted procedures. It is relatively easy to

find examples where current advertising standards are breached (for example mention of ‘botox®’ on front page of websites).

The Keogh 2013 Report<sup>4</sup> raised concerns that the growing normalisation of cosmetic procedures, coupled with its aggressive marketing, may be fuelling concerns with body image. The Girls Guides’ Association has been monitoring satisfaction with body image over the last five years. Amongst adolescents, there appears to be a growing dissatisfaction, as shown below.

**Figure 2: Percentage of girls who are happy with the way they look by age group, for the period 2009-2013**



Source: The Girl Guides’ Association, Girls Attitudes 2009-2012<sup>5</sup>

As a consequence of the Department of Health’s endorsement of most of the recommendations of the 2013 Keogh Review, the CSIC of the Royal College of Surgeons was established. Its work has been conducted in parallel to the SCIEG, with a remit that includes the development of minimum standards for the training and practice of cosmetic procedures (often referred to as ‘credentialing’).

The Department of Health also gave a mandate to Health Education England (HEE) to work with regulators, royal colleges and other stakeholders to conduct a review of the qualifications required for non-surgical cosmetic interventions, the qualifications required to be responsible prescribers and to make recommendations on

<sup>4</sup> Department of Health April 2013  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/192028/Review\\_of\\_the\\_Regulation\\_of\\_Cosmetic\\_Interventions.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192028/Review_of_the_Regulation_of_Cosmetic_Interventions.pdf)

<sup>5</sup> [http://girlsattitudes.girlguiding.org.uk/video/girls\\_attitudes\\_video.aspx](http://girlsattitudes.girlguiding.org.uk/video/girls_attitudes_video.aspx)

accreditation of qualifications and course delivery. The non-surgical cosmetic interventions within the framework are:

- Botulinum toxin
- Dermal fillers
- Chemical peels
- Skin micro-needling
- Mesotherapy
- Laser treatments
- Intense pulsed light therapy
- Light emitting diode treatments
- Hair restoration surgery

The final document on training and competences will be available in the spring of 2015. At that stage, there will be a need to assess the work with stakeholders on the relevance for Scotland.

Given the overlapping regulatory framework, with some matters organised at a UK-level and others at a Scotland-level, the SCIEG has liaised with relevant stakeholders across the four nations.

### **3. Purpose and operation of the SCIEG**

Following the publication of the Keogh Review in England, the Chief Medical Officer of Scotland asked Mr Andrew Malyon in his role as expert advisor on plastic surgery to consider the report's implications for Scotland. This request recognised that not all of the recommendations could be implemented in the same manner as for England, given the different legislative system, regulatory mechanisms and political institutions.

After an initial scoping meeting in December 2013, the SCIEG was established as a short-life working group on 4<sup>th</sup> March 2014. Following this, it met on a further three occasions, with its final meeting in February 2015. Members of the SCIEG were invited as representatives of their speciality and are listed in Annex 1. The secretariat to support the working group was provided by the Scottish Government.

#### **Purpose of the SCIEG**

At the first meeting, the purpose of the SCIEG was agreed as follows:

1. To provide advice in early 2015 on options to assure safe, effective and quality care for users of cosmetic interventions in Scotland.
2. It is envisaged that advice will include options on:
  - a. Legislation to regulate independent clinics providing cosmetic intervention services

- b. New competency-based training modules for health professionals and health practitioners
- c. A social marketing programme to empower the public to make informed choices about use of a service
- d. Mechanisms to facilitate adherence to the Advertising Standards Authority guidance on marketing of cosmetic intervention services
- e. Improvements to cosmetic surgery training and accreditation
- f. Monitoring the impact of changes, potentially with process and outcome indicators

3. Subject to Ministers' views, implementation is expected to begin late 2015, with a commencement order for existing legislation in 2016 and a social marketing programme proposed to commence in late 2015 .

### **Structure and function of the SCIEG**

The membership of the SCIEG agreed the establishment of two subgroups, with a focus on two areas of recommendations in the Keogh Review. Each of the subgroups met on three occasions between their establishment and February 2015.

#### *High Quality Care subgroup*

This subgroup was established with a remit to make recommendations to SCIEG on high quality care of cosmetic interventions in Scotland. In particular, its tasks included defining which procedures should be considered by the SCIEG, clarifying options for improved quality of care, liaising with the CSIC of the Royal College of Surgeons and making recommendations to SCIEG for a framework to ensure safe access to appropriate services.

The composition of the High Quality Care (HQC) subgroup is detailed in Annex 1. At the SCIEG's first meeting, there was agreement that Mr Andrew Malyon should also chair this subgroup. The HQC subgroup defined the following list of non-surgical procedures as being under the remit of the SCIEG:

- Injection of botulinum toxin (there are several brands and an example is 'botox®')
- Dermal fillers
- Chemical peels and skin rejuvenation
- Lasers, Intense Pulsed Light (IPL) & Light Emitting Diode (LED)
- Hair transplantation

These procedures were defined on the basis of the Keogh Report, with the addition of hair transplantation occurring in reflection of recent market changes and to ensure consistency with the work of other UK administrations.

#### *Informed and Empowered Public subgroup*

The remit for the Informed and Empowered Public (IEP) subgroup was to make recommendations to SCIEG on improving the methods for informing and empowering the public on cosmetic interventions in Scotland. The IEP's tasks

included exploring the understanding and information requirements consumers and the public have of cosmetic procedures, establishing good practice for consent, exploring options for increasing public understanding about cosmetic procedures and considering how appropriate protection (including indemnity) for consumers could be achieved.

A lay chair, Ms Christine Jess, a Public Partner with Healthcare Improvement Scotland was identified through the Scottish Health Council representative to SCIEG, and agreed to take on this work. The composition of the membership is stated in Annex 1.

### **Principles**

A set of principles to guide the SCIEG's work were developed by the SCIEG and its subgroups. These were:

1. People have a right to safe, effective and high quality care delivered by trained personnel competent and up to date in their field.
2. Cosmetic procedures are offered as a service and can be provided as such as part of the commercial/independent health care sector and should be subject to at least the same standards as the NHS.
3. People should decide what clinically appropriate services to purchase with full and frank information and discussion on the expected benefits and risks and with all necessary follow-up arrangements in place.
4. The governance procedures are in place with a risk assessment conducted and recorded which should be subject to inspection.
5. Services must abide by all relevant legislation and best practice with regard to health and safety of their workforce and clients.
6. Continuous provider development and on-going training appropriate to the activity areas is an essential prerequisite and as new procedures come into force, providers must be appropriately trained and risk assessed for these procedures prior to any provision.
7. Complaint and redress systems must be in place and easily communicated to all potential and actual service clients.
8. Where problems occur service providers must take responsibility for rectifying these problems.
9. The NHS is the provider of last resort, but cannot be responsible for unreasonable financial burden, and will consider whether cost recovery is an option.
10. Providers should comply with published guidelines and not make unsubstantiated claims with regard to the services they provide.

## **4. Existing regulation in Scotland**

### **History**

Regulation of cosmetic interventions provided by the independent health care sector in Scotland was set out in the Regulation of Care (Scotland) Act 2001. There are a range of National Care Standards published by the Scottish Government which apply to various services including:

- Independent hospitals
- Private psychiatric hospitals
- Independent specialist clinics
- Independent medical consultants and GP services

The regulation of independent hospitals and private psychiatric hospitals was introduced but the remainder of the powers to inspect independent clinics and independent medical agencies were not commenced.

Following reports on the provision and regulation of cosmetic surgery in England, the Chief Medical Officer for Scotland requested the Scottish Medical and Scientific Advisory Committee (SMASAC) to review the situation in Scotland in 2005. Their report in December 2006 included recommendations on professional accountability, training and patient safety. A key recommendation was the regulation of all remaining parts of the independent health care settings should commence. There is a lack of clarity on the rationale for the non-progression of the recommendations from the SMASAC report. However, the challenges in implementation included the rapidly evolving nature of the sector, with its diverse range of providers and consumers.

In addition, prior to the commencement of those sections of the 2001 Act the responsibility for regulating independent health care transferred to Healthcare Improvement Scotland (HIS) on the 1st April 2011 via the Public Service Reform (Scotland) Act 2010. This Act uses the same definition of an independent clinic as the Regulation of Care (Scotland) Act 2001 i.e. “means a clinic which is not comprised in a hospital and in or from which services are provided, other than in pursuance of this Act, by a medical practitioner or a dental practitioner”. As comments had been received that the extant legislation was insufficient, the Scottish Government consulted on the future arrangements for the regulation of independent health care in Scotland and sought views on the definition and scope of these services. The report on the consultation was published in 2011<sup>6</sup>.

From 2010 to 2012 the Poly Implant Prothese (PIP) silicone breast implant fraud dominated much of the cosmetic industry workload. The results of these events ultimately led to the setting up of SCIEG.

### **Protection and gaps**

As the above indicates, for over a decade regulation providing some protection has been in place for those receiving cosmetic procedures in independent hospitals. Regulated health care professionals working in any setting are also responsible to their regulatory bodies for their practice and therefore need to adhere to guidance on

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<sup>6</sup><http://www.scotland.gov.uk/Topics/Health/Quality-Improvement-Performance/HealthCareImprovementScotland>

consent, prescribing, clinical care and reporting adverse events. In non-health care settings there is a range of health and safety legislation applicable to beauty therapists, most of whom have trained for a minimum of three years. The guidance on the delivery of botulinum toxin, a medicine that must be prescribed has been regularly updated. In 2013, the General Medical Council (GMC) updated its guidance on remote prescribing, stating:

“62. You must undertake a physical examination of patients before prescribing non-surgical cosmetic medicinal products such as Botox, Dysport or Vistabel or other injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video-link, or online”.<sup>7</sup>

The Nursing and Midwifery Council and the General Dental Council have similar guidance on the delivery of botulinum toxin.

The gaps identified both in the 2011 consultation report and in the work of the SCIEG are any inspection of the premises and all staff in independent clinics; the definition of a clinic in terms of which regulated health care professional provides the services; and the lack of any regulation apart from health and safety legislation of the provision of non-surgical procedures in any facility other than a hospital.

In the UK the gaps include the use of dermal fillers, some of which are not subject to the EU’s Medical Devices Directive and therefore only subject to General Product Safety Regulations. The replacement of the Directives for Regulations currently going through the European Parliament process seeks to ensure that a range of currently unregulated cosmetic products are included by extending the scope to include “certain implantable or other invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile (e.g. non-corrective contact lenses, implants for aesthetic purposes);” As part of the replacement of the Directives for Regulations, the Member States and the European Commission are in discussion on whether to introduce legislation as proposed to mandate the recording of device unique device identifier (UDI). The impact will be that once a UDI is recorded electronically, it will give speedier and better information on use and traceability. The outcome of the debates for new legislation will be known in 2015/6, and the SCIEG backs this development.

The CAP provided updated guidance on marketing both surgical and non-surgical cosmetic interventions in 2011<sup>8</sup> and new guidance on the social responsibility of time-limited deals for cosmetic interventions<sup>9</sup>. SCIEG supports these guidance documents with non-confirmed reports of a reduction in unacceptable marketing campaigns but poor practice is still occurring. It is not clear whether the general public and relevant businesses know that these guidance documents exist.

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<sup>7</sup> [http://www.gmc-uk.org/guidance/ethical\\_guidance/14326.asp](http://www.gmc-uk.org/guidance/ethical_guidance/14326.asp)

<sup>8</sup> <http://www.cap.org.uk/Advice-Training-on-the-rules/Help-Notes/Cosmetics-interventions-marketing.aspx>

<sup>9</sup> <http://www.cap.org.uk/Advice-Training-on-the-rules/Advice-Online-Database/Cosmetic-Interventions-Social-Responsibility.aspx>

## **National Care Standards**

The Standards were first published in 2002 and based on “outcomes for services users”. They have informed the process by which Healthcare Improvement Scotland inspects services, such as independent hospitals. As the environments have changed in terms of day services, more complex care, and as the care of users has become more multi-focal, the Scottish Government undertook a review in 2014<sup>10</sup>.

Responses to the consultation provided support for a shared set of standards for health and care to be developed so that people working in health and care services have a common understanding of what quality means and work to common core values.

## **Legal implications**

To improve regulation usually requires legislative changes. Major primary new legislation (ie a new Bill or section of one) has to compete for Parliamentary consideration. The timescale for introducing new Bills is long and Parliamentary time is very limited. It is possible to make secondary legislative changes to existing laws through Statutory Instruments which have a formal but faster process as they are adapting extant legislation. For example, commencing the inspection of independent clinics requires a Statutory Instrument, while linking the use of dermal fillers to regulated health care professionals requires new legislation.

## **5. Summary of evidence gathered**

### **a) Literature review**

To inform the deliberations of the SCIEG’s HQC subgroup, and in turn the SCIEG, a rapid literature review was conducted (methodology in Annex 3). In keeping with the broader SCIEG work, the following five categories of procedures were focused upon: botulinum toxins; dermal fillers; lasers, IPL and LED; chemical peels and skin rejuvenation; and hair restoration surgery.

The academic literature was searched to answer the following questions:

- What is the reported frequency of uptake of different procedures?
- What are the rates of complications for different procedures?
- What are the positive and negative impacts of different procedures?
- Are there any specific population groups who may be differentially impacted by cosmetic procedures?
- What regulatory approaches have been tried and what lessons can be learnt from these?

In October 2014 the Medline and Embase databases were searched for review articles in October 2014. Systematic review evidence was prioritised but individual studies were considered when no other available evidence was identified.

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<sup>10</sup> <http://www.scotland.gov.uk/Publications/2014/06/7325>

## *Overarching findings*

The literature suggests there has been a very rapid increase in the use and variety of non-surgical cosmetic procedures that are used in high-income countries, but little robust data are available. Use of procedures appears most common amongst middle-aged women. However, there are indications that the target demographic may be expanding, with one author arguing that there should be a shift from asking 'when is it too early [to start treatment]?' to 'when is it too late?' [1].

In general, serious adverse events were reported to be exceedingly rare for non-surgical procedures, with most complications being mild and self-limiting. However, the quality of the evidence base for many non-surgical procedures was found to be poor. A high proportion of the scientific literature declared financial conflicts of interest, with many authors receiving funding from the manufacturers of cosmetic treatments. Overall, most studies report people are generally happy with the outcome of cosmetic procedures, although again noting the considerable limitations in the evidence base [2].

Several articles raise concerns about the marketing of cosmetic procedures. For example, one study investigated advertising of cosmetic procedures on Scottish websites [3]. Failing to adhere to marketing regulations was common (26 websites, 20.8%), with advertising of prescription only medicines on the homepage or dropdown menu (n=20) and offering enticements inappropriately (n=6). Over a quarter of websites did not display the qualifications of practitioners while only 16.6% of websites described the side effects of "anti-wrinkle injections" and 12.5% mentioned alternative treatments.

## *Botulinum toxins*

The safety of botulinum toxin was investigated in a recent systematic review [4]. The authors identified 35 papers which provided a total of 8,787 subjects. The most investigated area was the glabella<sup>11</sup> (51.4%), followed by the upper face (25.7%), crow's feet (11.4%), and lower face (11.4%). Adverse events included blepharoptosis<sup>12</sup> (2.5%), brow ptosis<sup>13</sup> (3.1%), and eye sensory disorders (3%) in the upper face and lip asymmetries and imbalances in the lower face (6.9%). In all cases, the events were reported as resolving without further treatment.

## *Dermal fillers*

In general, the overall safety of dermal fillers appears good. In a retrospective study of medical records at a single American centre, 2089 injectable soft-tissue filler treatments were performed, comprising 1047 with hyaluronic acid, 811 with poly-L-lactic acid, and 231 with calcium hydroxylapatite [5]. Of these, fourteen complications were identified. Nodule or granuloma formulation was observed most commonly, with treatment using calcium hydroxylapatite having the highest complication rate. Cellulitis was seen in four patients and skin necrosis in one. The authors concluded

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<sup>11</sup> Glabella = 'frown area' of face

<sup>12</sup> Blepharoptosis = droopy eyelid

<sup>13</sup> brow ptosis = droopy brow

that mild bruising, pain and swelling were commonly observed and expected side-effects, but true complications occurred rarely in their study.

### *Chemical peels and skin rejuvenation*

Chemical peel and dermabrasion are two approaches to resurfacing the skin in order to bring about a more youthful appearance [6, 7]. Chemical peels are generally applied to a broad area of the skin (often face), while dermabrasion is most frequently used in the refinement and revision of scars as a local or 'spot' technique. There are typically three categories of chemical peel, based on depth: light, medium and deep (to generate a second-degree burn). Medium and deep chemical peels poses specific health risks while light chemical peels are safer but less effective. Patient selection was deemed to be important – with a past medical history of cold sores, herpes simplex virus and fever blisters being questions to specifically ask about. Following a deep peel, frequent post-procedure appointments are needed for the first two weeks, coupled with good wound care.

Complications of chemical peels and dermabrasion include herpes simplex, persistent erythema\*, hypertrophic scarring\*, pigmentation problems\* and milia\* [6]. Scarring following medium or deep peels has been estimated at 1% [8]. Caution is particularly necessary for people with dark complexion as deep peels bleach the skin and may result in hypertrophic scarring or keloid formation.

### *Lasers, IPL and LED*

Lasers can be used for treating a broad variety of skin-related conditions [9]. Common uses of lasers include hair removal, vascular lesions, wrinkles, pigmented lesion, acne and tattoo removal. Complications from laser treatments that may occur, even when administered appropriately, include purpura<sup>14</sup>, hyperpigmentation, hypopigmentation, pain, erythema, oedema, blister formation, scarring, darkening of cosmetic tattoos and allergic reactions to liberated tattoo pigments [9]. It is also recommended that any pigmented lesion with atypical features should be biopsied to rule out the possibility for malignant degeneration.

A broader range of complications are possible if treatments are not delivered appropriately. Safe practice when using lasers is necessary, with errors posing considerable risks [10]. The administration of chlorhexidine may cause corneal<sup>15</sup>ulceration while the use of alcohol to clean skin, dry gauze, hairspray and make-up all lead to incendiary potential. In a survey of American dermatologic surgeons, 111/480 had seen patients with serious adverse effects from laser and light-based hair removal procedures by non-physicians, such as second- and third-degree burns, permanent nerve damage and scarring [11]. The majority of these severe complications were attributed to 'non-physician operators' ("such as cosmetic technicians, aestheticians, and employees of medical/dental professionals who performed various invasive medical procedures outside of their scope of training or with inadequate or no physician supervision").

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<sup>14</sup> Purpura = bruising

<sup>15</sup> Corneal = front tissue of eye

### *Hair restoration surgery*

Hair transplantation involves harvesting hair follicles from one part of the body to another. It has been most widely used to treat male pattern baldness and while its uptake appears to have increased recently, the procedure is not new [12]. Treatment involves harvesting hair follicles from a 'donor' site (typically elsewhere on the scalp, when treating male pattern baldness). Increasingly, micro grafts (one or two hair follicles) or mini-grafts (three or four hair follicles) are performed, with the treatment being time-consuming, as 1000-2500 grafts are often carried out per session.

Little robust evidence was found on complications, with identified review articles describing the range of complications possible, rather than providing quantitative estimates of rates of specific complications [13, 14]. Expert opinion noted that serious complications are uncommon if procedures are well-planned and well-performed, with temporary inconveniences (such as pain, pronounced oedema, temporary thinning within the surgical site, prolonged crust formation over operated areas and short-term hypo-aesthesia) far more likely. In particular, authors emphasised the importance of patient selection and pre-procedure counselling, with realistic expectations needing to be conveyed.

**Table: Minimally invasive aesthetic procedures**

<b>Procedure</b>	<b>Indication</b>	<b>Treatments required and duration of action</b>	<b>Advantages</b>	<b>Disadvantages</b>
Botulinum toxin A	Dynamic facial lines and wrinkles in the upper one third of the face	One treatment every three to four months	Short procedure time, dramatic results	Small margin for technical error with injection placement; high patient expectations
Dermal filler injection	Facial wrinkles and folds in the lower two thirds of the face; lip enhancement	One treatment every three to 24 months; duration of action varies with product composition and treatment area	Immediate results	Post-procedure swelling and bruising; injection proficiency and consistency of outcomes require practice
Laser hair reduction	Unwanted hair	Series of six treatments with at least one-month intervals; long-term reduction in hair growth of 50 % or more	Faster and less painful than other methods of permanent hair reduction, such as electrolysis	Risk of burns, hyperpigmentation, and hypopigmentation (particularly for people with darker skin); reduced effectiveness with fine, lighter-coloured hair
Laser photo-rejuvenation	Benign epidermal pigmented and vascular lesions	Series of two to five treatments every two to four weeks, based on severity of lesions and device used; results last up to several years	Highly selective for lesions without damaging surrounding skin	Risk of burns, hyperpigmentation, and hypopigmentation, particularly for people with darker skin
Micro-dermabrasion	Benign epidermal pigmentation, rough skin texture, acne, fine lines, superficial acne scars	Series of six treatments every two to four weeks with monthly or quarterly maintenance treatments; short-term Results	Safe for all skin types; few absolute contraindications	Worsening telangiectasia and erythema possible; minimal change with single treatment
Chemical peels	Benign epidermal pigmentation, rough skin texture, acne, fine lines, superficial acne scars	Series of six treatments per month with monthly to quarterly maintenance treatments; short-term results	Inexpensive: can give good results depending on patient selection, depth and clinician competence	Less control over depth of exfoliation; post procedure skin peeling; minimal change with single superficial treatment; risk of scarring, hyperpigmentation, and hypopigmentation with deeper peels
Hair transplant	Hair loss	Can be performed as a one-off but repeated procedures may be needed	Effective treatment	Time-consuming and expensive; broad range of potential complications; requires availability of hair follicles from a donor site

## **b) Analytical Programme for Evidence Gathering**

The IEP subgroup noting the lack of information available from routine sources, committed to an Analytical Programme for Evidence Gathering which includes five different mechanisms of primary data collection to find out about current cosmetic procedure uptake, benefits and risks in Scotland.

The analytical framework was developed and delivered by the Health Analytical Services Division (ASD) in the Scottish Government. When appropriate the different data collection methods mechanisms were piloted with the general public. The specific objectives for the evidence gathering process and the methods agreed are shown in Annex 4.

As part of the analytical programme an Omnibus survey<sup>16</sup> was commissioned from YouGov (Executive summary in Annex 5). A number of focus groups took place across Scotland run by the Scottish Health Council<sup>17</sup>. These provided evidence on the Scottish population's views, knowledge and experience of cosmetic interventions. Additionally two separate online surveys were conducted with consumers and with providers of cosmetic interventions in Scotland (tables with detailed results are available from the SCIEG secretariat). Lastly, a number of questions on cosmetic interventions has been introduced into the Scottish Health Survey (a repeated cross-sectional survey) which will provide a baseline for monitoring prevalence and developments of cosmetic interventions in Scotland.

While the results from the Omnibus survey are representative of the Scottish population, the focus groups and online surveys are more limited in this respect as those samples include a large proportion of self-selected respondents. Moreover, the number of responses for the questionnaires was low, with 37 people responding to the consumers' questionnaires and 43 people responding to the providers questionnaire. Therefore the evidence provided from the online surveys and focus groups needs to be considered with caution.

### **1) The consumer perspective: Summary of findings from the Omnibus survey, focus groups and online survey.**

The Omnibus survey asked a question on how familiar are you, if at all familiar with the following cosmetic procedure. For breast implants the responses were:

Not at all familiar	15%
Just heard the name	31%
Somewhat familiar	40%
Very familiar	12%
Don't know	3%

So while 82% are aware, just 51% were somewhat or very familiar. The assumption of the latter is those who are somewhat or very familiar have an understanding of what is involved in the procedure.

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<sup>16</sup> YouGov Omnibus Survey can be found on the publication section of the Scottish Government website

<sup>17</sup> The report of the focus groups will be published on the Scottish Health Council website in April 2015

Using these answers the Omnibus survey found a significant proportion of the adult Scottish population were somewhat familiar with a range of cosmetic procedures, with the most common being:

- Cosmetic dental treatments (53% of population)
- Breast enlargements / reductions (51%)
- Nose jobs (47%)
- Surgical liposuction / sculpture (46%)
- Surgical neck/ face lifts (39%).

The Omnibus survey found that 4% of the adult Scottish population reported having had a private cosmetic procedure in their lifetime (varied between 3% in the 18-24 age group and 7% among the 25-34 age group), of which:

- 54% have had a cosmetic dental treatment
- 17% have had an injectable cosmetic treatment
- 16% have had a laser skin procedure

In the adult Scottish population:

- 1% had a cosmetic procedure in the last 12 months
- 4% plan to have one in the next 12 months

The ethnic group split followed nationally representative proportions of white and minority ethnic groups in the Scottish adult population ie 4% of those who has a cosmetic procedure are in the minority ethnic group, 96% in the white ethnic group. Geographically the split of those who have had a cosmetic procedure follows the population spread although those who had a procedure and live in Glasgow, are a larger proportion than the Glasgow residents are in the national population split (ie 18% compared to 12% in the national adult population).

The online survey shows that the most frequently used cosmetic procedures are non-surgical, with the exception of breast implants and laser eye surgery (note that many consumers had received more than one type of procedure):

- 70% injectable such as botulinum toxin (n=27)
- 60% dermal fillers (n=23)
- 20% injectable cosmetic dental treatments (teeth whitening or veneers) (n=9)
- 10% breast enlargement (n=3)
- 10% laser eye surgery (n=4)

The Omnibus survey asked which sources people would use to find information on cosmetic procedures, the results show that most would use their GP (50%) or do an internet search (49%), accessing specific websites such as the NHS Scotland (40%) or NHS Choices (29%) was also common. Around a fifth (21%) would use friends of family and a tenth (11%) use articles in newspapers or magazines.

The focus groups found people had good knowledge of cosmetic interventions, usually gained through newspapers, magazines, social media or friends' experiences. Most participants in the focus groups would make a judgement on the reputation of services through word of mouth and sharing of experiences with friends.

There were clear messages from the focus groups that advertising which used young attractive people could play on peoples insecurities. One person commented *"it is outrageous and very misleading. Most look like they are from the same mould, airbrushed. Men would see this and think it is normal and girls would look at this as what they should look like"*. It was felt that the full implications of the procedures were never shown in advertising or marketing with no scars or swelling shown in photos.

In terms of who performed the procedures that consumers had, the online survey provided a mixed picture:

- Nurses and doctors were the most common providers of botulinum toxin (for example 'botox®') and dermal fillers, while beauty therapists and nurses provided similar amounts of the skin rejuvenating treatments such as chemical peels, microdermabrasion and skin resurfacing.
- Cosmetic dental treatments were mainly provided by dentists but almost 30% of procedures were provided by beauty therapists
- A quarter of non-surgical face / neck lifts were provided by doctors, three quarters by nurses (n=4).

The focus groups felt that doctors should do most of the work but were more accepting of the second procedure being delivered by a nurse.

Looking at consumers' experience of their treatment the Omnibus survey found over three quarters found their most recent private cosmetic procedure had achieved what they expected (78%). This is similar to the online survey which found that 75% found their service satisfactory, with the main reason (40%) for a lack of satisfaction being the procedure not making enough difference to their appearance. The benefits of procedures were mainly, according to the focus groups, "to give you a boost, makes you feel better, look better" and could help with jobs.

On reported health problems in the first month after a private cosmetic procedure more than a quarter (27%) of the Omnibus responders reported difficulties such as slow healing, bleeding or numbness.

On complaints, the Omnibus survey found the first point of contact if something went wrong would be the provider (40%) but with 22% saying their first point of contact would be the GP and 8% saying a solicitor. The view from the focus groups was that

people did not always know where to go to complain. This seemed to be especially the case for some minority groups – Asians reported being less likely to complain as they had less knowledge of where to complain. This finding was echoed by the Omnibus survey, with 7% of adults belonging to minority ethnic groups saying they would turn to a hospital first, compared to 3% of white adults.

The online survey found that:

- 40% of those dissatisfied did not make a complaint
- 60% found out about their provider through word of mouth

In terms of their experience of consent, the online survey responses showed that:

- 100% felt they were able to make an informed choice with the information they were given. However only 61% were given written information on what might go wrong with the procedure
- 96% were asked for verbal consent
- 90% were asked for consent in writing

It should be noted that SCIEG members, as well as other approaches, were used to disseminate the survey and therefore the sample is likely to be atypical.

Some of the focus group participants thought patients should perhaps have a psychological assessment before surgery or consider other ways to think about how they view themselves, and then assess the options available. Others felt they benefited from attending some group meetings prior to the procedure to learn about what was involved. One comment from the focus groups was *“anything that is done to the body needs to be explained in detail and may take longer to explain from start to finish with someone with learning disabilities”* It was also noted that regular customers would already have built up a relationship with staff and have confidence in the service.

It was found that people’s beliefs in terms of regulation and qualifications in this sector do not match the current situation in Scotland. The Omnibus survey found that: 43% believe cosmetic surgery is regulated, 39% believe cosmetic dentistry is regulated, 12% believe non-surgical cosmetic procedures are regulated – but these figures differed by age with young adults (18-29 year olds) and those with no formal educational qualifications being more likely to believe that non-surgical services are regulated (24% and 19% respectively). The online survey showed that: 60% of people think that currently all non-surgical cosmetic services are registered with an independent regulator and also that there is a regular inspection of services.

People showed strong support for the regulation of the sector with views from the online survey showing that 75% of people thought that there should be minimum training standards for staff and 65% of people supported a requirement to have

insurance which provides compensation to customers if things go wrong with their procedures. This was supported by views from the focus groups.

There was a general consensus across the focus groups that providers of cosmetic interventions should be regulated. There was surprise at the lack of regulation with comments such as “*you would think that if you had to deal with injections that you would have some training/licence to practice*”. There was a view that there had to be accountability on the part of the provider. For example if a procedure went wrong under the NHS it would be expected that the NHS would meet the cost of rectifying the mistake. But was this the case in the private sector? The same standards were expected for private practitioners as for the NHS. Participants thought there should be a regulatory body to inspect clinics and make sure they are meeting the required standards and have the power to close them down if they don't.

There was a mixed response as to whether there should be any age restrictions for receiving cosmetic procedures. Some felt older people could be manipulated or younger people may not be emotionally mature enough. Others thought each case should be assessed on an individual basis.

There were strong views about whether the NHS should treat people unhappy with the outcome of their procedures: “*absolutely not*”; “*yes but then seek the costs from where the original surgery took place*”; “*why should we pay for someone's incompetence?*” There was agreement that the NHS should provide treatment for medical emergencies and sometimes the NHS has a greater role. For example, in the case of the PiP breast implants, to remove the implants, but not to provide treatment if it was not an emergency and had no medical indication.

This was also borne out by the Omnibus survey which showed that 67% did not agree that it is acceptable for the NHS to cover the costs of caring for someone whose private cosmetic procedures has gone wrong. Again however there was a marked difference between the age groups with more young adults (48%) agreeing with the principle that the NHS should cover these costs.

## **2) The provider perspective: Summary of findings from the surveys, and discussions with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Scottish Colleges representative.**

- The large majority of providers undertake non-surgical procedures, with 25% of respondents doctors (60% surgeons, 30% GPs) and the rest mainly nurses and dentists.
- The age ranges of people that use these services are generally similar for surgical and non-surgical. While consumers' ages ranged widely, providers reported mainly delivering services to people in their late 30s to late 50s, with some services given to people in their 20s and 30s. This is supported by the results from the Omnibus survey which shows that 13% are in the 18-29 age

group, 29% are in the 30-49 age group, 40% are in the 50-69 age groups and 8% are in the 70 plus age group.

- Both males and females are clients, using a similar mix of surgical and non-surgical services, with male clients seen less often. This is corroborated by the results from the Omnibus survey which found that 71% of those who had a cosmetic procedure in their lifetime are women, 29% are men.

From the online survey it was noted that:

- There was an interesting spread of premises used for delivering procedures, especially for non-surgical (20% in clients' homes).
- Very high consent rate and high levels of refusal in both surgical and non-surgical provision: 60% of providers sometimes refused potential consumers of surgical services, 75% sometimes for non-surgical. The overwhelming reason for refusal was procedure being unlikely to meet client's expectations; although for non-surgical services, a significant proportion (30% of refusals) was due to the client having another medical condition (including pregnancy).
- 100% of surgical providers reported they routinely arrange a follow-up appointment, and 75% of non-surgical providers.
- Of all the providers, 40% offered deals or discounts once or twice in the previous year, and 10% every couple of months for non-surgical procedures.

The survey also provided views on regulation from providers:

- There is a high compliance with indemnity insurance in this self-selected sample of providers
- Amongst providers, 75% think the overall level of regulation for cosmetic services is too little.
- Regular inspections were thought to be necessary by a majority responding to the questionnaire, with inspection required for both premises and practitioners.
- There were differing views on the amount of regulation required in free text responses to the questionnaire, although the majority still favoured more regulation.
- 90% have qualifications for cosmetic interventions, with the most common (30%) being a certificate course lasting less than 2 days.

The MHRA reported that from their adverse incident database there were 194 adverse incident reports for dermal fillers and 2,702 reports for breast implants between 1 October 2009 and 1<sup>st</sup> October 2014. Inclusion in the MHRA adverse incident database only indicates a report has been received and cannot be interpreted as a summary of known or proven adverse reactions to the device<sup>18</sup>.

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<sup>18</sup> Communication from MHRA Feb 2015

It is estimated that Scotland produces up to 1,400 beauty therapists a year, according to figures provided on the entry rate to all Scottish Colleges for beauty and hairdressing and specific figures on types of courses and pass rates from one specific college. This excludes those who may gain qualifications through a private training provider.

## **6. Options for regulation**

### **Relevant existing regulation**

Several regimes of regulation are pertinent to independent health services, including regulation of professionals (often through compulsory registration with professional bodies), the product (e.g. via the EU Directives) and service provision (the clinic) itself, including the premises, facilities available and clinical governance arrangements.

HIS are given legal powers in relation to independent health care services through amendments made to the National Health Service (Scotland) Act 1978 (“the 1978 Act”) by the Public Services Reform (Scotland) Act 2010. Provision is made for HIS to have powers in relation to the regulation of independent clinics but these powers have not been commenced – at least in part because the scope of the legislation was felt to be too limited. The definition of the object of regulation (‘clinic’) in the 1978 Act is as follows:

*“independent clinic” means a clinic which is not comprised in a hospital and in or from which services are provided, other than in pursuance of this Act, by a medical practitioner or dental practitioner.*

From the Act, ‘provided’ is defined to include managing a service but a medical or a dental practitioner must be present, so delegation of all services is not acceptable. Commencement of this provision would therefore exclude regulation of nurses who commonly act as independent providers of cosmetic procedures.

It is worth noting that regulation of many independent clinics which provide comparable services is already carried out by the Care Quality Commission (CQC) in England under existing legislation. Cosmetic surgery providers were included as part of CQC’s recent consultation on their independent acute hospital inspection methodology.

### **Weighing up risk and financial/regulatory burden**

In order to commence regulation of independent clinics in Scotland, an appropriate legal definition for ‘independent clinic’ is necessary. In keeping with the three existing spheres of relevant regulation, at least three different and non-exclusive ways of defining an independent clinic exist – on the basis of who provides the service, the types of services provided and where the service is provided.

There is an inherent tension between minimising risks faced by consumers and the regulatory burden (which incurs associated financial costs) required for such a governance arrangement. The most comprehensive inspection regime is likely to minimise risks of adverse events and may improve quality of care received.

However, this may be achieved at a very high financial cost, may not be enforceable, may reduce business and may not be cost-effective.

Depending on whether the intention is to provide the broadest coverage, or ensure that inspection is targeting procedures with the greatest risks, a variety of approaches to the definition of an independent clinic are possible. Each of the three potential criteria for defining an independent clinic (regulation on the basis of the person, procedure and location) can be combined in three ways:

- Narrow remit: The service is regulated on the basis of both criteria being fulfilled e.g. an independent clinic exists if a service is provided by a doctor AND s/he is providing a dermal filler.
- Intermediate remit: The service is regulated on the basis of a single criterion e.g. an independent clinic exists if a service is provided by a doctor.
- Broad remit: The service is regulated on the basis of either criterion being fulfilled e.g. inspection if a service is provided by a doctor OR dermal fillers are being provided.

The first option results in the least regulatory burden but is likely to leave consumers with the least protection. In contrast, the third option will minimise risk but results in the greatest financial/regulatory burden. It is also worth noting that a very broad remit may result in the inspection capacity of HIS being overwhelmed so that inspections of the most 'at risk' clinics are not being conducted at an adequate frequency or with enough depth.

In their deliberations, the SCIEG and HQC expressed a desire to adopt a 'risk-based' approach to regulation of cosmetic procedures. The key features of such an approach included:

- Regulation (and inspection) of services on the basis of the anticipated likelihood of harms.
- Flexibility over time to add or remove procedures, in line with market changes and changing evidence base.
- Broad scope that could apply proportionately to all practitioners and providers.

### **A phased approach to regulation**

In addition, it was noted that many of the most high-risk procedures are provided by health care professionals. However, considerable concerns existed about omitting regulation of cosmetic practitioners, with a need for regulation to protect consumers receiving dermal fillers noted.

Following extensive discussion by the HQC and SCIEG, a phased approach to the introduction of regulation to assure the safety and quality of cosmetic procedures was concluded as most appropriately balancing the needs for consumer protection and minimising regulatory burden. Such an approach has the advantages of building on existing legislation to allow timely action to be taken and facilitates a coordinated response to risk across the four nations.

### Phase one: Commencing inspection of independent clinics

Phase one involves the commencement (through the use of Scottish Statutory Instruments legislation) of an existing power to allow the inspection of independent clinics. Given the rapidly evolving nature of the cosmetic procedures market, it was determined that defining an 'independent clinic' for the purposes of legislation on the basis of specific procedures was not appropriate. Similarly, the possibility of restricting the services subject to regulation on the basis of providing specific 'cosmetic' treatments or procedures was explored. However, this approach was viewed as unsatisfactory since defining specific procedures or treatments as 'cosmetic' within legislation could be difficult or impossible to achieve.

For these reasons, the SCIEG recommends that the definition of an 'independent clinic' for the purposes of commencing inspection and regulation of cosmetic clinics be based on the health care professional providing a service. Following consultation with a range of professional representatives, the following groups were deemed most likely to perform cosmetic procedures or other specific high-risk procedures that necessitated regulation:

- Doctors
- Dentists, & dental care professionals
- Nurses
- Midwives

In making a judgement, the SCIEG gave consideration to likely trends in future provision while being cognisant of the need to ensure regulation would be proportionate to the potential risks imposed. There was also recognition that this service is additional to current HIS activities and must be based on a cost-recovery mechanism. In addition it is recognised very small numbers from other health practitioner groups provide some cosmetic interventions and may wish additional accreditation in due course (see phase three).

### Phase two: Regulation of cosmetic providers

Phase one as described above would allow regulation to be commenced for independent clinics being provided by (or on behalf of) specific regulated health care professionals. This would bring regulation in Scotland into closer alignment with existing protections afforded to clients using similar services in England. However, its coverage would not include non-surgical cosmetic procedures being provided by independent cosmetic practitioners who are not members of a statutory register. For example, services being provided by beauticians, hairdressers or similar therapists would not be subject to regulation. At present, many cosmetic practitioners will have received training at further education colleges or similar settings which are often necessary for insurance purposes.

Phase two would allow regulation of these services to be introduced in a manner that is proportionate and risk-based. The introduction of regulation in a second phase has a number of important advantages:

- **Timely:** Commencement of phase one could be achieved without primary legislation whereas introducing regulation of cosmetic practitioners would be best achieved through proportionate primary legislation. A longer period of time is required to introduce primary legislation, both for the preparatory work required and its introduction to the Scottish Parliament.
- **Risk-based:** Many services provided by cosmetic practitioners carry lower risks than those provided by regulated health care professionals. Compulsory registration and inspection by HIS could therefore be viewed as disproportionate to the risks presented and may be more likely to be subject to legal challenge.
- **Coordination across the four nations:** During the SCIEG's deliberations, plans are being considered to introduce regulation of cosmetic practitioners in England. Awaiting the outcome of such discussion will allow greater coordination of regulation to be achieved across the four nations. Harmonisation of regulation was viewed favourably to mitigate the risk of cross-border tourism.

Three options were considered for introducing primary legislation to regulate cosmetic practitioners providing cosmetic procedures. First, regulation of the cosmetic practitioner providing the service could be achieved through a coordinated UK-wide policy. If the UK government decide to introduce legislation which requires specific cosmetic procedures to be only provided by regulated health care professionals, or on their behalf, similar provisions could be introduced in Scotland. Since health care professionals would have some responsibility for the actions of cosmetic practitioners to whom they delegate, this would introduce the expectation that all those providing specific procedures had met the minimum training requirements, such as those set by HEE.

Second, local authorities currently require certain services to be provided subject to the acquisition of a license. While detailed information about licensing was not available to the secretariat, the following summarises initial information gathered but may be subject to revision following further investigation. For some businesses (such as tattoo parlours, petrol stations and riding stables), meeting minimum standards is necessary prior to receiving a license. For other businesses (such as food outlets), licenses must be applied for from the local authority but are automatically dispensed. There is currently no licensing requirement for hairdressers or beauty parlours but premises that have tanning facilities are required to hold a license from local authorities in many areas.

In both licensing options, the local authority would hold a complete list of all businesses providing the service of interest and could take action to address reported concerns by clients or others. It is worth noting that licensing can be either compulsory for all local authorities or discretionary (which may result in large variation in implementation across different local authorities). Local authorities can

operate a cost recovery scheme for the registration process but are not allowed to charge for the costs of enforcement to address poor practice. Therefore the introduction of a licensing scheme would have financial implications for local authorities which would need to be explored further.

Lastly, it may be possible to combine the two approaches above i.e. to restrict provision to health care practitioners, either directly or on their behalf (and hence introducing the expectation of adherence of training standards, for example such as those set by the HEE training requirements), in combination with a compulsory local authority licensing scheme. The SCIEG expressed a preference for this third option, noting that a lack of available data on the provision of cosmetic procedures represents a major challenge for evidence-based policy and ensuring appropriate safeguards for consumers choosing to undertake cosmetic procedures.

Phase three will be to consider the voluntary or legislative options for any additional health care professionals who provide services and wish to be accredited. The aim is to ensure options for any other specific individuals who are providing services to be allowed entry into the regulated group. This may include for example, any clinical scientists who are supervising and performing aesthetic laser procedures can be regulated as independent clinics in their own right if necessary.

## **7. Recommendations**

### **1. REGULATION**

After extensive deliberation, the SCIEG recommends a three phase approach to introducing regulation of cosmetic procedures. The rationale for this approach is outlined in chapter 6. Regulation should operate on a cost-recovery basis, based on fairness. The three phase approach combines proportionality and timeliness:

**a. Phase 1: Regulation of health care professionals through a requirement to register independent clinics (on the basis of services being provided by a doctor, dentist, dental care professional, nurse or midwife) with Healthcare Improvement Scotland. Statutory arrangements for independent clinics and the capacity for Healthcare Improvement Scotland to receive complaints from the public will foster improvement in the delivery of high quality care.**

**b. Phase 2**

**i) Certain high-risk procedures (and especially dermal fillers) should only be provided by, or on behalf of, regulated health care professionals who have an appropriate level of expertise. If at all possible, this should be introduced in a coordinated manner across the UK, to reduce the chance of 'cross-border tourism'. When provided on behalf of a regulated health care professional, that professional should ensure that all reasonable steps have been taken to assure the training of those delivering the procedure and should have overall responsibility for the quality of care delivered.**

**ii) In addition, compulsory licensing by local authorities should be required for all cosmetic practitioners delivering specific cosmetic procedures (a broader range of procedures than covered by i).**

**c. Phase 3: progress on regulation will be monitored and consideration given to a new accreditation scheme, voluntary or legislative, for specified health care professional groups.**

### **2. GOOD PRACTICE**

According to the providers questionnaire, consent is taken mainly in writing for both procedures and the taking of photographs. Implied consent is used by a minority for non-surgical procedures. The main reason for health care professionals and cosmetic practitioners refusing treatment is that it will not meet the expectations of the clients. Ensuring the client / patient is fully informed about a procedure so that they are able to give genuinely informed consent is known to be difficult. Clients /

patients are often unable to recollect information they have been given or misinterpret what they have been told, despite the best efforts of professionals.

The new ruling from the recent Supreme Court (Montgomery vs Lanarkshire HB) dictates an explicit need to detail and record discussion around risk. Risk is 'material' if it is seen as of significance to a reasonable person in the patient's position.

A new concept developed from the plastic surgery speciality is a 'request for treatment' <sup>19</sup>agreement between the health care professional and client. This allows the client to state what is expected and an explicit discussion to be had on the likely outcomes. The first recommendation for good practice is:

**a. 'Request for treatment' should be used as the standard agreement between a health care professional and a consumer of cosmetic interventions to document consent**

Advertisements were seen as presenting an unrealistic image of cosmetic interventions by the participants in the focus groups. There are standards on what can and cannot be advertised, including restrictions on advertising prescription-only medicines and the need to present a fair portrayal of what outcomes are likely from treatments. Sales promotions should be guided by UK advisory bodies and must not pressurise consumers with time-limited offers. The SCIEG observed many instances in which existing guidance on the marketing of cosmetic procedures appears to be ignored. In order to reduce problematic marketing, poor practice needs to be notified. The second recommendation is:

**b. It should be the duty of regulated health care professionals and cosmetic practitioners providing cosmetic interventions to report breaches of advertising guidelines to the Advertising Standards Authority**

The training of all health care professionals and practitioners of cosmetic interventions must be kept up to date and linked to national standards. The newly developed certification for surgeons from the Royal College of Surgeons is helpful as is the Health Education England framework for qualifications for non-surgical procedures. Both reports are likely to be published by the middle of 2015. The third recommendation is:

**c. Health care professionals and cosmetic practitioners undertaking cosmetic interventions must be aware of training standards in their sphere of practice and keep up to date. The HEE training framework for nonsurgical cosmetic interventions will need to be assessed for relevance to Scotland.**

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<sup>19</sup> <http://www.ncbi.nlm.nih.gov/pubmed/20353637>

New procedures and medical devices and devices sold for cosmetic interventions without a medical purpose, can be introduced into independent health and beauty care with strict monitoring processes or without. For devices with a medical purpose, the Medical Device Regulations require the manufacturer to carry out post market surveillance on their CE marked devices. There needs to be additional evidence gathered robustly on effectiveness that is shared with consumers. The limitations in the evidence base for many procedures as shown by the literature review makes it difficult for health care professionals and cosmetic practitioners to inform potential consumers about the risks and benefits of many cosmetic procedures. Regulated health care professionals are required to demonstrate through revalidation how they are examining and reflecting on their practice. It is vital that all adverse events are reported promptly and feedback given on the outcome of reports. The fourth recommendation is:

**d. Providers are expected to have clear governance processes (similar to those in the NHS) and pursue evidence-based practice by collecting, analysing and making available comparable data.**

Focus group participants suggested that psychological assessment or group work would be beneficial to some people before having a cosmetic intervention. A representative of a patient group wrote to the secretariat highlighting the longer term need for specific, trained psychological support for people who want to change their appearance. Patient/ client group work has been used with success in certain other areas of surgery (e.g. bariatric surgery) where individuals provide support for each other. Therefore the fifth recommendation for good practice is:

**e. Providers of cosmetic services should always consider, and record the outcome of their assessment of the current and on-going psychological and emotional support requirements of their clients.**

### **3. INFORMED AND EMPOWERED PUBLIC**

Evidence from the focus groups and questionnaires found understanding of the potential risks of cosmetic intervention treatments varied widely. The gap in knowledge tends to be partly filled after a poor experience of a family member or friend. The consequences of some procedures are also masked when offered in situations where clients are under time pressure (e.g. offer ends today) or when alcohol is available. The likelihood of a procedure having long-term beneficial effects may not be clearly stated. The IEP subgroup identified a need to improve the public's knowledge so that the right questions can be asked by potential clients from their providers; they know what to reasonably expect from a provider; and know who to report any problems to if things go wrong. As creating a social environment can be done in many ways, the first recommendation for informing and empowering the public is:

- a. Conduct a social marketing campaign, targeted at groups with specific need, to inform and empower the public so that they have a realistic understanding of the potential risks and expected benefits of treatments.**

Cosmetic procedures are requested to change or improve an aspect of an individual's appearance, entirely within their control. The change is usually enjoyed and the market for new and improved procedures expanding. There is concern among some providers and sections of the public that a false image of what is normal, age appropriate or can be altered permanently may also be growing. Opportunities within personal development classes, young people's groups, older people's forums and elsewhere, to teach and explore body image could contribute to enhanced self-esteem and foster mental wellbeing. The second recommendation is:

- b. Consider ways of supporting positive views of body image through education, mental health and broader wellbeing initiatives amongst different population groups**

#### **4. ACCESSIBLE REDRESS AND RESOLUTION**

The consumer questionnaires and the focus groups found that sometimes clients are not aware of who is providing their cosmetic procedure or of their relevant qualifications. This is unprofessional and risks compromising follow-up with the provider should difficulties arise. The recommendation is:

- a. The client / patient must be given information on the name and the qualification(s) of the person providing the procedure**

The PiP silicone breast implant failure was followed by some independent providers indicating they had insufficient resources to respond to all those in need of care. This situation was unusual but the need for adequate indemnity is now a requirement for all health care professionals and must be a feature of the training and business developments for all those providing cosmetic interventions. The second recommendation is:

- b. All providers undertaking any cosmetic intervention must have sufficient indemnity for their services**

Healthcare Improvement Scotland receives complaints about those services which it inspects but it not clear that clients and the general public know where to complain when issues arise in different settings or after a course of treatment has finished. The Independent Sector Complaints Adjudication Service (ISCAS) requires all independent hospitals to have transparent complaints systems.

Follow-up needs to be clearly described for both clients and the general public for care in the independent health care sector. Local authorities may receive complaints either directly or through the Citizen Advice Bureau. However, there appears to be reluctance for members of the public to complain if they have experienced poor care or an adverse event. Clinicians have found people are often

not willing to complain about poor care but will seek out another practitioner. Being aware of how to complain and providing support to complain, in a manner that is sensitive to different ethnic groups, is a key component of accessible redress and resolution. The third recommendation is:

**c. Transparent complaints systems must be visible for all services, enforced by Healthcare Improvement Scotland for the services they regulate, the Local Authorities for their services and by the Independent Sector Complaints Adjudication Service**

Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practice. The process is also being introduced for dentists, nurses and midwives. The formal system is supported by annual appraisal meetings at which the outcomes of their NHS work and any other work should be discussed and examined. Appraisals can be informed by compliments and complaints and any significant adverse events reviewed. The fourth recommendation is:

**d. Appraisal of health practitioners should include discussion about all practice, including cosmetic procedures.**

The PiP silicone breast implants and metal on metal hips device failures highlighted the need for people to know what implant they have in place and for their medical records to be easily examined to find out if they are potentially at risk of an adverse outcome. The Private Healthcare Information Network (PHIN) is mandated by the Competition and Market Authority to collect data from all organisations undertaking cosmetic surgery. Currently all implants must be recorded in operation notes and kept for life. Some patients receive an implant card with all details listed. However patients' paper records may become detached from the operation notes and searching through all records to find those that might be affected by a device failure is time-consuming and may be impractical. Therefore there is a concurrent project examining whether the unique device identifier (barcode) can be entered into the electronic patient record so in case of device issues, patient requests, needs for certain medical scans, death certification, the information can be easily retrieved. This project has a number of additional requirements and the first report is likely to be at the end of 2015. To support this work the fifth recommendation is:

**e. Data including the UDI on all devices and implants must be included and easily extracted from electronic records of patients and clients and comply with any future / evolving UDI requirements.**

## **5. MONITORING AND EVALUATION**

It is important to monitor and evaluate the impact of any actions taken forward by Scottish Government and other stakeholders as a result of the recommendations of SCIEG. The Scottish Health survey questions on cosmetic procedures will provide a baseline picture, prior to the implementation of these actions. A draft logic model has

been developed and will be revised once the policy response to this report is available. A basket of process and outcomes indicators will be selected to keep track of progress and evaluate the outcomes of policies. The recommendation is:

**a. A framework for monitoring and evaluation is expected to be developed by the Scottish Government to ensure monitoring of the implementation of the recommendations and evaluation of their impact**

#### **Annexes – see separate document**

1. Scottish Cosmetic Interventions Expert Group (SCIEG) & subgroups membership & declarations of interest
2. Record of meetings
3. Methodology for the literature review
4. Methodology for the gathering the views of the public & providers
5. Omnibus survey executive summary
6. Equality Impact Assessment
7. References

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## Scottish Cosmetic Interventions Expert Group (SCIEG) & subgroups membership & declarations of interest

### SCIEG Remit

4. The remit of SCIEG will be as follows:
  - a. Formulate an outline of the current position in respect of the cosmetic interventions sector in Scotland;
  - b. Analyse the recommendations in the Keogh report for applicability and implementation in Scotland;
  - c. Produce recommendations based on its findings; and
  - d. Engage with all stakeholders throughout each stage of its work in this area.
  
5. SCIEG will report directly to the Chief Medical Officer.

### Chair

6. The meetings will be chaired on behalf of the Scottish Government Health & Social Care Directorates (“**SGHSCD**”) by Mr Andy Malyon, Chief Medical Officer Specialty Advisor.

### Group Membership

7. The initial membership of SCIEG will consist of the following:

Mr Andy Malyon, Chair	SGHSCD
Other clinical reps to be agreed at 1 <sup>st</sup> meeting	NHS
Chief Executive / COO NHS Board	NHS
Representative from Local Government Trading Standards	LA
Chief Inspector	HIS
Medical Director	NHS NES
Scottish Health Council nominee	SHC
DCMO	SGHSCD
Dr Sara Davies CPH	SGHSCD
Head of Quality Team	SGHSCD
Professional Regulation	SGHSCD
Education & Training	SGHSCD
Capital and Facilities Policy	SGHSCD
Primary Care Division	SGHSCD
Business Lead, SG	TBC

## 5. Declarations of interest

Andy Malyon stated he undertakes some private work related solely to breast surgery and that he had no involvement with the use of fillers or other non-surgical cosmetic interventions

### **SCIEG High Quality Care (HQC) subgroup**

#### **SCIEG HQC Remit**

To make recommendations to SCIEG on high quality care of cosmetic interventions in Scotland

#### **Tasks:**

- Define the procedures to be covered by the recommendations, with particular reference to non-surgical procedures, laser & Intense pulsed light (IPL)
- Clarify the options noting that statutory legislation for service regulation is one option
- Key workstreams:
  - Review whether there is just cause to regulate aspects of cosmetic surgery
  - Ensure the subgroup does not propose legislating for the sake of it.
  - Identify gaps in the current regulation,
  - Assess the risks around current legislation and then recommend appropriate action
- Make recommendations to SCIEG for a framework to ensure safe access to appropriate services
- Consider what is the role of inspection in this sector noting the caveat that HIS can only work within their legal powers as permitted under current legislation.
  - Consider which organisation(s) should perform inspections
- Review the deliberations of the CSIC & their relevance to Scotland

#### **Membership**

- Chair –Andy Malyon, Chair of SCIEG
  - Clinical: Plastic Surgeon; Dermatologist, Maxillo Facial; ENT; Oph; Cosmetic Nursing representative
  - Policy & legislative
  - Public partners (advised by Scottish Health Council)
  - Pharmacy representative
  - Cosmetic Nursing representative

- SG Surgery Senior Medical Officer
- Secretariat – Sara Davies, plus Quality Team

### **Declarations of interest**

**Andy Malyon** indicated that he undertakes some private work related to breast surgery but had no involvement with the use of fillers or other non-cosmetic interventions.

**Awf Quaba** indicated all his work is now as an independent plastic surgeon

**Suzanne Armstrong** indicated all her work is as an independent aesthetic nurse practitioner

**Harry Moseley** indicated that he undertakes some private work where he is the Clinic Director of Tayside Laser Clinic

**Sanjay Rajpara** indicated that he undertakes some private work where he is the Medical Director, of SK:N, Aberdeen

**Natarajan Balaji** indicated that he undertakes some private work which includes most aspects of rhinoplasty and nasal tip reconstructions.

**Jeff Downie** indicated that he undertakes some private work which includes all aspects of oral-facial surgery.

**Iain Mackay** indicated that he undertakes some private work on the use of lasers, dermal fillers and botox.

**Terry O’Kelly** indicated that he undertakes some private colorectal work.

### **SCIEG Informed and Empowered Public (IEP) subgroup**

#### **SCIEG IEP Remit**

To make recommendations to SCIEG on improving the methods for informing and empowering the public on cosmetic interventions in Scotland.

#### **Proposed tasks for the subgroup are:**

- Seek background information on the requirements of the consumer/patient group
- Consider the available resources for members of public seeking information regarding cosmetic procedures
- Consider how to increase awareness of these resources
- Explore what additional resources are needed
- To examine the (recently updated) advertising guidelines, their application and implementation
- To explore the issues surrounding the possibility of ‘benchmarking’ existing sources of information.
- Consider developments on indemnity
- What sanctions are/should be available against individuals/organisations

## **Proposed Membership**

- Chair
- Two providers (<http://www.habia.org/> & <http://www.babtac.com/>)
- Two lay representatives (older and younger age groups)
- One regulatory/legislative adviser
- One communications expert
- One Clinician
- Scottish Health Council representative
- Trading Standards representative
- Analytical Services adviser
- Secretariat from SG

## **Declarations of interest**

Dave McGill noted he is a Medical Director for S:kin and works occasionally for Transform.

**Record of meetings**

SCIEG meetings

4<sup>th</sup> March 2014  
22 July 2014  
25<sup>th</sup> November 2014  
24<sup>th</sup> February 2015

SCIEG High Quality Care subgroup meetings

1<sup>st</sup> April 2014  
28<sup>th</sup> May 2014  
21<sup>st</sup> October 2014  
17<sup>th</sup> February 2015

SCIEG Informed and Empowered Public subgroup

19<sup>th</sup> August 2014  
2<sup>nd</sup> December 2014  
16<sup>th</sup> February 2015

## Methodology for the literature review

The High Quality Care subgroup identified a need for a rapid literature review to collate relevant academic evidence which could help inform their deliberations. In keeping with the broader SCIEG work, the following procedures were focussed upon:

- Botulinum toxins
- Dermal fillers
- Chemical peels and skin rejuvenation
- Lasers, IPL & LED
- Hair restoration surgery

It was noted that the Keogh Review<sup>20</sup> had summarised some of the relevant evidence base and therefore the following key questions were identified as gaps, accepting that the academic literature may be limited:

- What is the reported frequency of uptake of different procedures?
- What are the rates of complications for different procedures?
- What are the positive and negative impacts of different procedures?
- Are there any specific population groups who may be differentially impacted by cosmetic procedures?
- What regulatory approaches have been tried and what lessons can be learnt from these?

Where possible, there was a desire to find evidence that was as locally relevant as possible.

The Medline and Embase databases were searched on 6<sup>th</sup> October 2014. Searches were limited to review articles (Medline only), 'Human' and published after 1980. Search terms for the population group included "Cosmetic", "Aesthetic" and "Beauty". Terms for the interventions included "Botox", "Botulinum toxin", "wrinkle", "hair AND transplant", "dermal AND filler" etc. The outcomes searched for include "side-effects", "risks" and "adverse impacts". Additional articles were also identified through scrutinising the citations of included studies.

The titles and abstracts of 4911 articles were screened, with data extracted from 74 full-text articles. Given the heterogeneity of interventions, research questions and available evidence, key themes to answer the research questions were summarised through narrative synthesis.

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<sup>20</sup> <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>

## **Methodology for the gathering the views of the public & practitioners**

Evidence was required to support the development of SCIEG's recommendations, including determining the most appropriate role for government in this area. In particular, evidence is needed to determine the current use of different types of cosmetic intervention services (including by population subgroups of interest), their associated risks and benefits, and develop an understanding of public expectations for governmental safeguards for the sector.

Scottish Government's Analytical Services Division developed and devised an analytical programme that could be adopted to gather appropriate evidence for this work.

### **Background and objectives**

There is currently a lack of objective data on the uptake of cosmetic interventions and the magnitude of any harms experienced in the Scottish population as a result. Previous qualitative research has been conducted in England to inform the Keogh review and identified a desire for regulation of the cosmetic interventions sector, to safeguard the care of patients.

Further evidence is required to inform SCIEG's deliberations. Accurate and unbiased evidence that robustly demonstrates the population situation in Scotland is unlikely to be possible. However the specific high-level objectives for the evidence gathering process include:

- Scope the range of cosmetic intervention services (i.e. types of intervention) and providers (i.e. practitioners/professionals who provide the service) in Scotland
- Review the evidence on the potential health benefits and risk of cosmetic interventions services
- Determine the uptake of different types of cosmetic intervention services, by subgroups of interest
- Understand service providers' views about current regulation, required developments and potential implementation challenges
- Explore public understanding, by subgroups required for market segmentation, of the risks and benefits of cosmetic interventions and establish if there is unmet need for public education in this area

- Explore consumers' understanding of the risks and benefits of cosmetic interventions and establish if information provision (including for the consent process) is accurate and balanced
- Explore public understanding of the risks and benefits of cosmetic intervention services and establish if marketing of services is accurate and balanced
- Understand consumers' and public expectations of mechanisms to assure safe, effective and quality care when they undergo cosmetic interventions, including their expectations of regulation
- Understand consumers' and public expectations of the role of the NHS in safeguarding health following cosmetic intervention services
- Develop population-based monitoring of uptake and rate of complications of cosmetic intervention services in Scotland
- Develop an evaluation framework for the impact of government intervention in this area

In order to fulfil the eleven stated objectives, the following approaches to gathering evidence are being enacted.

	<b>Objective</b>	<b>Options for approaches</b>	<b>Status</b>
A	Scope the range of services and providers	Exercise reviewing advertising of services. <b>Interview providers.</b>	Two interviews completed but difficulty with recruitment. However, this information has been gathered via informal feedback from HQC.
B	Establish the potential health benefits and risks of cosmetic intervention services	Review existing scientific literature. High Quality Care subgroup to identify expert opinions, where evidence lacked.	Searches, data extraction and advice from clinicians. Final report peer reviewed by members of SCIEG.
C	Determine the uptake of different services, by subgroups of interest	<b>Omnibus Survey</b>	Questionnaire ready: commissioned from YouGov
D	Understand service providers' views about current regulation and required future regulation	<b>Questionnaire - providers.</b>	Provider questionnaires through questback

	<b>Objective</b>	<b>Options for approaches</b>	<b>Status</b>
E	Explore public understanding of the risks and benefits of cosmetic interventions	<b>Focus groups with public.</b>	FGs are ongoing. Further FG on consumers required in Dec 2014/ Jan 2015, with assistance needed for recruitment
F	Explore consumers' understanding of the risks and benefits and establish if information provision is accurate and balanced	<b>Questionnaires - consumers.</b> <b>Questionnaires - providers.</b>	Providers' and consumers' questionnaires through questback
G	Establish if information provision to consumers and the public (e.g. marketing) is accurate and balanced	<b>Focus group with consumers and the public.</b> <b>Questionnaires with consumers.</b>	See above
H	Understand consumers' and public expectations of mechanisms to assure care, including expectations of regulation	<b>Focus group with consumers and the public.</b> <b>Questionnaires with consumers.</b>	See above
I	Understand consumers' and public expectations of the role of the NHS in safeguarding health following cosmetic interventions	<b>Focus group with consumers and the public.</b> <b>Questionnaires with consumers.</b>	See above
J	Develop population-based monitoring of uptake and rate of complications	<b>Add questions into existing repeated cross-sectional surveys e.g. Scottish Health Survey – starting 2015</b>	Scottish Health Survey questions being incorporated in 2015 survey
K	Develop an evaluation framework for the impact of government intervention	Possible indicators and methods to be worked up	Initial framework has been created

### **Omnibus survey executive summary**

1. This report presents the key findings from an online survey of Scottish adults. It is based on research about private cosmetic procedures in Scotland and focuses on topics including public awareness and perceptions, procedures the public have undergone, expectations and understanding of procedures, resulting health problems, consideration for future procedures, and seeking advice through resources.
2. Unless stated otherwise, differences between sub-groups in this summary section and the rest of the report are statistically significant.
3. The survey was undertaken to gather data which will inform the development of policy by the Scottish Government regarding cosmetic interventions. It provides baseline data on the public perceptions and experiences of the Scottish public related to surgical and non-surgical private cosmetic procedures.

#### ***The sample***

4. The sample consisted of 1,980 Scottish adults aged 18 and over, and has been weighted to be representative of the national population.

#### ***Public awareness and perceptions***

5. Nearly one quarter of Scottish adults report that they have at least a fair amount of confidence in the treatment provided by both the surgical (22%) and non-surgical (23%) cosmetic procedures industries.
6. Roughly two-in-five Scottish adults believe the cosmetic surgery and cosmetic dentistry industries are 'regulated' (43% and 39% respectively), with the non-surgical cosmetic procedures industry believed to be regulated by a smaller proportion (12%).
7. Young people aged 18-29 are significantly more likely than older adults aged 50-69 and 70+ to have confidence in the treatment provided by both the surgical and non-surgical cosmetic procedures industries. They are also most likely to believe that the cosmetic surgery and non-surgical procedures industries are regulated.
8. When considering specific procedures, the Scottish public are most familiar with cosmetic dental treatments (53%) and breast enlargement/reductions (51%).
9. Two thirds (67%) of Scottish adults do *not* agree that it is acceptable for the NHS to cover the costs of caring for someone whose private cosmetic procedure has gone wrong. Older adults aged 50+ years are particularly likely to hold this opinion.

### ***Private cosmetic procedures among the Scottish public***

10. Four per cent of the Scottish adult population report that they have had a private cosmetic procedure in their lifetime.
11. The most commonly reported private cosmetic procedure is a dental treatment, with 2% of Scottish adults having had one. Secondly, 0.6% have had an injectable cosmetic treatment or a laser skin procedure.
12. Overall, 1% of Scottish adults have had a cosmetic procedure in the past 12 months.

### ***Experience of private cosmetic procedures***

13. Two thirds (66%) of Scottish adults who have had a cosmetic procedure indicate that they feel they had a strong understanding of what the experience would involve in advance of their most recent procedure. Only a very small proportion (1%) indicate that they had little understanding.
14. More than three quarters (78%) of Scottish adults who have had a cosmetic procedure agree that their most recent procedure achieved what they expected.
15. More than one quarter (27%) of Scottish adults who have undergone a private cosmetic procedure in their lifetime report that they have had at least one health problem within the first month following. The most common problems experienced are slow healing (11%), bleeding (8%) and infection (7%).

### ***Public consideration for future cosmetic procedures***

16. Sixteen per cent of Scottish adults who have *not* had a cosmetic procedure report that they have thought about doing so, with 7% having considered it very or somewhat seriously.
17. Women (22%) are significantly more likely than men (9%) to state that they have thought about having a procedure, and young adults aged 18-29 (21%) are significantly more likely than older adults aged 50+ years to have done so (12% for 50-69 years and 5% for 70+ years). Younger adults are also significantly more likely than older adults to report that they have *very* seriously considered having a cosmetic procedure.
18. Overall, 4% of Scottish adults who have never had a cosmetic procedure report that they are likely to have one in the next three years.
19. Among Scottish adults who have never had a cosmetic procedure, dental treatments are the most commonly considered procedure, with 8% overall indicating they have thought about having one.
20. Four per cent of Scottish adults report they are planning to have a cosmetic procedure in the next 12 months. Women (5%) are significantly more likely than men (3%) to say they plan to do so, as are younger adults aged 18-29 (5%) more likely than older adults aged 50-69 (3%) and 70+ (1%).

21. On par with earlier findings, Scottish adults are most commonly planning to have a cosmetic dental treatment (1.7%) in the next 12 months.

***Resources and seeking advice***

22. When Scottish adults are asked which sources they would use if seeking information about cosmetic procedures, they most commonly say they would turn to their GP practice (50%) or search on the internet (49%). A significant proportion also say they would use the NHS Scotland website (40%).
23. The Scottish public are most likely to report that their first point of contact if something were to go wrong with a cosmetic procedure would be the practitioner who conducted the work (40%). Approximately one-in-five (22%) say they would first contact their GP.

## **Equality Impact Assessment initial scope**

The SCIEG secretariat developed a scope for an Equality Impact Assessment at the beginning of the process which will be continued following the acceptance of any recommendations. The report that follows was from the initial scope.

## **Draft Equality Impact Assessment scope for Cosmetic Interventions**

### **Summary & Request**

A workshop was held on 19 May 2014 to run a screening analysis for an equality impact assessment (EQIA) on the work proposed for cosmetic interventions regulation. The attenders are noted in Appendix 1. The aim was to check initial impacts and consider where any gaps in knowledge and the evidence base are to ameliorate or remove any negative impacts and spread the positive impacts of the policies being developed.

We request the review of the EQIA scope and welcome any volunteers

### **Background**

A screening EQIA was proposed by the Scottish Health Council member of the Scottish Cosmetics Interventions Expert Group (SCIEG) and supported by them in finding relevant attenders. A summary of the current situation (Appendix 2) was laid out for the workshop attenders together with a brief background on the work in Scotland reflecting our experience with the PiP breast implant device removal and the Department of Health's response<sup>21</sup> to the Keogh Report on the Regulation of Cosmetic Interventions from April 2013<sup>22</sup>.

The volume of procedures are predominantly in the non-surgical field and include 5 main areas: dermal fillers, botulinum toxin, lasers and intense pulsed light; chemical peels and hair restoration surgery. These account for 9 out of 10 cosmetic interventions and are worth 75 per cent of the market in total. The screening process started with this area, before considering the potential impacts on the equality fields of both cosmetic surgical interventions and information / redress requirements.

This report will be shared with the workshop attenders, the SCIEG groups and evidence will be sought for the specific areas. As the work continues and questionnaires and policies get framed, the workshop attenders will be asked again for their input.

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<sup>21</sup> DH response Feb 2014 to the Keogh report <https://www.gov.uk/government/publications/regulation-of-cosmetic-interventions-government-response>

<sup>22</sup> Keogh April 2013 report <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>

## Assessment

The assessment found the majority of impacts require further information to reduce any negative impacts and through a new and varied public information campaign, many of the impacts will be positive. Regulation is useful if carefully managed and implications on services for both providers and users carefully considered. Questions were asked on how other European countries run services and how would a non-surgical cosmetic service provider set-up in Scotland. The effect of alcohol on all ages to change risk behaviours was noted and to ameliorate this, a paperwork of consent, consideration of capacity and and possible 7 day waiting period must be necessary. The screening assessments are shown below.

### **Non surgical cosmetic interventions ie botox, dermal fillers, lasers, chemical peels**

<b>Characteristic</b>	<b>Impact (+/-)</b>	<b>Data gaps identified and action taken</b>
<b>AGE</b>	Teenagers – ensure capacity	If age restrictive (not ideal) make sure not too restrictive. Ensure policy supports care of vulnerable people; do not require too many hoops for consumers; ensure follow-up arrangements can be in place and followed. Careful not to replicate NHS system only
<b>DISABILITY</b>	People with mental ill health – ensure not excluded nor exploited	Ensure policy supports care of vulnerable people; ensure follow-up arrangements can be in place and followed.
<b>SEX</b>	No impact for non-surgical interventions	
<b>PREGNANCY AND MATERNITY</b>	Information/ safety	Part-time workers keeping competency to standard could be an issue

<b>Characteristic</b>	<b>Impact (+/-)</b>	<b>Data gaps identified and action taken</b>
<b>GENDER REASSIGNMENT</b>	Nil	
<b>SEXUAL ORIENTATION</b>	Nil	
<b>RACE</b>	Providers should provide information on skin colour / types and procedures to different ethnicities	Skin lightening Hair removal Tailored information
<b>RELIGION OR BELIEF</b>	Animal fat or pork substances in products	Better labelling across EU

**Non surgical cosmetic interventions ie botox, dermal fillers, lasers, chemical peels continued**

<b>Characteristic</b>	<b>Impact (+/-)</b>	<b>Data gaps identified and action taken</b>
<b>Criminal Justice</b>	Lasers for hair removal	Check with the Scottish Prison Service Beauticians in women's' prisons ?
<b>Homelessness</b>	Access to follow-up if no address / no postal receipts	
<b>Language or social origin</b>	Information available in correct format (language, sign if deaf etc)	
<b>Poverty / social deprivation</b>	Removal of 2 for 1 deals and free deals from training colleges working with trainee beauticians will impact of people with less disposable income	

**General comments**

Careful not to replicate NHS system in terms of how to enable people to access services as the adult exceptional aesthetic protocol for the NHS is also to reassure services will be targeted and provides a filtering system.

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However an approval system must be in place in the independent sector as well as the protocol in the NHS as the rationale is the same in terms of allowing a period of reflection, freedom from undue pressure on consumers and careful safe medical and health interventions.

Ensure the European dimension is considered.

**Surgical procedures, information and redress.**

<b>Characteristic</b>	<b>Impact (+/-)</b>	<b>Data gaps identified and action taken</b>
<b>AGE</b>	Literacy levels	
<b>DISABILITY</b>	Literacy levels	Information of use to individual
<b>SEX</b>	Impact for surgical services for certain groups, particularly male to female transgender	Also in general be wary of impacting badly on NHS current contracts to the independent sector in some boards.  Awareness raising campaigns need to be in different outlets ie gyms for men possibly, and not only concentrating on women.
<b>PREGNANCY AND MATERNITY</b>		
<b>GENDER REASSIGNMENT</b>	Cosmetic tattooing not mentioned so far and uncertain whether always included in NHS services	Genital laser hair removal not always available – can be subcontracted by NHS to independent sector so be wary of unintended impacts
<b>SEXUAL ORIENTATION</b>		
<b>RACE</b>		Information in language that is required is provided by provider and provider should not assuming English “will do”.
<b>RELIGION OR BELIEF</b>		Information to providers and consumers on female genital cosmetic surgery and boundaries and consent, capacity and capability to reduce coercion.
<b>Criminal Justice</b>		
<b>Homelessness</b>		
<b>Language or social origin</b>		
<b>Poverty / social deprivation</b>		

**Attenders to the cosmetic interventions equality impact assessment screening workshop 19 May 2014**

Rosemary Hill, Participation Network Manager, Scottish Health Council

Leeze Lawrence, transperson, documentary film-maker

James Morton, Scottish Transgender Alliance manager

Vittal Katikireddi, registrar in public health, Scottish government

Sara Davies, consultant in public health, Scottish government

Terry O'Kelly, senior surgeon, Scottish government

## **Regulation of Cosmetic interventions**

Developments in 4 areas :

### **1 Surgical interventions – cosmetic surgery**

- Standards & training for cosmetic surgery
- Inspection of cosmetic surgery providers, including clinics
- Patient information / decision aids / consent formats

### **2 Non-surgical interventions (botulinum toxin, dermal fillers, chemical peels, lasers & lights)**

- Training for
  - The practice
  - The supervision
- Considering legislation on controls of cosmetic interventions & regulators of healthcare professionals codes of practice
- Credentialing

### **3 Ensuring safe products**

- EU Medical Devices Directive & EU General Product Safety Directive
- EU register of medical devices & unique device identifier
- Pilot breast implant registry
- Improved reporting of suspected devices failures to MHRA

### **4 Responsible information, resolution & redress**

- Patient information / decision aids / consent formats
- Socially acceptable advertising & Committee on Advertising Practice new guidance
- Follow-up care promoted / Medical Directors required
- Complaints on independent healthcare to the Parliamentary & Healthservice Ombudsman
- Professional indemnity
- Device manufacturer risk pools
- NHS recouping costs

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