

Cosmetic Procedures



Cosmetic treatments are becoming increasingly popular in the UK. A review commissioned by the Department of Health (DH) in response to the Poly Implant Prothèse (PIP) breast implant scandal identified a range of concerns about the sector. This POSTnote summarises the procedures on offer, the factors driving the increase in demand, and the health, ethical and regulatory issues that arise.

Background

A diverse range of elective surgical and non-surgical cosmetic procedures is available. These procedures are largely carried out for aesthetic rather than medical reasons. Popular treatments include:

- **Surgical procedures** such as breast implantation, face-lifts and tummy tucks.
 - **Non-surgical procedures** such as Botulinum Toxin A (commonly known as Botox) injections, dermal fillers, laser treatments, chemical skin peels and teeth whitening.
- Surgical procedures must take place in regulated clinical settings, such as independent hospitals. Providers of non-surgical procedures are subject to less stringent controls and are carried out in a range of contexts, including clinics, beauty parlours, hairdressers and in the home.

The value of the UK cosmetic procedures market is growing. It was worth £2.3bn in 2010 and is estimated that it will grow to £3.6 billion by 2015. Non-surgical procedures account for 75% of this total.¹ However, data on the number and profiles (age, gender and so on) of people having surgical and non-surgical cosmetic procedures in the UK is not collated by Government. This means that only indicative data are available, primarily from small-scale surveys conducted by professional bodies, market research companies and cosmetic procedure providers. For example, the

Overview

- There is a growing UK market for surgical and non-surgical cosmetic treatments. Around 90% of procedures are carried out on women.
- Growth in the sector reflects increasing cultural acceptance of cosmetic procedures, particularly amongst young people.
- There is a lack of reliable and comprehensive data on the range and number of procedures performed and medical complications resulting from non-surgical treatments.
- Some cosmetic treatments are currently unregulated, despite the potential health risks to consumers.
- Regulators are faced with several challenges, including the international nature of the market and enforcing regulations intended to protect the public from harm.

British Association of Aesthetic Plastic Surgeons (BAAPS), one of the largest professional associations for plastic surgeons in the UK, collects annual data from its members on the type and number of cosmetic surgical procedures. Indicative key trends from BAAPS are outlined in Box 1.

A recent poll found that cosmetic surgery is the third most common reason for people taking out a loan (after mortgages and buying a car).² The effects of some treatments may be temporary. For example, treatments such as Botox may be re-administered as frequently as every four months in order to maintain the effect. With practitioners offering an increasing range of services, return custom is common, although this is based on anecdotal

Box 1. Cosmetic Surgical Procedures in the UK

One in three cosmetic surgeons is registered with The British Association of Aesthetic Plastic Surgeons (BAAPS).

- In 2012, over 43,000 procedures were performed by BAAPS registered surgeons in the UK.
- Approximately 90% of procedures are carried out on women.
- The most popular treatment for women is breast augmentation, with twice as many procedures as the next most popular procedure (eyelid surgery). The most popular treatment for men was rhinoplasty (nose surgery), followed by breast reduction surgery.
- Treatments perceived to have an anti-ageing effect are gaining popularity. Examples are brow lifts, eye lid surgery and fat transfer.

observations. A recent survey found that 75% of people who had undergone a facial cosmetic procedure would consider having another.³ The growth in this market reflects the increasing cultural acceptance of such procedures, particularly among young adults. There is evidence that an increasing number of women in their early to mid-twenties as well as men are considering 'anti-ageing' cosmetic treatments.⁴ However there is no publicly available and comprehensive data on this trend. There is limited research evidence about the effect of the outcomes of cosmetic procedures on long-term psychological health.

Motivations for Seeking Cosmetic Procedures

Medical Reasons

Cosmetic surgery is provided on the NHS, but only for psychological and other health reasons. This includes for example: breast implants for severe underdevelopment or asymmetry, nose reshaping for breathing problems, or tummy tucks for excess fat or skin after weight loss or pregnancy. Currently however, many patients eligible for NHS treatment choose to go private to avoid waiting lists.⁵ There are no centralised data on the NHS's annual spend on cosmetic surgery.

Psychological Factors

A recent market research report found that fewer than 10% of cosmetic interventions were carried out primarily for health reasons. Most people opt for cosmetic interventions based on dissatisfaction with appearance, a desire to improve confidence and self-esteem, and to look younger.³ Patient satisfaction with procedures is based on the quality of services provided but also relates to patients' expectations and their psychological profile. There is no standardised way to measure patient satisfaction across the sector, even in the case of cosmetic surgery. A new tool to collect this information is being piloted by BAAPS.

Academic research has highlighted that those who undergo cosmetic interventions are statistically more likely to worry about their weight, have been subject to domestic violence or bullying, or be on medication for sleep disorders and anxiety. Those seeking treatments are also statistically more likely to have mental health issues.⁶ Such research draws attention to the potential vulnerabilities of some groups seeking cosmetic interventions. In response there have been calls for better screening of patients undergoing surgery for pre-existing psychological disorders. One screening initiative is discussed in Box 2.

Box 2. Identifying Vulnerable Patients

Cosmetic procedures may be inappropriate for some vulnerable patients. Academics based at the Centre for Appearance Research at the University of West England have been working with practitioners to develop standardised tools to screen patients for psychological disorders, such as body dysmorphia. The screening involves assessing patient responses to a series of questions. Patients deemed to be at risk may then be referred for further assessment. This project has received funding to roll out the screening tool to a larger number of providers during 2013.

Risks of Cosmetic Procedures

Health Risks

There are a wide range of known risks and complications associated with surgery, injectable products, cosmetic implants, chemical peels and laser treatments. These range from localised infection and scarring to permanent and debilitating effects, such as blindness and nerve damage.¹

There is no centralised and comprehensive data on the scale of adverse health complications associated with cosmetic treatments. This includes treatments occurring on premises registered with UK health care regulators (such as the Care Quality Commission, which regulates hospitals in England). Independent hospitals in Scotland are regulated by Healthcare Improvement Scotland. Reporting of adverse incidents is sporadic across the sector.

Systems of reporting in relation to specific products to manufacturers and regulators have also faced criticism. For example, in the wake of the PIP scandal it was estimated that only 15-18% of incidents were reported to the relevant regulator.⁷ Current estimates of health complications are based largely on small scale investigations by industry and professional bodies, as well as anecdotal evidence. Data on adverse outcomes from using injectable cosmetic products is given in Box 3. Even less is known about non-surgical procedures carried out on other types of premises. These may be carried out despite providers having no professional or legal responsibilities to report adverse incidents or to provide suitable aftercare.

Economic Risks

The annual cost of complications from cosmetic interventions to the NHS is unknown. However the NHS bears the costs for a large proportion of complications that result from treatments carried out by less reputable providers. This issue is particularly acute for non-surgical procedures, as there is no guarantee that practitioners will be insured, or have systems of patient aftercare in place. One recent small scale survey of admissions to a single London hospital recorded 12 cases of patients presenting with complications resulting from dermal filler injections over a 15 month period. The average cost of each patient to the NHS was over £3,000.⁸ This suggests significant costs to the NHS hospitals across the UK and in relation to other non-surgical procedures that carry comparable levels of risk.

Box 3. Complications Associated with Injectable Products

- The Independent Healthcare Advisory Service (IHAS) recently gathered data on 12 of its member clinics. It was reported that medical complications arose from 0.13% of Botox® procedures, 0.25% of dermal fillers procedures and 0.07% of cosmetic procedures.⁴ However these figures represent only those providers registered with the trade body who chose to share data.
- A recent BAAPS report highlighted that around two-thirds of its members had treated a patient who has suffered complications after filler injection treatments between 2011-2012.⁵
- The BAAPS report also highlighted that 84% of cases of medical complications resulting from dermal fillers that were presented to its surgeons required surgery or were untreatable.

Protecting Consumers

The cosmetic sector is subject to a complex regulatory environment which covers products, providers and premises. This regulation covers how products are developed and sold, as well as the legal responsibilities of manufacturers and service providers. The overarching policy challenges are outlined in the following sections.

Regulating Cosmetic Products

All products marketed for direct use by consumers are regulated to ensure safety. The most basic and wide ranging provision is the EU General Product Safety Directive, implemented at national level primarily through the General Product (Safety) Regulation 2005. This places a responsibility on manufacturers and distributors to ensure that their products are safe in normal foreseeable use. However this general framework does not extend to products that are marketed for use as part of a service.

In addition, there are frameworks which set more specific rules for categories of products, such as cosmetics. Cosmetic products are subject to the EU Cosmetic Product Directive, implemented primarily through the Products (Safety) Regulations Act 2008. This framework defines cosmetic products broadly and includes all products which are applied to and act upon external surfaces of the body for cosmetic purposes. This framework sets rules on ingredients, packaging and safety assessment. Rules may also specify to whom products can be supplied.

Product safety regulation is primarily enforced in the UK by local Trading Standards authorities. However, in the case of medical products, responsibility falls to the Medicines and Healthcare products Regulatory Agency (MHRA).

Regulating Cosmetic Medical Devices

Many devices used in cosmetic procedures are subject to the EU Medical Devices Directive (see Box 4). This includes medical class lasers, some dermal fillers, liposuction equipment and implants. The scope of this regulation includes devices primarily designed to serve a medical purpose. However, devices with a primary cosmetic purpose are not covered by this framework. This has created a situation in which different brands of the same type of product may be subject to different regulatory frameworks. Dermal filler products are an example of this. The Keogh review (Box 5 gives an overview of the key points) has recommended broadening the scope of the medical device regulation to include all dermal fillers and implants used for cosmetic purposes. The European Commission has proposed a new medical devices directive, which is being scrutinised in the European Parliament.

Medicines used in Cosmetic Procedures

There are concerns about how Botox is prescribed and administered following cases where the person undergoing a Botox procedure is not seen by a medical professional, despite it being a prescription only medicine (POM). Remote prescription of this and similar cosmetic injectables was

Box 4. Regulation of Medical Devices and Medicines

Medical devices are subject to the EU Medical Devices Directive, which is implemented at national level primarily through the Medical Devices Regulations 2008. This means that products which enter the market as medical devices hold a licence issued by a recognised non-governmental body. In the UK these bodies are audited by the MHRA. The MHRA is also responsible for monitoring products once they enter the market. It is currently the manufacturer who decides if a specific product is made subject to this framework, based on the product's primary intended purpose. This means that some brands of the same product may be subject to this framework, and others may not.

Medicines are subject to the EU Medicines Directive which is implemented in the UK primarily through the Medicines Act. The MHRA assesses and licenses medicines for the UK market. It also determines which products become prescription only medicines.

prohibited in 2012. The General Medical Council (GMC), the General Dental Council (GDC) and the Nursing and Midwifery Council (NMC) stipulate that the prescriber must meet the patient face-to-face. There is no available data on the impact of the ban on practices across the sector since the guidance was issued. There are no legally mandated standards of qualification for those administering the treatment, or a requirement for these practitioners to have indemnity insurance in the case of negligence. From October 2013 medical practitioners must have adequate insurance cover.

Unregulated Products

Some products marketed for use by practitioners are not covered by either the General Product Safety Directive or any other specific product safety framework. This includes products involving hazardous chemicals, such as chemical peels, as well as Intense Pulsed Light equipment.¹ This means that there are no existing legally defined standards specific to the sale of these products at EU level. The Keogh review (see Box 5) recommended that the General Product Safety Directive should be revised so that products provided as part of a service are no-longer exempt. This would mean that products which are not currently covered by either the general, cosmetic or medical product regulation would be brought within the scope of a product safety framework. This would reform existing self-governance by industry and practitioners.

Box 5. The Keogh Review: the Department of Health's Independent Review of the Regulation of Cosmetic Interventions

Primarily in response to the PIP breast implant scandal, the DH commissioned a review by Professor Sir Bruce Keogh of the regulation of cosmetic interventions. The PIP scandal involved breast implants which had unusually high rupture rates. The report identified ethical and regulatory challenges raised by the cosmetic sector, including:

- loopholes in European and national regulation of cosmetic products and devices
- the use of prescription products and other treatments by unlicensed professionals
- lack of professional oversight of those performing non-surgical cosmetic procedures
- absence of or inadequate screening of patients for psychological and health issues by some providers
- lack of legal redress for consumers when things go wrong
- misleading advertising and marketing practices.

Regulating Cosmetic Practitioners and Services

There is a societal expectation that risky procedures are administered only by competent individuals with appropriate levels of technical expertise. There is also an expectation that practitioners provide patients with meaningful informed consent and will assess the suitability of individuals for procedures which may carry health risks.⁴ However, consumers currently struggle to identify reputable practitioners which meet these expectations.¹

Surgery is the only cosmetic treatment which must be carried out by a qualified doctor. Others, including dermal fillers, laser treatments and chemical peels, can be provided by anyone from medically trained professionals such as registered nurses to beauty therapists. Health professionals must be registered with relevant professional regulatory bodies (for individual professions and sub-specialities) which set standards for qualifications, practice and practitioner indemnity. They include the GMC, the NMC and the GDC. There are also voluntary standards and professional accreditation available for both medical and non-medical practitioners. There is no comprehensive UK-wide requirement for providers of non-surgical interventions to be registered or to receive product-specific training from manufacturers, or other forms of ethical and safety training.

Improving Standards of Surgery

Surgeons are required to act within their competence under GMC guidelines, but such competence is not well defined since cosmetic surgery is not a defined surgical speciality. This means that there is no common set of qualifications for those undertaking cosmetic surgery, who are likely to be trained primarily in specialities such as plastic surgery, ear nose and throat surgery and eye surgery (although these specialities include an aspect of cosmetic training). Several recommendations have arisen from the Keogh review to ensure that practising surgeons:

- are suitably trained and maintain competency
- have adequate liability insurance
- ensure that patients receive adequate information to make an informed choice when selecting a surgeon.

The Royal College of Surgeons welcomed these recommendations and will be working with key professional organisations to convene an interdisciplinary group to establish training standards. It will build on recent work which defines specific guidance, published in the Professional Standards for Cosmetic Practice report.⁹

Improving standards of non-surgical treatments

The Keogh review identified the need for better training through improved professional regulation and accreditation of non-surgical treatment providers. Currently, there is no catch-all system of education and accreditation for practitioners within the UK. Instead the maintenance of standards is dependent on a patchwork of practitioner codes and voluntary training and accreditation schemes. This includes the voluntary Treatments You Can Trust scheme developed by the IHAS. However this covers only injectable products. This scheme is based on a system of certification

and inspection. A comparable scheme is under development in relation to cosmetic laser and Intense Pulsed Light service providers. However, many providers continue to operate without any form of certification.

Advertising Cosmetic Procedures and Products

Advertising in the UK is regulated by a system of co-regulation and self-regulation enforced by the Advertising Standards Authority (ASA) through codes of practice. There is no specific code for non-surgical procedures. These procedures are currently regulated through codes covering medicines, medical devices, health-related products and beauty products. The Independent Healthcare Advisory Service (IHAS), the main trade body of the cosmetic sector, has also developed industry wide codes of practice. However, enforcing these policies remains a challenge, particularly in relation to online marketing.

The Keogh Review (see Box 5) has recommended that the ASA and industry take a more proactive stance in addressing bad practice, which includes:

- unrealistic claims about the benefits of cosmetic products
- advertising that trivialises risks associated with cosmetic procedures
- misleading claims about the qualifications of practitioners
- the targeting of people below the age of 18
- high pressure sales techniques.

Protecting Consumers When Things Go Wrong

Health professionals working in the cosmetic sector will be expected to hold insurance from October 2013 under the EU Health Care Cross Border Directive. Organisations that provide products and services directly to the consumer are also bound by general consumer protection regulation. However, there is no current legal requirement for the providers of cosmetic treatments to have specialist insurance or systems of redress and resolution. A series of recommendations were made in the Keogh review including the requirement that all practitioners and premises providing cosmetic services should be insured. The review committee also advocated the establishment of 'risk' pools for manufacturers, to meet medical costs in the event of device malfunction. However, adopting these recommendations across the whole sector would require changing existing EU and UK law.

Endnotes

- 1 Review of the Regulation of Cosmetic Interventions, Dept of Health, 2013
- 2 www.ymca.co.uk/bodyimage/
- 3 Market research data, British Association of Beauty Therapy and Cosmetology
- 4 Review of Regulation of Cosmetic Interventions: Research among the General Public and Practitioners (2013), Creative Research
- 5 www.nhs.uk/Conditions/Cosmetic-surgery/Pages/Introduction.aspx
- 6 Brunton et al. *Psychosocial predictors, assessment and outcomes of cosmetic interventions: a systematic rapid evidence review*. London: EPPI-Centre, Institute of Education, University of London, 2013
- 7 Review of Regulation of Cosmetic Interventions Committee Meeting 2. Paper 5c
- 8 Collier et al. Complications of Facial Fillers: Resource Implications for NHS Hospitals, *British Journal of Oral and Maxillofacial Surgery* 50 Suppl(2012)S23
- 9 Professional Standards for Cosmetic Practice, Royal College of Surgeons of England, 2013