British

Association of

Dermatologists

The British Association of Dermatologists
Response to the Department of Health's
Review of the Regulation of Cosmetic Interventions
Call for Evidence

October 2012

Executive Statement

The British Association of Dermatologists is pleased to respond to the Review of Cosmetic Interventions. We aim to provide a professional viewpoint whose main objective is improved patient care. Our comments are informed by case reports and audits from our membership, national and international scientific symposia and the peer-reviewed literature. In the context of this report, comments will pertain to nonsurgical cosmetic procedures. Many of these procedures, ie dermal fillers, botulinum toxin injection, laser and light-based therapies, chemical peels, sclerotherapy and others were pioneered by dermatologists as an extension of treatments for disease.

Our specialist knowledge of the skin, hair and nails, our understanding of the basic science pathomechanisms involved in skin ageing, and our expertise in medical and procedural treatments for rejuvenation position us to comment authoritatively on nonsurgical cosmetic interventions. Many of the conditions addressed by these procedures are in fact mild forms of skin disease or pathology, such as rosacea, melasma, solar elastosis to name a few. In addition, patients with complications from these procedures are often referred to dermatologists by NHS colleagues who have little knowledge of the cosmetic sector.

Our main concerns with respect to nonsurgical cosmetic interventions involve increased regulation of who is allowed to engage in nonsurgical cosmetic practice with emphasis on training and assessment. Motivation for increased regulation is driven by improved standards for patient benefit, which include: minimising the risk for inappropriately treated disease and missed diagnosis; promotion of evidence-based practice; and ability to recognise and treat complications.

We highlight the need for adverse event reporting in order to inform evidence-based practice and ensure high quality care. A preliminary audit on adverse events associated with nonsurgical cosmetic interventions has been completed and subsequently sent to all members of the British Association of Dermatologists (BAD), British Association of Aesthetic Plastic Surgeons (BAAPS) and British Association of Plastic, Reconstructive and Aesthetic Surgeons (BAPRAS). Other issues to reflect upon include work-force planning relating to professional groups that are allowed, or encouraged, to engage in nonsurgical cosmetic practice, and mechanisms to regulate developing technologies.

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Regulation of medical devices and implants and other products

1) What are the risks and benefits presented by dermal fillers?

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

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

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

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

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

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

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

Non-permanent or temporary fillers are unlikely to elicit granuloma formation, however, other allergic reactions can occur, such as delayed-type hypersensitivity with bovine collagen. Bluish discoloration due to an optical phenomenon called the Tyndall effect can occur if the product is injected in the wrong plane. It may be possible to mitigate some adverse events caused by hyaluronic acid filler with hyaluronidase. There is evidence documented in the literature that even hyaluronic acid fillers are not "inert" and stimulate a tissue response through fibroblast proliferation and collagen production.

2) What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?
3) Are there any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out above?
4) Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?

Though products may not claim medical purpose or benefit, there is clear evidence many can cause significant harm to patients requiring long-term medical and surgical treatment. Those associated with high risk, such as the permanent fillers, should be required to produce long term safety data, for example to establish relative risk of granuloma formation.

No filler is "inert" and a better understanding of the effects of such products, including possible mechanistic pathways is required. Due to concerns regarding deregulation of nonsurgical cosmetic practice, the British Association of Dermatologists' position has been to call for reclassification of fillers to that of prescription only medicines (POMs). Noted is the stark contrast taken by the FDA (Food and Drug Administration) with only six dermal fillers licensed in the USA compared with over 160 in the UK. It may be that patient protection can be achieved in other ways besides reclassification, such as increased regulation of who can administer fillers. By limiting practitioners to those with breadth of knowledge to independently analyse available scientific and clinical data and make evidence-based decisions, poor and unsafe products are less likely to thrive.

5) Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can health providers, professional bodies, regulators and patient groups promote the best possible understanding of the role of the incident reporting system and ensure that professionals in particular understand what they have a duty to report?

A preliminary BAD audit on non-surgical cosmetic procedures highlight fillers and laser/light-based treatments as those associated with the most common and chronic adverse events. Although clinical governance, audit and adverse event reporting is important in all areas of non-surgical cosmetic practice, in the first instance it may be focus on these two types of procedures will result in maximum benefit.

The BAD supports establishment of a Filler Adverse Event Register based on existing pharmacovigilance registers, in order to collect data on the types of filler associated with highest risk, the types of adverse events encountered and more. This should be a national register which engages dermatologists, plastic surgeons, GPs and other professionals who may encounter complications from nonsurgical cosmetic procedures in their clinics. It is understood they may not have been involved with the initial procedure, and in fact may not even engage in nonsurgical cosmetic practice themselves. Those who engage in nonsurgical cosmetic practice should also be obligated to report these events to the Register, though it is acknowledged they may have no medical knowledge and may be unable to recognise such complications. It is likely some funding for a register could be obtained from industry.

With deregulation, nonsurgical cosmetic procedures can be administered by those with no medical or paramedical training. These individuals may have no concept of governance, audit and reporting. Limiting those allowed to engage in nonsurgical cosmetic practice to medical professions already familiar with this culture, would be of significant and immediate benefit.

Regulation of practitioners

6) Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, ie be on the Specialist Register?

7) Currently 'cosmetic surgery' is not recognised as a specialty for which doctors can train and achieve CCT leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for 'Cosmetic Surgery' or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?

8) Do people who deliver cosmetic interventions like fillers, Botox®, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?

Most nonsurgical cosmetic procedures such as dermal fillers, botulinum toxin injection, laser treatment and chemical peels were initially developed as treatment for dermatological disease. Although the application of these procedures has moved from a medical/therapeutic focus to that of a cosmetic nature, many of the risks remain the same and are inherent to the procedures themselves. Deregulation has allowed those with limited or no medical training to engage in nonsurgical cosmetic practice. For this reason, the answer to the question "do people who deliver cosmetic interventions… have the appropriate skills to deliver them?" is NO in the extreme.

The European standards suggest these procedures should be carried out by doctors only. It is acknowledged that current practice in the UK deviates from these standards quite significantly. Some feel nonsurgical cosmetic practice in the UK should be restricted to doctors, dentists and independent nurse prescribers. However, there is still active debate, and merit is recognised in limiting practice to: doctors; dentists with a medical degree and; healthcare professionals such as nurses working under the supervision of a doctor.

What is clear is that appropriate training and assessment for those engaging in such practice is required. This should be aligned with the recognised UK medical training bodies such as the Joint Royal College of Physicians Training Board (JRCPTB) and Royal College of General Practitioners (RCGP) with set curricula and workplace based assessments."Cosmetic" is an area of practice and not a recognised specialty. The terms "cosmetic doctor, cosmetic physician, cosmetic dermatologist, cosmetic nurse and cosmetic surgeon" are ambiguous and confusing to patients. When an individual refers to himself/herself as a Cosmetic Doctor, the public assumes he/she is a GP, which may not be the case.

The lines between "cosmetic" and disease are often blurred. Without the breadth of knowledge to distinguish between these, a practitioner may not provide the patient with best care. Dermatologists have concern about missed diagnoses --for example missed skin cancer treated as a "blemish," and inappropriate treatment of disease--a practitioner who is ignorant of treatment options denies the patient best care. Dermatologists raise concern about practitioners who claim to be "skin specialists" who demonstrate little or no evidence of recognised training in dermatology. Ability to develop the knowledge and skills required for nonsurgical cosmetic practice is highly dependent on the practitioner's baseline knowledge and skill set. The diversity of practitioner background in the current workplace makes this difficult to assess or standardise. With the trend towards increasing numbers of GPs, dentists and nurses engaging in nonsurgical cosmetic practice, the Department of Health will need to reflect upon workforce planning issues.

9) Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can medical revalidation be used to promote this?

Demonstration of good practice should be evidenced by CPD (Continuous Professional Development), audit etc through routine appraisal. Those solely in private practice will need to comply with these measures through their Responsible Officer. Regulating who is allowed to engage in nonsurgical cosmetic practice will promote a stronger culture through the governing professional bodies. Obligation to report adverse events could be made statutory by these governing bodies.

10) Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?

Mandatory records should be kept for dermal fillers. There are reports of patients who presented to their dermatologist stating they had hyaluronic acid (temporary) filler injections, with subsequent nodule formation. On further examination it was found through biopsy that the nodules were in fact granulomas which developed as a response to permanent fillers, such as polymethacrylate. This suggests that at best patients are confused about which products are being used, or at worst that practitioners are injecting products fraudulently.

Regulation of organisations providing cosmetic interventions

11) Is it right that private providers of cosmetic surgery meet the standards expected of the NHS?
12) The CQC registration requirements place a duty on providers to protect their patients from unsafe treatment, but it is not clear how far this extends in the private sector to providing appropriate after-care where a patient has suffered harm as an unexpected consequence of treatment. Do we need to impose a clearer legal requirement on registered organisations to provide after-care to their patient? If so, for how long after the original treatment?

For patient protection, it is reasonable that private providers be required to meet the standards expected in the NHS. The private sector should provide appropriate after-care for patients suffering from complications of nonsurgical cosmetic treatment. If the practitioner does not have the expertise to address the complication himself, an appropriate referral should be made. In order to do this, the practitioner must have breadth of knowledge and insight into potential complications as a prerequisite for engaging in this practice.

13) Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?

The BAD feel that existing regulation with regards to laser and lights is decidedly inadequate. These medical devices are highly sophisticated instruments which require careful handling and precaution--blindness and reflected radiation to people beyond the local treatment area are potential risks, irrespective of the reason for treatment. The preliminary audit identifies laser and light procedures, in addition to fillers, as those most frequently associated with adverse events and they correlate most strongly with complications which are chronic/permanent. Our members report that it is not uncommon to see patients with burns and scarring, mainly due to laser hair removal, and those who engage in medicolegal work cite adverse events associated with laser and lights are the most frequent cause of litigation for nonsurgical cosmetic procedures. With the deregulation of the cosmetic use of laser and light treatments , a double standard has arisen where those most able to administer the treatments safely – ie doctors working in CQC (Care Quality Commission) certified clinics with a requirement to demonstrate appropriate training are more tightly regulated than those with no medical training operating in cosmetic/non-medical environments.

The European consensus is that the cosmetic use of laser and light treatments should be restricted to medical doctors or healthcare professionals working under the direct supervision of a medical doctor. The current situation in the UK deviates from these standards quite significantly.

14) Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?
15) Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?
16) Should providers be required to ensure that records are kept on the implants and devices they implant? If so for how long?

The BAD do not feel injectable non-surgical cosmetic procedures such as dermal fillers and botulinum toxin injections should be administered in a non-clinical setting. Home "Botox® parties" trivialise the risks of this POM and send the wrong message to the public, in addition to raising issues about consent. The risks of dermal fillers and laser and lights have already been discussed, and those who engage in these procedures should support an adverse event reporting system. Medical records should be maintained with respect to development of complications and outcomes. Information on dermal filler products should be recorded in the medical record and kept for 10 years. This is based on reports of new onset granuloma formation up to 10 years after injection.

Questions on insurance and indemnity requirements
17) Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?
Those who engage in nonsurgical cosmetic practice should be required to have professional indemnity insurance which covers the procedures relevant to their practice.
18) How could cosmetic surgery organisations make it easier for patients to access their health records?
19) What can be done to protect patients if their provider goes out of business?

With regard to nonsurgical cosmetic procedures, patients should be able to access their health records on request. If a provider goes out of business, the patient may have to seek treatment for complications which develop through their NHS GP who can then refer to specialist/secondary care as appropriate.

Questions on consent, information and advertising for cosmetic interventions
20) What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?
21) Should providers be required to carry out a two-stage consent process (ie allowing a 'cooling-off' period between consultation and surgery)?

It is doubtful that non-healthcare related practitioners are qualified to obtain properly informed consent from patients, as they will not have the basic scientific or medical understanding to be cognisant of all the potential medical complications which may occur from the procedure. For nonsurgical cosmetic procedures examples include, but are not limited to: delayed immunologic reactions; immediate hypersensitivity and anaphylaxis; vascular occlusion and necrosis or blindness; neurologic damage; ptosis; facial asymmetry; muscle paralysis with functional impairment (swallowing, speaking); temporary or permanent dyspigmentation; permanent scarring; xanthelasma; milia formation; reactivation of HSV (Herpes Simplex Virus); infection; bio-film formation.

It is felt a "cooling off" period is not required for nonsurgical cosmetic procedures, but clinical judgement is paramount to providing an accurate and immediate psychological assessment of patients. This skill comes with medical training and clinical experience, which is why the BAD supports regulation of professional groups allowed to engage in such practice.

22) Do you think the existing regulation of the advertising of cosmetic interventions is proportionate?
23) Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?
24) What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?

Numerous nonsurgical cosmetic procedures have been developed, largely by dermatologists, as an extension of treatments for disease. Therefore, our view is that although the indication for treatment has moved from that of disease to cosmetic/aesthetic issues, the procedures may still carry the same inherent risk. This is sometimes difficult for the general public to understand, and aggressive advertising, for example with time-limited offers or price reduction for multiple procedures, trivialises these risks even for nonsurgical cosmetic procedures. It may be difficult for sales staff who have no medical training and are incentivised by targets to provide clear and accurate advice to patients. The absence of professionalism is evident in the flouting of advertisement for botulinum toxin, a POM, even by those medically qualified. Some advertising gives unrealistic expectations with regards to risks and benefits.

A national implant registry

25) How could a national implant registry be set up and funded? Which treatments should it cover? Should participation be a statutory requirement for providers? Should patients have the right to opt out of having their information recorded?

A national Fillers Adverse Event Register is achievable. It could be led by the BAD as with other pharmacovigilance registers, with the realistic expectation of part-funding from industry. Such a Register would provide a great source for data to inform evidence-based practice. Dermatologists, plastic surgeons, GPs or other clinicians who encounter patients with complications from fillers would be obligated to report information. It is acknowledged that the reporting clinician may not have been involved in the original procedure. Those who practice nonsurgical cosmetic procedures should also be obligated to engage with the Register, but depending on their professional background may not be able to do so effectively, for example ascertaining cause and effect of the complication. These situations should trigger referral to an NHS GP who can then direct the patient appropriately and reporting to the Register can then take place. Patients should have the right to opt out, though it may still be possible to collect anonymised data.

Specific sectors/forms of treatment

26) Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification eg tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

It is difficult to comment due to lack of information regarding the scope of the problem. There are anecdotal reports of serious complications from various tattoo and piercing procedures. Medical professionals who encounter these situations should be encouraged to publish case reports in the literature to disseminate knowledge and build data bases.

Chemical peels are another cosmetic intervention with a broad range of potential complications depending on the type of peel used. Chemical peeling involves application of a caustic solution (eg trichloracetic acid, salicylic acid, glycolic acid) to the skin which causes controlled destruction of varying depth which triggers a regenerative wound healing response. The efficacy for skin rejuvenation is directly proportional to the depth of damage, medium and deep peels can result in significant skin tightening and improve irregular pigmentation. However, the depth of the peel is also directly proportional to risk and require days to weeks of recovery time. These risks include but are not limited to: significant pain, scarring with potential for contracture, infection, irregular pigmentation, reactivation of HSV, and even systemic fluid imbalance depending on the area treated. Deep phenol peels require sedation and cardiac monitoring due to potential cardiotoxic effects. The preliminary audit did not flag complications from chemical peels as a significant issue. It is likely non-medical practitioners primarily use superficial peels, which have a minor temporary effect but are also low risk.