

Safety of non-surgical aesthetic treatments

14 June 2022

House of Commons

Meeting with Maria Caulfield MP, Minister for Patient Safety and Primary Care

Chair: Professor Ray Powles CBE, Chairman of Conservative Health

Introduction

Cosmetic interventions are expanding rapidly in the United Kingdom. They were worth £2.3 billion in 2010, rising to £3.6 billion in 2015 and have continued to rise year on year. They are classified into surgical procedures, which include face-lifts, breast implants and blepharoplasty, or non-surgical procedures such as dermal fillers, Botulinum toxin (Botox) and the use of laser or intense pulsed light. These latter account for nine out of ten procedures and 75% of the market value. Presently, the non-surgical interventions market is almost entirely unregulated and requires no qualifications to perform.

Sir Bruce Keogh's report into the Regulation of Cosmetic Interventions singled out dermal fillers as a "crisis waiting to happen". This was corroborated by a British Association of Aesthetic Plastic Surgeons survey which found 69% of its surgeons had seen patients presenting with complications following temporary fillers, and 49% had seen complications following semi- or permanent fillers. Furthermore, 41% of surgeons reported having seen patients who either required corrective surgery or were assessed as being untreatable due to the damage that had been caused.

A recent *Times* investigation uncovered practitioners regularly using non-licensed Botox to increase profit margins and bypass the prescription process. Many patients have been scarred for life with side effects such as hard painful lumps when injected with unlicensed or counterfeit products. Other practitioners regularly performed treatments on individuals under the age of 18 in direct contravention of the law.

A summary of recommendations is available at the end of this report.

DR PAUL CHARLSON

A leading cosmetic doctor in the UK
Past-President of the British College of Aesthetic Medicine
Trustee of the Joint Council of Cosmetic Practitioners
Former Chair of Conservative Health

Introduced the discussion by presenting a range of images of complications that had arisen from the provision of a range of non-surgical cosmetic invasive treatments.

He discussed the importance of evidence being collected in a coordinated and efficient manner to inform complications management and to provide an evidence base to inform the need for regulatory reform that is universally applied across the sector.

SALLY TABER

Trustee of the Joint Council of Cosmetic Practitioners
Director of the Independent Sector Complaints Adjudication Service

The JCCP's mission is patient safety. It gathers evidence of actual risks to real patients. Below is a recent example of a complaint:

Concern was expressed to the JCCP by a Consultant Microbiologist at the Royal Free NHS Trust. A patient had come through their TB Service with an infection acquired through an aesthetic procedure. He was concerned at the waste of NHS time and money, and that other patients may be infected in the future unless regulation of practices and substances prevented non-medical professionals from legally providing these kinds of procedures.

The infection was Mycobacterium abscessus, an invasive organism with multi-drug resistance often requiring multiple antibiotics for many months – a similar infection had been seen in a patient returning from Brazil with infected buttock implants. Such cross-infection is a marker of poor practice in aseptic technique that should not happen to properly trained practitioners using properly supplied materials.

The treatment was performed in a non-clinical home environment by a beauty therapist who had done a one-day training course to administer Botox and Dermal Fillers at the Centre for Medical Sciences & Research (CMSR) in London. CMSR has not sought to meet JCCP Standards for training providers.

- The products were obtained from Fox Clinic Wholesale. They operate online, their origin is obscure.
- CMSR arranged a prescriber for the prescription-only drug – a doctor on the GMC Register. CMSR failed to inform the practitioner of the GMC rule that the prescriber must do a face-to-face interview with the patient before issuing a prescription. An interview did not take place.
- The beauty therapist has confirmed that her name was on the prescription not the prescriber. This is illegal as she is not qualified to prescribe.

RECOMMENDATIONS

1. Appropriately trained practitioners, who are required to achieve the JCCP training standards, should be on a professional register open to the public.
2. Access to a redress scheme.
3. Premises standards to be adhered to and inspected.
4. MHRA to take action regarding wholesale supplies of these drugs and fillers (MHRA are being receptive which is excellent).
5. Other regulators should follow the MHRA's leadership.

DAWN KNIGHT

Patient safety advocate and campaigner

Lay member and Trustee of the Joint Council of Cosmetic Practitioners

Spoke about predatory advertising and presented a range of examples of poor practice:

- Online celebrity endorsements
- Advertisements that contravene ASA regulations such as: The 'magic of anti-wrinkle treatment'; 'Don't miss out on our offer' – £160.00 for 3 areas'; 'Treatment usually £190.00'; '1ml of juicy perfection'; 'Free Botox'!
- Advertisements for Botox and fillers sandwiched between advertisements for second-hand sofas and child's high chairs on Facebook Market Place.

TAMARA SANDOUL

Policy and Campaigns Manager, Chartered Institute of Environmental Health

Has worked on the regulation of cosmetic procedures for the past three years

Co-author of two reports together with the Institute of Licensing

The Chartered Institute of Environmental Health (CIEH) believes the new licensing regime should be designed so that it can work well in practice from an enforcement and regulatory perspective. The CIEH has been closely involved in this policy area and has strongly supported the amendment to the Health and Care Act, which gives SofS the power to introduce a new licensing scheme for cosmetic procedures.

Across England, local authorities (LAs) can register procedures such as tattooing, semi-permanent make-up, piercing, electrolysis and acupuncture. Four out of five of these are considered high risk, due to the fact that they penetrate the skin and can carry a risk of blood borne virus transmission. Some of these also have a well-documented history of outbreaks of infections, which require hospital treatment and can lead to permanent disfigurement and scarring.

Of course, this list of five procedures misses out most of the newer non-surgical beauty procedures which you will have heard about today and this is the first problem with registration. It is based on some seriously outdated legislation, which has not been updated since it was introduced in 1982. [Local Government (Miscellaneous Provisions) Act 1982]

There are several key reasons why the current system does not work even for those five registrable procedures

- Regulators have no grounds to refuse a registration – once the fee is paid and 30 days passes, the business is allowed to legally trade. There are no set standards or requirements they need to meet and a court order is required to take a practitioner off the register.
- There are also some potential safeguarding issues – for example, it might be relevant to check whether someone has a sexual offences conviction if they intend to perform intimate piercings. As there is no legal minimum age limit for those wishing to get piercings, the practitioner could very well be dealing with minors when performing this procedure.
- Once the business is registered, regulators have no grounds to go back in again to inspect the premises unless there is a complaint. The business can therefore bring in new practitioners and standards may drop over time but the LA would not necessarily be aware of this. Members of the public often also don't know where they can report their concerns.
- At the moment, each LA holds its own list of registered practitioners. This is not transparent or helpful for consumers looking to find out whether a business or practitioner is safe to use.

- Many practitioners also perform procedures from their home or at the client's home. However, domestic premises are not necessarily be included as part of current powers and, arguably, some of these practitioners are likely to have the least training and be operating under the radar.
- With registration, there are no enforcement powers, such as Improvement Notices. And penalties for non-registration are very small, so unsurprisingly, prosecution is rare under current legislation.

So, what do we need from the new licensing regime to ensure it delivers on its key objectives of making the cosmetic non-surgical procedures safer for the public? And how could it work well on the ground for both the businesses and regulators?

1. We need a system of licensing both premises and practitioners

There will need to be one clear set of standards and requirements for every type procedure. These standards should be set nationally, so that there is a level playing field across England and all practitioners as well as regulators are clear on what conditions would need to be met to obtain a licence. Of course, the standards would need to be set relative to the level of risk involved and the skills required to perform the procedure safely.

A significant issue to be resolved before a licensing scheme can be set up is how to ensure the training and qualifications that practitioners are getting are of a good standard. Unfortunately, training courses vary greatly in quality and in length – some are as short as one day – and most training courses are not accredited. A system of accreditation for training courses and training providers will be needed to make the licensing scheme works well at protecting the public.

There will need to be periodic inspections of the premises to ensure that these continue meet the standards for infection control and the practitioners working there are all appropriately licensed. It is vital that the new licensing regime includes a way of regulating practitioners working from home – not necessarily mobile practitioners – but those who are working from a dedicated space which is set up appropriately to perform these treatments safely.

One national list of licensed practitioners and premises is essential to provide greater transparency for consumers so they can easily check who is licensed and which procedures they are licensed to perform. This register can also act as an important hub, giving members of the public accurate information about the risks of procedures and where they can log a complaint about a practitioner.

The new licensing regime should also provide a real deterrent for practicing without a licence and fines need to be significant enough to help fund local authorities' regulatory activities in this area.

2. Current registration powers should be revoked, and the five registrable treatments should be brought into scope of the new licensing regime

Failing to do so would lead to two very different regulatory systems operating side by side. Many businesses offer a range of procedures and will want to be regulated in an efficient way.

There would also be a danger of some procedures falling into the grey area between the two regulatory regimes – treatments such as derma-rolling, micro needling, advanced electrolysis, vampire facials, and scarification could fall outside of scope of either regime.

In the context of diminished resources at a local level, it will be seriously counterproductive to have two parallel and different regimes running at the same time.

This is a complex area and the challenge is to help to simplify it for consumers and regulators as well as creating a level playing field for businesses.

SUMMARY OF RECOMMENDATIONS

(ST = Sally Taber, DS = David Sines, TS = Tamara Sandoul, DK = Dawn Knight)

Practitioner licensing

- 1 TS Introduction of a system of local authority licensing of practitioners.
- 2 DS CQC to develop a memorandum of understanding with local authority licensing organisations to perform an integrated and enhanced scheme of regulation for aesthetics to avoid duplication for those healthcare professionals who are already registered with the CQC.
- 3 ST Licensed practitioners, achieving all requirements and standards, should be on a national professional register open to the public. This register should also feature information for the public about risks of different procedures and where to log complaints about practitioners.

Premises

- 4 TS Introduction of a system of local authority licensing and periodic inspection of premises used for cosmetic procedures.
- 5 DS Extended powers to be given to the CQC to inspect all premises where invasive procedures that are included in the license are to be performed.
- 6 ST Premises standards to be adhered to and inspected.

Training standards

- 7 DS Implementation of a national register of approved qualifications and of approved education and training providers.
- 8 DS To consider whether the PSA (Professional Standards Authority) could be given extended powers to oversee registers of approved education and training providers and qualifications in the sector in addition to their current statutory function of overseeing practitioner registers.
- 9 DS Ofqual to be requested to ensure that they only approve qualifications in the future that meet the new Government standard for education and training for the aesthetics sector.

Prescribing drugs, fillers etc

- 10 DS The Minister is requested to write to all professional regulatory bodies with responsibility for prescribing to seek assurance that they will enforce guidance to ensure that prescribers do not perform remote prescribing in the aesthetics sector.
- 11 DS Dermal fillers to become a prescription-only device – this to be agreed with the MHRA.
- 12 ST MHRA to take action regarding wholesale supplies of these drugs and fillers (MHRA are being receptive which is excellent).

Procedures/treatments

- 13 TS Current Local Authority registration powers (Part 8, Local Government Miscellaneous Provisions Act 1982) should be revoked, and the five registrable treatments should be brought into scope of the new licensing regime.

Other

- 14 DK The new Advertising Standards Authority 'Guidance on the marketing of surgical and non-surgical cosmetic procedures' (effective 25 May 2022) should be rigorously enforced to protect the public.
- 15 ST Access to a redress scheme.
- 16 ST Other regulators should follow the MHRA's leadership.