PERSPECTIVE

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Unnecessary or Negligent? A Look into the Regulation of Non-Surgical Cosmetic Intervention in Europe

Garrett Huwyler

School of Medicine, Trinity College Dublin, University of Dublin, Ireland (GarrettHuwyler@gmail.com)

Abstract

The regulation of medical devices and associated procedures is common across the globe, with country and regional variations directly impacting patient safety and ease of access. When considering non-surgical cosmetic interventions within Europe, the variations seen between member states of the European Union and that of the United Kingdom are quite dramatic. These regulations encompass procedures such as dermal fillers, botulinum toxin injections, and the application of lasers for skin rejuvenation treatments. Currently, the regulations in the European Union place an emphasis on quality control and safety for the products used by classifying them as medical devices and enforcing medical licensing requirements for their application. In contrast, the United Kingdom lacks regulation around both quality control and licensing requirements, placing patients at an increased risk for harm. This discussion recognises that patient autonomy and freedom of choice are key principles to be protected within this field, yet emphasis should also be placed on the proper regulation of expert practitioners and on the need for safe medical devices. The regulation of non-surgical cosmetic interventions holds substantial value for societal good, with an increase in safety, efficacy, accountability, and ultimately, patient well-being.

Keywords: Non-surgical interventions, Regulatory, European Union, United Kingdom, Patient safety, Medical device

Introduction

Augmenting the human physique is a concept that has existed across many cultures for thousands of years. As society and medicine have changed and evolved over this time period, the manner in which augmentation is conducted has also developed and grown[1]. In modern society, physical alteration can generally be described within the medical field as being cosmetic-orientated medicine[2]. This field can subsequently be split into surgical-based interventions and non-surgical-based interventions[2]. For the scope of this discussion, an in-depth look will be applied to non-surgical-based interventions and their regulation within the European Union (EU), as well as the United Kingdom (UK). In doing so, this discussion aims not only to identify what consists of non-surgical interventions and their subsequent current regulation, but to also highlight the implications of altering these existing regulatory laws.

Defining Non-Surgical Interventions

In order to be able to discuss the regulatory components surrounding "non-surgical interventions", one must first clearly identify what constitutes these procedures. Inherent to the definition itself, all approaches involving surgical components are excluded from this field. This leaves a wide variety of other procedures, with varying complexity and corresponding risk, excluded and unregulated. As highlighted by Mikhail et al. in 2019, non-surgical cosmetic procedures (NSCPs) refer to interventions that "are, broadly, used in order to enhance cosmetic appearance and mask signs of ageing, by altering volume and contours and by changing the quality of the skin."[3]

Mikhail et al. continues by stating that these types of procedures range from injections of dermal fillers or botulinum toxin, to hair transplantation and skin rejuvenation treatments[3]. The way these types of treatments are administered is relative to the regulations that are enforced in the country of practice. Currently, in the UK, NSCPs can be performed in a variety of environments, ranging from outpatient medical clinics to dentistry offices, "medical spas," and beauty salons. The latter settings are of particular concern due to the dramatic variation in training that practitioners have. As highlighted by Kamouna et al. in 2015, there have been direct consequences of patients having unnecessary side effects due to untrained individuals administering dermal fillers[4]. Exacerbating this problem is the escalating trend towards beauty salons providing this type of treatment. As a result, more patients have been presenting to hospitals with infections, often due to a lack of proper technique of untrained practitioners[5]. The expansion in

Table 1. **Sample of the Existing Regulation of Non-Surgical Procedure and Complications in the United Kingdom. (Referenced from United Kingdom Department of Health, 2013[6])**

Non-Surgical Cosmetic Procedure	Product Regulations	Medical Practitioner Required for Administration?	Location of Administration	Risks and Complications
Botulinum Toxin	Prescription Required	No	No Requirement	Bleeding, unintended muscle weakness, eyelid droop, double vision, speech and breathing difficulties, asymmetry, infection, allergic reaction. Not to be used in pregnancy
Chemical Peel	General Product Safety Directive if sold directly to end user	No	No Requirement	Burns, infection, scarring, changes in pigmentation, alteration of skin texture, persistent redness, asymmetry
Dermal Filler	Non-regulated unless self-described as a medical device (most do not)	No	No Requirement	Infection, scarring, persistent inflammatory response, thickening, pain, infection, asymmetry, tissue loss, poor aesthetic outcome, visual disturbance, blindness
Laser Treatment	Equipment is classified as a medical device	No	No Requirement	Burns, infection, changes in pigmentation, scarring, asymmetry, visual disturbance, blindness.
Intense Pulsed Light	Not considered a medical device	No	No Requirement	Burns, infection, changes in pigmentation, scarring

the number of patients receiving these procedures can be highlighted by the fact that NSCPs are a growing field, accounting for 9 out of 10 of all cosmetic procedures, and is estimated to be worth more than £3 billion in the UK alone[3]. With this lucrative field being responsible for over 75% of the market value in cosmetic interventions, it provides ample motivation for many different types of practitioners to become involved[6]. This is where the concept of regulation of the industry particularly comes into focus, and is directly linked to the risks that are associated with such procedures. Malpractice can result in complications that include poor injection technique, idiosyncratic immunological response, maiming, or other life-altering side effects[7,8] (**Table 1**).

Current Regulations in the European Union and the United Kingdom

Ensuring patient safety and practitioner expertise is firmly embedded into the concept of regulation within the medical field. As such, countries have various forms of medical legislation ranging from drug access regulations to requisites for conducting surgery[9]. Inconsistencies are apparent when contrasting the EU and the UK's regulation of non-surgical cosmetic intervention.

When examining the regulations surrounding devices that are used in NSCPs, the issue of the UK being untethered to European Union legislation has a profound impact. The UK has little to no quality control or safety requirements for its cosmetic products such as dermal fillers. As a result, individuals can easily order what may be a counterfeit or unsafe product through accessible retailers such as Amazon or Google[10]. One exception does exist; botulinum toxin is classified as a "prescription only medical device" due to its innate harmful characteristics. Despite this classification, it has been shown that non-medical practitioners are able to find a legal loophole in acquiring the toxin, with the only legal requirement being for a medical practitioner to prescribe the toxin to the patients at the clinic[11]. Unfortunately, this does not necessarily mean that the patient must attend a consultation with the doctor, but rather the toxin can be prescribed by proxy, and subsequently be administered by a non-medical practitioner. This practice is of much debate in its legality and ethics[11]. Furthermore, the application of these products is not regulated within the UK, and as such, there is no requirement for individuals to meet regulatory standards to administer substances such as botulinum toxin or dermal fillers[6].

In contrast, the member states of the EU fall under the European Medical Device Regulation which officially came into effect on May 26, 2021[12]. Crucial to being a regulation instead of its predecessor, the Medical Device Directive, these laws are directly applicable at a national level rather than having to go through subsequent country-level legislation[13]. Under this regulation, collagen implants, dermal fillers, skin resurfacing equipment, and laser hair removal equipment are all classified as medical devices. The aim is for NSCPs and products to meet the CE Mark Certification for safety, comply with quality management competencies according to EN ISO 13485:2016 standards, and to have an EU company registration if the company is located out of the EU[13]. Furthermore, the EU regulation surrounding the application and conduction of NSCPs is highly regulated, with the procedures being restricted to highly trained individuals with a medical license[14,15].

Advocacy for Change

When considering the differences between the legislation in the UK and the EU, one key issue that should be recognised is the primary motivation for the legislation. Modern medical practice emphasises the need to avoid paternalism and instead aims to promote patient autonomy and decision-making[16]. Therefore, it is imperative that the concept of medical regulation stems from an obligation to beneficence. The regulations in the EU are directed at this in two ways. First by ensuring the safety and quality of the products through the incorporation of CE marking, and second through restricting their usage to individuals with a medical license[14].

In direct comparison, the lack of regulation in the UK appears to subject a greater proportion of risk to patients. However, this does not indicate that individuals in the UK are content with the present level of regulation. A 2013 report, signed by former Medical Director of the UK National Health Service, Bruce Keogh, directly highlighted the vulnerabilities in the existing regulations surrounding non-surgical cosmetic interventions in the UK[6]. This report was specifically commissioned by the Department of Health in response to serious health

concerns regarding other cosmetic interventions[17]. To highlight the level of concern generated by the findings of this report, Keogh stated that, "All devices, whether they are solid or liquid, that are implanted into humans and stay there should be covered by the Medical Devices Regulations."[17] This was further elaborated on by the response of the health minister at the time, Dan Poulter, who stated, "The independent panel has made some far-reaching recommendations, the principles of which I agree with entirely. We will consider the report carefully and respond in detail in the summer."[17]

Yet, as time has gone on, the effects of the report findings have faced difficulty in their actual implementation, regardless of further support from the medical community in the need for new regulation. In an article published in 2015, Dr. Tamara Griffiths, a member of the British Association of Dermatologists, called again on the government for the establishment of a mandatory register for practitioners who conduct NSCPs[18]. She went on to elaborate on the rationale for having a mandatory register, stating that the lack of regulation leaves patients vulnerable to having to make medical decisions without being necessarily properly informed, and that it does not hold practitioners accountable for their actions[18]. However, the lack of substantial changes in legislation and regulation does not indicate a complete lack of action on behalf of the UK regulators. As highlighted in 2019, the publication of guidance from the Joint Council for Cosmetic Practitioners for non-surgical cosmetic treatments was described by Dr. Caroline Mills of the British Association for Oral and Maxillofacial Surgeons, as a step in the right direction[15]. Yet again though, Dr. Mills indicated that the guidelines did not go far enough, specifically stating that, "In the EU practitioners have to have a medical license to inject fillers, and we need similar regulation in the UK."[15] The lack of this regulation puts patients at serious medical complications argues Dr. Mills, with risks of severe allergic reactions or vascular occlusion being among the potential side effects[15].

Conclusion

Ultimately, when looking at the state of regulations in the UK in comparison to the EU it does not appear to be a matter of one region simply taking a different approach into the regulation of NSCPs, but rather a lack of action on the part of regulators in the UK. Furthermore, to simply state that it is a lack of attention to the issue that fuels this would be false, as evidenced by the commission of the 2013 Keogh report and the alteration in guidelines from the Joint Council for Cosmetic Practitioners in 2019. Additionally, it is rather easy to state that a country should simply adopt the regulations of another, but again this would be an overly simplistic statement to make—as much as one set of regulations may appear superior to another for various reasons, they still need to be adapted and implemented in a sustainable manner specific to the country. As such, it would likely be more effective for the UK to alter their regulations in a manner similar to that seen in the EU, or perhaps in a way that could be implemented more effectively than what presently exists.

Finally, self-identity and self-worth have a direct impact on an individual's mental health. How one goes about improving or achieving that is ultimately up to that individual, and as such, the freedom of choice to modify their body can be articulated as their right. However, it is arguably the responsibility of medical professionals and legislators to ensure that in providing these interventions they mitigate as much risk as possible. Through regulations that emphasise safety, accountability, ethical conduct, and informed consent, regulatory bodies not only help improve the implementation of non-surgical cosmetic interventions in Europe, but set standards that could be replicated across the globe. ◄

Declarations

The author declares no conflicts of interest.

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