

This response was submitted to the call for evidence issued by the Nuffield Council on Bioethics' Working Party on Cosmetic procedures. Responses were gathered from 11 January to 18 March 2017. The views expressed are solely those of the respondent(s) and not those of the Council.

## **HOW COSMETIC PROCEDURES ARE REGULATED**

### *The Scottish Government*

#### **Background**

In response to a number of highly publicised incidents including the PIP breast implants scandal, the Department of Health commissioned Sir Bruce Keogh to undertake a review of cosmetic interventions, including their safety and regulation. The Keogh Report was published in April 2013 and the Department of Health responded in February 2014 indicating the intention:

- to improve the surgical standards and systems for cosmetic surgery
- to consider regulation and training for non-healthcare providers of cosmetic interventions
- to enhance the work on the safety of medical devices used in cosmetic procedures including the use of the unique device identifier and a feasibility study on a new cosmetic implant register
- to provide greater resolution processes and information to the public.

Whilst this review was primarily focussed on provision of these services in England, concerns over the provision and regulation of these procedures was shared with the other Devolved Administrations, who were kept up to date with the content and follow up action from the review. A Scottish Cosmetic Interventions Expert Group ("SCIEG") was established, chaired by Andy Malyon, Chief Medical Officer's Specialty Advisor in Plastic Surgery. Broadly, the remit of SCIEG was to examine the current position in respect of provision of cosmetic surgery and interventions in Scotland; analyse the recommendations contained in the Keogh Report for possible implementation in Scotland; and provide recommendations based on its findings.

The SCIEG recommended a three phase approach to introducing regulation of cosmetic procedures and that regulation should operate on a cost-recovery basis, based on fairness. The three phase approach combines proportionality and timeliness:

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 Health Improvement Scotland to receive complaints from the public will foster improvement in the delivery of high quality care.

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).

Phase 3: A few individuals with health care professional training who are out with 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 compulsory statutory, for additional health care professional groups who need to be included.

The first phase of this work will be completed on 1 April 2016 when legislation will be introduced through the Scottish Parliament requiring independent clinics to register with Healthcare Improvement Scotland who will ensure that these clinics are inspected and fully meet the requirements of the new legislation.

Failure to register a clinic with Healthcare Improvement Scotland from this date, whilst conducting cosmetic or any other health related procedure from the premises, will lead to the clinic managers/owners being reported to the appropriate legal authorities. In Scotland this would be the Crown Office and Procurator Fiscal Services.