NUFFIELD COUNCIL DE BIOETHICS

Regulation of non-surgical cosmetic procedures: consultation response

27 May 2020

Summary

1 We welcome the opportunity to respond to the Scottish Government's consultation on the regulation of non-surgical cosmetic procedures. Our response draws on the conclusions and recommendations of our 2017 report on cosmetic procedures.¹

Response

Do you agree that further regulation of non-surgical cosmetic procedures is needed?

- 2 We agree that further regulation is needed.
- 3 There are two sections of the Government's consultation document that we would like to comment on. The first concerns the question of a blanket ban:

"We are not averse to this SCIEG recommendation [that non-surgical procedures should only be provided by regulated healthcare professionals with appropriate expertise] in principle and recognise that the safety of everyone that chooses to have a cosmetic intervention carried out is of paramount importance, regardless of provider or location. However, there is currently a lack of evidence of harm from all activities and therefore we do not want to cause undue financial difficulties for reputable small businesses, if this can be avoided by the introduction of other appropriate regulation. We consider that a blanket ban on non-medical professionals carrying out non-surgical cosmetic procedures could be difficult to enforce and might drive unregulated providers underground."

4 The second concerns licensing options that the Government is considering introducing.

"We therefore offer... a way forward that ensures the visibility of all services and licensing backed with rigorous implementation guides (specific conditions) to ensure best practice in all circumstances. Conditions could include that services are provided in a clean and safe

Nuffield Council on Bioethics (2017) Cosmetic procedures: ethical issues, available at: http://nuffieldbioethics.org/project/cosmetic-procedures.

environment; individuals would be 18 years of age or older; cooling off periods would be offered and sharps etc. would be disposed of appropriately."

- 5 We would like to make four arguments in response to these sections:
 - Rather than imposing a blanket ban on non-medical professionals, practitioners should be licensed to practise on the basis of relevant qualifications.
 - The Government should take action to ensure the evidence base on potential harms is improved.
 - The treatment for under 18s should be banned, other than as part of care provided by a multidisciplinary healthcare team.
 - The Government has a responsibility to develop high-quality information resources for people considering having a procedure.

Focusing on appropriate qualifications and clinical supervision, rather than professional status

- We do not think a blanket ban on non-medical professionals carrying out cosmetic procedures should be introduced. The professional status of the provider is not the only relevant criterion. The more important point for the Government to consider is the system of qualifications for people who carry out non-surgical procedures. From an English perspective, we endorse the work carried out by Health Education England (HEE) that sets required standards for training and practice (regardless of professional background of the practitioner) across a range of non-surgical procedures.² HEE takes a 'stepladder' approach to qualifications for different aspects of practice ranging from level 4 (equivalent to the first year of a foundation degree) to level 7 (postgraduate level). It also sets out clearly what procedures may be offered, with or without clinical oversight, at different levels.³ We think this is a good way of approaching qualifications in this sector, and urge the Scottish Government to take a similar stance.
- 7 Regulation will be required in order to ensure that only providers with relevant qualifications are able to practise. Otherwise potential users / patients will remain at risk from practitioners who are unqualified and unsafe.

The role of the Government in taking action to ensure the evidence base on potential harms is broadened

² Health Education England (2015) Non-surgical cosmetic procedures, available at: https://www.hee.nhs.uk/our-work/non-surgical-cosmetic-procedures.

Nuffield Council on Bioethics (2017) Cosmetic procedures: ethical issues, available at: https://www.nuffieldbioethics.org/assets/pdfs/Cosmetic-procedures-full-report.pdf, at Box 4.4.

- 8 There is a dearth of evidence and data particularly good quality data that focuses on the potential harms of cosmetic procedures. This makes evidence-based policy to some extent aspirational.
- 9 The lack of shortage of evidence first became apparent to us when we undertook a literature review of the harms associated with cosmetic procedures.⁴ Although this review identified a number of relevant papers, it also concluded that there is general paucity of high quality evidence in this area, making the drawing of conclusions with any confidence problematic. A particular issue is the fragmented nature of the sector, with no publicly available data source on the number of procedures carried out, and no coordinated system for reporting adverse events. Given what is known of possible risks associated with these invasive procedures, this lack of data suggests actual levels of adverse reactions will be much higher than those reported. Since this literature review, other papers have been published on the potential harms of non-surgical procedures (see list at **Appendix 1**), but the picture remains highly incomplete.
- 10 As a funder of research,⁵ the Government has an opportunity, and indeed a responsibility, to act so that there are fewer unknowns around the practice of cosmetic procedures. We suggest that the Government should encourage high quality interdisciplinary research proposals that could fill the gap in evidence in this area. Without a complete picture, it is hard to imagine how the ethical practice of cosmetic procedures can be realised. Areas of research that the Government might consider supporting include:
 - Understanding factors associated with poor outcomes after non-surgical procedures.
 - Improving the evidence base on the long-term physical and psychological outcomes of procedures.
- 11 To complement these research aims, the Government should also **require better** data collection from all providers of non-surgical procedures in Scotland, making this a condition of future changes to its licensing scheme.

Regulation of treatments for under 18s

12 The note that "individuals would be 18 years or older" presumably relates to recipients of treatments, rather than practitioners. If this reading is correct, it is a step which we endorse wholeheartedly. It is important that those under the age of 18 should not just be able to have a cosmetic procedure unless it is undertaken as part of multidisciplinary healthcare. This is a further area that requires regulation.

⁴ Nuffield Council on Bioethics (2015) Review of the evidence of harms caused by the use of nontherapeutic cosmetic procedures, available at: https://www.nuffieldbioethics.org/assets/pdfs/Cosmeticprocedures-Review-of-harms-caused-by-cosmetic-procedures.pdf.

⁵ For example, through its Chief Scientist Office: https://www2.gov.scot/Topics/Research/bytopic/health-community-care/chief-scientist-office/6863.

The need for high-quality information for people considering having a procedure

13 Like all invasive procedures on people's bodies, it is important that those who choose to have a cosmetic procedure have access to high quality information so that any decision they make is informed. It is also important for people to be supported to ask the right questions of practitioners before having a procedure. Initiatives such as the English Department of Health's 'Clued up on cosmetic procedures' campaign and its accompanying information pages for those considering having a procedure set out some helpful prompts for people to consider. A similar approach in Scotland would set people on the right track to finding out the potential consequences of their decision to have a non-surgical procedure.

Conclusion

14 We would welcome the opportunity to discuss our response further with the Government. More information on our work on *cosmetic procedures: ethical issues* is available on our website.⁷

Hugh Whittall Director, Nuffield Council on Bioethics

Department of Health and Social Care (3 May 2019) Before you have a cosmetic procedure, available at: https://www.nhs.uk/conditions/cosmetic-procedures/before-you-have-a-cosmetic-procedure/.

Nuffield Council on Bioethics (2017) Cosmetic procedures: ethical issues, available at: http://nuffieldbioethics.org/project/cosmetic-procedures.

Appendix 1: list of recent papers on physical harms following non-surgical procedures

The literature below is a selection of the papers on physical harms from non-surgical procedures that have been captured by our evaluation and monitoring processes since we published our report.

- Koh IS and Lee W (2019) <u>Filler complications: filler-induced hypersensitivity reactions, granuloma, necrosis, and blindness</u> (Singapore: Springer (e-book)).
- Liu L, Yin M, Liu S et al. (2020) <u>Facial filler causes stroke after development of cerebral fat embolism</u> *The Lancet* **395(10222)**: 449.
- Rayess HM, Svider PF, Hanba C et al. (2018) A cross-sectional analysis of adverse events and litigation for injectable fillers JAMA Facial Plastic Surgery 20(3): 207-14.
- Urdiales-Gálvez F, Delgado NE, Figueiredo V et al. (2018) <u>Treatment of soft</u> <u>tissue filler complications: expert consensus recommendations</u> Aesthetic Plastic Surgery 42(2): 498-510.
- Wang LL, Thomas WW, and Friedman O (2018) <u>Granuloma formation secondary to silicone injection for soft-tissue augmentation in facial cosmetics: mechanisms and literature review Ear, Nose & Throat Journal 97(1-2)</u>: E46-E51.