

Response to the Department of Health's consultation on 'Promoting professionalism, reforming regulation'

January 2018

Introduction

- The Nuffield Council on Bioethics is an independent organisation that examines and reports on ethical issues arising from developments in biological and medical research that concern the public interest. We welcome the opportunity to respond to the Department of Health's consultation *Promoting professionalism, reforming regulation*.
- The Council's response draws from the conclusions and recommendations of our report, <u>Cosmetic procedures: ethical issues</u>, published in 2017. We have focused on a limited number of questions, and responded in terms of general approach, rather than in terms of detailed operational requirements which we are not best placed to judge.

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

- It is critical for public and patient safety that decisions as to which groups of healthcare professionals should be regulated are made independently and based on consistent and transparent criteria. The PSA would seem well-placed to take on this role.
- We suggest that it is also important that a broad definition is applied when interpreting what groups of practitioners count as 'healthcare' professionals. In our 2017 report *Cosmetic procedures: ethical issues*, we echoed the earlier concerns of Sir Bruce Keogh² in highlighting the dangers of unregulated and potentially unqualified practitioners providing invasive non-surgical cosmetic procedures that carry substantial risks.³ It remains unclear to us why recommendations for statutory regulation made by a number of enquiries have not been followed. It would therefore be highly valuable to have an independent

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

Department of Health (2013) Review of the regulation of cosmetic interventions.

Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, paragraph 8.24.

body, free of political pressure, applying consistent rules to determine when statutory regulation is required and when it is not.

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

A prohibition order would be better than no regulation at all, in that it would offer the potential to prevent unsafe practitioners from continuing (lawfully) to provide services, once patients have been harmed. However, it is not a good alternative to regulation where the practices in question (such as the provision of invasive cosmetic procedures) carry known risks, and hence the dangers of unqualified practitioners are clearly known in advance. In our 2017 report, we highlight the parallel risks that arise with respect to the inadequate regulation of novel products and procedures (i.e. permitting marketing authorisations to be granted without sufficient evidence of safety or efficacy) – and call for the need for both safety and efficacy to be demonstrated in advance of such authorisations being granted.⁴

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

- We agree that regulators have a role in supporting professionalism. In the context of cosmetic procedures (both surgical and non-surgical), the General Medical Council has led the way in setting high professional standards, and there is a need for other bodies to follow suit. In our *Cosmetic procedures:* ethical issues report, we specifically highlight the need for other regulatory bodies whose registrants provide cosmetic procedures, in particular the General Dental Council and the Nursing and Midwifery Council, to develop specific guidance on cosmetic practice for their own registrants, to complement the guidance issued by the General Medical Council and the Royal College of Surgeons.⁵
- However, in emphasising the importance of supporting professionalism, we think it is important to highlight how there are currently limitations on the scope for professional regulatory bodies proactively to 'police' their guidance: for example it is clear from ongoing concerns about inappropriate access to prescription-only medicines such as botox that the current reactive approach is quite inadequate to protect users. We suggest that further work needs to be undertaken in this area, for example through exploring ways in which regulators

⁴ Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, paragraphs 8.25-26.

Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, paragraph 8.33 and Recommendation 17.

- could work with other organisations, for example Trading Standards, Citizens Advice, and the Care Quality Commission (CQC), to alert them to examples of malpractice that might otherwise not reach them in the form of a complaint.⁶
- We further note that that regulating for patient safety involves not only concern with professional conduct, but also with appropriate regulation and scrutiny of the premises where professionals conduct their practice, and the products that they use as part of that practice. How well these different parts of the regulatory jigsaw fit together will have a significant impact on the effectiveness of the system as a whole.

Q13: Do you agree that the regulators should work more closely together? Why?

Yes: see response to Q12 above. Many aspects of practice raise similar professional concerns for all the different regulated professions, and it makes sense to learn from each other rather than reinventing the wheel. Such cooperation also reflects the reality that much professional practice involves teamwork across the professions.

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

10 Yes. It has become clear in a number of our enquiries that quite small technical regulatory change is often required to keep pace with developments: for example, the current need for change in primary legislation to permit the General Medical Council to document that surgeons have received a 'credential' for specific areas of practice such as particular aspects of cosmetic surgery. Waiting for opportunities to change primary legislation is not the most effective approach.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

At present, lack of flexibility may make it difficult for regulators to respond to developments (such as the growth in the unregulated cosmetic procedures market, or the challenges of ensuring training opportunities for practitioners where practice is mainly being carried out in the private sector⁸), in an effective

Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, paragraph 8.34.

Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, Recommendation

Nuffield Council on Bioethics (2017), Cosmetic procedures: ethical issues, Recommendation 15.

or timely way. In some cases, this will inevitably lead to lower safety standards. Both greater flexibility (with appropriate oversight), and a greater focus on professionalism (e.g. through the proactive development of standards in relevant areas) are likely to lead to greater public/patient protection.

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