RCN response to the call for evidence on the Department of Health (England) Review of the Regulations of Cosmetic Interventions

With a membership of over 410,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

Introduction

This document is the RCN’s response to the Department of Health’s (DH) Review of the Regulations of Cosmetic Interventions, Call for Evidence (see link to access the consultation document http://www.dh.gov.uk/health/2012/08/cosmetic-procedures/).

The RCN surveyed members as part of their evidence collection process. We invited those involved in, and thought to be involved in, aesthetic practice to take part. In total 121 responses were received and we have incorporated the information into our response.

Consultation Questions

Regulation of medical devices and implants and other products

1. What are the risks and benefits presented by dermal fillers?

Any cosmetic intervention that fall out with of systems or professional regulation and legislation covering medicinal products and devices could be deemed risky for patients. Beauty therapists administering dermal fillers which aren’t classified as medical devices is one such instance. The RCN believes that the Health and Safety at Work Act and General Product Safety Directive
are insufficient to provide assurances of safety and adequate levels of quality and opportunity for recourse in the event of harm for patients.

More than two thirds (69%) of respondents to our survey did not believe that existing regulations covering aesthetic practice are sufficient to protect public and patient safety.

2. What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?

The RCN believe that information on side effects of dermal fillers, including details from medical indemnifies of claims following cases of clinical negligence following their administration could form the basis of clinical evidence to regulate.

3. Are any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out above?

Providing the products to be administered / implanted fall under sufficient regulatory processes to ensure patient safety the RCN believes no further changes are need aside from those detailed in the review document.

4. Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?

The RCN is not aware of the need for additional strengthening of the regulatory system aside from those addressed in the forthcoming revision of the medical devices legislation.

5. Earl Howe’s review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should ‘examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.’ How can health providers, professional bodies, regulators and patient groups promote the best
possible understanding of the role of the incident reporting system and ensure that professionals in particular understand what they have a duty to report?

Clinical governance is an umbrella term that covers activities that help sustain and improve high standards of patient care. Nurses should already be familiar with some of these activities, such as clinical audit, for example. Clinical Governance should bind any number of assurance activities together to make them more effective.

The RCN believes that all health care organisations have a duty to the communities they serve for maintaining the quality and the safety of care. Whatever structures, systems and processes an organisation puts in place, it must be able to show evidence that standards are upheld. This includes being able to demonstrate that when mistakes or near misses happen that appropriate data is gathered, lessons learned, and changes made to systems and processes to prevent or minimise risks in future. Based on the current guidance from across the UK, we believe that such a system should have:

- Patient focus - how services are based on patient needs
- Information focus - how information is used
- Quality improvement - how standards are reviewed and attained
- Staff focus - how staff are developed
- Leadership - how improvement efforts are planned
- Public health - how health can be improved and inequalities reduced (although this aspect may be less prevalent in cosmetic surgical settings)

It will be important for there to be agreed standards for reporting which are proportionate and relevant to the industry but which are also rigorous enough to engender public confidence. Preferably such systems should be subject to independent evaluation and the data available for academic as well as public scrutiny.

It will also be important to also ensure that staff receive appropriate training and clinical supervision. This will enable them not only to use the systems
appropriately but also to develop other skills in leadership and change management strategies needed to redesign care processes where necessary.

The majority of respondents to our survey (88%) reported that they fully understood the role of the registered nurse in incident reporting, and the role reporting plays in good clinical governance.

**Regulation of practitioners**

6. Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, ie be on the Specialist Register?

The RCN has no evidence that the current requirements for doctors practising cosmetic surgery are insufficient, however all clinicians should be suitably trained and competent to undertake any clinical procedure or intervention.

7. Currently ‘cosmetic surgery’ is not recognised as a specialty for which doctors can train and achieve a Certificate of Completion of Training (CCT) leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for ‘Cosmetic Surgery’ or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?

The RCN has no evidence to suggest a need to introduce a new specialty for ‘Cosmetic Surgery’, however all clinicians should be suitably trained and competent to undertake any clinical procedure or intervention.

8. Do people who deliver cosmetic interventions like fillers, Botox®, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?

The RCN offers a range of services to its members such as telephone advice, on line learning and indemnity insurance. One condition of the indemnity scheme we offer is that RCN members;
"Have undertaken appropriate training which ensures that you are competent in your practice (i.e. you have the knowledge, skills and experience to perform the task or role to the appropriate standard of care)."

This is also reflected in the Nursing and Midwifery Council's Code of Conduct which states that registrants should provide a high standard of practice and care at all times by keeping their skills and knowledge up to date for safe and effective practice when working without direct supervision. Registrants are also advised to work within the limits of their competence and keep their knowledge and skills up to date throughout their working life. All nurses must take part in appropriate learning and practice activities that maintain and develop your competence and performance.

Observations from our clinical negligence lawyers have highlighted several issues that have arisen from representing Nurses in cosmetics including:

- Poor record keeping
- Inappropriate prescribing by medical practitioners of Botox®, for subsequent administration by a nurse, although recent GMC action may eliminate this
- The clinical credibility and effectiveness of some training courses offered to practitioners to enable them to administer certain treatments

We asked our members whether they believed that the practitioners they meet who deliver interventions like fillers, Botox®, laser treatments or chemical peels ‘clearly have the appropriate skills and knowledge to deliver them’. The results were mixed. Just under half (48%) agreed or agreed strongly that this was the case. However, over a quarter (26%) didn’t know, and a similar amount disagreed (26%). There could be a number of explanations behind this difference. A register of suitably qualified practitioners might help alleviate that confusion. In addition this uncertainty around practitioners’ skills and
knowledge may explain why the overwhelming majority of respondents (96%) believe that cosmetic interventions should only be administered by individuals who are registered with a professional regulator.

The RCN believes that appropriate national standards of clinical practice and governance will help address this issue. However enforcement can only be done through an agreed framework which accredits training and which maintains a register of those who have undertaken such training. The ultimate aim must be to give the public confidence that they are being treated by a competent individual who is up to date, registered with a professional regulator and that they can check that individuals qualifications easily prior to receiving treatment.

9. Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should ‘examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.’ How can medical revalidation be used to promote this?

As part of the requirements for revalidation, it is expected that all doctors will record and reflect on serious incidents in their portfolios, with a particular focus on what they have learnt as a result of the event(s). Proactive clinical audit of practice to look at trends and near misses should also be included.

10. Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?

Good clinical governance dictates that high quality care needs 'an information rich environment'. The RCN believes that proper patient records are essential component of safe and effective practice. The writing of the patient record and accurate and contemporaneous recording keeping of cosmetic interventions is an integral part of nursing practice and is essential to the provision of safe and effective care.
Respondents to our survey unanimously (100%) agreed that practitioners should be required to keep records of all cosmetic interventions.

**Regulation of organisations providing cosmetic interventions**

11. Is it right that private providers of cosmetic surgery meet the standards expected of the NHS?

The RCN believes that standards for clinical governance as outlined above are appropriate for all sectors.

12. The CQC registration requirements place a duty on providers to protect their patients from unsafe treatment, but it is not clear how far this extends in the private sector to providing appropriate after-care where a patient has suffered harm as an unexpected consequence of treatment. Do we need to impose a clearer legal requirement on registered organisations to provide after-care to their patients? If so, for how long after the original treatment?

An appropriate system of clinical governance would ensure that best practice in terms of patient follow up care is identified and implemented consistently and appropriately. A regulator would be able to take a view on whether or not a provider has addressed this matter in a manner comparable to recognised benchmarks whether those benchmarks are set by the NHS or the private sector.

13. Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?

The RCN has no evidence on whether the existing regulations are proportionate to the risks lasers and lights present.

14. Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?

Yes
15. Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?

Yes, however The RCN believe that only regulated healthcare professions should provide non-surgical cosmetic interventions.

16. Should providers be required to ensure that records are kept on the implants and devices they implant? If so, for how long?

Yes – contemporaneous and detailed records should be kept on all interventions including implants and devices implanted. The length of time they are kept should be comparable to the standards set in the NHS.

Questions on insurance and indemnity requirements

17. Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?

The RCN believe all providers should take out adequate indemnity arrangements.

18. How could cosmetic surgery organisations make it easier for patients to access their health records?

Records in relation cosmetic interventions should be accessible to patients. Utilising systems similar to those employed in the NHS may work.

19. What can be done to protect patients if their provider goes out of business?

The RCN has no specific comment to make in this area.

Questions on consent, information and advertising for cosmetic interventions

20. What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?
Informed consent is an essential pre-requisite for treatment. Experience gained from supporting nurses in practice suggests that consent is particularly important when patients may have very high expectations of what can be achieved through cosmetic therapies, and that there are often side effects that patients claim later not to have been aware of.

For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.

The patient’s consent should be given to the healthcare professional directly responsible for the person’s current treatment, such as the nurse or surgeon.

If someone is going to have major intervention, such as an operation, their consent should be obtained well in advance so that they have plenty of time to study any information provided about the procedure and are able to ask questions.

To enable fully informed consent, all providers should supply information which is clear, concise, and free from jargon and marketing information. The written information should be clear about the treatment proposed (covering for example any potential side effects, pre and post procedure instructions and so on) and the patient should then be taken through all of this by the responsible practitioner.

The RCN believes that the sector should be looking to achieve accredited standard for patient information such as the Crystal Mark or sign up a certification scheme such as the Information Standard. The Information Standard is a certification scheme for all organisations producing evidence-based health and social care information for the public. It helps patients identify reliable sources of high quality, evidence-based information through the use of an easily recognised quality mark. The absence or presence of such certification will enable the public to decide for themselves what weight to give the information they are provided prior to treatment.

Where practitioners are concerned about the ability of the patient to receive and adequately reflect on any information given, a suitable period of time must
be given before a procedure is carried out. If the practitioner remains concerned they should politely but firmly refuse to continue with the treatment.

To enable practitioners to give adequate time to seeking informed consent, additional training might be appropriate and levels of information provided may need to be reviewed. Such training may encompass simple assessment strategies to be able to understand the patient’s capacity to make an informed decision to proceed with treatment.

RCN members demonstrated a strong commitment to ensuring proper informed consent. Of those respondents who administer non-surgical aesthetic interventions, 80% reported that they always provide written and verbal information to clients’ before administering the intervention. The overwhelming majority (97%) agreed or strongly agreed that it is important to give clients’ sufficient time to ask questions about the treatment in order to give informed consent.

21. Should providers be required to carry out a two-stage consent process (i.e. allowing a ‘cooling-off’ period between consultation and surgery)?

The RCN believes that it may be ethically and practically important to provide a two stage process where the procedure has profound implications for the patient’s well-being and physical health. See also comments above.

22. Do you think the existing regulation of the advertising of cosmetic interventions is proportionate?

Please see response to question 24.

23. Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?

The RCN have no evidence at this time that advertising on cosmetic interventions needs to be regulated using a different system.

24. What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?
RCN asked members whether they believe the current regulations covering the advertising of cosmetic interventions are appropriate. The response overall was mixed. Around a third (35%) felt that they are; a similar number disagreed (36.5%); and the final group (28.8%) simply did not know.

However, there was a clearer picture when analysing our survey results according to whether respondents were themselves currently engaged in aesthetic practice. The majority of members who are currently aesthetic nurse practitioners did believe the current regulation of advertising was appropriate (69%).

However on the issue of incentives such as time-limited price offers, there was broad consensus. Three quarters (76%) did not think incentives such as these relating to the sale of cosmetic interventions were appropriate.

A national implant registry

25. How could a national implant registry be set up and funded? Which treatments should it cover? Should participation be a statutory requirement for providers? Should patients have the right to opt out of having their information recorded?

The RCN would welcome a national implant registry based on the National Joint Registry System. We believe it should be funded by the industry with patients given the option to opt out; however we do not have sufficient information to comment on the range of treatments this should cover.

Specific sectors/forms of treatment

26. Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification eg tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

There are no specific forms of treatment or sectors that the RCN has evidence for that should be subject to more (or less) regulation at present.