

RCN Scotland response to Scottish Government consultation on:

Regulation of non-surgical cosmetic procedures



Introduction

The Royal College of Nursing (RCN) is the world's largest nursing union and professional body. It is the leading national and international authority in representing the nursing profession. We represent over half a million nurses, student nurses, midwives, nursing associates and nursing support workers in the UK and internationally.

The RCN has over 50,000 members in Scotland. We campaign on issues of concern to nursing staff and patients, influence health policy development and implementation, and promote excellence in nursing practice.

Background

The Scottish Government is seeking to further regulate non-surgical cosmetic procedures (NSCPs). It is seeking a model of regulation which protects the public while being proportionate and proposes splitting NSCPs into three groupings.

Group 1 procedures can take place in a premises which is licensed by a local authority and carried out by a trained but non healthcare professional.

Group 2 procedures would take place in a setting regulated by Healthcare Improvement Scotland (HIS) by a trained practitioner, supervised by a healthcare professional.

Group 3 procedures would take place in a setting regulated by HIS, but carried out only by a healthcare professional.



Consultation questions

Question 1. Proposed Group 1 procedures

We propose that Group 1 will contain those procedures which carry the lowest level of risk, are the least invasive, and which we propose can be safely carried out by a trained and licensed practitioner who is not a healthcare professional.

We propose that Group 1 procedures can be undertaken in either a licensed premises or a HIS regulated setting. These questions invite you to consider procedures that we propose to include in group 1. For each procedure you are invited to consider which group you believe the procedure belongs to, and whether:

- the procedure can be carried out in a licensed premises or HIS regulated setting, (Group 1 Our recommendation for these procedures)
- only in a HIS regulated setting, (Group 2) or
- in a HIS regulated setting and only by an appropriate healthcare professional. (Group 3)

The proposed Group 1 procedures are:

- Microneedling.
- Chemical peels that only affect the outermost level of skin.
- IPL/LED therapy.
- Use of lasers for tattoo removal.
- Laser hair removal.

RCN Scotland notes the consultation acknowledges that no procedures are without risks and this is true of even procedures proposed to be under Group 1. The use of lasers carry risks of permanent optical damage, microneedling carries infection risks and chemical peels have a risk of burns and skin damage, for example. It is therefore important that these are carried out only by trained individuals, who have an understanding of the risks and complications involved and who are able to follow up or signpost for any after care required.

RCN Scotland has some concerns that the proposals for these procedures would allow them to be carried out in a local authority licensed premises by an unregulated non-healthcare professional. In order for this to be safe, there would need to be assurance that training and licensing ensures that those carrying out these procedures were aware of the risks, complications and escalation procedure.



In the absence of any reliable data on the current cost to the NHS of complications arising out of these procedures, it is difficult to make a decision on whether or not this is a safe approach and therefore alongside any changes to the regulatory regime, it is suggested that a better understanding of this issue is achieved through data gathering.

2. Proposed Group 2 procedures

We propose that Group 2 will contain procedures which carry a higher level of risk, and are more invasive than those in Group 1. We propose that Group 2 procedures should only be undertaken in a HIS regulated premises. We propose they can be safely carried out by a trained practitioner who is not a healthcare professional, but such practitioners should be supervised by an appropriate healthcare professional.

These questions invite you to consider procedures that we propose to include in group 2. For each procedure you are invited to consider which group you believe the procedure belongs to.

The group 2 procedures are:

- Mesotherapy (injection of certain drugs, or other products into the middle layer of the skin)
- Injections of toxins (e.g. Botox[®]) for cosmetic purposes
- Injections of drugs for cosmetic purposes
- Injections of semi permanent dermal fillers in small quantities (<2ml e.g. to reduce wrinkles, or plump lips)
- Any other injections of a product, even if it is not a drug or toxin, for lifestyle or cosmetic purposes. (not including tattooing which is already licenced)
- Medium depth peels (that penetrate and destroy the outer layer of skin fully and penetrate into the next layer or upper dermis)
- Photo rejuvenation
- Radiofrequency treatments
- HIFU (high frequency ultrasound)
- Cryolipolisis (the use of cold to destroy pockets of fat under the skin)

RCN Scotland is again concerned by the suggestion that some of these procedures, particularly those which involve penetration of the skin, should be carried out by a non-healthcare professional, even under supervision.

Given the lack of information about what "supervision" entails in this context, it is difficult to be confident that this grouping would appropriately protect service users. The risk of serious complications of some of these procedures,



including necrosis, vascular occlusion, nerve damage and sepsis and the need to have a skilled understanding of physiology and anatomy, means that supervision may have to be so close it would effectively require a healthcare professional to be carrying out the procedure themselves.

The safety of group 2 procedures very much depends on which precautions are put in place as outlined in Question 12, below.

A safer option may be to only allow these procedures to be carried out by a healthcare professional, in a HIS licenses premises for this group of procedures, thus bringing Group 2 procedures into what is proposed for Group 3 (possibly with additional safeguards introduced for Group 3).

We are also concerned about the implications for Healthcare Improvement Scotland of this proposal. Given that it will result in a significant number of additional premises requiring to be registered with HIS, there will be a requirement for significant additional investment for HIS in order for the organisation to be able to regulate effectively.

Question 3. Proposed Group 3 procedures

We propose that Group 3 will contain the procedures which carry the highest levels of risk and which are more invasive than Group 1 or 2 procedures. We propose that, as well as being undertaken in a HIS regulated premises, these procedures should always be undertaken by an appropriate healthcare professional.

These questions invite you to consider procedures that we propose to include in group 3. For each procedure you are invited to consider which group you believe the procedure belongs to.

Group 3 procedures are:

- Platelet rich plasma, biotherapy or injections of any products derived from the patient's blood
- Injection microsclerotherapy (use of injections to treat visible spider veins)
- Injection lipolysis or injections of fat dissolving agents
- Dermal micro coring (removal of small amounts of skin to reduce visible signs of aging)
- Hay fever injections
- Any procedure involving intravenous fluids or drawing and processing bloods for cosmetic or lifestyle purposes, for instance provision of intra venous vitamins and minerals, or intra venous blood oxygenation.
- Use of dermal fillers for the purpose of augmentation of e.g. the breasts and buttocks



- All laser treatments not specified above, including lasers which target the deeper layers of the dermis.
- Deeper chemical peels such as phenol peels
- Carboxytherapy (the injection of CO2 under the skin to promote collagen production)
- Cellulite subcision (making small incisions to reduce appearance of cellulite)
- Electrocautery (removal of skin tags through electricity)
- Cryotherapy and cryocautery (use of extreme cold to remove e.g. skin tags)
- Thread lifting and cogs (placement of dissolvable material under skin to tighten appearance and promote collagen)
- All group 1 or 2 procedures where procedures are carried out in an intimate area (except hair removal and not including procedures such as tattooing and skin piercing which are already licenced)

As noted above, if group 2 procedures are only to be carried out by healthcare professionals, additional safeguards could be justified for group 3 procedures. This may take the form of limiting these procedures to a smaller group of healthcare professionals, with additional qualifications, or additional requirements in terms of recording complications.

Given the additional risks, there is an argument for all group 1 or 2 procedures carried out in intimate areas to be automatically categorised as a group 3 procedure, as well as the suggestion that all procedures carried out on young people should be similarly classified as group 3. There may be an argument for procedures carried out on other groups of people at higher risk to be automatically categorised as group 3, such as older adults, those with learning disabilities, or those with certain conditions.

Question 4. Please provide any comments you have in relation to the grouping of procedures and the level of regulation required.

RCN Scotland's concern with the grouping approach is that it may create an incentive to providers to seek to try to 'downgrade' their procedures in order to fall into a lower group. There is some overlap in some of the procedures, such as chemical peels, with "deeper" peels being categorised as group 3, but "medium depth" peels falling into group 2. While it may be straightforward to accurately categorise these procedures, it may be that new products are developed which can be categorised as marginally lower risk in order to avoid a higher classification.



RCN Scotland would also point out that any list will require to be constantly reviewed and updated as new evidence about the risks of procedures emerges and new procedures are developed.

Requiring regulation by both local authorises and HIS, in what we know is likely to be a sizeable market is likely to require significant additional resourcing. Without adequate support to monitor and enforce regulations, there is a risk that licensing will simply be a tick box exercise which does little to protect the safety of service users. This is particularly a concern for Healthcare Improvement Scotland which are under considerable financial pressure and have increased responsibilities under the Health and Care (Staffing) (Scotland) Act 2019.

Question 5. Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a licensed premises should also require a licence?

RCN Scotland supports this approach as a basic safeguard.

Question 6. Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a HIS regulated setting should not require a licence?

RCN Scotland supports this approach given that practitioners will be regulated through HIS.

Question 7: Please provide any comments about the answers you have given to questions 5 and 6 about the proposals for the establishment of licensing arrangements for Group 1 procedures.

RCN Scotland is of the view that the premises and the practitioner should be licenced. Otherwise, they could move from one premises to another without being subject to inspections.

RCN Scotland is of the view that a person operating in a HIS-regulated premises should not also require a local authority licence.



Question 8. To what extent do you agree or disagree that the Scottish Government should establish:

- Standards of hygiene and health and safety for licensed premises?
- Standards of training and qualification for licensed practitioners?
- Mandatory insurance and indemnity to compensate clients who suffer harm as a result of negligence or malpractice?

RCN Scotland agrees with the above. We would add that standards need to be followed and therefore enforced. Mandatory insurance would also provide an opportunity to monitor claims to help understand the risks associated with specific procedures and therefore the impact of these changes.

Question 9. To what extent do you agree or disagree that local authority officers should have powers of inspection and enforcement, including:

- The removing of a licence from premises or practitioners who cannot demonstrate compliance with standards established by the Scottish Government?
- Barring individuals from holding a licence if they are associated with serious or repeated non-compliance with the standards established by the Scottish Government?

Agree, but as noted above, local authorities will need sufficient additional resourcing to carry out these functions.

Question 10. Which of the following statements do you agree with in relation to whether a vehicle can receive a licence as a premises? (Pick one)

- Local authorities should have discretion to decide whether a vehicle can receive a licence as a premises
- Vehicles should be eligible for a licence in all local authorities
- Vehicles should not be eligible for a licence in any local authority

RCN Scotland is of the view that vehicles are not an appropriate setting for any procedures which carry risk.



Questions 11. To what extent do you agree or disagree that the Scottish Government should establish:

- Standards of training and qualification for non-healthcare and healthcare professionals undertaking procedures in HIS regulated services?
- Mandatory insurance and indemnity to compensate clients who suffer harm as a result of negligence or malpractice?

Agree. We would add that standards need to be followed and therefore enforced. Mandatory insurance would also provide an opportunity to monitor claims to help understand the risks associated with specific procedures and therefore the impact of these changes.

Question 12. Do you agree or disagree that the healthcare professional supervising a group 2 procedure should:

- Conduct the / any initial consultation(s) with the client?
- Prescribe any medications (e.g. Botox TM, lidocaine) required during the procedure, or required for the management of any complications that arise?
- Remain available on site for the duration of any procedure?
- Be responsible for ensuring the practitioner is suitably trained for the procedure?
- Be responsible for ensuring the procedure will be undertaken safely?
- Be themselves suitably trained and qualified in the procedure being undertaken?

Agree to all as a way to reduce risks associated with group 2 procedures. In particular, it is important for prescribers to remain on site for the duration of any procedure and for a detailed initial consultation to take place. In addition, there should be a requirement for a healthcare professional to offer follow up appointments, where appropriate, in order to review the procedures.



Question 13. Thinking about the healthcare professional undertaking a group 3 procedure, which statement below do you agree with:

- These procedures should be undertaken by a suitably trained and qualified healthcare professional working within their scope of practice, but not otherwise be limited.
- These procedures should only be undertaken by certain healthcare professionals please see list in next question and tick all that apply;

As well as having a limited list of certain healthcare professionals who can carry out procedures, they should be undertaken only by suitably trained professionals working within their scope of practice. Not every Registered Nurse will be suitable trained to carry out every procedure listed and the same applies to all other categories. Registrants are already obliged to work within their scope of practice, which is an important safeguard established by limiting the type of professionals who can carry out these procedures.

Question 14. If your answer to the last question was that these procedures should only be undertaken by certain healthcare professionals, please tick all the healthcare professionals to which they should apply:

- Medical practitioners (Doctors)
- Dental practitioners
- Dental care professionals
- Registered nurses
- Registered midwives
- Registered pharmacists
- Registered pharmacy technicians

See above.

Question 15. Do you agree or disagree that the following settings should be required to register with Healthcare Improvement Scotland if they are offering non-surgical cosmetic procedures?

- GP practices
- Dental practices
- Community pharmacies

It would appear to be perverse that GP practices are not required to register with Healthcare Improvement Scotland, while other independent settings are, even if registrants work there. RCN Scotland therefore agrees that GP practices



offering these procedures should have to register with Healthcare Improvement Scotland in relation to these services. We offer no view about community pharmacies and dental practices.

Question 16. Do you agree or disagree that Healthcare Improvement Scotland should have powers of inspection, including powers of entry and inspection of unregistered settings where there is reason to believe registration is required?

Agree, but as noted above, HIS will need sufficient additional resourcing to carry out these functions.

Question 17 Which of the following statements is closest to your view? (please select only one option)

- There should be a lower age limit under which clients should not be allowed to undertake an NSCPs (different ages are considered in Question 18)
- There should be no lower age limit under which clients should not be allowed to undertake an NSCPs, but all procedures for under 18s should be treated as a group 3 procedure and be required to be carried out by an appropriate healthcare professional

RCN Scotland is concerned that we don't have sufficient evidence or data about the longer-term effects of some of these procedures and would therefore suggest a cautious approach in allowing them for younger adults. As well as a age limit, there may be merit in limiting the number of times a procedure can be accessed, given the higher risks involved to young people, although enforcing this may be difficult.

RCN Scotland is therefore, on balance, of the view that there should be a lower age limit under which clients should not be allowed to undertake an NSCP.

Question 18. Regardless of your answer to question 17, if an age limit is to be put in place please indicate for each procedure group what you think is the appropriate age to be set for the procedures in that group.

There are different risks associated with procedures within the same group for younger people and young people develop at a different rate, meaning a single age limit for each procedure group may not be appropriate. Some procedures, particularly those which involve penetration of the face, carry much higher risks for a developing face.



A single age limit would have to take this into account to ensure that, if this approach was taken, procedures took place safely. RCN Scotland would therefore suggest a very cautious approach and perhaps additional safeguards (such as requiring GP approval) to get some procedures done right, including above the age of 18.

Question 19. Do you agree or disagree that procedures on intimate areas should only be available to clients of 18 years of age and over?

Agree. As above in terms of facial features, intimate areas continue to develop in young adults and therefore some of these procedures would simply not be appropriate.

Question 20. What are your views on how, if at all, the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect anyone based on their protected characteristics?

No view.

Question 21. What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect people differently based on their financial situation?

No view.

Question 22. What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect access to safe, high-quality services in island communities?

No view.

Question 23. What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland and the potential of age restrictions might affect respecting, protecting and fulfilling the rights of children and young people as set out in the UN Convention on the Rights of the Child?

No view.