Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

Announced Inspection Report: Independent Healthcare

Service: Grand Aura Skin & Wellbeing Clinic, Aberdeen

Service Provider: Grand Aura Limited

23 November 2023

This report is embargoed until 10.00am on Wednesday 13 March 2024

NHS SCOTLAND

Healthcare Improvement Scotland is committed to equality. We have assessed the inspection function for likely impact on equality protected characteristics as defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation (Equality Act 2010). You can request a copy of the equality impact assessment report from the Healthcare Improvement Scotland Equality and Diversity Advisor on 0141 225 6999 or email his.contactpublicinvolvement@nhs.scot

First published March 2024

www.healthcareimprovementscotland.org

Contents

1 Progress since our last inspection

What the service had done to meet the recommendation we made at our last inspection on 17 November 2020

Recommendation

The service should ensure all staff follow national guidance in Health Protection Scotland's national infection prevention and control manual when managing blood spillages. This will reduce the risk of cross-infection.

Action taken

The service had updated its infection prevention and control policy to include information on managing blood and other bodily fluid spillages in line with national guidance. We saw evidence that all staff had read and signed to say they agreed and understood this policy and their role in dealing with blood spillages.

2 A summary of our inspection

Background

Healthcare Improvement Scotland is the regulator of independent healthcare services in Scotland. As a part of this role, we undertake risk-based and intelligence-led inspections of independent healthcare services.

Our focus

The focus of our inspections is to ensure each service is person-centred, safe and well led. We evaluate the service against the National Health Services (Scotland) Act 1978 and regulations or orders made under the Act, its conditions of registration and Healthcare Improvement Scotland's Quality Assurance Framework. We ask questions about the provider's direction, its processes for the implementation and delivery of the service, and its results.

About our inspection

We carried out an announced inspection to Grand Aura Skin & Wellbeing Clinic on Thursday 23 November 2023. We spoke with four members of staff, including the service manager, during the inspection. We received feedback from two patients through an online survey we had asked the service to issue to its patients for us before the inspection.

Based in Aberdeen, Grand Aura Skin & Wellbeing Clinic is an independent clinic providing non-surgical and minor surgical treatments.

The inspection team was made up of one inspector.

What we found and inspection grades awarded

For Grand Aura Skin & Wellbeing Clinic, the following grades have been applied.

Direction	*How clear is the service's vision and purpose and how supportive is its leadership and culture?*
Summary findings	**Grade awarded**
The service's leadership structure and governance framework helped deliver safe, evidence-based, person-centred care. Staff we spoke with said they felt valued, respected and well supported. Although the service had clear aims and objectives, which were available for patients to view, a process should be developed to ensure these identified aims and objectives are being met. Regular formal staff meetings should be re-introduced.	Unsatisfactory
Implementation and delivery	*How well does the service engage with its stakeholders and manage/improve its performance?*
Patients were fully informed about treatment options and involved in all decisions about their care. Informal patient feedback was used to help continually improve the service. Clear procedures were in place for managing complaints. Medication was in-date and checked regularly. All appropriate background safety checks must be carried out as part of the recruitment process, and ongoing checks should also be carried out. Staff must have annual appraisals. Certain key policies should reflect current guidelines and Scottish guidance, and all policies and procedures should be regularly reviewed and updated. A risk register must be implemented in the service. A quality improvement plan, contingency plan and annual audit programme should be introduced. Records of updated fire risk assessments and equipment maintenance records, including laser maintenance, must be kept.	Unsatisfactory
Results	*How well has the service demonstrated that it provides safe, person-centred care?*
The environment was clean and well equipped. Patients reported good levels of satisfaction and told us they felt safe in the service, and that the service was clean and tidy. Although patient assessments were completed and signed consent to treatment forms were in place, detailed patient care records must be kept. Laser safety must be improved, including updating local rules and staff training, and ensuring	Unsatisfactory

a contract is in place with a laser protection advisor. Medicines governance processes, including obtaining informed consent, must be followed.	

Grades may change after this inspection due to other regulatory activity. For example, if we have to take enforcement action to improve the service or if we investigate and agree with a complaint someone makes about the service.

More information about grading can be found on our website at: http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/ihc_inspection_guidance/inspection_methodology.aspx

Further information about the Quality Assurance Framework can also be found on our website at: https://www.healthcareimprovementscotland.org/scrutiny/the_quality_assurance_system.aspx

What action we expect Grand Aura Limited to take after our inspection

The actions that Healthcare Improvement Scotland expects the independent healthcare service to take are called requirements and recommendations.

- **Requirement:** A requirement is a statement which sets out what is required of an independent healthcare provider to comply with the National Health Services (Scotland) Act 1978, regulations or a condition of registration. Where there are breaches of the Act, regulations or conditions, a requirement must be made. Requirements are enforceable.
- **Recommendation:** A recommendation is a statement which sets out what a service should do in order to align with relevant standards and guidance.

This inspection resulted in eight requirements and 10 recommendations.

Direction
Requirements
None

Direction (continued)	
Recommendations	
a	The service should ensure a system is in place to make sure its identified aims and objectives are being met (see page 14). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
b	The service should re-introduce a programme of regular staff meetings, including agendas, and a record of discussion and decisions reached at these meetings should be kept (see page 15). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19

Implementation and delivery	
Requirements	
1	The provider must ensure that all healthcare professionals employed in the service are not included on the children and adults' lists in the Children and Young People (Scotland) Act 2014 and The Protection of Vulnerable Groups (Scotland) Act 2007 (see page 20). Timescale – immediate *Regulation 9(1)(2)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
2	The provider must ensure that staff have updated personal development plans and receive regular individual performance reviews and appraisals. This includes staff who have practicing privileges and the service manager (see page 21). Timescale – immediate *Regulation 12(c)(i)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*

Implementation and delivery (continued)	
Requirements	
3	The provider must develop effective systems that demonstrate the proactive management of risks to patients and staff (see page 21). Timescale – immediate *Regulation 13(2)(a)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
4	The provider must notify Healthcare Improvement Scotland of certain matters as noted in the notifications guidance and in specified timeframes (see page 21). Timescale – immediate *Regulation 5(1)(b)* *The Healthcare Improvement Scotland (Applications and Registrations) Regulations 2011*
5	The provider must develop, implement and maintain a risk register to ensure effective oversight of how the service is delivered (see page 22). Timescale – immediate *Regulation 3(a)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
Recommendations	
c	The service should adhere to its participation policy to direct the way it engages with its patients and uses their feedback to drive improvement. This feedback should be audited at agreed set intervals with improvement action plans implemented (see page 17). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.8
d	The service should ensure that all policies reflect Scottish legislation and best practice guidance (see page 21). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.11

Implementation and delivery (continued)	
Recommendations	
e	The service should develop and implement a system to determine review dates for all its policies and procedures with documented evidence of when reviews are undertaken and what changes or updates were subsequently made (see page 21). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
f	The service should ensure that a system is in place to make sure that staff are subject to ongoing professional registration and indemnity insurance checks (see page 21). Health and Social Care Standards: My support, my life. I have confidence in the people who support and care for me. Statement 3.14
g	The service should develop a more detailed programme of regular audits to cover key aspects of care and treatment such as infection prevention and control, the clinic environment and patient care records. Audits must be documented and improvement action plans implemented (see page 22). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
h	The service should develop and implement a quality improvement plan to formalise and direct the way it drives and measures improvement (see page 22). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
i	The service should develop a contingency plan that sets out arrangements for patient aftercare and follow-up arrangements if the service ceased trading (see page 23). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.14

Results

Requirements

6 The provider must ensure that detailed patient care records are kept so that safe care of patients can be demonstrated (see page 26).

Timescale – immediate

Regulation 4(2)(a)(b)(c)
The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

7 The provider must review its laser safety arrangements to ensure that:

a) the laser protection advisor has a signed contract in place detailing appointment of this post with the service
b) the laser protection advisor supplies the service with information of their registration with a professional awarding body
c) the local rules are updated annually, and
d) staff's core of knowledge training is updated regularly (see page 27).

Timescale – immediate

Regulation 3(d)(v)
The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

8 The provider must ensure that when products are not used according to the Summary of Product Characteristics that good medicine governance processes are in place, including obtaining informed patient consent (see page 27).

Timescale – immediate

Regulation 3(d)(iv)
The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

Results (continued)	
Recommendation	
j	The service should ensure botulinum toxin is used in line with the manufacturer's and best practice guidance, and update its medicines management and consent policy to accurately reflect the processes in place (see page 27). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.11

An improvement action plan has been developed by the provider and is available on the Healthcare Improvement Scotland website: www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/find_a_provider_or_service.aspx

Grand Aura Limited, the provider, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Grand Aura Skin & Wellbeing Clinic for their assistance during the inspection.

3 What we found during our inspection

Key Focus Area: Direction

Domain 1: Clear vision and purpose	Domain 2: Leadership and culture
How clear is the service's vision and purpose and how supportive is its leadership and culture?	

Our findings

The service's leadership structure and governance framework helped deliver safe, evidence-based, person-centred care. Staff we spoke with said they felt valued, respected and well supported. Although the service had clear aims and objectives, which were available for patients to view, a process should be developed to ensure these identified aims and objectives are being met. Regular formal staff meetings should be re-introduced.

Clear vision and purpose

The service had clear aims and objectives. These were to provide the highest standard of person-centred care to patients and provide continuous personal and professional development for staff. The aims and objectives and culture statement were available on the service's website, and patients were also able to see this information in a patient information folder kept in the reception area. This folder also contained information on the service's vision and mission statement.

The service's vision and purpose for the future was to provide a flexible service, developing current and existing resources to meet the needs of their client base. This included providing new skin treatments to all patients, including their existing adolescent patients of 14 years and over. Included in the service's vision and purpose was a culture statement where there was a commitment of having 'the right people in the right jobs with the skills and training to meet the patients' needs'.

The service had identified key short-, medium- and long-term priorities. These priorities included:

- the service will engage with the local community and businesses to ensure they are offering a service to meet their needs
- further investment in staff training and development, and
- developing and implementing a quality assurance system.

What needs to improve

Although the service had a vision of delivering a high quality person-centred service with identified aims, objectives and timeframes, it did not have a process in place to ensure it was meeting the aims and objectives (recommendation a).

- No requirements.

Recommendation a

- The service should ensure a system is in place to make sure its identified aims and objectives are being met.

Leadership and culture

The service is owned and managed by a medical practitioner registered with the General Medical Council (GMC) as a consultant dermatologist. The service had adequate staff numbers who were suitably qualified to carry out all treatments offered to patients. This included clinical (medical and nursing) healthcare professionals, one of whom was an independent nurse prescriber, and laser technicians with suitable vocational qualifications.

The service leadership structure had defined roles, responsibilities and support arrangements. All staff reported to the service manager. The service manager met with individual staff members and as a group to give updates on any changes to clinics, staffing or resources, and to review workload.

We saw evidence of meetings taking place in 2020/2021 where all members of staff attended either in person or online. Set agendas for these meetings included staff feedback and ideas, opportunities for training and learning, audit results, and accidents or incidents. Minutes of meetings were documented.

Online staff surveys were carried out. Survey results showed staff were satisfied at work, had an appropriate work/life balance, felt supported and valued by senior management, and felt able to offer recommendations and suggestions for how to improve the service.

Staff we spoke with told us they felt valued and listened to by the owner. They were able to make suggestions and voice ideas for improvements to the service, for example adding additional treatments for skin conditions. They also felt there was an ‘open door’ policy and they could approach senior management at any time with any concerns or issues they may have identified.

Staff members were consulted on all decisions about improving the service. We were told improvements had been made as a direct result of staff feedback, for example implementing new documentation for patient consultations.

What needs to improve

We were told informal meetings with staff took place either daily or on a regular basis. However, the associated agendas and minutes of the formal staff meetings we saw were only for2020/2021. There was no evidence of any recent formal meetings taking place (recommendation b).

- No requirements.

Recommendation b

- The service should re-introduce a programme of regular staff meetings, including agendas, and a record of discussion and decisions reached at these meeting should be kept.

Key Focus Area: Implementation and delivery

Domain 3: Co-design, co-production	Domain 4: Quality improvement	Domain 5: Planning for quality
How well does the service engage with its stakeholders and manage/improve its performance?		

Our findings

Patients were fully informed about treatment options and involved in all decisions about their care. Informal patient feedback was used to help continually improve the service. Clear procedures were in place for managing complaints. Medication was in-date and checked regularly.

All appropriate background safety checks must be carried out as part of the recruitment process, and ongoing checks should also be carried out. Staff must have annual appraisals. Certain key policies should reflect current guidelines and Scottish guidance, and all policies and procedures should be regularly reviewed and updated. A risk register must be implemented in the service. A quality improvement plan, contingency plan and annual audit programme should be introduced. Records of updated fire risk assessments and equipment maintenance records, including laser maintenance, must be kept.

Co-design, co-production *(patients, staff and stakeholder engagement)*
Patients could contact the service in a variety of ways, including by telephone, email, text messages and online enquiries either through the service's website or social media pages.

A number of patients were returning patients who had used the service for many years. New patients were usually patients who had been recommended to the service by existing patients or by word of mouth, including social media reviews. All consultations were by appointment only.

The service's website contained information on treatments available, the booking system and treatment costs, as well as detailed information on staff working in the service, including their qualifications.

The service encouraged patients to leave feedback and/or suggestions using a variety of methods, in line with its participation policy. For example, feedback was collected both formally and informally, including verbal feedback, bespoke patient questionnaires emailed to patients routinely 24-48 hours after receiving treatment, and through online apps. This helped to encourage patients to participate in the future direction of the service.

We were told additional skin treatments were now offered to patients due to informal conversations taking place between staff members and patients.

What needs to improve

Although the service had a process in place for gathering feedback, there was no evidence to suggest this feedback was formally shared with staff. We were told the service manager reviewed this feedback on a regular basis and discussed with staff any issues or praise. However, there was no formal evidence of these discussions taking place. While the feedback recorded was useful, there was also no evidence available to suggest this feedback was being analysed formally. We discussed with the service the importance of having a structured approach to reviewing feedback which included implementing changes to drive improvement and measuring the impact of such improvements (recommendation c).

- No requirements.

Recommendation c

- The service should adhere to its participation policy to direct the way it engages with its patients and uses their feedback to drive improvement. This feedback should be audited at agreed set intervals with improvement action plans implemented.

Quality improvement

We saw that the service clearly displayed its Healthcare Improvement Scotland registration certificate and was providing care in line with its agreed conditions of registration.

A clear system was in place to record and manage accident and incident reporting. For example, we noted there had been an incident with laser treatment burning a patient's skin. The service followed its own processes, procedures and guidelines to ensure staff and patient safety. This incident was discussed at a subsequent team meeting and lessons learned were documented and shared with staff to minimise any future risk of this type of incident re-occurring.

Arrangements were in place to deal with medical and aesthetic emergencies, including mandatory staff training. Emergency medicines were available for patients who may experience aesthetic complications following treatment. We saw regular, documented checks carried out for all emergency equipment in the service.

Information about how to make a complaint was available in the patient information folder. This included information should patients wish to make a complaint to Healthcare Improvement Scotland at any stage of the process. The correct information and details for Healthcare Improvement Scotland were included in this information. We were told that no formal complaints about the service had been received since the service was registered with Healthcare Improvement Scotland in November 2018. We were told complaints handling was discussed with staff and how this would inform lessons learned should a complaint be received. Staff had received training in complaints handling.

Duty of candour is where healthcare organisations have a professional responsibility to be honest with patients when something goes wrong. Staff we spoke with fully understood their responsibilities for this and the service had published an annual duty of candour report. This report was included in the patient information folder.

The service had policies and procedures in place to support the safe delivery of person-centred care. These included:

- safeguarding (public protection)
- health and safety
- emergency arrangements
- medication, and
- infection prevention and control.

We noted that the majority of the policies had been reviewed in 2022 with a further review date identified for 2024. Policies were kept both electronically and in paper copies in the patient information folder for patients to view.

Patient care records were electronic and password protected. This protected confidential patient information in line with the service's information management policy. We were told the service was registered with the Information Commissioner's Office (an independent authority for data protection and privacy rights) and we saw that it worked in line with data protection regulations.

Patients received all information electronically before attending for treatment. Formal consultations with patients were carried out on their first visit to the service, with an appropriate cooling-off period included to allow them time to consider the treatment options. If patients experienced an adverse event following treatment, they could contact clinical staff by telephone or by social media app outwith clinic times and emergency appointments were offered, if

required. This information was detailed in the aftercare leaflets and discussed with patients during and after treatments.

Staff members were recruited in line with the service's recruitment policy. The service had a continuous learning culture. Staff had a personal development plan which they agreed with the service manager. All new members of staff carried out an induction programme and were issued with a staff handbook to complete. This contained service-specific information about:

- the service's vision, mission, aims and objectives
- policies and procedures
- annual leave and sick leave arrangements
- staff training, and
- learning and development opportunities.

Once a new staff member had completed this handbook, the service manager would formally review and agree staff competence.

Staff files were kept in a locked cabinet in the service manager's office and were only accessible to the service manager and the individual staff member who was responsible for updating their own file, as required.

The medical practitioner engaged in regular continuing professional development. This is managed through the GMC registration and revalidation process. Revalidation is where clinical staff are required to regularly send evidence of their competency, training and feedback from patients and peers to their professional body, such as the GMC.

The medical practitioner was actively involved in clinical research and teaching and had delivered national and international presentations and published articles. They were a member of the British Medical Laser Association, and the Laser and Aesthetics Group in Europe. They were also a member of the Scottish Cosmetic Interventions Expert Group - High Quality Care subgroup.

The independent nurse prescriber engaged in regular continuing professional development and had completed their revalidation. This was managed through the Nursing and Midwifery Council (NMC) registration and revalidation process, and yearly appraisals.

All clinicians working in the service provided peer support for each other and had additional peer support in their permanent roles within the NHS.

What needs to improve

Part of a safe recruitment process is ensuring appropriate checks are carried out on potential employees to ensure they are fit to work with vulnerable adults and children. There was no evidence of Protecting Vulnerable Groups (PVG) background checks carried out on staff (requirement 1).

Staff personal development plans were out of date and there was no evidence staff had received a recent annual appraisal. This would ensure staff were given the opportunity to discuss progress in their role or raise any concerns (requirement 2).

We were told the service had up-to-date risk assessments which included a fire risk assessment and a safety maintenance log for all laser devices and equipment. However, this information was not available on the day of inspection. The service also did not produce this information as requested after the inspection (requirement 3).

We saw documented evidence of a minor burn caused by laser treatment to a patient. However, there was no evidence to suggest either in the service or with Healthcare Improvement Scotland that this incident had been reported to Healthcare Improvement Scotland, in line with our notifications guidance. There was also no evidence of a notification being received by Healthcare Improvement Scotland about a change of premises for the service (requirement 4).

We noted some policies did not reflect the correct Scottish legislation or best practice. For example, the safeguarding policy did not reference the Adult Support and Protection (Scotland) Act 2007, the Children (Scotland) Act 1995 or the National Guidance for Child Protection in Scotland 2021 (recommendation d).

Although the service updated most of its policies every 2 years, or in response to changes in national guidance and best practice, not all policies were up to date, such as the health and safety policy (recommendation e).

We saw no evidence of ongoing checks on staff's professional registration status or up-to-date indemnity insurance. This is needed to ensure staff remain safe to work in the service (recommendation f).

Requirement 1 – Timescale: immediate

- The provider must ensure that all healthcare professionals employed in the service are not included on the children and adults' lists in the Children and Young People (Scotland) Act 2014 and The Protection of Vulnerable Groups (Scotland) Act 2007.

Requirement 2 – Timescale: immediate

- The provider must ensure that staff have updated personal development plans and receive regular individual performance reviews and appraisals. This includes staff who have practicing privileges and the service manager.

Requirement 3 – Timescale: immediate

- The provider must develop effective systems that demonstrate the proactive management of risks to patients and staff.

Requirement 4 – Timescale: immediate

- The provider must notify Healthcare Improvement Scotland of certain matters as noted in the notifications guidance and in specified timeframes.

Recommendation d

- The service should ensure that all policies reflect Scottish legislation and best practice guidance.

Recommendation e

- The service should develop and implement a system to determine review dates for all its policies and procedures with documented evidence of when reviews are undertaken and what changes or updates were subsequently made.

Recommendation f

- The service should ensure that a system is in place to make sure that staff are subject to ongoing professional registration and indemnity insurance checks.

Planning for quality

The service had a procedure for reviewing risks in the service. This involved identifying, assessing and mitigating risks promoting a culture of safety and continuous improvement. Risk assessments included:

- clinical procedures
- use of equipment, and
- data management.

The service manager was the designated risk officer and was responsible for overseeing and co-ordinating the risk reporting process.

We saw evidence of an infection prevention and control audit carried out, with results discussed at a team meeting. An action plan had been produced to identify areas for improvement.

What needs to improve

While the service had an identified process for risk management, there was no evidence of a supporting risk register. This would help the service to ensure appropriate processes were in place to help manage any risks identified (requirement 5).

Although we saw evidence of an infection prevention and control audit, this had been carried out approximately 3 years ago and there was no evidence of any more recent audits carried out. There was no formal audit programme to determine what and when audits would take place. This would help to ensure the service reviews all key aspects of care and treatment, including infection prevention and control, the clinical environment and patient care records (recommendation g).

A formal quality improvement plan would help the service to structure and record its improvement processes. This could include outcomes identified from audits, complaints, accidents and incidents, patient feedback, and education and training events (recommendation h).

There was no evidence of a contingency plan in place setting out arrangements for patients' aftercare and follow-up arrangements if the service ceased trading (recommendation i).

Requirement 5 – Timescale: immediate

- The provider must develop, implement and maintain a risk register to ensure effective oversight of how the service is delivered.

Recommendation g

- The service should develop a more detailed programme of regular audits to cover key aspects of care and treatment such as infection prevention and control, the clinic environment and patient care records. Audits must be documented and improvement action plans implemented.

Recommendation h

- The service should develop and implement a quality improvement plan to formalise and direct the way it drives and measures improvement.

Recommendation i

- The service should develop a contingency plan that sets out arrangements for patient aftercare and follow-up arrangements if the service ceased trading.

Key Focus Area: Results

Domain 6: Relationships	Domain 7: Quality control
How well has the service demonstrated that it provides safe, person-centred care?	

Our findings

The environment was clean and well equipped. Patients reported good levels of satisfaction and told us they felt safe in the service, and that the service was clean and tidy. Although patient assessments were completed and signed consent to treatment forms were in place, detailed patient care records must be kept. Laser safety must be improved, including updating local rules and staff training, and ensuring a contract is in place with a laser protection advisor. Medicines governance processes, including obtaining informed consent, must be followed.

Every year, we ask the service to submit an annual return. This gives us essential information about the service such as composition, activities, incidents and accidents, and staffing details. The service submitted an annual return, as requested. As part of the inspection process, we ask the service to submit a self-evaluation. The questions in the self-evaluation are based on our Quality Assurance Framework and ask the service to tell us what it does well, what improvements could be made and how it intends to make those improvements. The service submitted a comprehensive self-evaluation.

We saw the service was clean and tidy, of a high standard and well maintained. Cleaning schedules were in place, and were fully completed and up to date. All equipment for procedures was single use to prevent the risk of cross-infection. Personal protective equipment, such as disposable aprons and gloves, was readily available to staff. A clinical waste contract was in place, and clinical waste and used sharps equipment was disposed of appropriately. Equipment used in the service was clean and well maintained. Staff we spoke with were aware of the infection prevention and control measures required, including cleaning materials needed for sanitary fittings in the service.

Patients who responded to our online survey told us they felt safe and were reassured by the cleaning that took place in the service. All patients stated the clinic was clean and tidy. Some comments we received from patients included:

- ‘Always clean, welcoming and ready to go.’
- ‘Extremely clean and sterile looking. Any equipment used were freshly opened in front of me.’

The medicines refrigerator was clean and in good working order. A temperature recording log book was used to record fridge temperatures every day, and this was fully completed and up to date. This made sure medicines were being stored at the correct temperature. We noted the service kept a stock of prescription-only medication, for example botulinum toxin. All stock had individual patient names and were all in date. We saw a safe system for the procurement and prescribing of medicines.

The service worked in line with its medicines management policy. Practitioners completed a risk assessment for every patient where bacteriostatic saline was used to reconstitute botulinum toxin. This is when a liquid solution is used to turn a dry substance into a fluid for injection.

Patients who responded to our online survey told us they were extremely satisfied with the care and treatment they received from the service. Some comments we received included:

- 'I return time and time again to this service… .'
- 'The clinic was a fantastic find and I always recommend it to others.'

The five patient care records we reviewed showed that patients received a face-to-face consultation. This consultation included gathering information about their expectations before any treatments were administered with an appropriate cooling-off period. Patient and staff members' signatures were visible on most of the patient care record documentation, including consenting to treatments.

The staff files we reviewed contained information on initial mandatory training, previous supervision sessions and appraisals with evidence of training completed in 2020/2021. We also saw evidence of additional role-specific training for staff members.

The service delivered laser therapy skin treatments to patients. The service had a laser protection advisor and local rules were in place to make sure lasers were managed safely to ensure patient and staff safety. All appropriate safety measures were in place, including safety warning signs on the locked treatment room door. We saw evidence of previous core of knowledge training completed by staff. We also saw dates for the new laser technician to attend an online knowledge update session. All checks on the laser equipment had been carried out and documented. Details of patch testing and treatments for patients were available in the patient care records we reviewed.

What needs to improve

The patient care records we reviewed were not fully completed with different parts of the assessment process not documented. For example, consultation and initial assessments for patients, medicine dosage and batch numbers, and information to share consent with other healthcare professionals was not always documented (requirement 6).

There was no evidence of a contract or agreement with the laser protection advisor. There was also no evidence to show they were registered with an appropriate professional laser safety association. The service's local rules had not been updated since 2018. Staffs' core of knowledge training was also 5 years out of date (requirement 7).

The manufacturer's license for a product is awarded on the basis that the product is used according to the Summary of Product Characteristics, which is a legal document. As soon as the product is not used according to its license in any way, its use is categorised as unlicensed. If the prescriber's judgement is that unlicensed use of the medicine is in the best interest of the patient's care, good medicines governance must be followed, including the patient's consent to being treated outwith manufacturer's guidelines.

We saw the service used an alternative sterile saline solution from that recommended in the manufacturer's guidance for the reconstitution of botulinum toxin. This is when a liquid solution is used to turn a dry substance into a fluid for injection. We were told this provided better pain relief for patients. However, there was no evidence that the unlicensed use of this product had been discussed with patients (when a medicine is being used in a way that is different to that described in the product license) and that informed consent had been sought (requirement 8).

We saw a used vial of botulinum toxin in the medicines refrigerator. Any used and opened vials should be discarded and not re-used, in line with current medicine management guidance (recommendation j).

Requirement 6 – Timescale: immediate

- The provider must ensure that detailed patient care records are kept so that safe care of patients can be demonstrated.

Requirement 7 – Timescale: immediate

- The provider must review its laser safety arrangements to ensure that:
  a) the laser protection advisor has a signed contract in place detailing appointment of this post with the service
  b) the laser protection advisor supplies the service with information of their registration with a professional awarding body
  c) the local rules are updated annually, and
  d) staff's core of knowledge training is updated regularly.

Requirement 8 – Timescale: immediate

- The provider must ensure that when products are not used according to the Summary of Product Characteristics that good medicine governance processes are in place, including obtaining informed patient consent.

Recommendation j

- The service should ensure botulinum toxin is used in line with the manufacturer's and best practice guidance, and update its medicines management and consent policy to accurately reflect the processes in place.

Appendix 1 – About our inspections

Our quality assurance system and the quality assurance framework allow us to provide external assurance of the quality of healthcare provided in Scotland.

Our inspectors use this system to check independent healthcare services regularly to make sure that they are complying with necessary standards and regulations. Inspections may be announced or unannounced.

We follow a number of stages to inspect independent healthcare services.

Before inspections

Independent healthcare services submit an annual return and self-evaluation to us.

We review this information and produce a service risk assessment to determine the risk level of the service. This helps us to decide the focus and frequency of inspection.

Before

During inspections

We use inspection tools to help us assess the service.

Inspections will be a mix of physical inspection and discussions with staff, people experiencing care and, where appropriate, carers and families.

We give feedback to the service at the end of the inspection.

During

After inspections

We publish reports for services and people experiencing care, carers and families based on what we find during inspections. Independent healthcare services use our reports to make improvements and find out what other services are doing well. Our reports are available on our website at: **www.healthcareimprovementscotland.org**

We require independent healthcare services to develop and then update an improvement action plan to address the requirements and recommendations we make.

We check progress against the improvement action plan.

After

More information about our approach can be found on our website: https://www.healthcareimprovementscotland.org/scrutiny/the_quality_assurance_system.aspx

Complaints

If you would like to raise a concern or complaint about an independent healthcare service, you can complain directly to us at any time. However, we do suggest you contact the service directly in the first instance.

Our contact details are:

Healthcare Improvement Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

Telephone: 0131 623 4300

Email: his.ihcregulation@nhs.scot

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality and Diversity Advisor on 0141 225 6999
or email his.contactpublicinvolvement@nhs.scot

Healthcare Improvement Scotland

Edinburgh Office	Glasgow Office
Gyle Square	Delta House
1 South Gyle Crescent	50 West Nile Street
Edinburgh	Glasgow
EH12 9EB	G1 2NP
0131 623 4300	0141 225 6999

www.healthcareimprovementscotland.org