Healthcare Improvement Scotland | Inspections and reviews
To drive improvement

Announced Inspection Report: Independent Healthcare

Service: Therapie Clinic (Braehead), Glasgow

Service Provider: Therapie Medical (UK) Ltd

17 April 2024

NHS SCOTLAND

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1 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 Therapie Clinic (Braehead) on Wednesday 17 April 2024. We spoke with staff, the registered manager and other members of the management team. We received feedback from nine patients through an online survey we had asked the service to issue to its patients for us before the inspection. This was our first inspection of this service.

Based in Braehead, Glasgow, Therapie Clinic (Braehead) is an independent clinic providing non-surgical treatments.

The inspection team was made up of two inspectors.

What we found and inspection grades awarded

For Therapie Clinic (Braehead), 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 provider had a clear vision and purpose. Key performance indicators helped the service identify and measure the quality of the service provided. For example, collecting and evaluating feedback from patients and quality assurance processes, such as audits and risk management. Staff told us leaders were visible, inclusive and approachable. Clinical governance leads provided appropriate support, advice and training to staff. Reporting structures between the provider and the service should be reviewed to ensure they remain effective in addressing any issues or concerns raised. The interim arrangements for the regional compliance officer role should be monitored. A record of the compliance officer's visits to the service should be maintained.	✓ Satisfactory
Implementation and delivery	*How well does the service engage with its stakeholders and manage/improve its performance?*
Patient feedback was actively encouraged and showed high satisfaction levels. Patients were involved in planning their care. Although key policies and procedures were in place to ensure safe patient care, the service's policies manual should be reviewed and updated. Clear procedures were in place for managing accidents, incidents and complaints. Quality assurance processes, including audits and risk management, supported the service to monitor the quality of care delivered to patients. Healthcare Improvement Scotland must be formally notified about certain matters that occur in the service. Audits of patient care records should be further developed to identify areas of non-compliance and any improvement actions required. A quality improvement plan should be developed.	✓ Satisfactory

Results	*How well has the service demonstrated that it provides safe, person-centred care?*
Summary findings	**Grade awarded**
Patients spoke positively about the service. The care environment and patient equipment was clean and fit for purpose. Cleaning schedules were fully completed, and infection control precautions were in place. Although medicines were stored securely, the storage arrangements for emergency medicines should be reviewed. Patient care records should include a more detailed summary of the consultation and assessment process. Consent forms should be signed by the practitioner. Disclosure Scotland background checks must be completed for all staff. Immediate action must be taken to address the outstanding fire safety issues. The ceiling in the temporary storeroom must be repaired. Botulinum toxin must be administered according to the manufacturer's guidance. Medicines governance processes, including obtaining informed consent from patients, must be followed. A copy of the clinical waste contract must be available in the service.	Unsatisfactory

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: Guidance for independent healthcare service providers – Healthcare Improvement Scotland

Further information about the Quality Assurance Framework can also be found on our website at: The quality assurance system and framework – Healthcare Improvement Scotland

What action we expect Therapie Medical (UK) Ltd 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 seven requirements and 11 recommendations.

Direction	
Requirements	
None	
Recommendations	
a	The service should ensure an effective system is in place to quickly respond to any issues identified in the service that require urgent attention (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
b	The service should ensure that minutes of staff meetings detail the staff responsible for taking forward any actions (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
c	The service should ensure the interim cover arrangements for the regional compliance officer is kept under review to ensure that monthly compliance visits are taking place and reports of findings, and any improvements identified from these visits, are documented and actioned (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	
Requirement	
1	The provider must notify Healthcare Improvement Scotland of certain matters as detailed in our notifications guidance within the specified timescales (see page 21). Timescale – immediate *Regulation 5(1)(b)* *The Healthcare Improvement Scotland (Applications and Registrations) Regulations 2011*
Recommendations	
d	The service should develop clear and measurable action plans to monitor and evaluate the impact of any service changes from patient feedback, and ensure patients are informed of any changes made to the service as a result of their feedback (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
e	The service should review and update its corporate policies and procedure manual to ensure it includes the correct regulations governing independent healthcare services in Scotland, and customise and align each policy to Scottish legislation and national guidance (see page 22). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.11
f	The service should further develop its risk register to ensure effective oversight and management of all risks and the actions taken to reduce each risk (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
g	The service should further develop its audits of patient care records to include the outcome of each audit and, where non-compliance is identified, an improvement action plan should be developed (see page 23). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19

Implementation and delivery (continued)

Recommendations

h The service should develop and implement a quality improvement plan to help structure and record improvement processes and outcomes, and demonstrate how it measures the impact of service change (see page 23).

Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19

Results

Requirements

2 The provider must ensure that appropriate Disclosure Scotland background checks are carried out on:
a) all staff before they begin working in the service, and
b) all staff currently working in the service.
Checks must be recorded and retained in staff files (see page 28).

Timescale – by 14 August 2024

Regulation 8(2)(c)
The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011

3 The provider must ensure that all significant hazards requiring immediate attention detailed in the January 2024 fire risk assessment report are addressed (see page 28).

Timescale – immediate

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

Results (continued)	
Requirements	
4	The provider must ensure that, once reconstituted, the botulinum toxin vial is only used for a single patient, during a single treatment session, and that any unused solution is discarded to comply with the manufacturer's guidance for botulinum toxin. The medicines management policy and toxin policy must also be updated (see page 28). Timescale – immediate *Regulation 3(d)(iv)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
5	The provider must ensure that when unlicensed medicines are used that appropriate medicine governance arrangements are in place, including documented rationale for use and informed patient consent (see page 28). Timescale – immediate *Regulation 3(d)(iv)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
6	The provider must ensure the service is provided with a copy of its clinical waste contract to demonstrate that all clinical and hazardous waste generated by the service is disposed of safely to comply with clinical waste legislation (see page 29). Timescale – immediate *Regulation 3(d)(iii)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*

Results (continued)	
Requirements	
7	The provider must ensure the ceiling in the temporary storeroom is repaired to reduce potential safety and infection risks (see page 29). Timescale – immediate *Regulation 10(2)(a)(b)(c)* *The Healthcare Improvement Scotland (Requirements as to Independent Health Care Services) Regulations 2011*
Recommendations	
i	The service should ensure the store cupboard in the clinical treatment room is clean, tidy and not overstocked (see page 29). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
j	The service should review where the emergency medicine box is located, and ensure medicines are in date and only emergency medicines that can be administered without a prescription are stored in the emergency medicine box (see page 29). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19
k	The service should ensure that patient care records include a more detailed summary of the consultation and assessment process. Consent forms should be signed by the practitioner (see page 29). Health and Social Care Standards: My support, my life. I have confidence in the organisation providing my care and support. Statement 4.19

An improvement action plan has been developed by the provider and is available on the Healthcare Improvement Scotland website: [Find an independent healthcare provider or service – Healthcare Improvement Scotland]

Therapie Medical (UK) Ltd, the provider, must address the requirements and make the necessary improvements as a matter of priority.

We would like to thank all staff at Therapie Clinic (Braehead) for their assistance during the inspection.

2 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 provider had a clear vision and purpose. Key performance indicators helped the service identify and measure the quality of the service provided. For example, collecting and evaluating feedback from patients and quality assurance processes, such as audits and risk management. Staff told us leaders were visible, inclusive and approachable. Clinical governance leads provided appropriate support, advice and training to staff. Reporting structures between the provider and the service should be reviewed to ensure they remain effective in addressing any issues or concerns raised. The interim arrangements for the regional compliance officer role should be monitored. A record of the compliance officer's visits to the service should be maintained.

Clear vision and purpose

A strategic policy set out the provider's vision and purpose to support and direct the future development of the business. We saw the provider identified four key strategic priorities. These included growth and expansion of its clinics across the UK, as well as further expansion and development of its aesthetic services. It also stated its intention to:

- invest in and develop the workforce (to ensure the safe and effective delivery of care), and
- create an inclusive environment for all stakeholders, including patients and staff.

The provider's mission was to be the best aesthetic provider in the market by making sure that patient satisfaction is at the heart of everything it does. A set of core values, aims and objectives helped direct the service to deliver care and treatment. These were:

- to be patient-focused
- to be built on trust
- to nurture growth by providing affordable and accessible treatments, and
- to promote accountability across its workforce.

Key performance indicators were used to help identify and measure the effectiveness of the quality of the service delivered to patients. This included collecting and evaluating data from:

- patient feedback
- complaints
- compliance audits
- recruitment
- retention, and
- workforce development.

- No requirements.
- No recommendations.

Leadership and culture

The service was one of a number of independent healthcare services that the provider had registered with Healthcare Improvement Scotland. The chief executive officer led this business as one of the owners supported by a senior leadership team based in its headquarters in Dublin.

A regional manager provided external line management support to all of the registered clinic managers in Scotland. The regional manager reported directly to the director of operations in the provider's senior leadership team to report on how each service was performing.

The provider employed a compliance officer to carry out monthly visits to all of its registered clinics in Scotland. Their role was to review and report on how well each of the services performed against the provider's aims, objectives and key performance indicators. This included:

- complaints
- clinical excellence
- health and safety
- reviewing patient feedback, and
- staff training and development.

A medical director (a doctor registered with the General Medical Council (GMC) and a clinical services manager (a nurse prescriber registered with the Nursing and Midwifery Council [NMC]) provided clinical support, advice and training to staff directly employed in all of the provider's services. They were also the

clinical governance leads responsible for implementing the provider's clinical governance policy. Key aspects of their role included acting as an expert resource and advisor in investigating and reviewing significant events, initiating and reviewing clinical audits and risk compliance, and overseeing the implementation and development of key clinical policies in each service.

We were told the provider's clinical governance team was accessible to staff when they needed advice and support. For example, if staff needed to determine a patient's suitability for laser treatment if they had certain pre-existing medical conditions or were currently prescribed specific medicines.

The clinic-based management team comprised of a registered manager, assistant manager and supervisor supported by a team of therapists who delivered laser and skin care treatments. Staff we spoke with had a clear understanding of their roles and responsibilities and felt supported by the management team. Staff appeared motivated to provide high standards of care and treatment to patients. Staff benefits included employee discounts and gifts on special birthdays.

We saw that the service had adequate staffing to support the delivery of safe and person-centred care to patients. Plans were in place to backfill the planned temporary absence of the registered manager in the coming months.

Staff meetings were held every month and a morning briefing of all the planned activity for that day took place with all staff on duty. We saw that complaints, health and safety issues, incidents and patient feedback were standing items on the staff meeting agenda. The regional manager held meetings every 3 months and had a weekly telephone call with all of the clinic managers. We saw that the provider was committed to making sure that staff were suitably skilled and experienced for the role, and had regular opportunities for training and development. Staff told us they received regular training and managers attended yearly conferences and events to keep them up to date with developments in the business. They also told us that senior leaders were visible, approachable and encouraged staff to share their ideas for improving the service.

The service also employed registered healthcare professionals to deliver injectable aesthetic treatments such as botulinum toxin and dermal fillers. These included doctors and independent nurse prescribers under a practicing privileges arrangement (staff not employed by the provider but given permission to work in the service.

What needs to improve

The provider's organisational framework outlined the key reporting structures between the service and the provider to ensure effective communication and resolution of any identified issues and concerns. However, we saw this was not working as effectively as it should and managers told us this was impacting on the service, for example long delays before essential repairs were addressed (recommendation a).

Minutes of staff meetings should be further developed to ensure they identify staff members responsible for taking any actions forward to help ensure better accountability (recommendation b).

We were told the regional compliance officer's post was vacant and plans were under way to fill the position permanently. One of the clinic managers from another of the provider's Scottish services was currently covering this role. Although we were told that compliance visits to the service were taking place, we saw no evidence of the findings from these visits or any record of any improvement actions to be taken (recommendation c).

- No requirements.

Recommendation a

- The service should ensure an effective system is in place to quickly respond to any issues identified in the service that require urgent attention.

Recommendation b

- The service should ensure that minutes of staff meetings detail the staff responsible for taking forward any actions.

Recommendation c

- The service should ensure the interim cover arrangements for the regional compliance officer is kept under review to ensure that monthly compliance visits are taking place and reports of findings, and any improvements identified from these visits, are documented and actioned.

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

Patient feedback was actively encouraged and showed high satisfaction levels. Patients were involved in planning their care. Although key policies and procedures were in place to ensure safe patient care, the service's policies manual should be reviewed and updated. Clear procedures were in place for managing accidents, incidents and complaints. Quality assurance processes, including audits and risk management, supported the service to monitor the quality of care delivered to patients. Healthcare Improvement Scotland must be formally notified about certain matters that occur in the service. Audits of patient care records should be further developed to identify areas of non-compliance and any improvement actions required. A quality improvement plan should be developed.

Co-design, co-production *(patients, staff and stakeholder engagement)*

Key information about the service was available on its website and in the clinic. This included information about treatments and costs, and allowed prospective patients to book a free consultation and treatment with the therapist or clinician of their choice. A 'client guide' was available in the main reception area. This provided patients with information about staff, treatments and how to make a complaint. Patients could also request a copy of this information. A range of leaflets providing pre- and post-treatment information was also available in the service. We were told that plans were under way to include a copy of the client guide on the service's website.

The service's participation policy aimed to collect feedback from its patients at least once during their treatment to help direct and inform service improvement. An email or text message with a link to an online survey was sent to every patient following their treatment. This provided an opportunity for the service to collect and analyse feedback from patients about the quality of their care and treatment. Patients could also leave reviews on the website or social media sites.

We saw that patients were asked to rate their experience of the service using a five-star system. A one-star review was rated as poor, and a five-star review was excellent. A report detailing outcomes from patient feedback was completed

every month and we saw results were routinely discussed and included in minutes of staff meetings.

The monthly reports we reviewed of patient feedback from January-March 2024 showed high satisfaction levels. We received similar results from patients who completed our online survey. Patients told us that staff were friendly, professional and treated them with dignity and respect. Comments included:

- 'Always treated as an individual and make you feel welcome.'
- 'Never rushed, always given time to make an informed decision.'
- 'The staff are always friendly and professional.'

A recent positive development from patient feedback, and a recommendation from one of our recent inspections to one of the provider's other services, had led to all of the Scottish clinics now having a dedicated telephone number. This allowed patients to contact the Scottish services directly instead of having to call or email a centralised team. Staff told us this helped them to quickly respond to patient enquiries or any issues or concerns.

What needs to improve

Although some changes were made in the service following patient feedback, we saw no formal action plan to allow the service to monitor and measure the impact of the improvements made, or how patients were informed of how their feedback was used to help improve the service (recommendation d).

- No requirements.

Recommendation d

- The service should develop clear and measurable action plans to monitor and evaluate the impact of any service changes from patient feedback, and ensure patients are informed of any changes made to the service as a result of their feedback.

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.

Appropriate arrangements were in place to maintain patient privacy and dignity in line with the service's privacy and dignity policy. All consultations were by appointment and carried out in private consulting rooms to maintain patient confidentiality. Access to these rooms was controlled through reception and doors were locked during patient treatments.

The service had a range of policies and procedures to set out the agreed ways of working to help make sure it delivered safe and person-centred care. We saw the policies included the date of when they were implemented and when they were due to be reviewed. We saw some of the key policies included those for:

- health and safety
- infection control
- medicines management, and
- safeguarding (public protection).

We were told that staff could access the provider's staff intranet to keep up to date with any policy changes or changes in practice, and to access training courses.

A system was in place for managing complaints and an electronic log was maintained. The provider evaluated complaints to monitor any trends. We saw that complaints and concerns were a standing item on the agenda at monthly staff meetings. The service's complaints policy included the contact details for Healthcare Improvement Scotland and made clear that patients could contact us directly at any stage if they had a complaint. We were told that plans were under way to enable patients to access the complaints policy on the service's website.

The service had a duty of candour policy. This is where healthcare organisations have a professional responsibility to be honest with people when something goes wrong. Staff had received duty of candour training and we saw the service had produced its first annual duty of candour report. This was available in the client guide in the main reception area. We noted that no duty of candour incidents were reported.

The provider was registered with the Information Commissioner's Office (an independent authority for data protection and privacy rights) to make sure patients' confidential information was safely stored. A combination of paper-based and electronic patient care records was used to record patient information. Paper files were stored in a locked filing cabinet and electronic devices were password protected. We saw that staff received training on information governance and the service had a policy in place detailing how confidential patient information was stored in the service.

A system was in place for recording and managing accidents and incidents. We were told that no accidents had occurred in the service since it was registered with Healthcare Improvement Scotland in February 2022.

Infection prevention and control procedures were in place to reduce the risk of infection to patients. Cleaning schedules demonstrated compliance with standard infection control precautions, including the clinical treatment room, and sanitary fixtures and fittings. Only single-use personal protective equipment (such as aprons and gloves) and medical devices (such as needles and syringes) were used in the service. Staff received training in hand hygiene. The service disposed of clinical waste in sharps boxes and colour-coded bags.

We saw the fire safety equipment, ventilation system and lasers were maintained every year. The most recent electrical wiring certificate was in date and was due to be re-inspected in December 2024. Portable electrical appliances had also been tested to make sure they were safe to use.

Medicines were obtained from an appropriately registered supplier and the service was registered to receive safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA). A stock control system enabled the service to monitor medicines supplies. Temperature-sensitive medicines were stored in locked medical refrigerators and medical devices, such as dermal fillers, were stored in a lockable cupboard. The temperature of the refrigerators was monitored and recorded every day to make sure medicines were safe to use. The clinic manager was responsible for controlling access to medicines. For example, clinical staff had to sign the keys to the medical refrigerator out and in after each treatment session.

The service had a first aid kit, oxygen and resuscitation equipment such as airways and masks, and a stock of emergency and prescription-only medicines to quickly respond to any medical emergencies or complications from treatment. We saw that all staff received training in first aid and life support techniques.

Patients were involved in planning their treatment as part of the consultation and assessment process. All patients completed a pre-treatment questionnaire before they had a face-to-face consultation with the laser consultant or the clinical practitioner to assess their suitability for treatment. Patients received a copy of their treatment plan which included treatment options and the estimated cost of the treatment. Our online survey results confirmed that patients were given time to discuss and ask questions and did not feel pressured to go ahead with treatment.

Before receiving treatment, patients signed a consent form to confirm they understood the risks, benefits and likely outcome of the proposed treatment. We saw that consent to share information with their GP or other healthcare professional where necessary, and for taking pre- and post-treatment photographs, was also obtained. Patients were given verbal aftercare advice

and written aftercare instructions following their treatment. Where appropriate, patients would attend a review appointment to review the outcome of their treatment.

The service had a registered external laser protection advisor to make sure laser safety rules and guidance were followed to support the safe delivery of laser treatments for its patients. We saw the advisor visited the service in March 2024, and an appropriate laser risk assessment and local rules (the local arrangements developed by the laser protection advisor to manage laser safety) were in place for each laser. Staff authorised to operate the lasers had completed their laser safety core of knowledge training. They were also required to carry out regular refresher training, and had signed to say they had read and understood the local rules. The clinic supervisor was the service's named laser protection supervisor responsible for making sure the local rules were followed. Access to laser treatment rooms was controlled by locks on doors, warning lights and appropriate signage to alert staff when lasers were in use and to prevent unauthorised entry.

Staff employed by the provider, and clinical staff who worked under a practicing privileges agreement, were recruited according to their skills, experience and qualifications required for the role. For example, the provider only employed GMC registered doctors or NMC registered independent nurse prescribers.

The service's recruitment policy stated that all offers of employment were subject to receiving satisfactory pre-employment checks, including proof of ID, two references and criminal record background checks. A professional registration check, immunisation screening and evidence of professional indemnity insurance was also requested for the clinical staff employed under a practicing privileges arrangement.

The service had a practicing privileges policy and clinical staff had a signed contract in place. We saw that all staff received an induction and attended mandatory training., such as infection control, first aid, fire safety and manual handling. Employed staff had a weekly one-to-one meeting with their line manager and a yearly appraisal to identify training needs and set personal development objectives. Staff told us they received good opportunities for training and career progression.

What needs to improve

Healthcare Improvement Scotland's notification guidance details specific events and circumstances which providers are required to report to us. Information we received before the inspection stated that three adverse incidents involving patients had occurred in the service in 2023. We had not been notified about these incidents. We asked the registered manager to submit the relevant notifications to us for review. Although these have now been received, we were not assured the service was fully aware of the formal process to notify Healthcare Improvement Scotland about any serious incidents, adverse events or complications from treatment (requirement 1).

When we reviewed the service's corporate policies and procedure manual, we found that issues that had been identified following a recent inspection to one of the provider's other registered services in Scotland had still not been addressed. These were:

- The manual incorrectly referenced the Regulation of Care (Scotland) Act 2001, (the Care Inspectorate's regulations for social care services in Scotland), as the regulations governing Healthcare Improvement Scotland's independent healthcare services.
- The safeguarding policy referred to a vulnerable adult in Scotland as '18' instead of '16' years.
- The recruitment policy referred to Criminal Record Bureau (CRB) or Disclosure and Barring Service (DBS) checks, which only apply in England and Wales. Disclosure Scotland is the agency responsible for carrying out criminal record background checks in Scotland (recommendation e).

The service's emergency policy confirmed that patients could call or email the service direct during service opening hours if they had any issues or concerns following treatment. Patients were advised to attend their local hospital's accident and emergency department if they experienced an adverse reaction or complication from treatment out of hours. We were told there had not been any out-of-hours patient emergencies reported following treatment. However, the service should keep this under review to make sure patients could contact someone from the clinic out of hours if they experienced an adverse reaction or complication from treatment. We will follow this up at a future inspection.

Requirement 1 – Timescale: immediate

- The provider must notify Healthcare Improvement Scotland of certain matters as detailed in our notifications guidance within the specified timescales.

Recommendation e

- The service should review and update its corporate policies and procedure manual to ensure it includes the correct regulations governing independent healthcare services in Scotland, and customise and align each policy to Scottish legislation and national guidance.

Planning for quality

A business continuity plan was in place if the service experienced a disruptive incident, such as a power failure. The plan provided details of key contacts and contractors to help reinstate services and when to contact patients.

The service's audit programme and risk management policy supported the quality assurance processes in place for managing and monitoring risk. We saw appropriate environmental risk assessments were carried out for the lasers, fire safety, cleaning products, moving and handling, needlestick injuries, and slips, trips and falls. Clinical risks associated with treatments were also documented and included the preventative measures that patients should follow before and after treatment to reduce the risk of a complication following treatment.

There was evidence of audits taking place for infection control, patient care records, and medicines stock including emergency medicines and equipment. This helped the service monitor compliance with its policies and procedures to ensure it delivered safe care and treatment for its patients.

The clinic management team carried out weekly infection control audits of the environment and regular staff hand hygiene audits. All staff had received infection control training.

Patients' laser notes were audited every week to make sure treatment protocols were followed and to check the required information was recorded in each file in line with the service's laser policy.

We saw that 20 clinical patient care records were audited every month to ensure these were being fully and accurately completed.

What needs to improve

Although the service had a risk register, this did not include all the risks in the service and the actions that would be taken to reduce each risk (recommendation f).

Audits of clinical records carried out in the service between January-March 2024 showed some areas of non-compliance. For example, not obtaining patient consent for taking photographs, and not documenting and signing the patients'

treatment plans. However, the audits were not detailed in terms of describing any gaps that had been found, and what actions the service had taken to improve record keeping. This would help staff to plan actions and timescales for improvement (recommendation g).

The service had not developed a quality improvement plan. This would enable the service to measure the impact of service change and demonstrate a culture of continuous improvement in the service (recommendation h).

- No requirements.

Recommendation f

- The service should further develop its risk register to ensure effective oversight and management of all risks and the actions taken to reduce each risk.

Recommendation g

- The service should further develop its audits of patient care records to include the outcomes of each audit and, where non-compliance is identified, an improvement action plan should be developed.

Recommendation h

- The service should develop and implement a quality improvement plan to help structure and record improvement processes and outcomes, and demonstrate how it measures the impact of service change.

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

Patients spoke positively about the service. The care environment and patient equipment was clean and fit for purpose. Cleaning schedules were fully completed, and infection control precautions were in place. Although medicines were stored securely, the storage arrangements for emergency medicines should be reviewed. Patient care records should include a more detailed summary of the consultation and assessment process. Consent forms should be signed by the practitioner.

Disclosure Scotland background checks must be completed for all staff. Immediate action must be taken to address the outstanding fire safety issues. The ceiling in the temporary storeroom must be repaired. Botulinum toxin must be administered according to the manufacturer's guidance. Medicines governance processes, including obtaining informed consent from patients, must be followed. A copy of the clinical waste contract must be available in the service.

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 satisfactory self-evaluation.

The reception area and all treatment rooms were clean, the fabric and finish of the clinic was in good condition and patient equipment was fit for purpose.

Daily, weekly and monthly cleaning schedules were fully completed and up to date. Colour-coded mop handles and single-use mopheads were used for floor cleaning. We saw that the correct cleaning products were used. For example, chlorine-based cleaning products were used for sanitary fixtures and fittings.

We saw good compliance with infection prevention and control procedures. This included clear procedures for the safe disposal of medical sharps such as syringes and needles, clinical waste and single-use patient equipment (used to prevent the risk of cross-infection). We saw a good supply of alcohol-based hand rub, and appropriate personal protective equipment such as disposable gloves, aprons and face masks was available. Hand hygiene audits were completed every month and showed good compliance. Posters were displayed in the treatment rooms to promote good hand hygiene.

We saw that medicines that required to be stored in a refrigerator were monitored and temperatures were recorded every day to make sure they remained safe to use. An audit of fridge temperatures completed in April 2024 showed full compliance. The majority of medicines and medical devices such as needles and syringes were in date. The medical fridge was clean and not overstocked and temperature sensitive prescription-only medicine such as botulinum toxin was in date. The service maintained a stock of emergency medicines, oxygen and other equipment such as masks and airways to respond to medical emergencies. Patient care records we reviewed included the batch number and expiry date of medicines used during clinical treatments.

We reviewed six patient care records, including electronic care records for patients who had received aesthetic and laser treatments. We saw fully completed medical questionnaires and signed consent to treatment forms in all the patient care records we reviewed. This included obtaining consent to share information with patients' GPs and for taking photographs. Consent forms documented the risks and benefits of treatment. A record of the patients' emergency contact or next of kin was also documented. We saw that patients received a treatment plan outlining their treatment options and the estimated cost of the treatment. Patient care records also included a facial map to indicate the dosage administered to each area.

We reviewed six recruitment files for staff, including clinical staff employed under a practicing privileges arrangement. The files contained a record of professional qualifications, proof of identity, two references and evidence of training attended. All files we reviewed confirmed that staff had attended an induction before they started working in the service and had an employment contract or practicing privileges agreement. Clinical staff files provided evidence of their professional registration, heath clearance and indemnity insurance.

Patients who completed our online survey said they were involved in decisions about their care and treatment, and were given sufficient time to reflect on their options before consenting to treatment. This helped to make sure they

had realistic expectations of the proposed treatment. They also told us they were satisfied with the facilities, equipment and environment where they were treated. Comments included:

- ‘It’s a new facility so it’s fresh, clean and inviting.’
- ‘The staff are very friendly, and the clinic is clean and tidy.’
- ‘Thorough consultation all questions answered honestly and professionally with excellent communication before and after treatment including follow-up.’
- ‘All treatments were delivered with experience and knowledge and of course excellent customer care.’

What needs to improve

At a recent inspection of another registered Therapie clinic, we reported that Disclosure Scotland background checks were not being carried out by the provider before staff started working in the service. During this inspection, we found a similar issue in the staff recruitment files we reviewed. We were told that staff employed in the service completed their own Disclosure Scotland background checks, which they then submitted to the provider upon recruitment. While we saw that clinical staff working under practicing privileges were all Protecting Vulnerable Groups (PVG) scheme members, the Disclosure Scotland certificates we saw in their recruitment files were linked to current or previous employers. The provider must either register as a counter-signatory with Disclosure Scotland or commission an ‘umbrella body’ to carry out PVG checks on its behalf. A risk-based Disclosure Scotland background check for employed staff must also be completed by either of the two approaches. This will ensure that staff are fit and not barred from doing regulated work and provide assurance that all staff are safe to work in the service (requirement 2).

An external fire safety contractor had carried out a fire risk assessment in the service in January 2024. Their report classified the risk of fire on the premises as a high and substantial risk, due to the lack of adequate control measures for some significant fire hazards. The report identified a number of significant hazard areas needing immediate attention, most of which remained outstanding. This included issues with the fire alarm detection panel, the fire exit doors and the smoke detection system. Although work had taken place to address some of the issues, we were told that all the outstanding essential areas of work requiring immediate attention were scheduled for repair in April 2024.

The report also made recommendations about ensuring that combustible materials and potential ignition sources were stored separated to comply with Control of Substances Hazardous to Health (COSHH) regulations. It also

recommended that a record of the weekly and monthly fire safety checks should be completed, and staff fire safety training should be documented in the service's fire safety log (requirement 3).

During the inspection, we identified a number of issues relating to the administration and preparation of botulinum toxin.

- The same vial of reconstituted botulinum toxin was being used to treat multiple patients (when a liquid solution is used to turn a dry substance into a fluid for injection) (requirement 4).
- We saw the service used bacteriostatic saline to reconstitute the vials of botulinum toxin. The bacteriostatic saline used is an unlicensed product and the use of this instead of normal saline for reconstitution means that the botulinum toxin is being used outwith its Summary of Product Characteristics and is therefore termed as unlicensed use. We were told this provided better pain relief for patients. However, there was no evidence in the patient care record that the use of unlicensed bacteriostatic saline and the unlicensed use of botulinum toxin had been discussed with patients nor that informed consent had been sought before treatment was administered (requirement 5).

Although we saw some clinical waste transfer notes to confirm clinical waste was being uplifted from the service, the service did not have a copy of its clinical waste contract. Therefore, we were unable to confirm the frequency of uplifts or ensure that hazardous waste such as botulinum toxin was being disposed of correctly (requirement 6).

We saw the service was planning to renovate three rooms to expand the facilities available in the clinic. At the time of the inspection, one of the rooms was being used as a temporary store for stock supplies and equipment. We were told the provider intended to develop this room into a training facility for Therapie staff. We noted that some refurbishment work had taken place in this room to extend the ventilation and fire sprinkler systems and two clinical hand wash basins had been installed. However, the ventilation duct and fire sprinkler were currently exposed, and the room was poorly lit as the main light was not fully and properly attached. In its present condition, the room increased potential risks of accidents, fire safety and infection control issues while being used as a store room (requirement 7).

Although the items we checked in the store cupboard in the clinical treatment room were in date, we found a bag of unused needles and several items of rubbish at the bottom of the cupboard (recommendation i).

We found one of the emergency medicines and a face mask in the emergency medicine box was out of date. The emergency medicine box was stored on top of the medical refrigerator inside a cupboard and the box was warm to touch. We also saw that the prescription-only medicines used to treat complications were being stored in the emergency medicine box. Only those medicines that can be administered without a prescription, such as adrenaline to treat severe allergic reactions, should be stored in the emergency medicine box (recommendation j).

Patient care records did not detail a summary of the outcome of the face-to-face consultation and assessment between the patient and practitioner. Although the patient care records we reviewed showed that all patients had signed their consent form, this should also be signed by the practitioner to confirm the risks and benefits had been fully discussed with patients (recommendation k).

Requirement 2 – Timescale: by 14 August 2024

- The provider must ensure that appropriate Disclosure Scotland background checks are carried out on:
  a) all staff before they begin working in the service, and
  b) all staff currently working in the service.

  Checks must be recorded and retained in staff files.

Requirement 3 – Timescale: immediate

- The provider must ensure that all significant hazards requiring immediate attention detailed in the January 2024 fire risk assessment report are addressed.

Requirement 4 – Timescale: immediate

- The provider must ensure that, once reconstituted, the botulinum toxin vial is only used for a single patient, during a single treatment session, and that any unused solution is discarded to comply with the manufacturer's guidance for botulinum toxin. The medicines management policy and toxin policy must also be updated.

Requirement 5 – Timescale: immediate

- The provider must ensure that when unlicensed medicines are used that appropriate medicine governance arrangements are in place, including documented rationale for use and informed patient consent.

Requirement 6 – Timescale: immediate

- The provider must ensure the service is provided with a copy of its clinical waste contract to demonstrate that all clinical and hazardous waste generated by the service is disposed of safely to comply with clinical waste legislation.

Requirement 7 – Timescale: immediate

- The provider must ensure the ceiling in the temporary storeroom is repaired to reduce potential safety and infection risks.

Recommendation i

- The service should ensure the store cupboard in the clinical treatment room is clean, tidy and not overstocked.

Recommendation j

- The service should review where the emergency medicine box is located, and ensure medicines are in date and only emergency medicines that can be administered without a prescription are stored in the emergency medicine box.

Recommendation k

- The service should ensure that patient care records include a more detailed summary of the consultation and assessment process. Consent forms should be signed by the practitioner.

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: [The quality assurance system and framework – Healthcare Improvement Scotland]

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

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

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