

Announced Care Inspection Report 05 March 2020



Therapie Optilase

Type of Service: Independent Hospital (IH) – Refractive Eye lasers

Address: Unit O, Erneside Shopping Centre, Enniskillen, BT74 6JQ

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Inspector: Emily Campbell

www.rgia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for



2.0 Profile of service

Therapie Optilase is registered as an Independent Hospital (IH) with the following category of care: PT (L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers; PT (IL) Prescribed techniques or prescribed technology: establishments using intense light sources; and private doctor (PD). Since prior to the previous inspection, laser hair removal services only have been provided.

The establishment provides a range of cosmetic/aesthetic treatments. This inspection focused solely on those treatments using a laser machine that fall within regulated activity and the category of care for which the establishment is registered with RQIA.

Laser equipment

Manufacturer: Cynosure
 Model: Elite+
 Serial Number: ELM+1947
 Laser Class: 4

Manufacturer: Cynosure
 Model: Elite+
 Serial Number: ELM+1977
 Laser Class: 4

Laser protection advisor (LPA):

Mr Alex Zarneth

Laser protection supervisor (LPS):

Ms Gemma Knightly

Medical support services:

Dr Paul Reddy

Authorised operators:

Ms Gemma Knightly, Ms Catriona Knox, Ms Clare O'Doherty, Ms Yadira Nugent

Types of treatment provided:

Hair removal

3.0 Service details

Organisation/Registered Provider: Therapie Optilase (Enniskillen) Ltd Responsible Individual: Mr Phillip McGlade	Registered Manager: Ms Gemma Knightly
Person in charge at the time of inspection: Ms Gemma Knightly	Date manager registered: 17 November 2016
Categories of care: Independent Hospital (IH) PT (L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers; PT (IL) Prescribed techniques or prescribed technology: establishments using intense light sources; and PD private doctor.	

4.0 Inspection summary

An announced inspection took place on 5 March 2020 from 10:05 to 12:40.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care

Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DoH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidence in all four domains. These included the arrangements for staffing, recruitment, safeguarding, laser safety, the management of medical emergencies, infection prevention and control, information provision, the care pathway, the management and governance and maintenance arrangements.

No areas requiring improvement were identified.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and client's experience.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Ms Gemma Knightly, Registered Manager, as part of the inspection process and can be found in the main body of the report.

Enforcement action did not result from the findings of this inspection.

4.2 Action/enforcement taken following the most recent care inspection dated 09 January 2019

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 9 January 2019.

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- the returned QIP from the previous care inspection

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned completed clients questionnaires were analysed prior to the inspection.

RQIA invited staff to complete an electronic questionnaire prior to the inspection. Returned completed staff questionnaires were analysed prior to and following the inspection.

A poster informing clients that an inspection was being conducted was displayed.

During the inspection the inspector met with Ms Gemma Knightly, Registered Manager and authorised operator and two other authorised operators.

The following records were examined during the inspection:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- information provision
- care pathway
- management and governance arrangements
- maintenance arrangements

Areas for improvement identified at the last care inspection were reviewed and assessment of compliance recorded as met, partially met, or not met.

The findings of the inspection were provided to the person in charge at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 09 January 2019

The most recent inspection of the establishment was an announced care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 09 January 2019

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		Validation of compliance
Area for improvement 1 Ref: Regulation 26 Stated: First time	<p>The registered person shall ensure that six monthly unannounced visits by the responsible individual or their nominated representative, as outlined in Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended, are carried out.</p> <p>Written reports of the unannounced visits should be available for inspection.</p>	Met
	<p>Action taken as confirmed during the inspection:</p> <p>Review of documentation evidenced that six monthly unannounced visits by an individual nominated by the responsible individual had been carried out.</p> <p>Reports dated 4 April and 5 November 2019 were reviewed and were found to be comprehensive and in keeping with the legislation.</p>	

<p>Area for improvement 2</p> <p>Ref: Regulation 12</p> <p>Stated: First time</p>	<p>The registered person shall submit a variation to registration application to remove the private doctor (PD) category of care to ensure that the categories of care registered with RQIA reflect the services being provided in the establishment.</p> <hr/> <p>Action taken as confirmed during the inspection: A variation to registration application to remove the private doctor (PD) category of care had not been submitted to RQIA.</p> <p>However, Therapie Optilase is relocating to Omagh, in the near future, under the entity Therapie Clinic Ltd and a new application for registration has been received by RQIA in this regard. Ms Knightly confirmed that a voluntary cancellation of registration would be submitted to RQIA in respect of Therapie Optilase. Although this area for improvement has not been met, it no longer applies.</p>	<p>Not met</p>
<p>Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)</p>		<p>Validation of compliance</p>
<p>Area for improvement 1</p> <p>Ref: Standard 20</p> <p>Stated: Second time</p>	<p>The registered person shall ensure that a wall mounted disposable paper towel dispenser is installed adjacent to the wash hand basin in the laser room.</p> <hr/> <p>Action taken as confirmed during the inspection: Observations made evidenced that wall mounted disposable paper towel dispensers had been installed in both laser rooms adjacent to the wash hand basins.</p>	<p>Met</p>
<p>Area for improvement 2</p> <p>Ref: Standard 48.4</p> <p>Stated: First time</p>	<p>The registered person shall consult with the appointed laser protection advisor (LPA) to ensure that the details of the total blocking shields provided are included in the local rules.</p> <hr/> <p>Action taken as confirmed during the inspection: Review of both sets of local rules evidenced that the details of total blocking shields had been included.</p>	<p>Met</p>

Area for improvement 3 Ref: Standard 6.7 Stated: First time	The registered person shall submit the insurance certificate relating to employers and public liability upon return of this quality improvement plan (QIP).	Met
	Action taken as confirmed during the inspection: The insurance certificate relating to employers and public liability was submitted to RQIA on submission of the QIP.	

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Ms Knightly confirmed that all staff working in the establishment are also authorised operators for the laser equipment. Ms Knightly and staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and clients.

Ms Knightly and staff confirmed that laser treatments are only carried out by authorised operators. A register of authorised operators for the lasers is maintained and kept up to date.

Discussion with Ms Knightly and review of documentation evidenced that one new authorised operator has been recruited since the previous inspection. Review of documentation evidenced that the newly recruited authorised operator had completed an induction programme.

A review of training records evidenced that authorised operators have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety awareness and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

Discussion with Ms Knightly and staff, and review of documentation confirmed that authorised operators take part in appraisal on an annual basis.

Recruitment and selection

As discussed, one authorised operator has been recruited since the previous inspection. Review of records in respect of the newly recruited authorised operator evidenced that all records as outlined in regulation 19 (2) schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 had been sought and retained.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Safeguarding

It was confirmed that laser treatments are not provided to persons under the age of 18 years.

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was confirmed that the safeguarding lead has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

Laser safety

A laser safety file was in place which contained all of the relevant information in relation to laser equipment.

There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA) which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires in December 2020.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Reddy in May 2019. Systems are in place to review the medical treatment protocols on an annual basis. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

Up to date local rules were in place which have been developed by the LPA in respect of each laser. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the premises in May 2019 and no recommendations were made.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised operators is maintained. Authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator, who is suitably skilled to fulfil the role, to deputise for the LPS in their absence. Discussion with staff

confirmed that systems are in place to ensure other authorised operators are aware of who the LPS on duty is.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The door to the treatment rooms are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The lasers are operated using a key. Arrangements are in place for the safe custody of the laser keys when not in use. Protective eyewear is available for the client and operator as outlined in the local rules.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has two laser registers, one for each laser, which are completed every time the equipment is operated and includes:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure
- any accident or adverse incident

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. The most recent service reports of September 2019 and January 2020 were reviewed as part of the inspection process.

Management of emergencies

As discussed, authorised operators have up to date training in basic life support. Discussion with staff confirmed they were aware what action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

The laser treatment rooms were clean and clutter free. Completed cleaning schedules were in place including a monthly deep cleaning log. Discussion with staff evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided.

As discussed previously, authorised operators have up to date training in infection prevention and control (IPC).

Discussion with staff confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits have been carried out including:

- environmental
- hand hygiene
- decontamination of equipment

There was a range of IPC policies and procedures in place.

Risk Management

A risk management policy was in place which incorporated arrangements for reviewing safety notices, incident reporting, quality monitoring, audit and incident management. Ms Knightly confirmed that risk management procedures are in place to ensure that risks are identified, assessed and managed. Discussion with Ms Knightly demonstrated that arrangements were in place to review risk assessments.

Environment

The premises were maintained to a good standard of maintenance and décor.

Arrangements are in place for maintaining the environment. This included portable appliance testing (PAT), servicing of fire-fighting equipment and servicing of the air conditioning.

A fire risk assessment had been undertaken and staff confirmed fire training and fire drills had been completed. Staff demonstrated that they were aware of the action to take in the event of a fire.

Observations made evidenced that carbon dioxide (CO₂) fire extinguishers were available which has been serviced within the last year.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff recruitment, induction, training, supervision and appraisal, adult safeguarding, laser safety, management of emergencies, infection prevention and control, risk management and the environment.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment has a list of fees available for each laser procedure.

Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the client.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner, with their consent, for further information if necessary.

Five client care records were reviewed. There is an accurate and up to date treatment record for every client which includes:

- client details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

A system is in place for the auditing of client records.

Observations made evidenced that client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Discussion with Ms Knightly and review of the management of records policy confirmed that patients have the right to apply for access to their clinical records in accordance with the General Data Protection Regulations May 2018 and where appropriate Information Commissioners Office (ICO) regulations and Freedom of Information legislation.

The establishment is registered with the ICO.

Communication

As discussed, there is written information for clients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

Staff confirmed that management is approachable and their views and opinions are listened to. Staff confirmed that staff meetings are held on a monthly basis and that minutes of staff meetings are retained.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records, the range and quality of audits, and ensuring effective communication between clients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with Ms Knightly and staff regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely.

Client satisfaction surveys are carried out by the establishment routinely. The results of these are collated to provide a summary report which is made available to clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that clients were highly satisfied with the quality of treatment, information and care received.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining client confidentiality ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow clients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment and authorised operators were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Authorised operators confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Arrangements were in place to facilitate annual staff appraisal. There was a nominated individual with overall responsibility for the day to day management of the service.

A visit by the registered provider was undertaken as required under Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005; a report was produced and made available for clients, their representatives, staff, RQIA and any other interested parties to read. An action plan was developed to address any issues identified which include timescales and person responsible for completing the action. As discussed previously, Regulation 26 reports viewed were found to be comprehensive and in keeping with the legislation.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed at least on a three yearly basis. Staff spoken with were aware of the policies and how to access them.

There was a complaints policy and procedure in place which was in accordance with legislation and DoH guidance on complaints handling. Clients and/or their representatives were made aware of how to make a complaint by way of the client guide. Discussion with staff confirmed that they were knowledgeable about how to respond to complaints.

There have been no complaints since the previous inspection, however, discussion with Ms Knightly and review of documentation evidenced that there are robust arrangements in place on a corporate level for the management of complaints.

Discussion with Ms Knightly confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

A whistleblowing/raising concerns policy was available. Discussion with staff confirmed that they were aware of who to contact if they had a concern.

Ms Knightly demonstrated a clear understanding of her role and responsibility in accordance with legislation. As discussed previously, Therapie Optilase is relocating to Omagh, in the near future, under the entity Therapie Clinic Ltd and a new application for registration has been received by RQIA in this regard.

Ms Knightly confirmed that the statement of purpose and client’s guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

Observation of insurance documentation confirmed that current insurance policies were in place.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to governance arrangements, management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 Equality data

Equality data

The arrangements in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients was discussed with Ms Knightly.

6.9 Client and staff views

Sixteen clients submitted questionnaire responses to RQIA. All indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All clients indicated that they were very satisfied with each of these areas of their care. All clients made comments in submitted questionnaires commending the staff attitude, professionalism and quality of treatment.

Three staff submitted electronic questionnaire responses to RQIA. One staff member indicated that they were very satisfied that the client care was safe and effective, that clients were treated with compassion and that the service was well led. Two staff members indicated that they were very unsatisfied with each of these domains. No staff spoken with during the inspection indicated they were unsatisfied in relation to any aspect of client care or the management and operation of the establishment and two staff also made very positive comments about working in the establishment in questionnaire responses. It is therefore considered that responses were made in error.

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a QIP is not required or included, as part of this inspection report.



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