

Announced Care Inspection Report 28 February 2017



Therapie Optilase

Type of Service: Independent Hospital (IH) – Cosmetic Laser Service
Address: Unit 1, Canal Court, Merchant's Quay, Newry, BT30 8HF
Tel No: 02830832799
Inspector: Winnie Maguire

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Assurance, Challenge and Improvement in Health and Social Care

1.0 Summary

An announced inspection of Therapie Outilase took place on 28 February 2017 from 10.00 to 13.45

The inspection sought to assess progress with any issues raised during and since the last care inspection and to determine if the laser service was delivering safe, effective and compassionate care and if the service was well led.

Is care safe?

Observations made, review of documentation and discussion with Mr Mark Shortt, registered person, Ms Orla Mulholland, registered manager and staff demonstrated that further development is needed to ensure that care provided to patients is safe and avoids and prevents harm. Areas reviewed included laser safety, staffing, recruitment and selection, safeguarding, management of medical emergencies, infection prevention control and decontamination and the general environment. Three requirements have been made in relation to recruitment and selection, mandatory training and the provision of the installation report and ongoing servicing arrangements for the laser equipment serial number S12ICE0217. Three recommendations have been made in relation to re-establishing appraisals, amendments to the adult safeguarding policy and the resuscitation policy.

Is care effective?

Observations made, review of documentation and discussion with Mr Shortt, Ms Mulholland and staff demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included care pathway, audits and communication. No requirements or recommendations have been made.

Is care compassionate?

Observations made, review of documentation and discussion with Mr Shortt, Ms Mulholland and staff demonstrated that arrangements are in place to promote patients' dignity, respect and involvement in decision making. No requirements or recommendations have been made.

Is the service well led?

Information gathered during the inspection identified that further development is needed to ensure that effective leadership and governance arrangements are in place and create a culture focused on the needs of patients in order to deliver safe, effective and compassionate care. Areas reviewed included organisational and staff working arrangements, the arrangements for policy and risk assessment reviews, the arrangements for dealing with complaints, incidents and alerts, insurance arrangements and the registered persons' understanding of their role and responsibility in accordance with legislation. A number of quality assurance processes were in place. However, as discussed previously there were issues identified under the 'is care safe' domain. Addressing the requirements and recommendations made will further enhance the quality and governance arrangements in place

This inspection was underpinned by 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, Social Services and Public Safety (DHSPPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and recommendations made at this inspection	3	3

Details of the Quality Improvement Plan (QIP) within this report were discussed with Mr Mark Shortt, registered person and Ms Orla Mulholland, registered manager as part of the inspection process. The timescales for completion commence from the date of inspection.

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

1.2 Actions/enforcement taken following the most recent care inspection

Other than those actions detailed in the QIP there were no further actions required to be taken following the most recent inspection on 3 November 2015.

2.0 Service details

Registered organisation/registered person: Therapie Clinic Ltd Mr Mark Thomas Shortt	Registered manager: Ms Orla Mulholland
Person in charge of the establishment at the time of inspection: Ms Orla Mulholland	Date manager registered: 20 January 2014
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers	

Laser equipment

Manufacturer: Alma
Model: Soprano ICE
Serial Number: S12ICE0217
Laser Class: 4
Wavelength: 755nm

Laser protection advisor (LPA) - Alex Zarneth

Laser protection supervisor (LPS) - Orla Mulholland

Medical support services - Dr Ross Martin

Authorised users - Orla Mulholland, Georgina Brannigan, Louise Linkins, Lisa McNally and Sarah Redmond

Types of treatment provided - Hair removal/reduction

3.0 Methods/processes

Questionnaires were provided to clients and staff prior to the inspection by the establishment on behalf of the RQIA. Prior to inspection we analysed the following records: notifiable events, complaints declaration and returned completed staff and client questionnaires.

During the inspection the inspector met with Mr Mark Shortt, registered person, Ms Orla Mulholland, registered manager, who is also an authorised user and two other authorised users. A tour of the premises was also undertaken.

Records were examined during the inspection in relation to the following areas:

- 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

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated 3 November 2015

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

4.2 Review of requirements and recommendations from the last care inspection dated 3 November 2015

Last care inspection statutory requirements		Validation of compliance
Requirement 1 Ref: Regulation 21(1) Stated: First time	The registered person must ensure all client records and the laser register are accurately completed. Action taken as confirmed during the inspection: Review of six client records and the laser register found them to be accurately completed.	Met

4.3 Is care safe?

Staffing

Discussion with Mr Shortt, Ms Mulholland and staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and clients.

It was confirmed that laser treatments are only carried out by authorised users. A register of authorised users for the laser is maintained and kept up to date.

A review of two completed induction programmes evidenced that induction training is provided to new staff on commencement of employment. It was confirmed staff appraisals had not been undertaken in the last year. A recommendation was made to re-establish staff appraisals.

A review of training records evidenced that authorised users have up to date training in core of knowledge training, application training for the equipment in use and fire safety. Four of the five authorised users had up to date basic life support training and infection prevention control (IPC) training. A requirement was made to ensure all authorised users have evidence of up to date basic life support training and IPC training.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

Recruitment and selection

It was confirmed that two staff have been recruited since the previous inspection. A review of the personnel files for these staff evidenced that they had not been fully recruited in line with Regulation 19(2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005. It was noted that the enhanced AccessNI check in respect of both staff members was not received until after the commencement of employment and a criminal declaration had not been undertaken as part of the recruitment process. A requirement has been made on this matter.

A recruitment policy and procedure was in place however, it was not fully in accordance to legislation. An amended recruitment and selection policy was forwarded to RQIA following inspection.

Safeguarding

It was confirmed that a policy and procedure is in place for the safeguarding and protection of adults at risk of harm.

Review of the policy indicated that it needs to be updated to ensure it fully reflects the new regional policy and guidance issued during July 2015. A recommendation has been made to address this. Mr Shortt confirmed that staff would receive refresher training in safeguarding adults at risk of harm when the policy and procedure had been updated in keeping with the Minimum Standards for Independent Healthcare Establishments July 2014.

Mr Shortt confirmed he had received the following information by electronic mail from RQIA following an inspection to another Therapie Optilase registered service:

- 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015)
- the relevant contact details for onward referral

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

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 it expires in January 2018.

Laser procedures are carried out by trained operators in accordance with a medical treatment protocol produced by Dr Ross Martin on May 2015 and revalidated in January 2017 until May 2019. Systems are in place to review the medical treatment protocol on a two yearly basis. The medical treatment protocol 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. 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 January 2017 and no recommendations were made.

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

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 user, 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 users are aware of who the LPS is on duty.

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 room is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using a key. Arrangements are in place for the safe custody of the laser key when not in use. Protective eyewear is available for the client and operator as outlined in the local rules. However, it was noted that the total block eyewear's outer plastic covering was peeling off. Immediately following the inspection RQIA received written confirmation that the damaged eyewear had been removed from use and had been replaced by a new pair of total block eyewear.

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 a laser register which is 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

A new laser machine has been installed in the clinic since the previous inspection. Mr Shortt confirmed it had been installed by a laser engineer. However, there was no installation report or evidence of ongoing service arrangements in line with manufacturer's instructions. A requirement was made on this matter.

Management of medical emergencies

As discussed, four of the five authorised users have up to date training in basic life support. This has been reported on under the staffing section of this report. 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. It was advised to re-name this policy, management of medical emergencies and include details of training, incident reporting and recording of any medical emergency and debriefing arrangements. Following the inspection an amended policy was forwarded to RQIA, the title had been changed however the areas as outlined above were not included. A recommendation was made on this matter.

Infection prevention and control and decontamination procedures

The treatment room was clean and clutter free. 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, four of the five authorised users have up to date training in infection prevention and control. This has been reported on under the staffing section of this report.

An IPC audit was carried out in the clinic in December 2016 by the regional manager for Therapie Optilase. Two recommendations were made and both had been addressed.

Environment

The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place.

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

Client and staff views

Three clients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. The following comment was provided:

- “The girls are great at explaining everything.”

Five staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas for improvement

Re-establish staff appraisals.

Ensure all authorised users have evidence of up to date basic life support training and IPC training.

Staff must be recruited and staff files retained in line with Regulation 19(2) Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

The adult safeguarding policy and procedure should be updated to ensure it fully reflects the new regional policy and guidance issued during July 2015.

An installation report and evidence of ongoing service arrangements in line with manufacturer’s instructions must be in place for the laser equipment, serial number S12ICE0217.

The management of medical emergencies policy should include details of training, incident reporting and recording of any medical emergency and debriefing arrangements.

Number of requirements	3	Number of recommendations	3
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4.4 Is care effective?

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.

Six 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)

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.

The establishment is registered with the Information Commissioners Office (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.

The establishment has a policy for advertising and marketing which is in line with legislation.

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

Client and staff views

All clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. The following comment was provided:

- “Would like six month reviews to see how effective treatment and aftercare is.”

All submitted staff questionnaire responses indicated that they felt that clients get the right care, at the right time and with the best outcome for them. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with the authorised users 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 user 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 in a locked filing cabinet and electronic records are password protected.

Client satisfaction surveys are carried out by the establishment on a monthly basis and 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.

Client and staff views

All clients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care. The following comment was provided:

- “Very professional, discreet and helpful staff.”

All submitted staff questionnaire responses indicated that they felt that clients are treated with dignity and respect and are involved in decision making affecting their care. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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4.6 Is the service well led?

Management and governance

There was a clear organisational structure within the establishment and authorised users were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Authorised users confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Ms Mulholland has overall responsibility for the day to day management of the service. Mr Shortt confirmed he visits the clinic at least four to six weekly.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a yearly basis. The policies and procedures were re-indexed following inspection to provide ease of access to them. Staff spoken with were aware of the policies and how to access them.

Discussion with Mr Shortt and staff demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. A minor amendment was made to the procedure during inspection. Discussion with Mr Shortt demonstrated good awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The returned questionnaire indicated that no complaints have been received for the period 1 April 2015 to 31 March 2016.

It was 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.

Discussion with Ms Mulholland and staff confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to clients at appropriate intervals.

It was confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. The following audits were reviewed:

- weekly laser machine
- weekly infection control
- monthly deep clean log
- monthly client feedback
- monthly client record

A whistleblowing/raising concerns policy was available. Public concern at work details were added to the policy following inspection and an electronic copy forwarded to RQIA. Discussion with authorised users confirmed that they were aware of who to contact if they had a concern.

Mr Shortt and Ms Mulholland demonstrated a clear understanding of their roles and responsibilities in accordance with legislation. It was confirmed that the statement of purpose and client's guide are kept under review, revised and updated when necessary and available on request. Amendments were made to both documents and forwarded to RQIA following the inspection.

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

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

Client and staff views

All clients who submitted questionnaire responses indicated that they felt that the service is well managed. The following comments were provided:

- "Very gentle."
- "I have recommended this place to many friends, I wouldn't do that unless I thought in it was top class. 100% happy."

All submitted staff questionnaire responses indicated that they felt that the service is well led. Staff concurred with this on inspection. No comments were included in submitted questionnaire responses.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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5.0 Quality improvement plan

Any issues identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mr Mark Shortt, registered person and Ms Orla Mulholland, registered manager as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of the cosmetic laser service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

5.1 Statutory requirements

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on 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

5.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The DHSSPS Minimum Care Standards for Independent Healthcare Establishments(July 2014). They promote current good practice and if adopted by the registered person(s) may enhance service, quality and delivery.

5.3 Actions to be taken by the registered provider

The QIP should be completed and detail the actions taken to meet the legislative requirements and recommendations stated. The registered provider should confirm that these actions have been completed and return the completed QIP to web portal for assessment by the inspector

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 registered provider from their responsibility for maintaining compliance with the regulations and standards. It is expected that the requirements and recommendations outlined in this report will provide the registered provider with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

Quality Improvement Plan	
Statutory requirements	
Requirement 1 Ref: Regulation 18(2) a Stated: First time To be completed by: 28 March 2017	<p>The registered provider must ensure all authorised users have evidence of up to date basic life support training and IPC training.</p> <p>Response by registered provider detailing the actions taken: Completed - certificates of training also provided.</p>
Requirement 2 Ref: Regulation 19(2)(d) and Schedule 2, as amended Stated: First time To be completed by: 28 March 2017	<p>The registered person must ensure that they have obtained all of the relevant information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 for all staff recruited since registration with RQIA and any new staff recruited. Records must be retained and available for inspection including:</p> <ul style="list-style-type: none"> • an enhanced AccessNI check prior to commencement of employment • criminal conviction declaration <p>Response by registered provider detailing the actions taken: Completed.</p>
Requirement 3 Ref: Regulation 15(2) Stated: First time To be completed by: 28 March 2017	<p>The registered person must ensure an installation report and evidence of ongoing service arrangements in line with manufacturer's instructions is in place for the laser equipment, serial number SI2ICE0217.</p> <p>Response by registered provider detailing the actions taken: Completed.</p>
Recommendations	
Recommendation 1 Ref: Standard 10.6 Stated: First time To be completed by: 28 April 2017	<p>Re-establish staff appraisals on at least on an annual basis.</p> <p>Response by registered provider detailing the actions taken: Completed and planned for upcoming months.</p>

<p>Recommendation 2</p> <p>Ref: Standard 3.1</p> <p>Stated: First time</p> <p>To be completed by: 28 March 2017</p>	<p>The adult safeguarding policy and procedure should be updated to ensure it fully reflects the new regional policy and guidance issued during July 2015.</p>
<p>Recommendation 3</p> <p>Ref: Standard 18.1</p> <p>Stated: First time</p> <p>To be completed by: 28 March 2017</p>	<p>Response by registered provider detailing the actions taken: Updated and complete.</p> <p>Response by registered provider detailing the actions taken: Updated and complete.</p>



The Regulation and Quality Improvement Authority

9th Floor

Riverside Tower

5 Lanyon Place

BELFAST

BT1 3BT

Tel 028 9051 7500

Fax 028 9051 7501

Email info@rqia.org.uk

Web www.rqia.org.uk

 @RQIANews