

Announced Care Inspection Report 28 November 2016



Laserase Clinic

**Type of Service: Independent Hospital (IH) – Cosmetic Laser and IPL
Service and Private Doctor Service**

Address: 525 Antrim Road, Belfast, BT15 3BS

Tel No: 028 9077 7772

Inspector: Stephen O'Connor

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

1.0 Summary

An announced inspection of Laserase Clinic took place on 28 November 2016 from 09:55 to 12:55.

The inspection sought to assess progress with any issues raised during and since the last care inspection and to determine if the 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 Mrs Therese McKeown, registered person, and staff demonstrated that in the main systems and processes were in place, to ensure that care to patients was 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. A requirement has been made to ensure that the authorised user register is maintained up-to-date and all authorised users sign to confirm they have read and understood the local rules. Recommendations have been made that all authorised users undertake mandatory safeguarding training and that the laser safety file is updated to include a copy of the in date local rules and medical treatment protocols.

Is care effective?

Observations made, review of documentation and discussion with Mrs McKeown 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. A recommendation has been made that the Laserase Clinic should establish if they need to register with the Information Commissioner's Office.

Is care compassionate?

Observations made, review of documentation and discussion with Mrs McKeown 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 evidenced that there was effective leadership and governance arrangements in place which creates a culture focused on the needs clients 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 person's understanding of their role and responsibility in accordance with legislation. No requirements or recommendations have been made.

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	1	3

Details of the Quality Improvement Plan (QIP) within this report were discussed with Mrs McKeown, registered person, 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 18 September 2015.

2.0 Service details

Registered organisation/registered person: Laserase Medical Skincare Clinic Mrs Therese McKeown	Registered manager: Mrs Therese McKeown
Person in charge of the home at the time of inspection: Mrs Therese McKeown	Date manager registered: 11 April 2007
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.	

Combined IPL & Laser

Manufacturer: ESC - Sharplan
 Model: Vasculight
 Serial Number: SA 234 7001
 Laser Class: Class 4
 Wavelength: Nd:YAG (1064nm)
 IPL: Single IPL head with interchangeable filters

Dye Laser

Manufacturer: Euphotonics
 Model: NLite – V Multifunction Laser
 Laser Class: Class 4
 Wavelength: 580nm – 590nm

Nd YAG Laser

Manufacturer: Cynosure
 Model: Affirm
 Serial Number: AFRM0037
 Laser Class: Class 4
 Wavelength: 1440nm

Nd YAG Laser

Manufacturer: Cynosure
 Model: Affinity QS
 Serial Number: QPA0470-0508
 Laser Class: Class 4a
 Wavelength: 1064nm & 532nm

IPL Equipment

Manufacturer: Lumenis
 Model: Quantum SA35011000
 Serial Number: 045-01625
 Laser Class: Single head IPL

Laser protection advisor (LPA) – Mr Irfan Azam (Lasernet)

Laser protection supervisor (LPS) – Dr Donal McKeown

Medical support services – Dr Paul Myers (Lasernet)

Authorised users – Dr Donal McKeown, Ms Amanda Houston and Ms Shannon Boyle

Types of Laser and IPL treatments provided – Hair removal, vascular lesions, acne, rosacea, tattoo removal, brown pigmentation lesions, fine lines/wrinkles, photo aging and facial flushing and erythema.

Private Doctor treatments provided – Botox and cosmetic fillers

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: complaints declaration and returned completed staff and client questionnaires.

During the inspection the inspector met with Mrs Therese McKeown, registered person and one authorised user. A tour of some areas 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 18 September 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 18 September 2015

Last care inspection statutory requirements		Validation of compliance
Requirement 1 Ref: Regulation 18 (2) (a) Stated: Second time	The registered person must ensure that all authorised users complete the mandatory training as outlined in the main body of the report.	Partially Met
	Action taken as confirmed during the inspection: Review of authorised user training records evidenced that in the main mandatory training had been completed, with the exception of safeguarding training. Additional information in this regard can be found in section 4.3 of this report.	
	A separate requirement has been made that authorised users complete safeguarding training.	

Requirement 2 Ref: Regulation 15 (7) Stated: First time	The registered person must ensure that the lids of sharps containers are fully locked in place, the temporary closure device should be in operation when not in use and the labels must be fully completed on assembly and permanent closure.	Met
	Action taken as confirmed during the inspection: Observation of sharp containers in treatment rooms one and two evidenced that the labels had been fully completed and that the temporary closure device was being used.	

4.3 Is care safe?

Staffing

Discussion with Mrs McKeown confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and clients. Two medical practitioners provide services in this establishment. However, only one of the medical practitioners is a private doctor.

Mrs McKeown confirmed that laser and IPL treatments are only carried out by authorised users. A register of authorised users was retained in the laser/IPL safety file. Review of the authorised user register evidenced that it contained the name of one of the three authorised users. This is discussed further under Laser/IPL safety.

Mrs McKeown confirmed that the laser protection supervisor (LPS) completes an induction with new authorised users on commencement of employment. Mrs McKeown was advised that a formal induction programme should be developed and records retained.

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, basic life support, infection prevention and control and fire safety.

All other staff employed at the establishment, but not directly involved in the use of the laser and IPL equipment, had received laser safety awareness training on 06 September 2016.

Evidence was available that staff who have professional registration undertake continuing professional development (CPD) in accordance with their professional body's recommendations. Discussion with Mrs McKeown and review of documentation confirmed that authorised users take part in appraisal on an annual basis.

Recruitment and selection

There have been no authorised users recruited since the previous inspection. During discussion Mrs McKeown confirmed that should authorised users be recruited in the future robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

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

Safeguarding

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. Staff were aware of who the nominated safeguarding lead was within the establishment.

Mrs McKeown confirmed that staff including authorised users had not undertaken training in safeguarding adults. A recommendation has been made that all authorised users complete training on safeguarding and the protection of adults at risk of harm and abuse as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014.

Laser/IPL safety

A laser safety file was in place which contained relevant information in relation to laser and IPL equipment. Review of the file evidenced that the local rules and medical treatment protocols had expired. Mrs McKeown confirmed that the LPA visited the establishment during November 2016 and that they had yet to receive the documentation in relation to this visit. This documentation will include updated local rules and document control confirming that the medical treatment protocols have been validated for another year. A recommendation has been made that the laser safety file should be updated to include a copy of the in date local rules and medical treatment protocols.

There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA). The service level agreement between the establishment and the LPA in the laser safety file was reviewed and this expired on 09 September 2016. As discussed a recommendation has been made in this regard.

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers on 17 June 2015. As discussed the establishment is awaiting confirmation that the medical treatment protocols in place are valid and a recommendation has been made in this regard. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

The local rules contained the relevant information pertaining to the IPL and laser equipment being used.

The establishment's LPA completed a risk assessment of the premises on 10 September 2015 and all recommendations made by the LPA have been addressed.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised users is maintained. As discussed review of the authorised user register evidenced that it contained the name of one of the three authorised users. It was also noted that only one of the three authorised users had signed the local rule to confirm that they had read and understood them. A requirement has been made in this regard.

When the laser and IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

The environment in which the laser and IPL 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 and IPL equipment is in use but can be opened from the outside in the event of an emergency.

The laser and IPL equipment is operated using keys. Arrangements are in place for the safe custody of the laser and IPL 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 and IPL equipment is in use and removed when not in use.

The establishment has laser and IPL registers 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 and IPL equipment in line with the manufacturer's guidance. The most recent service reports were reviewed as part of the inspection process.

Management of emergencies

As discussed, authorised users 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 treatment rooms were clean and clutter free. Discussion with Mrs McKeown and an authorised user evidenced that appropriate procedures were in place for the decontamination of equipment between uses. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, authorised users have up to date training in infection prevention and control.

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.

Arrangements are in place for maintaining the environment to include portable appliance testing (PAT) of electrical equipment and routine servicing of the oil fired central heating burner, fire detection system and firefighting equipment.

Mr McKeown confirmed that a fire risk assessment has been undertaken by an external organisation during August 2016, routine checks are undertaken in respect of the fire detection system and review of records confirmed staff have participated in fire drills and fire awareness training.

Client and staff views

Eight clients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. The following comments were provided:

- “I would not pay for a private health service if no protection, clean and safe”
- “Very safe”

Four staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. No comments were included in submitted questionnaire responses.

Areas for improvement

All authorised users must complete safeguarding training as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014.

The laser safety file should be updated to include a copy of the in date local rules and medical treatment protocols.

The authorised user register must be kept up-to-date and all authorised users must sign to confirm that they have read and understood the local rules.

Number of requirements	1	Number of recommendations	2
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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 and IPL 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)

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.

Mrs McKeown confirmed that the establishment is not registered with the Information Commissioners Office (ICO). A recommendation has been made in this regard.

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. Mrs McKeown confirmed that staff meetings are held on a routine basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Mr McKeown confirmed that any learning from complaints and incidents would be disseminated to staff.

Client and staff views

All eight clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. No comments were included in submitted questionnaire responses.

All four 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. No comments were included in submitted questionnaire responses.

Areas for improvement

The establishment should establish if they are required to register with the Information Commissioner's Office.

Number of requirements	0	Number of recommendations	1
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4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with an authorised user regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is provided in private rooms 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.

Client satisfaction surveys are carried out by the establishment on an annual 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. Some comments from clients included:

- “Very good”
- “Great results”
- “Great staff and clinic”
- “Great clinic”

Client and staff views

All eight 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 included in a questionnaire response:

- “Brilliant service”

All four 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. 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 the authorised user spoken with was able to describe her role and responsibilities and she was aware of who to speak to if she had a concern. An authorised user 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. Mrs McKeown has overall responsibility for the day to day management of the service.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed every one to two years. Staff spoken with were aware of the policies and how to access them.

Discussion with Mrs McKeown demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Mrs McKeown and staff demonstrated a 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.

Discussion with Mrs McKeown 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 Mrs McKeown 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. Mrs McKeown confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

In addition to the laser and IPL treatments provided; the establishment also offers a range of cosmetic injectable objects including Botox and fillers which are provided by Dr McKeown, who is a private doctor.

Medical treatment protocols have been developed and implemented for treatments provided by the private doctor.

A range of comprehensive information is provided to clients undergoing Botox and filler treatment that clearly outlines the risks, complications and expected outcomes.

A review of the private doctor's personnel file confirmed that it contained all of the information required by legislation and that he has an appointed responsible officer.

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

Mrs McKeown, registered person/manager demonstrated a clear understanding of her role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. 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.

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

- "I enjoy getting this service as gives me confidence after cancer, staff so professional and I trust them all"
- "Very well"

All four submitted staff questionnaire responses indicated that they felt that the service is well led. 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 Mrs McKeown, registered person/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 IH-Cosmetic Laser\Intense Pulsed Light and Private Doctor. 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 Independent.Healthcare@rqia.org.uk 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 15 (1) (b) Stated: First time To be completed by: 28 December 2016	<p>The authorised user register must be kept up to date. All authorised users must sign to confirm they have read and understood the local rules.</p> <p>Response by registered provider detailing the actions taken:</p> <p><i>Completed</i></p>
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Recommendations

Recommendation 1 Ref: Standard 3.9 Stated: First time To be completed by: 28 December 2016	<p>All authorised users must complete mandatory safeguarding adults training. Records of training must be retained for inspection.</p> <p>Response by registered provider detailing the actions taken:</p> <p><i>In process</i></p>
Recommendation 2 Ref: Standard 48.3 and 48.5 Stated: First time To be completed by: 28 December 2016	<p>The laser safety file should be updated to include a copy of the in date local rules and medical treatment protocols.</p> <p>Response by registered provider detailing the actions taken:</p> <p><i>awaiting from Lasernet</i></p>
Recommendation 3 Ref: Standard 8.5 Stated: First time To be completed by: 28 December 2016	<p>Laserase Clinic should establish if they are required to register with the Information Commissioner's Office in keeping with the Data Protection Act 1988.</p> <p>Response by registered provider detailing the actions taken:</p> <p><i>To be established.</i></p>