

Announced Care Inspection Report 30-31 August 2016



Optilase Therapie

Type of service: Independent Hospital - Refractive Laser Eye Surgery and Cosmetic Laser Service Address: Unit 4 Cleaver House, Donegall Place, Belfast BT1 5BB Tel No: 02890438397 Inspectors: Winnie Maguire and Emily Campbell RQIA's Medical Physics Advisor: Dr Ian Gillan

<u>www.rqia.org.uk</u>

Assurance, Challenge and Improvement in Health and Social Care

1.0 Summary

An announced inspection of Optilase Therapie took place on 30 and 31 August 2016 from 10.10 to 16.30 and 10.00 to 15.30 respectively.

Dr Ian Gillan, RQIA's Medical Physics Advisor accompanied the inspectors to review the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

The inspection sought to assess progress with any issues raised during and since the previous 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 Mr Mark Shortt, registered person/manager and staff demonstrated that systems and processes were in place to ensure that care to patients was safe and avoids and prevents harm. Areas reviewed included, staffing, recruitment and selection, safeguarding, laser safety, management of medical emergencies, infection prevention control and decontamination and the general environment. Four recommendations were made in relation to the revision of the medical treatment protocols in accordance with the treatments provided using the Harmony XL machine, the revision of the medical treatment protocols for refractive laser eye surgery by the current consultant ophthalmologists, the further development of the safeguarding policy and procedure and the identification of a laser protection supervisor (LPS) for the dermatological laser service on a daily basis.

Is care effective?

Observations made, review of documentation and discussion with Mr Shortt 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 and communication. No requirements or recommendations have been made.

Is care compassionate?

Observations made, review of documentation and discussion with Mr Shortt 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 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, arrangements for practising privileges, 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	0	Л
recommendations made at this inspection	0	4

Details of the QIP within this report were discussed with Mr Mark Shortt, registered person/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 previous QIP there were no further actions required to be taken following the last inspection..

2.0 Service details

Registered organisation/registered person: Therapie Clinic Ltd Mr Mark Shortt	Registered manager: Mr Mark Shortt
Person in charge of the establishment at the time of inspection: Mr Mark Shortt	Date manager registered: 3 October 2012

Categories of care:

(IH) Independent Hospital - 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

Laser Equipment

The laser services are provided in two distinct categories:

- Refractive laser eye surgery
- Dermatological laser service

Refractive Laser Eye Surgery

Laser Equipment

Manufacturer: Laser Class: Model: Serial Number:	Schwind A Class 4 Armaris 500 M110	E
Manufacturer: Laser Class: Model: Serial Number:	Abbott Medical Systems (AMO) Class 3B Intralase IFS Advanced Femtosecond F50511-70169	
Laser Protection Adviso	r (LPA):	Alex T Zarneh
Laser Protection Superv	isor (LPS):	Lawrence Dowie Lisa McDowell
Clinical authorised user	s:	Antonio Montanes (Consultant Ophthalmologist) Evangelos Minos (Consultant Ophthalmologist)
Non clinical authorised	Users:	Lawrence Dowie Lisa McDowell Samantha Mallon
Types of Treatment prov	vided:	Refractive eye surgery - Lasix and Lasex

Dermatological Laser Services

Laser Equipment

Manufacturer:	Alma	
Laser Class:	Class 4	
Model:	Harmony XL	
Serial Number:	HXL01057	
Manufacturer:	Alma	
Locar Cloce:	Class 1 infrared	

Laser Class:	Class 4 + infrared
Model:	Soprano
Serial Numbers:	S12P0071, S12P0072, S12P1079 (3 machines)

Associated equipment

Equipment:	Plume evacuator
Manufacturer:	Quatro
Model:	Fresh Air 400
Serial number:	18461

Equipment: Manufacturer: Model: Serial number:	Skin Cooler ABC Lasercryo aii 110310483	r
Laser protection advisor	r (LPA):	Alex Zarneh
Laser protection superv	isor (LPS):	Michelle Connor and in her absence another named authorised user
Medical support service	S:	Dr Ross Martin
Authorised users		
Alma Soprano laser:		Michelle Connor Collette Murray Emma Douglas Nicola McKee Rachel Mullan
Harmony XL laser:		Michelle Connor Emma Douglas Collette Murray Nicole McKee
Types of Treatment Prov	vided	
Alma soprano laser:		Hair removal/reduction
Harmony XL laser:		Skin resurfacing Skin rejuvenation

3.0 Methods/processes

Questionnaires were provided to patients/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 patient/client questionnaires.

During the inspection the inspectors met with Mr Shortt, registered person, a consultant ophthalmologist who is a clinical authorised user, a non-clinical authorised user (refractive laser eye service) and two authorised users (dermatological laser service). 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
- care pathway
- communication
- management and governance arrangements
- practising privileges
- maintenance arrangements

4.0 The inspection

4.1 Review of requirements and recommendations from the most recent inspection dated 4 August 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 4 August 2015

Last care inspection	statutory requirements	Validation of compliance
Requirement 1 Ref: Regulation 23 Stated: Second time	The registered person/manager must ensure complaints are robustly managed in line with the establishment's complaints procedure and legislation. Action taken as confirmed during the inspection: Review of the complaints records confirmed complaints are managed in line with the establishment's complaints procedure and legislation.	Met
Last care inspection	recommendations	Validation of compliance
Recommendation 1 Ref: Standard 7 Stated: First time	The registered person/manager should establish and implement an audit of complaints. Action taken as confirmed during the inspection: An audit of complaints has been incorporated into the establishment's quality assurance programme.	Met

4.3 Is care safe?

Staffing

Discussion with Mr Shortt and staff, confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients/clients. This includes a team of consultant ophthalmologists, an optometrist, a nurse and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery. The dermatological laser service is staffed separately by five authorised users.

Mr Shortt confirmed that refractive laser eye procedures are only carried out by trained medical practitioners acting as clinical authorised users and laser technicians acting as nonclinical authorised users. A register of clinical and non-clinical authorised users for the lasers is maintained and kept up to date in respect of the refractive laser eye surgery service. A register of authorised users is also maintained for the dermatological laser service.

A review of completed induction programmes evidenced that induction training is provided to new staff on commencement of employment.

A review of training records evidenced that all 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 equipment, have received laser safety awareness training.

Evidence was available that confirms that staff who have professional registration, undertake continuing professional development (CPD) in accordance with their professional body's recommendations.

Discussion with Mr Shortt and review of documentation confirmed that there are systems in place for undertaking, recording and monitoring all aspects of staff supervision and ongoing professional development for staff. Staff appraisal had been undertaken in respect of some staff and Mr Shortt confirmed staff appraisal for all other staff has been arranged in the coming weeks.

A review of two consultant ophthalmologist's details confirmed there was evidence of the following:

- confirmation of identity
- current General Medical Council (GMC) registration
- professional indemnity insurance
- qualifications in line with service provided
- ongoing professional development and continued medical education that meets the requirements of the Royal Colleges and GMC
- ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer
- arrangements for revalidation

Recruitment and selection

A review of two personnel files of authorised users recruited since the previous inspection and discussion with Mr Shortt confirmed that new staff have been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005.

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

Safeguarding

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.

Policies and procedures were in place for the safeguarding and protection of adults and children. A recommendation was made to revise the policy and procedure for adult protection in accordance to the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July2015) and ensure all staff sign to confirm they have read and understood the policy. A copy of the guidance was forwarded to Mr Shortt following inspection. A copy of the relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise was also shared with Mr Shortt during inspection. Mr Shortt confirmed he would implement the policy including the identification and training of a safeguarding champion for the organisation.

Laser Safety

Refractive laser eye surgery service

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 LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this expires in July 2017.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols approved by a consultant ophthalmologist who no longer works in the establishment. A recommendation was made that the current consultant ophthalmologists devise the medical treatment protocols for refractive laser eye surgery.

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 June 2016 and no recommendations were made.

A list of clinical and non-clinical authorised users was maintained and authorised users have signed to state that they have read and understood the local rules.

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

Discussion with staff confirmed that systems are in place to ensure other authorised users are aware 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 controlled area is clearly defined and not used for other purposes, or as access to areas, when surgery is being carried out.

The door to the laser suite 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 keys and passwords. Arrangements were in place for the safe custody of the laser keys when not in use and passwords are only known by authorised users.

Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

Protective eyewear was available for laser technicians if required, as outlined in the local rules.

The establishment has a laser surgical 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 review of the laser surgical register during the inspection found it to be comprehensively completed.

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 18 July 2016 and 8 August 2016 were reviewed as part of the inspection process.

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser safety arrangements for the refractive laser eye surgery service; the findings and report of Dr Gillan is appended to this report.

Dermatological laser service

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Ross Martin and reviewed on 3 May 2016. Systems are in place to review the medical treatment protocols on an annual basis. The medical treatment protocol for the use of the Soprano Ice machine contained the relevant information pertaining to the treatments provided in the establishment. The medical treatment protocols for the Harmony XL contained a wide range of information pertaining to treatments which the laser machine could provide, however, the establishment did not provide all of these treatments. A recommendation was made to revise the medical treatment protocols in accordance to the treatments provided in the establishment using the Harmony XL machine.

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 June 2016 and no recommendations were made.

Authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

The local rules stated all authorised users can act as LPS. When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. A recommendation was made that the LPS on duty for the dermatological laser service is clearly identified and other authorised users 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 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 keys. 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 a laser register for each laser 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

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 4 May 2016 were forwarded to RQIA following inspection.

Management of Medical Emergencies

A review of medical emergency arrangements evidenced that emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment.

The policy on resuscitation was in place and provided clear instructions on what to do in the event of a medical emergency.

Infection Prevention and Control and Decontamination Procedures

There were clear lines of accountability for infection prevention and control (IPC) in place.

A range of information was available for patients/clients and staff regarding hand washing techniques.

Arrangements were in place to ensure the decontamination of equipment and reusable medical devices is in line with manufacturer's instructions and current best practice. Staff confirmed single use equipment is used where possible. Theatre sterile packs are provided from an accredited organisation.

Staff have been provided with IPC training commensurate with their role.

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
- post treatment infection

The compliance rate was noted to be very high and an action plan was in place for areas of non-compliance.

There were a range of IPC policies and procedures in place which are held within an IPC manual.

A review of infection control and prevention arrangements indicated very good infection control practices are embedded in the establishment.

Environment

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

Detailed cleaning schedules were in place and completed records of cleaning were displayed in various areas. Carbon dioxide (CO2) fire extinguishers were available which had been serviced within the last year.

Arrangements are in place for maintaining the environment. A legionella risk assessment has been undertaken and water temperature is monitored and recorded as recommended. 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.

Patient/client and staff views

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

• "Staff are very approachable and friendly "

Fifteen staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. Staff spoken with during the inspection concurred with this. No written comments were provided.

Areas for improvement

Revise the policy and procedure for adult protection in accordance with the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015) and ensure all staff sign to confirm they have read and understood the policy.

The current consultant ophthalmologists should devise the medical treatment protocols for refractive laser eye surgery.

The medical treatment protocols should be amended to be in accordance with the treatments provided in the establishment using the Harmony XL machine.

The LPS on duty for the dermatological laser service should be clearly identified and other authorised users should be aware of who the LPS on duty is.

Number of requirements	0	Number of recommendations	4

4.4 Is care effective?	
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Care Pathway

Refractive laser eye surgery

Patients have an initial consultation with a qualified optometrist who discusses their treatment options and the cost of the surgery.

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

The establishment has a list of fees available for each type of surgical procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the individual patient's prescription and surgery options available to them.

The consultant ophthalmologist confirmed that in accordance to GMC guidance, patients meet with their surgeon on a separate day in advance of surgery, to discuss their individual treatment and any concerns they may have. They also meet the surgeon again on the day of surgery to complete the consent process for surgery.

Patients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

Patients are provided with clear post-operative instructions along with contact details for a senior optometrist if they experience any concerns. There are systems in place for the senior optometrist to refer patients directly to a consultant ophthalmologist if necessary.

Systems are in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

Seven patient care records were reviewed. The establishment retains hard copy care records which are supplemented with an electronic record system. The patient care records were well documented, contemporaneous and clearly outlined the patient journey. The care records reviewed contained the following.

- patient details
- medical history
- signed consent form
- initial consultation
- pre-operative notes
- intra-operative notes
- post-operative notes
- review/follow up notes

Dermatological laser service

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 was an accurate and up to date treatment record for every client which included:

- 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)

Records management

Systems were in place to audit the completion of clinical records and an action plan is developed to address any identified issues. The outcome of the audit is reviewed through the establishment's clinical governance structures.

Information was available for patients/clients on how to access their health records, under the Data Protection Act 1998.

The establishment is registered with the Information Commissioner's Office (ICO).

A review of documentation confirmed that the establishment has a range of policies and procedures in place for the management of records which includes the arrangements for the creation, use, retention, storage, transfer, disposal of and access to records.

The establishment also has a policy statement in place for clinical record keeping in relation to patient treatment and care which complies with GMC guidance and Good Medical Practice.

Communication

As discussed, there was written information for patients 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. Staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the establishment.

Patient/client and staff views

All of the sixteen patients/clients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. No written comments were provided.

Fifteen submitted staff questionnaire responses indicated that they felt that patients get the right care, at the right time and with the best outcome for them. Staff spoken with during the inspection concurred with this. No written comments were provided.

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0

4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with staff regarding the consultation and treatment or surgery confirmed that patients'/clients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient/client and the optometrist or authorised user. Laser surgery is provided within a designated laser suite.

Information is provided to the patient/client in verbal and written form at all consultations to allow the patient/client to make choices about their care and treatment and provide informed consent.

Patients meet with the surgeon on a separate day in advance of surgery and are fully involved in decisions regarding their treatment. Patients' wishes are respected and acknowledged by the establishment.

Appropriate measures are in place to maintain patient/client confidentiality and observations made evidenced that care records were stored securely in locked filing cabinets and electronic records are password protected.

Separate patient and client satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a monthly summary report which is made available to patients/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 patients/clients were satisfied with the quality of treatment, information and care received. Some comments from patients/clients included:

- "Friendly and knowledgeable"
- "Xxx was very pleasant and felt very comfortable with her"
- "Excellent therapist"
- "The amount of information was prefect"
- "Excellent customer service as she explained the process well and made me feel at ease"
- "Always very focused and helpful"
- "Overall everything good"
- "Fantastic service"
- "Level of care was excellent"
- "Shorter waiting times would help with the nerves"
- "The clinic was very busy a little unsettling"

Mr Shortt confirmed action had been taken in relation to the waiting times for the refractive laser eye service.

Patient/client and staff views

All of the sixteen patients/clients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care. No written comments were provided.

Fifteen submitted staff questionnaire responses indicated that they felt that patients/clients are treated with dignity and respect and are involved in decision making affecting their care. Staff spoken with during the inspection concurred with this. No written comments were provided.

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 staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Staff confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Mr Shortt 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 on annual basis. Staff spoken with were aware of the policies and how to access them.

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

A copy of the complaints procedure was available in the establishment. Discussion with Mr Shortt demonstrated an increased awareness of complaints management following last year's inspection. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice.

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.

Mr Shortt confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. A monthly

audit is conducted and 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 audit programme included the following:

- laser log completion
- laser goggles safety
- laser machine service records
- clinic policies/procedures
- cleaning schedules
- staff personnel files, training and certificates
- complaints
- patient/client files
- comment card completion

Mr Shortt outlined the process for granting practising privileges and confirmed medical practitioners meet with him prior to privileges being granted.

Two medical practitioner's personnel files reviewed confirmed that there was a written agreement between each medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years. One medical practitioner's practising privilege agreement stated a three year review date. Mr Shortt confirmed this would be amended immediately to a two year review date.

A policy and procedure was in place in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

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

Mr Shortt demonstrated an understanding of his role and responsibility in accordance with legislation. It was confirmed that the Statement of Purpose and Patient's 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.

Patient/client and staff views

All of the 16 patients who submitted questionnaire responses indicated that they felt that the service is well managed. The following comment was provided:

• "I have just had my first treatment with Xxx, her knowledge and expertise are excellent, she made me feel at ease and comfortable. All round excellence!"

Fifteen submitted staff questionnaire responses indicated that they felt that the service is well led. Staff spoken with during the inspection concurred with this. No written comments were provided.

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/manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/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 provider 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 refractive laser eye surgery and cosmetic laser service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the laser services 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 provider 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 provider/manager 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 <u>independent.healthcare@rqia.org.</u>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

Recommendations	
Recommendation 1 Ref: Standard 3	Revise the policy and procedure for adult protection in accordance with the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015) and ensure all staff sign to confirm they have read and understood the policy.
Stated: First time	
	Response by registered provider detailing the actions taken:
To be completed by:	Completed and on file.
30 September 2016	
Recommendation 2	The current consultant ophthalmologists should devise the medical
	treatment protocols for refractive laser eye surgery.
Ref: Standard 48	
	Response by registered provider detailing the actions taken:
Stated: First time	Completed and on file.
To be completed by:	
30 September 2016	
Recommendation 3	The medical treatment protocols should be amended to be in
	accordance with the treatments provided in the establishment using the
Ref: Standard 48	Harmony XL machine.
Stated: First time	Response by registered provider detailing the actions taken:
	Completed and on file.
To be completed by:	
30 September 2016	
·	
Recommendation 4	The LPS on duty for the dermatological laser service should be clearly
	identified and other authorised users should be aware of who the LPS
Ref: Standard 48	on duty is.
Stated: First time	Response by registered provider detailing the actions taken:
	Completed and on file.
To be completed by:	
30 September 2016	





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