Announced Care Inspection Report
10 November 2020

Optilase Therapie

Type of Service: Independent Hospital (IH) – Refractive Eye Lasers
Address: 36 Ann Street, Belfast BT1 4EG
Tel No: 080 0012 1565
Inspectors: Karen Weir and Norma Munn

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

1.0 What we look for

In respect of refractive eye laser services for the 2020/21 inspection year we are moving to a more focused, shorter inspection which will concentrate on the following key patient safety areas:

- management of operations in response to COVID-19 pandemic;
- infection prevention and control (IPC);
- laser safety;
- organisational and medical governance;
- staff and patient feedback; and
- review of areas for improvement identified during the previous care inspection (if applicable).

2.0 Profile of service

Optilase Therapie is registered with the Regulation and Quality Improvement Authority (RQIA) as an Independent Hospital (IH) with the following categories of care: Prescribed Techniques or Prescribed Technology: establishments using Class 3B or Class 4 lasers and establishments using Intense Light sources PT (IL); and Private Doctor (PD) service.

The laser services are provided in two distinct categories:

- Refractive laser eye surgery; and
- Dermatological laser service.

The establishment also provides a range of cosmetic/aesthetic treatments.

This announced inspection focused solely on those treatments provided using the refractive lasers that fall within regulated activity and the Private Doctor category of care for which the establishment is registered with RQIA.

We did not review the dermatological laser service during this inspection as this service had been the focus of our recent inspection on 25 September 2020.

During this inspection we reviewed progress made in addressing the areas of improvement, relating to the dermatological laser service, identified as a result of our inspection on 25 September 2020.

Refractive Laser Eye Surgery

Laser Equipment

Manufacturer:	Schwind A
Laser Class:	Class 4
Model:	Armaris 500E
Serial Number:	M110

Manufacturer:	Abbott Medical Systems (AMO)
Laser Class:	Class 3B
Model:	Intralase IFS Advanced Femtosecond
Serial Number:	F50511-70169

Laser Protection Advisor (LPA):

Mr Alex Zarneh

Laser Protection Supervisors (LPS):

Mr Lawrence Dowie
Ms Lisa McDowell

Clinical authorised operators:

Dr Jain Rantitlal (Consultant Ophthalmologist)
Dr Karim Tourkmani (Consultant Ophthalmologist)

Non clinical authorised operators:

Mr Lawrence Dowie
Ms Lisa McDowell

Types of Treatment provided:

Refractive laser eye surgery - Lasix and Lasex

Dermatological laser services

Laser equipment (six identical lasers, one of which had been recently installed)

Manufacturer:	Cynosure
Laser Class:	Class 4
Model:	Elite EM+
Wavelength:	Alexandrite- 755nm, Nd-Yag -1064nm
Serial Numbers:	ELM1703, ELM1978, ELM1975, ELM 1976, ELM1820 and ELM2667

Laser protection advisor (LPA):

Mr Alex Zarneh

Laser protection supervisor (LPS):

Ms Orla Mulholland

Medical support services:

Dr Paul Reddy (Medical Director of Therapie)

Authorised operators:

Ms Lisa Marie Saygivar, Ms Robyn McCullagh, Ms Aine Russell, Ms Rachael McGarry, Ms Kara Minnis, Ms Louise Smyth, Ms Eimear Fitzpatrick, Ms Rachael Murphy, Ms Rachael McCaughey, Ms Kate McMullan, Ms Emma McClure, Ms Megan Burke and Ms Niamh Quinn.

Types of treatment provided:

Hair removal/reduction

3.0 Service details

Organisation/Registered Provider: Therapie Clinic Ltd **Responsible Individual:** Mr Phillip McGlade	**Registered Manager:** Ms Orla Mulholland
Person in charge at the time of inspection: Ms Orla Mulholland	**Date manager registered:** 4 December 2018
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology; establishments using Class 3B or Class 4 lasers; PT(IL) intense light; and PD Private Doctor.	

4.0 Inspection summary

We undertook an announced inspection on 10 November 2020 from 10:00 to 15:00. We were accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor. The findings and report of Dr Gillan are appended to this report.

This inspection was underpinned by The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, The Independent Health Care Regulations (Northern Ireland) 2005, The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011 and the Department of Health (DoH) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

The purpose of this inspection was to focus on the themes for the 2020/21 inspection year. A poster informing an inspection was being conducted was displayed during the inspection.

We found evidence of good practice in relation to the management of operations in response to the COVID-19 pandemic; laser safety; IPC procedures; and the organisational and medical governance arrangements.

No immediate concerns were identified regarding the delivery of front line patient care.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	0

This inspection resulted in no areas for improvement being identified. We discussed the findings of the inspection with Ms Orla Mulholland, Registered Manager, as part of the inspection process and can be found in the main body of the report.

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

4.2 Action/enforcement taken following the most recent care inspection dated 25 September 2020

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 25 September 2020.

5.0 How we inspect

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

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

Questionnaires were provided to patients, prior to the inspection, by the establishment on our behalf. We also invited staff to complete an electronic questionnaire prior to the inspection. Returned patient and staff questionnaires, submitted to us, are discussed in section 6.9 of this report.

We undertook a tour of the premises, met with, Ms Orla Mulholland, Registered Manager; the clinic manager; a registered nurse and a receptionist; and reviewed relevant records and documents in relation to the day to day operation of the establishment.

We found evidence of good practice in relation to the management of operations in response to COVID-19 pandemic; IPC; laser safety; medical governance; staff and patient feedback; and follow up on previous areas for improvement.

No immediate concerns were identified regarding the delivery of front line patient care.

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

The findings of the inspection were provided to Ms Mulholland, Registered Manager, at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent unannounced care inspection dated 25 September 2020

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

6.2 Review of areas for improvement from the last unannounced care inspection dated 25 September 2020

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for improvement 1 **Ref**: Regulation 19 (2), as amended	The Registered Person shall ensure that all information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is obtained prior to the commencement of employment.	**Met**
	Action taken as confirmed during the inspection: We confirmed that several staff had been recruited in the past 12 months. We reviewed five personnel files of the newly staff employed and found that information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005,in general, had been sought and retained. We identified that two written references were not in place for staff members in two of the files reviewed. We evidenced that telephone references had been sought for these staff members and that verbal references had been documented in this regard. We advised that in the future two written references should be sought and retained. Ms Mulholland gave assurances that this issue would be addressed.	
Area for improvement 2 **Ref:** Regulation 21 (3), Schedule 3, Part II (8) **Stated:** First time	The Registered Person shall ensure that recruitment and selection records as specified in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 are available at all times for inspection.	**Met**
	Action taken as confirmed during the inspection: We were informed that all recruitment and selection records would be available at all times for inspection. We reviewed five personnel files of the newly staff employed and found that information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 had been	

	sought and retained with the exception of written references as discussed above.	
Area for improvement 3 **Ref:** Regulation 39 (2) **Stated:** First time	The registered person shall ensure that laser safety warning signs are illuminated outside of the laser room when the laser is in use and turned off when not in use.	**Met**
	Action taken as confirmed during the inspection: We were informed by staff that laser safety warning signs are illuminated outside of the laser rooms when the lasers are in use and turned off when not in use.	
Area for improvement 4 **Ref:** Regulation 15 (7) **Stated:** First time	The Registered Person shall address the identified infection prevention and control issues as follows: • ensure that hand hygiene posters are displayed in laser treatment rooms and in the visitors toilet area; • ensure that disposable hand towels are provided in the identified treatment room beside the hand wash basin; • ensure that cleaning records are kept up to date; • declutter the identified laser treatment room to ensure effective cleaning can take place; • ensure staff are adhering to hand hygiene and uniform policy in keeping with best practice; • ensure that staff have sufficient time scheduled between patient appointments to clean the environment effectively ; and • review and strengthen the IPC audit to provide an appropriate level of assurance regarding the issues identified.	**Met**
	Action taken as confirmed during the inspection: We reviewed arrangements for IPC procedures throughout the establishment and we confirmed that all of the issues identified, in regards to IPC, had been addressed.	

Area for improvement 5 **Ref:** Regulation 26 **Stated:** Second time	The Registered Person shall ensure that arrangements for six monthly unannounced quality monitoring visits are established and implemented in accordance to Regulation 26.	**Met**
	Action taken as confirmed during the inspection: We reviewed the most recent quality monitoring report undertaken on 9 October 2020, on behalf of the Registered Provider, as required under Regulation 26. We were informed that the report is made available for patients; clients; their representatives; staff; RQIA; and any other interested parties to read. Staff informed us that Regulation 26 reports would be conducted on a six monthly basis.	
Area for improvement 6 **Ref:** Regulation 23	The Registered Person shall ensure that complaints are managed in accordance to legislation and the establishment's complaints procedure. Comprehensive complaints records should be available for inspection.	**Met**
	Action taken as confirmed during the inspection: We reviewed the complaints policy and procedure and found that it was in accordance with current legislation. We examined complaints records and found evidence that complaints were being fully recorded and investigated, outcomes established and any learning implemented.	
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		**Validation of compliance**
Area for improvement 1 **Ref**: Standard 20.2 **Stated:** First time	The Registered Person shall ensure that COVID-19 policies and procedures are developed and updated in keeping with best practice guidance and made available for staff reference.	**Met**
	Action taken as confirmed during the inspection: We found that COVID-19 policies and procedures had been developed and were in keeping with best practice guidance. We noted that these policies were accessible to staff at any time.	

Area for improvement 2 **Ref**: Standard 48.13 **Stated:** Second time	The Registered Person shall ensure that staff who are not directly involved in the laser service, have laser safety awareness training and a record is maintained and available for inspection.	**Met**
	Action taken as confirmed during the inspection: We were informed that all staff, not directly involved in the use of the laser equipment, had received laser safety awareness training.	
Area for improvement 3 **Ref**: Standard 9.3 **Stated:** Second time	The Registered Person shall strengthen audit arrangements for the review of laser rooms to include inspection of the protective eyewear to ensure it is fit for purpose.	**Met**
	Action taken as confirmed during the inspection: We were informed that IPC audits of the laser rooms had been undertaken daily. We reviewed a sample of audits and found these had been strengthened to include the inspection of protective eyewear.	
Area for improvement 4 **Ref**: Standard 10.6 **Stated:** First time	The Registered Person shall ensure that staff appraisals are carried out and recorded at least annually. Consideration should be given to provide management personnel who conduct staff appraisals with training in relation to this role.	**Met**
	Action taken as confirmed during the inspection: We confirmed that staff appraisal systems were now in place. Ms Mulholland confirmed that staff appraisals will be carried out on an annual basis.	
Area for improvement 5 **Ref**: Standard 18.3	The Registered Person shall ensure the provision a portable suction machine as part of the emergency medical equipment available in the establishment.	**Met**
	Action taken as confirmed during the inspection: We confirmed a portable suction machine had been provided.	

Area for improvement 6 **Ref**: Standard 7.1 **Stated:** First time	The Registered Person shall ensure that the complaint's procedure should be updated to include a clear outline of roles and responsibilities in relation to complaints reflecting current organisational structures and RQIA's name, address and telephone number as a regulatory only.	**Met**
	Action taken as confirmed during the inspection: We reviewed the updated complaints policy and procedure and found that it included clear outline of roles and responsibilities in relation to complaints, reflecting current organisational structures and included RQIA's name, address and telephone number as a regulatory body.	

6.3 Inspection findings

6.4 Management of operations in response to the COVID-19 pandemic

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular businesses need to consider the risks to their patients and staff.

We discussed the management of operations in response to the COVID-19 pandemic with Ms Mulholland and staff. They outlined the measures taken by Optilase Therapie to ensure current best practice measures were in place. We determined that appropriate actions had been taken in this regard.

We found that COVID-19 policies and procedures were in place in keeping with best practice guidance.

Areas of good practice: Management of operations in response to COVID-19 pandemic

We confirmed the establishment had identified a COVID-19 lead; had reviewed and amended policies and procedures in accordance with DoH guidance to include arrangements to maintain social distancing; prepare staff; implement enhanced IPC procedures; and the patient pathway.

Areas for improvement: **Management of operations in response to COVID-19 pandemic**

We identified no areas for improvement regarding the management of operations in response to the COVID-19 pandemic.

	Regulations	Standards
Areas for improvement	0	0

6.5 Laser Safety

We reviewed the arrangements in respect of the safe use of the laser equipment.

We reviewed the laser safety file and found that it contained all of the relevant information in relation to the lasers. We found 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 had been reviewed and was up to date. We noted the establishment's LPA completed a risk assessment of the premises during November 2020 and no recommendations were made.

We evidenced that refractive eye surgical procedures are carried out by consultant ophthalmologists in accordance with medical treatment protocols they produced. We identified that the medical treatment protocols had not been signed off by the consultant ophthalmologists as being reviewed on an annual basis. Following the inspection we were informed that the medical treatment protocols had been reviewed and assurances were given that in the future these will be reviewed on an annual basis.

We found up to date Local Rules in place which have been developed by the LPA and these contained the relevant information pertaining to the laser equipment being used. We confirmed arrangements were in place to review the Local Rules on an annual basis. We reviewed the Local Rules and confirmed they included the following:

- the potential hazards associated with lasers;
- controlled and safe access;
- authorised operators' responsibilities;
- methods of safe working;
- safety checks;
- personal protective equipment;
- prevention of use by unauthorised persons; and
- adverse incident procedures.

We identified issues relating to the Local Rules in regards to protective eyewear and laser illumination signs that required minor amendments. Following inspection these were addressed by Ms Mulholland and a copy of the new local rules was submitted, to us, to reflect this.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Staff told us arrangements were in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to fulfil the role.

We reviewed training records and found that authorised operators had up to date training in core of knowledge; safe application for the equipment in use; basic life support; infection prevention and control; fire safety awareness; and safeguarding adults at risk of harm in keeping with the RQIA training guidance. As discussed in section 6.2 we were informed that all other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

We confirmed that a laser surgical register is maintained every time the lasers are operated and includes:

- the name of the person treated;

- the date;
- the operator; and
- the treatment given.

We reviewed the laser surgical register during the inspection and found it to be comprehensively completed.

We reviewed the laser suite and found the environment in which the laser equipment is used to be safe and controlled to protect other persons while treatment is in progress.

We noted 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. We confirmed that the laser suite is a controlled area that is clearly defined and not used for other purposes, or as access to areas when treatment is being carried out.

We observed the lasers are operated using keys and passwords that unauthorised staff do not have access to. We reviewed the arrangements in relation to the safe custody of the keys and passwords and confirmed the arrangements to be satisfactory.

We confirmed that protective eyewear was available for use. However, this eyewear was not outlined in the Local Rules for authorised operators if required. We advised if protective eyewear is available then the Local Rules should be amended to provide guidance on their use. Following the inspection we confirmed this had been addressed by the LPA.

We were informed by staff that laser safety warning signs are illuminated outside of the laser rooms when the lasers are in use and turned off when not in use. However, the laser safety warning signs contained in the Local Rules did not reflect the type of laser warning signs used in the establishment. We advised that the Local Rules should be reviewed to reflect the type of warning signs used. Following the inspection we confirmed this had been addressed by the LPA.

Arrangements have been established for equipment to be serviced and maintained in line with the manufacturers' guidance. We reviewed the most recent service reports which were dated July 2020.

We observed carbon dioxide (CO2) fire extinguishers, suitable for electrical fires were available in the establishment. We confirmed that arrangements were in place to ensure these fire extinguishers will be serviced, in keeping with manufacturer's instruction.

Laser Safety Care Pathway

We confirmed that all patients have an initial consultation with an optometrist who discusses their treatment options and the cost of the surgery.

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

We found 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.

We confirmed that in accordance to General Medical Council (GMC) and the Royal College of Ophthalmologists 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.

We found that 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 also provided with clear post-operative instructions along with contact details if they experience any concerns. We evidenced systems were in place to refer patients directly to a consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

We reviewed six patient care records. We found the establishment retains hard copy care records which are supplemented with an electronic record system. We confirmed that 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; and
- review/follow up notes.

Areas of good practice: Laser safety

We reviewed the current arrangements with respect to laser safety and the patient pathway and evidenced good practice that was being actively reviewed.

Areas for improvement: Laser safety

We identified no areas for improvement regarding the management of laser safety within the establishment.

	Regulations	Standards
Areas for improvement	0	0

6.6 Infection prevention control (IPC)

We reviewed arrangements for IPC procedures throughout the establishment to evidence that the risk of infection transmission to patients, visitors and staff was minimised. We confirmed that the clinic had an overarching IPC policy and procedures in place.

We undertook a tour of the premises and noted that the establishment was clean, tidy and uncluttered. We found that all areas of the establishment were fully equipped to meet the needs of patients. We reviewed arrangements in relation to IPC procedures throughout the

establishment and found that the risk of infection transmission to patients, visitors and staff was minimised.

We found that arrangements were in place to ensure that staff received IPC and COVID-19 training commensurate with their roles and responsibilities. Staff who spoke with us demonstrated good knowledge and understanding of IPC procedures.

We found that cleaning schedules were in place and completed. Ms Mulholland and staff described the arrangements to decontaminate the environment and equipment between patients and we found these to be satisfactory.

We confirmed that no reusable medical devices are used in the clinic. We established that personal protective equipment (PPE) was readily available in keeping with best practice guidance. We observed that there were social distancing screens in place at the reception desk and that hand sanitisers were readily available for staff and patient use throughout the clinic.

Staff told us that appointments are scheduled to minimise the number of patients in the waiting area and that following every appointment the seating in the waiting area and all touch points (door handles etc) are decontaminated.

We confirmed waste management arrangements were in place and we observed clinical waste bins were pedal operated in keeping with best practice guidance.

We found that arrangements were in place to ensure that staff received IPC and COVID-19 training commensurate with their roles and responsibilities. Staff who spoke with us demonstrated good knowledge and understanding of IPC procedures.

We noted that the laser suite provided dedicated hand washing facilities and were informed that hand sanitiser was available in each consultation room.

Areas of good practice: Infection prevention and control (IPC)

We reviewed the current arrangements with respect to IPC practice and evidenced good practice that was being actively reviewed.

Areas for improvement: Infection prevention and control (IPC)

We identified no areas for improvement regarding IPC practice.

	Regulations	Standards
Areas for improvement	0	0

6.7 Organisational and Medical governance

We examined various aspects of the organisational and medical governance systems in place and found there was a clear organisational structure within the clinic. We confirmed that Ms Orla Mulholland is the Registered Manager and is in day to day charge of the establishment. One of the authorised operators, who is the clinic manager, is in day to day charge of the refractive eye service.

Where the business entity operating a refractive laser eye surgery service is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the Registered Provider must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005.

We established that an unannounced quality monitoring visit was last undertaken on 10 October 2020 on behalf of the Registered Provider. A report was produced and we were informed that the report is made available for clients, their representatives, staff, RQIA and any other interested parties to read. We were informed that an action plan had been developed to address any issues identified during the visit which included timescales and identified the person responsible for completing the action.

Discussions with Ms Mulholland and staff confirmed that there is sufficient staff, in the various roles, to fulfil the needs of the establishment and clients. This included a team of two consultant ophthalmologists, four optometrists, one registered nurse and two laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery.

We confirmed that refractive laser eye surgery procedures are only carried out by consultant ophthalmologists acting as clinical authorised operators and laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the lasers was maintained and kept up to date.

We established that the consultant ophthalmologists involved in the establishment are considered to be private doctors. A medical practitioner is considered to be a wholly private doctor if they do not have a substantive post in the National Health Service (NHS) in Northern Ireland (NI) and /or are on the GP performers list in NI. A review of both consultant ophthalmologists' details confirmed there was evidence of the following:

- confirmation of identity;
- current GMC registration;
- professional indemnity insurance;
- qualifications in line with services 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 (RO); and
- arrangements for revalidation with the GMC.

We were informed that both consultant ophthalmologists were aware of their responsibilities under GMC Good Medical Practice.

We confirmed that there are arrangements in place for monitoring the professional body registration status of all clinical staff.

We established that robust arrangements are in place for monitoring the professional indemnity of all staff that require individual indemnity cover.

We reviewed the arrangements relating to the management of practising privileges for the consultant ophthalmologists working within the establishment. We confirmed that a practising privileges policy and procedure was in place which outlined the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges.

We reviewed records and evidenced that there was a written agreement between the consultant ophthalmologists and the establishment setting out the terms and conditions which had been signed by both parties. Ms Mulholland and staff told us that a system was in place to review the practising privileges agreements every two years.

We established that the consultant ophthalmologists working within Optilase Therapie have their own designated external RO. In accordance with the requirements of registration with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. Experienced senior doctors' work as RO's with the GMC to make sure doctors are reviewing their work. As part of the revalidation process, RO's make a revalidation recommendation to the GMC. Where concerns are raised, regarding a doctor's practice, information must be shared with their RO. The RO then has the responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. We were informed that the consultant ophthalmologists do not work in any other healthcare establishments in NI. However, we confirmed that arrangements are in place to link into the wider system of RO's for doctors with practising privileges who work in other healthcare systems beyond NI.

We reviewed records and confirmed that the consultant ophthalmologists had completed refresher training in keeping with our training guidance for Independent Hospital – Private Doctor services.

Ms Mulholland confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to patients at appropriate intervals. If required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

A whistleblowing/raising concerns policy was available and we were told that staff were aware of who to contact if they had a concern.

Mrs Mulholland demonstrated a clear understanding of her role and responsibilities in accordance with legislation. Information requested by us has been submitted within specified timeframes. We advised that the Statement of Purpose and Client's Guide should be kept under review, revised and updated when necessary and available on request.

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

We reviewed insurance documentation confirmed that current insurance policies were in place.

Areas of good practice:

We found examples of good practice in relation to organisational and medical governance arrangements.

Areas for improvement:

No areas for improvement were identified in relation to organisational and medical governance.

	Regulations	Standards
Areas for improvement	**0**	**0**

6.8 Equality data

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

6.9 Patient and staff views

Optilase Therapie distributed questionnaires to patients on our behalf and one patient submitted a response to us. We found the patient felt their care was safe and effective, that they were treated with compassion and that the service was well led. All patients indicated that they were very satisfied with each of these areas of their care.

We invited staff to complete an electronic questionnaire and no staff submitted responses to us.

7.0 Quality improvement plan

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

10th November 2020

Ms Karen Weir & Ms Norma Munn
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast BT1 3BT

Dear Karen & Norma

Laser Protection Report

Optilase & Therapie Clinics, 35 – 40 Ann Street, Belfast BT1 4EG

Introduction

Further to the inspection visit to the above premises earlier today this report summarises the main laser protection aspects where improvement may be required. The findings are based on the requirements of European Laser Standards and the Control of Artificial Optical Radiation at Work Regulations (Northern Ireland) 2010.

Deficiencies & Comments

OPTILASE

The Local Rules and associated Laser Risk Assessment are due for review later this month. When reviewing these documents the following points should be addressed:-

Lights or Warning Signs
The Local Rules state that a laser warning sign should be displayed on the entrance door during laser sessions, and a copy of the sign is contained in the Local Rules. As the practice is to illuminate the door warning light the comment on displaying the additional sign (which is not used) should be removed. The statement in the Local Rules covering the use of the door warning light should be amended to reflect the practice of illuminating the warning light when the laser is in use and switching off at the end of the treatment session.

Protective Eyewear
The Local Rules for both Ophthalmology lasers state that protective eyewear is not required, however two pairs of protective eyewear are available which offer protection against the 193nm Schwind laser. If the eyewear is required on occasions then the Local Rules should be amended to provide guidance on their use. Where eyewear is available details of the protection level provided should be contained in the Local Rules.

Treatment Protocols
The validity period of the Treatment Protocols used by one of the Ophthalmologists has been extended to December 2020. When minor changes such as this are made to the working copy of the Treatment Protocol then this amendment should be initialled by the documents author

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A minor change was suggested to the Local Rules to clarify the optional use of the controlled area sign, however all other Laser Protection aspects appeared to be of a high standard.

The clinic should inform RQIA when the above matters related to the Optilase Clinic have been addressed.

Dr Ian Gillan
Laser Protection Adviser to RQIA

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