Inspection Report

1 March 2022

Optimax Laser Eye Clinic

Type of service: Independent Hospital – Refractive Eye Lasers
Address: 7 Derryvolgie Avenue, Belfast, BT9 6FL
Telephone number: 028 9066 1118

Information on legislation and standards underpinning inspections can be found on our website https://www.rqia.org.uk/, The Independent Health Care Regulations (Northern Ireland) 2005 and the Minimum Care Standards for Independent Healthcare Establishments (July 2014)

1.0 Service information

Organisation/Registered Provider: Optimax Laser Eye Clinic **Responsible Individual:** Mr James Rowley	**Registered Manager:** Ms Fiona Quinn **Date registered:** 12 August 2019
Person in charge at the time of inspection: Ms Fiona Quinn	
Categories of care: Independent Hospital (IH) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor	
Brief description of how the service operates: Optimax Laser Eye Clinic is registered as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing refractive eye techniques using Class 3B or Class 4 lasers PT(L) and private doctor (PD) categories of care. **Equipment available in the service:** **Laser equipment:** Ophthalmology Ar F Excimer laser Manufacturer: Schwind Model: 250 Serial Number: S244 Laser Class: 4 Ophthalmology Nd YLF laser Manufacturer: Intralase Model: FS/F530 Serial Number: 0506-40039 Laser Class: 3B **Laser protection advisor (LPA):** Ms Julie Robinson (University College London Hospitals Laser Protection Services) **Laser protection supervisor (LPS):** Ms Fiona Quinn **Medical support services:** Dr B Illango, Medical Director Mr A Sokwala, Head Optometrist	

Clinical authorised operator:
Dr M Ghassan – Ayoubi

Non–clinical authorised operators:
Ms Fiona Quinn
Ms Valerie Smyth
Ms Kelly Braniff

Types of laser treatments provided:
Lasik, Lasek, Epi-lasek and Photorefractive Keratectomy

2.0 Inspection summary

This was an announced inspection, undertaken by a care inspector on 1 March 2022 from 10.30 am to 5.00 pm. RQIA's Medical Physics Expert, accompanied the inspector and reviewed the laser equipment and the laser safety arrangements. His findings and recommendations are appended to this report.

The purpose of this inspection was to assess progress with any areas for improvement identified during and since the last inspection and to assess compliance with the legislation and minimum standards.

There was evidence of good practice concerning staff recruitment; authorised operator training; safeguarding; laser safety; the management of the patients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the clinic's adherence to best practice guidance in relation to COVID-19; the management of clinical records; clinical and organisational governance; and effective communication between patients and staff.

Additional areas of good practice identified included maintaining patient confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

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

3.0 How we inspect

RQIA is required to inspect registered services in accordance with legislation. To do this, we gather and review the information we hold about the service, examine a variety of relevant records, meet and talk with staff and management and observe practices on the day of the inspection.

The information obtained is then considered before a determination is made on whether the clinic is operating in accordance with the relevant legislation and minimum standards. Examples of good practice are acknowledged and any areas for improvement are discussed with the person in charge and detailed in the Quality Improvement Plan (QIP).

4.0 What people told us about the service?

Posters were issued to the service by RQIA prior to the inspection, inviting patients and staff to complete an electronic questionnaire. One patient, one visiting professional and two staff questionnaires responses were submitted prior to the inspection. All responses indicated that they felt that the care was safe, effective, that patients were treated with compassion and that the service was well led. All indicated that they were very satisfied with each of these areas of care and included very positive comments pertaining to the high standard of care delivered to patients and the support provided by management for the team.

As patients were not present on the day of the inspection patient feedback was further assessed by reviewing the most recent patient satisfaction surveys compiled by Optimax Laser Eye Clinic. The clinic actively seeks the views of patients about the quality of care, treatment and other services provided. Patient feedback regarding the service was found to be very positive in all aspects of care received and it reflected that the team deliver a very high standard of care.

5.0 The inspection

5.1 What has this service done to meet any areas for improvement identified at or since last inspection?

Areas for improvement from the last inspection on 18 March 2021		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for Improvement 1 **Ref:** Regulation 15(2) **Stated:** First time	The registered person shall ensure that protective eyewear is provided as recommended by the laser protection advisor and as outlined in the local rules.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.8.	
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Clinics (July 2014)		**Validation of compliance**
Area for Improvement 1 **Ref:** Standard 13.1 **Stated:** First time	The registered person shall ensure that a robust system is developed to ensure that all staff undertake mandatory training in keeping with the RQIA training guidance.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.1.	

Area for Improvement 2 **Ref:** Standard 11.5 **Stated:** First time	The registered person shall ensure that practising privileges agreements are signed by both parties and reviewed at least every two years.	**Met**
	Action taken as confirmed during the inspection: This area for improvement has been assessed as met. Further detail is provided in section 5.2.9.	

5.2 Inspection outcome

5.2.1 How does the service ensure that staffing levels are safe to meet the needs of patients and that staff are appropriately trained to fulfil the duties of their role?

Staffing arrangements were reviewed and it was confirmed that there are appropriately skilled and qualified staff involved in the delivery of services. This includes a team of one consultant ophthalmologist, one optometrist, one nurse and laser technicians/surgical assistants. Ms Quinn confirmed that the staff have specialist qualifications and skills in refractive laser eye surgery patient care.

The clinic staff take part in ongoing training to update their knowledge and skills, relevant to their role. Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team. No new staff have been recruited since the previous inspection, however, it was confirmed that an induction programme would be provided to any newly staff recruited.

A system was in place to monitor all aspects of ongoing professional development and a record was retained of all training and professional development activities. A review of the records confirmed that all staff had undertaken training in keeping with RQIA training guidance. It was determined that the previous area for improvement 1 made against the standards, as outlined in section 5.1, has been met.

Discussion with Ms Quinn and review of documentation identified that arrangements were in place to check the registration status for all clinical staff on appointment and on an ongoing basis. The arrangements for monitoring the professional indemnity of all staff were also in place, as was a system for the monitoring of any practicing privileges (discussed further in section 5.2.9).

Discussion with staff confirmed there are good working relationships. Staff spoke positively regarding the clinic, felt valued as members of the team and confirmed they were supported by management.

It was determined that appropriate staffing levels were in place to meet the needs of patients and the staff were suitably trained to carry out their duties.

5.2.2 How does the service ensure that recruitment and selection procedures are safe?

The arrangements in respect of the recruitment and selection of staff were reviewed. As previously discussed no new staff had been recruited since the previous inspection. Ms Quinn confirmed that should staff be recruited in the future 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 review of the policy and procedure for the recruitment and selection of staff found that it only included the recruitment of doctors and optometrists. Ms Quinn was advised to further develop the policy to include all other staff. A revised policy and procedure was submitted to RQIA following the inspection and a review of the policy found that it was in accordance with legislation and best practice guidance.

The staff register reviewed was found to be up to date and included the names and details of all staff in keeping with legislation.

Robust recruitment and selection procedures were in place to ensure compliance with the legislation and best practice guidance should staff be recruited in the future.

5.2.3 How does the service ensure that it is equipped to manage a safeguarding issue should it arise?

Ms Quinn stated that treatments are not provided to persons under the age of 18 years.

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

Discussion with staff confirmed that they were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Clinics July 2014. Ms Quinn, as the safeguarding lead, had completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards.

It was confirmed that a copy of the regional guidance document entitled Adult Safeguarding Prevention and Protection in Partnership (July 2015) was available for reference.

The service had appropriate arrangements in place to manage a safeguarding issue should it arise.

5.2.4 How does the service ensure that medical emergency procedures are safe?

The arrangements in respect of the management of medical emergencies were reviewed.

The British National Formulary (BNF) and the Resuscitation Council (UK) specify the emergency medicines and medical emergency equipment that must be available to safely and effectively manage a medical emergency.

There was a medical emergency policy and procedure in place and a review of this evidenced that it was comprehensive, reflected legislation and best practice guidance. Protocols were available to guide the team on how to manage recognised medical emergencies.

Robust systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available.

Staff spoken with were able to describe the actions they would take, in the event of a medical emergency, and were familiar with the location of medical 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.

Review of the arrangements to manage a medical emergency identified that staff were suitably trained and appropriate medicines and equipment were in place to manage a medical emergency should one arise.

5.2.5 How does the service ensure that it adheres to infection prevention and control and decontamination procedures?

The arrangements for IPC procedures throughout the clinic were reviewed to evidence that the risk of infection transmission to patients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

A tour of the premises was undertaken and the clinic was found to be clean, tidy and uncluttered. Cleaning schedules were in place and records were completed and up to date. Staff described the procedure to decontaminate the environment and equipment between patients and this was in keeping with best practice.

A review of training records confirmed that staff had received IPC training commensurate with their roles and responsibilities. Staff spoken with on inspection demonstrated good knowledge and understanding of IPC procedures.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance and according to the treatments provided. The laser suite provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

The service had appropriate arrangements in place in relation to IPC and decontamination.

5.2.6 Are arrangements in place to minimise the risk of COVID-19 transmission?

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.

The management of operations in response to the COVID-19 pandemic were discussed with Ms Quinn and staff who outlined the measures taken by Optimax Laser Eye Clinic to ensure current best practice measures are in place. Appropriate arrangements were in place in relation to maintaining social distancing; implementation of enhanced IPC procedures; and the patient pathway to include COVID-19 screening prior to attending appointments.

The management of COVID-19 was in line with best practice guidance and it was determined that appropriate actions had been taken in this regard.

5.2.7 How does the service ensure that laser procedures are safe?

The arrangements in respect of the safe use of the laser equipment were reviewed.

The service has one laser suite and various consultation/treatment rooms. It was confirmed that refractive laser eye procedures are only carried out by the consultant ophthalmologist acting as the clinical authorised operator assisted by laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the laser was maintained and kept up to date.

A review of the laser safety file found that it contained all of the relevant information in relation to the lasers. There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis and the service level agreement between the clinic and the LPA reviewed was up to date. The clinic's LPA completed a risk assessment of the premises during March 2021 and no recommendations were made.

Ms Quinn confirmed that refractive eye surgical procedures are carried out by one consultant ophthalmologist in accordance with medical treatment protocols produced by the medical directors of Optimax Laser Eye Clinic and systems were in place to review the medical treatment protocols on an annual basis.

Up to date local rules were in place which have been developed by the LPA and these contained the relevant information pertaining to the laser equipment being used. Arrangements were in place to review the local rules on an annual basis.

Ms Quinn, as the LPS confirmed that when the laser equipment is in use, the safety of all persons in the controlled area is her responsibility. Arrangements were in place for another authorised operator to deputise for Ms Quinn in her absence, who is suitably skilled to fulfil the role.

Review of training records confirmed that both clinical and non-clinical authorised operators had up to date training in core of knowledge; basic life support; infection prevention and control; fire safety awareness; and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

Ms Quinn confirmed that the laser surgical register is maintained every time the lasers are operated to include:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure given
- any accidents or adverse incidents

A review of the laser surgical register found it to be comprehensively completed.

The laser suite where the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. Ms Quinn confirmed that the doors to the laser suite are locked, when the laser equipment is in use, but can be opened from the outside in the event of an emergency.

The lasers are operated using keys and passwords that unauthorised staff do not have access to and there were arrangements in place in relation to the safe custody of the keys and passwords of the laser equipment.

Ms Quinn confirmed that protective eyewear was available for non-clinical authorised operators if required. A minor amendment was made to the local rules following the inspection regarding the protective eyewear as recommended by RQIA's MPE. A review of the eyewear evidenced that it was provided as outlined by the LPA in the local rules. It was determined that the previous area for improvement 1 made against the regulations, as outlined in section 5.1, had been met.

The laser safety warning signs are illuminated outside of the laser suite when the laser is in use and turned off when not in use, as described within the local rules.

Arrangements have been established for laser equipment to be serviced and maintained in line with the manufacturers' guidance. The most recent service reports reviewed were dated December 2021.

Carbon dioxide (CO2) fire extinguishers, suitable for electrical fires were available in the clinic and arrangements were in place to ensure the fire extinguishers are serviced, in keeping with manufacturer's instruction. A fire risk assessment had been reviewed during February 2022.

It was determined that appropriate arrangements were in place to safely operate the laser equipment.

5.2.8 How does the service ensure patients have a planned programme of care and have sufficient information to consent to treatment?

Ms Quinn 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. Systems were in place to contact the patient's general practitioner (GP), with their consent, for further information if necessary.

The clinic 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.

In accordance with 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.

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. Systems were in place to refer patients directly to the consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery at regular intervals if necessary.

Three patient care records reviewed were found to be well documented, contemporaneous and clearly outlined the patient journey.

It was determined that appropriate arrangements were in place to ensure patients have a planned programme of care and have sufficient information to consent to treatment.

5.2.9 Are robust arrangements in place regarding clinical and organisational governance?

Organisational governance

Various aspects of the organisational and medical governance systems were reviewed and evidenced a clear organisational structure within Optimax Laser Eye Clinic. Mr James Rowley is the responsible individual in the clinic and Ms Quinn is the registered manager. Ms Quinn is in day to day charge of the clinic.

Where the business entity operating a refractive eye 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, or person acting on their behalf, must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. Ms Quinn informed us that the most recent quality monitoring visit was undertaken by Mr Rowley during February 2022. A report of the visit was produced and made available for patients, their representatives, staff, RQIA and any other interested parties to read and an action plan developed to address any issues identified which included timescales and person responsible for completing the action.

Optimax Laser Eye Clinic has a Medical Advisory Board (MAB) that includes Mr Rowley along with the chief executive officer, senior medical staff and directors of the organisation. The MAB meets quarterly and this meeting is also attended by other members of the senior management team.

Discussion with staff and a review of records evidenced that staff meetings take place every month and minutes were available to review.

Clinical and medical governance

A team of one consultant ophthalmologist, an optometrist, a nurse and laser technicians/surgical assistants who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

The consultant ophthalmologist is considered to be the only wholly private doctor as he no longer holds a substantive post in the HSC sector in Northern Ireland (NI) and is not on the GP performer list in NI. Review of the consultant ophthalmologist's details confirmed evidence of the following:

- confirmation of identity
- current 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 (RO)
- arrangements for revalidation

As previously discussed the consultant ophthalmologist had completed training in accordance with RQIAs training guidance for private doctors and is aware of his responsibilities under GMC Good Medical Practice.

All medical practitioners working within the clinic must have a designated responsible officer (RO). An RO is an experienced senior doctor who works with the GMC to make sure doctors are reviewing their work. In accordance 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're doing well and how they can improve. 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 who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. The consultant ophthalmologist working within the clinic has a designated external RO due to their prescribed connection with another health care organisation and has revalidated accordingly.

Practising Privileges

The only mechanism for a clinician to work in a registered independent hospital is either under a practising privileges agreement or through direct employment by the clinic.

Practising privileges can only be granted or renewed when full and satisfactory information has been sought and retained in respect of each of the records specified in Regulation 19 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended.

A policy and procedural guidance for the granting, review and withdrawal of practicing privileges agreements was in place.

A review of practising privileges records confirmed that all required documents were in place. It was confirmed that the practising privileges agreement is updated every two years. It was determined that the previous area for improvement 1 made against the standards, as outlined in section 5.1, had been met.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of appropriate medical governance arrangements within the organisation.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to patients at appropriate intervals. The results of audits are analysed and actions identified for improvement are embedded into practice. If required, an action plan is developed to address any shortfalls identified during the audit process.

A system was also 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.

The Statement of Purpose and Patient's Guide were kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately and current insurance policies were in place.

Notifiable Events/Incidents

A robust system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate.

Ms Quinn confirmed that any learning from incidents would be discussed with staff. There was a process in place for analysing incidents and events to detect potential or actual trends or weakness in a particular area in order that a prompt and effective response can be considered at the earliest opportunity. An audit would be maintained, reviewed and the findings presented to the directors during their quarterly meetings.

Complaints Management

A copy of the complaints procedure was available in the clinic and was found to be in line with the relevant legislation and Department of Health (DoH) guidance on complaints handling.

Ms Quinn confirmed that a copy of the complaints procedure is made available for patients/and or their representatives on request and staff demonstrated a good awareness of complaints management.

It was confirmed that no written complaints had been received since the previous inspection. Ms Quinn advised that any complaints received would be investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome; and any action taken. It was confirmed that any information gathered from complaints would be used to improve the quality of services provided.

Overall, the governance structures within the clinic provided the required level of assurance to the senior management team and the MAB.

5.2.10 Does the service have suitable arrangements in place to record 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 Quinn.

Discussion and review of information evidenced that the equality data collected was managed in line with best practice.

6.0 Quality Improvement Plan/Areas for Improvement

	Regulations	Standards
Total number of Areas for Improvement	0	0

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

Laser Protection Adviser's Inspection Report Site Details:

Optimax Laser Eye Clinic
7 Derryvolgie Avenue
Belfast BT9 6FL

Laser Protection Adviser appointed by site:
Julie Robinson (UCLH)

Laser equipment in use:

Make	Model	Class	Serial Number	Wavelength(s)
Schwind	Amaris 750s	4	-	193 nm (ArF)
Intralase	iFS	3B	-	1053 nm (Nd:glass)

Introduction:

A Laser Protection Adviser inspection of Optimax Laser Eye Clinic, 7 Derryvolgie Avenue, Belfast BT9 6FL was performed on 01/03/2022. This report summarises the outcome of the inspection and document review, including any improvements which may be required (where applicable). The review and consequent recommendations (where applicable) are based on the requirements of the Minimum Care Standards for Independent Healthcare Establishments published by the Health, Social Services and Public Safety (DHSSPSNI) July 2014 and other relevant legislation, guidance notes and European Standards.

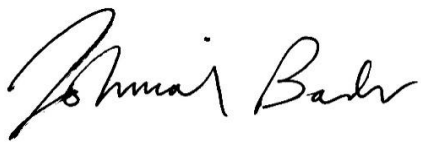
The LPA inspection included a review of:

- Protective eyewear
- Environment/signage
- Training records and user authorisation
- Laser device markings
- Maintenance records
- Treatment protocols
- Risk assessments
- Local rules

- Appointment of duty holders (LPS/LPA)

Recommendations

The information on protective eyewear for the Schwind Amaris 750s laser that appears in the local rules for the Intralase iFS laser should make clear that eyewear for the Schwind laser is only required during laser maintenance. The current wording appears to be ambiguous. Alternatively, the eyewear requirements for the Schwind laser could be removed from the Intralase local rules, as the information in the separate Schwind local rules is correct.



Dr Ishmail Badr
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