Inspection Report

5 December 2024

Optical Express

Type of Service: Independent Hospital (IH) – Refractive Eye Lasers
Address: The Vantage (4th Floor), 32-36 Great Victoria Street, Belfast, BT2 7BA
Telephone number: 028 9590 0234

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/Provider: Optical Express Limited **Responsible Individual:** Ms Mary Spellman	**Registered Manager:** Mrs Christine McMurray **Date registered:** 14 July 2022
Persons in charge at the time of inspection: Ms Mary Spellman and Mrs Christine McMurray	
Categories of care: PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor AH (DS) Acute hospitals (day surgery only)	
Brief description of how the service operates: Optical Express is registered with the Regulation and Quality Improvement Authority (RQIA) as an independent hospital (IH) with prescribed techniques or prescribed technology: establishments providing laser eye surgery using Class 3B or Class 4 lasers PT (L); private doctor (PD) and acute hospitals (day surgery only) AH (DS) categories of care. Optical Express Limited is the registered provider and Ms Mary Spellman is the responsible individual. **Equipment available in the service:** **Laser Suite** Manufacturer: VisX Model: Star 4 Serial Number: 5629 Laser Class: Class 4 Wavelength: ArF (193nm) Manufacturer: Intralase Model: iFS Serial Number: 0107-40185 Laser Class: Class 3b Wavelength: Nd: Glass (1053nm)	

Treatment Room
Manufacturer: Nidek
Model: YC-200
Serial Number: Y20500317
Laser Class: Class 3b
Wavelength: 1064nm Nd YAG

Types of treatment provided:

- Refractive eye surgery – LASEK and Lasik
- Capsulotomy procedures using Nidek YC-200 Yag
- Other vision corrective eye surgery such as cataract surgery (non-laser)

2.0 Inspection summary

This was an announced inspection undertaken by two care inspectors on 5 December 2024 from 10.00 am to 5.15 pm. RQIA's laser protection advisor (LPA) accompanied the inspectors and reviewed the laser equipment and the laser safety arrangements. Their findings and recommendations are appended to this report.

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

There was evidence of good practice concerning; authorised operator training; safeguarding; laser safety; the management of the clients' care pathway; the management of medical emergencies; infection prevention and control (IPC); the management of clinical records; clinical and organisational governance; and effective communication between clients and staff.

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

One area for improvement has been identified against the regulations regarding the recruitment of staff.

No immediate concerns were identified regarding the delivery of front line client 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. This inspection was facilitated by Ms Spellman and Mrs McMurray.

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?

Clients were not present on the day of the inspection and client feedback was assessed by reviewing the most recent client satisfaction surveys completed by Optical Express and this is discussed further in section 5.2.8.

Posters were issued to Optical Express by RQIA prior to the inspection inviting clients and staff to complete an electronic questionnaire.

No clients submitted responses.

Four staff submitted questionnaire responses. Three of the staff responses indicated that they were very satisfied that client care was safe, effective, that clients were treated with compassion and that the service was well led. One staff member indicated a level of dissatisfaction with these aspects of client care, this staff member did not provide comments in this regard. One staff members response included positive comments regarding working for Optical Express, communication and the availability of information.

5.0 The inspection

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

The last inspection to Optical Express was undertaken on 14 December 2023; no areas for improvement were identified.

5.2 Inspection outcome

5.2.1 How does this service ensure that staffing levels are safe to meet the needs of clients and 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 consultant ophthalmologists and anaesthetists, optometrists, registered nurses and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery.

It was established that Optical Express directly employs a number of authorised operators who can work in any of the Optical Express Limited clinics throughout the United Kingdom (UK) and Ireland. In this clinic there are two named consultant ophthalmologists and two senior optometrists who are the regular authorised operators of the laser equipment.

Arrangements were in place for all staff to take part in ongoing training to update their knowledge and skills, relevant to their role.

A robust electronic 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 and discussion with Ms Spellman confirmed that all staff had undertaken training in keeping with RQIA training guidance and legislation.

Induction programmes relevant to roles and responsibilities are required to be completed when new staff join the team.

Discussion with Ms Spellman in conjunction with a review of documentation confirmed that robust arrangements were in place to check the registration status for all clinical staff on appointment and on an ongoing basis. The arrangement for monitoring the professional indemnity of all staff was also in place.

It was determined that appropriate staffing levels were in place to meet the needs of clients and the staff were suitable 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.

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

Optical Express Limited has a corporate human resources (HR) shared services department. The corporate HR department supports the registered manager during the recruitment process. The HR department is responsible for developing job descriptions, induction templates and employment contracts bespoke to roles and responsibilities; issuing reference requests and for ensuring all recruitment records have been sought and uploaded to the electronic HR system. Ms Spellman confirmed that Mrs McMurrray had access to all recruitment records via the electronic system.

Discussions with Ms Spellman confirmed she had a good understanding of recruitment and selection legislation and best practice guidance.

Two personnel files of staff recruited since the previous inspection were reviewed. It was identified that an AccessNI enhanced disclosure check for one of the newly recruited staff member had been sought following the appointment of that staff member however, an outcome had not yet been received. An area for improvement has been made against the regulations in this regard. Following the inspection RQIA received confirmation that this matter had been addressed. It was futher observed that one recruitment record had not been sought for the two aforementioned newly recruited staff members. Advice and guidance was provided to Ms Spellman in this regard. Ms Spellman was receptive to this discussion.

It was confirmed that arrangements are in place to retain information equating to a staff register which was found to be up to date and included the names and details of all staff who are and have been employed, in keeping with legislation.

Addressing the area for improvement will ensure that recruitment and selection procedures in place will comply with the legislation and best practice guidance.

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

Ms Spellman confirmed 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 Trust should a safeguarding issue arise.

Review of records demonstrated that all staff had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. Ms Spellman confirmed that staff were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified.

The safeguarding champion named in the policy had completed safeguarding training at the level required in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) and minimum standards. The safeguarding lead is identified to all staff members on a daily basis during the morning safety brief.

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.

Appropriate arrangements were 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.

A review of the management of medical emergencies policy identified that it accurately reflected the arrangements that were found to be in place for managing a medical emergency. Protocols were also available to guide the team on how to manage recognised medical emergencies.

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.

Review of the emergency trolley found that 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.

Discussion with staff confirmed that the management of medical emergencies is included in the induction programme. A review of training records evidenced that the consultant ophthalmologists had competed advanced life support training and all other staff had completed basic life support training. Mrs McMurray advised that basic life support training is updated annually.

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 clients, visitors and staff was minimised. There were IPC policies and procedures in place that were in keeping with best practice guidance.

It was evidenced that a robust programme of IPC auditing is in place.

A tour of the premises was undertaken and the clinic was found to be clean, tidy and uncluttered. Staff described the arrangements to decontaminate the environment and equipment between clients in keeping with best practice.

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

Mrs McMurray informed us that reusable medical devices are used during cataract surgery. It was confirmed that 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. Optical Express Limited has a contract in place with the central sterile services department (CSSD) of the Ulster Hospital for this purpose.

Waste management arrangements were in place and clinical waste bins were pedal operated in keeping with best practice guidance.

The laser suite and treatment room provided dedicated hand washing facilities and hand sanitiser was available throughout the clinic.

Ms Spellman confirmed she is aware that the Department of Health (DOH) and Public Health Agency (PHA) websites provide advisory information, guidance and alert with regards to IPC.

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

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

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

A review of the laser safety files found that they contained all of the relevant information in relation to all the laser equipment in place. There were arrangements in place confirming the support and duties of a certified LPA. Advice and guidance was provided to Ms Spellman to further develop these arrangements so as to include written confirmation of the appointment of a certified LPA which is reviewed on an annual basis.

It was confirmed that refractive laser eye procedures are only carried out by the consultant ophthalmologists acting as the clinical authorised operators for all lasers, and two senior optometrists who are authorised to use the YAG laser. A register of clinical and non-clinical authorised operators for the lasers is maintained and kept up to date.

The clinic's LPA completed a risk assessment of the premises and the laser safety arrangements.

It was confirmed that laser eye surgical and YAG capsulotomy procedures are undertaken in accordance with medical treatment protocols produced by the clinical director of Optical Express 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. The local rules 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
- adverse incident procedures

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

As previously discussed a review of training records confirmed that all 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. Review of documentation and discussion with Ms Spellman confirmed that clinical authorised operators had undertaken application training for the equipment in use.

It was evidenced that dedicated laser surgical and YAG registers are in place for all the laser equipment which include:

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

Advice and guidance was provided to Ms Spellman to ensure the YAG register is fully maintained every time the laser is operated.

The laser suite and an identified treatment room (controlled areas) where the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. It was confirmed that the doors to the controlled areas 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 robust arrangements in place in relation to the safe custody of the keys and passwords of the laser equipment.

Protective eyewear was available for non-clinical authorised operators if required. A review of the eyewear evidenced that it was provided as outlined by the LPA in the local rules.

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

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

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.

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

5.2.7 How does the clinic ensure clients have a planned programme of care and have sufficient information to consent to treatment?

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

During the initial consultation, clients are asked to complete a health questionnaire. Systems were in place to contact the client'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 client's prescription and surgery options available to them.

In accordance with General Medical Council (GMC) and the Royal College of Ophthalmologists guidance, clients 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.

Clients are provided with written information on the specific procedure to be provided that explains the risks, complications and expected outcomes of the treatment. Clients are also provided with clear post-operative instructions along with contact details if they experience any concerns. Systems were in place to refer clients directly to the consultant ophthalmologist if necessary.

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

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

The management of records within the clinic was found to be in line with legislation and best practice.

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

5.2.8 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 Optical Express. Ms Spellman is the responsible individual in the clinic and Mrs McMurray is the registered manager who 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. The most recent unannounced monitoring visit was undertaken by Ms Spellman during July 2024. A report of the visit was produced and made available for clients, their representatives, staff, RQIA and any other interested parties to read and an action plan developed to address any issues identified during the visit which included timescales and person responsible for completing the action.

Optical Express has an international medical advisory board (IMAB) that includes the chief executive officer, clinical services director and internationally renowned consultants who meet annually over several days. This meeting includes review and update of the treatment protocols and other key documents and arrangements are in place should the IMAB need to convene in addition to this annual arrangement.

The clinical governance team hold a clinical governance committee meeting on a quarterly basis and this meeting fulfils the function of the medical advisory committee (MAC).

Discussion with Ms Spellman and review of records evidenced that monthly staff meetings and daily staff briefings take place and minutes were available to review. A range of additional means of staff communication were confirmed by Ms Spellman.

Staff working in different roles within the clinic confirmed that there were good working relationships and that management were responsive to any suggestions or concerns raised.

Clinical governance

As previously discussed, a team of consultant ophthalmologists, optometrists, registered nurses and laser technicians who have evidence of specialist qualifications and skills in refractive laser eye surgery work in the clinic.

There are two consultant ophthalmologists and a consultant anaesthetist who are considered to be wholly private doctors as they are not affiliated with the Health and Social Care (HSC) sector in Northern Ireland (NI) and are not on the GP's performer list in NI. Review of the three consultant 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

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 ROs 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 who then has a responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. It was established that Optical Express Limited is registered with the GMC as a designated body with and identified appointed RO.

As previously discussed the private doctors had completed training in accordance with RQIA's training guidance for private doctors and are aware of their responsibilities under GMC Good Medical Practice.

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.

It was confirmed that the three PDs are directly employed by Optical Express Limited and therefore practicing privileges agreements are not required.

Quality assurance

Arrangements were in place to monitor, audit and review the effectiveness and quality of care and treatment delivered to clients at appropriate intervals. These arrangements include seeking client feedback on the quality of services provided. The most recent client feedback survey findings were discussed during the inspection and it was found that the survey returned overall positive feedback.

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.

A statement of purpose and client's guide were in place and Ms Spellman is aware that these documents will be kept under review when and updated as necessary.

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. Discussion with Ms Spellman identified that two matters required retrospective notification to RQIA, and these were received by RQIA immediately following the inspection.

Ms Spellman 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 the DoH guidance on complaints handling.

Ms Spellman confirmed that a copy of the complaints procedure is made available for clients/and or their representatives on request and is also available via the Optical Express website. Ms Spellman demonstrated a good awareness of complaints management.

Optical Express Limited has a customer services and complaints handling department who manage all complaints received. Ms Spellman confirmed that complaints received since the previous inspection had been investigated and responded to appropriately to include details of all communications with complainants; the result of any investigation; the outcome and any action taken.

Ms Spellman demonstrated that any learning outcomes identified from the investigation of complaints received across the organisation will 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 MAC.

5.2.9 Does the service have suitable arrangements in place to record equality data?

Arrangements are in place in relation to the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients.

6.0 Quality Improvement Plan/Areas for Improvement

An area for improvement has been identified where action is required to ensure compliance with **The Independent Health Care Regulations (Northern Ireland) 2005**

	Regulations	Standards
Total number of Areas for Improvement	1	0

The area for improvement and details of the QIP were discussed with Ms Spellman, Responsible Individual as part of the inspection process. The timescales for completion commence from the date of inspection.

Quality Improvement Plan	
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005	
Area for improvement 1 **Ref:** Regulation 19 (2) (d) as amended **Stated:** First time **To be completed by:** 5 December 2024	The responsible individual shall ensure that an AccessNI enhanced disclosure check as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005, as amended, is sought and reviewed with the outcome recorded prior to any staff member commencing employment in the future. Ref: 5.2.2
	Response by registered person detailing the actions taken: The immediate issue of securing an AccessNI disclosure for the individual identified was resolved post inspection. We have engaged with our HR&Recruitment Team who have confirmed that they will ensure all future potential employees will have an AccessNI disclosure before commencing employment.

Please ensure this document is completed in full and returned via Web Portal

Appendix 1

15 January 2025

Laser Protection Report

Site Details:
Optical Express
The Vantage
4th Floor
32-36 Great Victoria Street
Belfast
BT2 7BA

Laser Protection Adviser: Mike Regan, Laser Safety Advisory

Laser/IPL Equipment:

Make	Model	Class	Serial Number	Wavelength(s)
Visx	Star S4	4	5629	193 nm (ArF)
Intralase	iFS	3B	0107- 40185	1053 nm (Nd:Glass)
Nidek	YC-200	3B	Y2050317	1064 nm (Nd:YAG)

Introduction

A Laser Protection Adviser inspection of Optical Express was performed on 5 December 2024. This report summarises the main aspects of the inspection and document review where improvements may be required. The findings are based on the requirements of the Minimum Care Standards for Independent Healthcare Establishments published July 2014 by the Department of Health, Social Services and Public Safety (DHSSPSNI) 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)

Comments / Recommendations:

1. **LPA Appointment:** Although there was clear evidence of LPA support demonstrated through updated documentation and email correspondence with the clinic, there was no written confirmation available of the LPA appointment.

In accordance with Standard 48.6 of the Minimum Care Standards for Independent Healthcare Establishments, the clinic should ensure there is written confirmation of the appointment and duties of a certified laser protection adviser that is renewed annually.

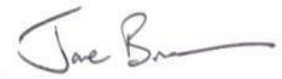
2. **YAG training records:** There were four authorised users for the YAG laser. Applications training records were available for the two Optometrists, however there were no records available for the Consultant Ophthalmologist users. During discussions with the clinic, they stated that the consultants were trained and performing YAG capsulotomy treatments within the NHS.

In accordance with the minimum care standards, the clinic should ensure records are kept of all training undertaken by staff; this should laser applications training for all authorised users.

3. **YAG Treatment Register:** A treatment register was available for the YAG laser and most records were completed correctly.

The clinic should ensure the laser treatment register is fully complete by all users.

The clinic should inform RQIA when the above points have been addressed.



Mrs Jane Brown
Laser Protection Adviser to RQIA

The Regulation and Quality Improvement Authority
James House
2-4 Cromac Avenue
Gasworks
Belfast
BT7 2JA

Tel 028 9536 1111
Email info@rqia.org.uk
Web www.rqia.org.uk
@RQIANews