The Regulation and Quality Improvement Authority

Inspection Report

1 March 2022

Optical Express

Type of service: Independent Hospital – 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/Registered Provider: Optical Express Limited **Responsible Individual:** Ms Mary Spellman	**Registered Manager:** Mrs Gail Caldwell **Date registered:** 28 September 2012
Person in charge at the time of inspection: Ms Mary Spellman	
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 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); private doctor (PD) and acute hospitals (day surgery only) AH (DS) categories of care. Optical Express Limited is the registered provider Optical Express and Ms Mary Spellman is the responsible individual. A variation to registration application was submitted to RQIA prior to this inspection as Optical Express has relocated to new premises. **Equipment available in the service:** **Excimer Laser** Manufacturer: VisX Model: Star 4 Serial Number: 5629 Laser Class: Class 4 Wavelength: ArF (193nm)	

Intralase Laser

Manufacturer:	Intralase
Model:	IFS
Serial Number:	0107-40185
Laser Class:	Class 3b
Wavelength:	Nd: Glass (1053nm)

Laser protection advisor (LPA):

- Mr Mike Regan

Laser protection supervisor (LPS):

- Mrs Gail Caldwell

Medical Advisory Board

- Mr David Teenan – UK Medical Director
- Mr Stephen Hannan – Clinical Services Director

Clinical authorised operators:

- Mr Rob Daniel
- Mr Manu Mathew
- Mr Alex George

Non –clinical authorised operators:

- Mrs Gail Caldwell

Types of treatment provided:

- Refractive eye surgery – Lasik and Lasek
- Other vision corrective eye surgery such as cataract surgery(non-laser).

2.0 Inspection summary

This was an announced care and variation inspection, undertaken by two care inspectors and an estates inspector, on 1 March 2022 from 10.00 am to 5.00 pm and concluded with a follow up visit by a care inspector on 7 April 2022. RQIA's Medical Physics Expert, accompanied the inspectors, on 1 March 2022, and reviewed the laser equipment and the laser safety arrangements. His findings and recommendations are appended to this report.

The purpose of the inspection was to assess progress with areas for improvement identified during the last care inspection, assess compliance with the legislation and minimum standards and review the readiness of the establishment associated with the variation to registration application.

An RQIA estates inspector reviewed the variation to registration application in relation to matters relating to the premises and confirmed approval of the variation application following the inspection.

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 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.

The variation to registration application in relation to the new premises is granted from a care and estates perspective.

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.

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

- the submitted variation to registration application
- the statement of purpose
- the client guide
- documentation in relation to the new premises

The information obtained is then considered before a determination is made on whether the establishment 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?

As the new premises had not yet been approved at the time of the inspection , patients were not present and patient feedback was assessed by reviewing the most recent patient satisfaction surveys completed by Optical Express. 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 respect to all aspects of care received and reflected that the staff deliver a very high standard of care.

Posters were issued to the service by RQIA prior to the inspection inviting patients and staff to complete an electronic questionnaire. No completed staff or patient questionnaires were submitted prior to the inspection.

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 21 September 2020		
Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments(July 2014)		**Validation of compliance**
Area for Improvement 1 **Ref:** Standard 48 **Stated:** First time	The Responsible Individual shall ensure; • the Laser Protection Advisor (LPA) confirms in writing whether the current Local Rules are satisfactory; • the current Local Rules which were originally produced in 2011are updated; • the contents of the Laser Safety File are reviewed and documents which have been superseded are archived; and • forward correspondence from the LPA regarding the status of the current Local Rules to RQIA.	**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	

5.2 Inspection outcome

5.2.1 How does the service ensure that staffing levels are safe to meet the needs of patients?

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, 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 Limited directly employs a list of 24 authorised operators who can work in any of the Optical Express Limited clinics throughout the UK and Ireland. In this clinic there are three named authorised operators who are the regular authorised operators of the laser equipment.

Ms Spellman advised that Optical Express hope to grow their in-house team in Belfast and will be actively recruiting once the team has settled into the new premises.

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.

A robust 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 and legislation.

Discussion with Ms Spellman 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 was also in place, as was a system for the monitoring of any practicing privileges (further discussed in section 5.2.10).

It was determined that appropriate staffing levels were in place to meet the needs of patients 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.

Ms Spellman confirmed that should authorised operators be recruited in the future robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

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; and issuing reference requests.

The registered manager is responsible for ensuring all recruitment records have been sought and uploaded to the electronic HR system. Discussion with Ms Spellman confirmed that she and Mrs Caldwell had a clear understanding of the legislation and best practice guidance.

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

The staff register reviewed 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.

Robust recruitment and selection procedures were in place to ensure compliance 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 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 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. It was also confirmed that 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.

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 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.

Review of the emergency trolley found robust systems were in place to ensure that emergency medicines and equipment do not exceed their expiry date and are immediately available.

A review of training records and discussion with Ms Spellman 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.

The clinic was still under renovation during the inspection on 1 March 2022 therefore IPC arrangements were not fully evidenced at that time. It was advised to undertake a robust IPC audit and an airborne particulates and microbiological survey of the treatment areas and furnish RQIA with the outcome. RQIA received evidence that both the robust IPC audit and the airborne particulate and microbiological survey had been carried out and the findings were in accordance with best practice and current standards. It was confirmed that a deep clean had been completed by external contractors on 3 March 2022 and further ongoing cleaning was taking place as part of the settling process.

A tour of the premises was undertaken on 7 April 2002 and the clinic was found to be clean, tidy and uncluttered. Cleaning records were completed and up to date. Staff described the arrangements to decontaminate the environment and equipment between patients 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.

Ms Spellman 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 has a contract in place with the CSSD (Central Sterile Services Department) of the Ulster Hospital for this purpose.

Personal protective equipment (PPE) was readily available in keeping with best practice guidance.

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

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 Spellman and staff who outlined the measures that will be taken by Optical Express to ensure current best practice measures are in place. Appropriate arrangements are 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. Social distancing was in place at the reception desk and 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.

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 the environment is safe?

The service has one spacious laser suite and various consultation/treatment rooms. The premises were maintained to a good standard of maintenance and décor.

The Building Control final completion certificate was in place following a final inspection on 28 February 2022.

The design, installation, and validation documentation for the premises mechanical and electrical services were inspected and noted as follows:

- Fire detection and alarm system was commissioned on 22 February 2022
- Emergency lighting installation was commissioned on 25 January 2022
- Portable fire-fighting equipment was suitably serviced and in place
- Fixed electrical installation was commissioned on 25 January 2022
- Uninterruptible power supplies were in place and subject to ongoing maintenance
- Passenger lifts and communal toilet facilities remain under the control of the Landlord
- Safe hot water is provided in accordance with current best practice guidance

The specialist ventilation and air handling units were installed and commissioned in accordance with current best practice guidance. A verification report for the installation was undertaken on 12 March 2022 and concluded that it exceeded the requirements of Health Technical Memorandum (HTM) 03-01. Subsequent microbiological tests and particulate counts were undertaken in the Laser Treatment Room on 14 March 2022. These results confirmed that the air quality was within the acceptable limits of HTM 03-01.

A risk assessment for the control of legionella and other water bourne pathogens in the premises hot and cold water systems had been undertaken on 18 February 2022. A water safety plan has been developed and suitable control measures identified and implemented.

A fire risk assessment for the premises was completed on 18 February 2022 and indicated a 'Low' risk rating for the premises. All required actions stemming from this risk assessment were completed and signed off by the appropriate responsible persons.

It was determined that appropriate arrangements were in place to maintain the environment.

5.2.8 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 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. The service level agreement between the clinic and the

LPA had been reviewed and was up to date. It was determined that the previous area for improvement 1 made against the standards, as outlined in section 5.1, had been met.

The clinic's LPA completed a risk assessment of the premises during March 2021 and no recommendations were made.
It was confirmed that refractive laser eye procedures are only carried out by the consultant ophthalmologists acting as the clinical authorised operators and are assisted by laser technicians acting as non-clinical authorised operators. Mrs Caldwell is the only non-clinical authorised operator working in the establishment. A register of clinical and non-clinical authorised operators for the lasers is maintained and kept up to date.

Ms Spellman confirmed that the consultant ophthalmologists undertake refractive eye surgical procedures in accordance with medical treatment protocols produced by the medical directors 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

Mrs Caldwell is the appointed LPS, Ms Spellman confirmed that Mrs Caldwell is aware 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 Mrs Caldwell, in her absence, who is suitably skilled to fulfil the role.

As previously discussed a 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 Spellman 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 Spellman 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 Spellman confirmed that 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 when the laser 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 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.

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

Ms Spellman 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 one day, one week, one month, three months and longer 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.

5.2.10 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 Caldwell 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 on 12 January 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 during the visit which included timescales and person responsible for completing the action.

Optical Express has a medical advisory board (MAB) that includes the medical director and clinical services director. The MAB meets quarterly and this meeting is also attended by other members of the organisations senior management team. Optical Express employs an external medical advisory committee (MAC) which is made up of renowned consultants who meet to review and update the treatment protocols and other key documents.

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

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 who are considered to be wholly private doctors as they do not hold a substantive post in the Health and Social Care (HSC) sector in Northern Ireland (NI) and are not on the General Practitioner's (GP's) performer list in NI. Review of the consultant ophthalmologists' 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 ophthalmologists had completed training in accordance with RQIAs training guidance for private doctors and are aware of their responsibilities under GMC Good Medical Practice.

All medical practitioners working within the clinic must have a designated RO. 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 are doing well and how they can improve. Experienced senior doctors (called Responsible Officers) work 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.

The consultant ophthalmologists working within the clinic each have a designated external RO due to their prescribed connection with other health care organisations.

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 practising 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.

A review of the oversight arrangements of the granting of practicing privileges agreements has provided assurance of robust 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.

It was confirmed that the Statement of Purpose and Patient's Guide had been revised and updated in relation to the application of variation to registration . Ms Spellmen confirmed that these documents will be kept under review when and updated as necessary.

It was also evidenced that 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 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 Department of Health (DoH) guidance on complaints handling.

Ms Spellman 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 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 Spell demonstrated that information gathered from complaints 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 MAB.

5.2.11 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 Spellman.

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 Spellman, Responsible Individual, as part of the inspection process and can be found in the main body of the report.

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