

Announced Care Inspection Report 13 December 2017



Optical Express

Type of Service: Independent Hospital (IH) – Refractive Eye Laser
Address: 32 Donegall Place, Belfast BT1 5BB
Tel No: 028 9590 0234
Inspector: Carmel McKeegan
Dr Ian Gillan, RQIA's Medical Physics Advisor

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

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

1.0 What we look for



2.0 Profile of service

This is a registered independent hospital providing refractive laser eye surgery.

Laser Equipment

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) – Dr Roy Henderson (Bioptica)

Laser Protection Supervisor (LPS) – Mrs Gail Caldwell

Medical Support Services – Medical Advisory Board -
 Mr David Teenan – UK Medical Director
 Mr Steve Schallhorn – Chief Medical Officer
 Mr Stephen Hannan – Clinical Services Director

Clinical Authorised Operators – Mr Stefan Kloppe
 Mr Luca Antico
 Mr Waseen Aziz
 Mr Johnathan Carr

A further seven consultant ophthalmologists are included in the list of authorised operators. These consultant ophthalmologists work in other branches of Optical Express, however, may be called upon to provide services in the Belfast branch if the service needs direct this.

Non-Clinical Authorised Operators – Mrs Gail Caldwell

Types of Treatment Provided – Refractive eye surgery – LASIK and LASEK

3.0 Service details

Organisation/Registered Provider: Optical Express Limited Responsible Individual: Ms Mary Spellman	Registered Manager: Mrs Gail Caldwell
Person in charge at the time of inspection: Ms Mary Spellman	Date manager registered: 28 September 2012
Categories of care: AH (DS) – Acute Hospital Day Surgery, PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor (Other)	Number of registered places:

4.0 Inspection summary

An announced inspection took place on 13 December 2017 from 14.00 to 16.45.

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

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

The inspection assessed progress with any areas for improvement since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidenced in all four domains. These related to: patient safety in respect of staff training and development; safeguarding; infection prevention and control; laser safety arrangements; the management of medical emergencies; and the environment. Other examples included: the management of the patients' care pathway; communication; records management and engagement to enhance the patients' experience.

There were no areas requiring improvement identified.

Patients who submitted questionnaire responses provided a mixed response with a similar number of respondents indicating that they were either satisfied or unsatisfied with the services provided. The following comments were included and were discussed during the inspection:

- "Very good friendly staff."
- "Coffee machine not working."
- "I don't always get to see the same member of staff."

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients' experience.

4.1 Inspection outcome

	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 Mary Spellman, registered person and Mrs Gail Caldwell, registered manager, as part of the inspection process and can be found in the main body of the report.

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

4.2 Action/enforcement taken following the most recent care inspection dated 20 December 2016

No further actions were required to be taken following the most recent inspection on 20 December 2016.

5.0 How we inspect

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

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report
- submitted complaints declaration

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of RQIA. Returned completed patient were analysed prior to the inspection. No completed staff questionnaires were received by RQIA.

A poster informing patients that an inspection was being conducted was displayed.

During the inspection the inspector met with Ms Mary Spellman, registered person and Mrs Gail Caldwell, registered manager and non-clinical authorised operator. A tour of the premises was also undertaken.

A sample of records were examined during the inspection in relation to the following areas:

- staffing
- recruitment and section
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- care pathway
- communication
- management and governance arrangements
- practising privileges
- maintenance arrangements

The findings of the inspection were provided to Ms Spellman and Mrs Caldwell at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 20 December 2016

The most recent inspection of the establishment was an announced care inspection.

6.2 Review of areas for improvement from the last care inspection dated 20 December 2016

There were no areas for improvement made as a result of the last care inspection.

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Discussion with Ms Spellman and Mrs Caldwell confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients. This includes a team of consultant ophthalmologists, optometrists, nurses and a laser technician who have evidence of specialist qualifications and skills in refractive laser eye surgery.

Ms Spellman and Mrs Caldwell confirmed that refractive laser eye procedures are only carried out by trained medical practitioners acting as 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.

No new staff have been recruited since the previous inspection, however it was confirmed by Ms Spellman and Mrs Caldwell that a four week induction programme, specific to the role and responsibility of the employee, is provided for all new staff on commencement of employment.

A review of training records evidenced that all authorised operators have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control, fire safety and safeguarding.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, have received laser safety awareness training.

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

Discussion with Ms Spellman and review of documentation confirmed that there are rigorous systems in place for undertaking, recording and monitoring all aspects of staff supervision, appraisal and ongoing professional development.

A review of a sample of two ophthalmic surgeons' details confirmed there was evidence of the following:

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

Recruitment and selection

There have been no authorised operators recruited since the previous inspection. During discussion Ms Spellman and Mrs Caldwell confirmed that, should staff 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.

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

Safeguarding

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. Staff were aware of who the nominated safeguarding lead was within the establishment.

Review of records demonstrated that all staff in the establishment had received training in safeguarding adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was also confirmed that adult safeguarding training in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016) had been undertaken by the safeguarding lead.

Policies and procedures were in place for the safeguarding and protection of adults 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. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

Laser safety

A laser safety file is in place which contains all of the relevant information in relation to laser equipment.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and seen to be up-to-date.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by the medical advisory board in December 2014. Systems are in place to review the medical treatment protocols on an annual basis.

Up to date local rules are in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the laser equipment being used.

The establishment's LPA completed a risk assessment of the laser service and no recommendations were made.

A list of clinical and non-clinical authorised operators is maintained and authorised operators have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for another authorised operator to deputise for the LPS in their absence, who is suitably skilled to fulfil the role. Discussion with Ms Spellman and Mrs Caldwell confirmed that systems are in place to ensure other authorised operators are aware who is the LPS on duty.

The environment in which the laser equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when surgery is being carried out.

The door to the laser suite is locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using digital codes which unauthorised staff do not have access to.

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

Protective eyewear is available as outlined in the local rules for laser technicians/surgical assistants if required.

The establishment has a laser surgical register which is completed every time the equipment is operated and includes:

- the name of the person treated
- the date
- the operator
- the treatment given
- the precise exposure
- any accident or adverse incident

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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance. Quarterly preventative maintenance servicing is in place.

A laser safety file is in place which contains all of the relevant information in relation to laser.

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser protection arrangements of the establishment which were of a high standard. Dr Gillan's report is appended to this inspection report.

Management of medical emergencies

A review of medical emergency arrangements evidenced that an anaphylaxis kit, oxygen and an automated external defibrillator (AED) were provided. A robust system was in place to ensure that emergency medicines and equipment do not exceed their expiry date. There was an identified individual with responsibility for checking emergency medicines and equipment.

A review of training records and discussion with staff confirmed that the management of medical emergencies is included in the induction programme and training is updated on an annual basis in keeping with best practice guidance. It was also confirmed that a resuscitation drill is carried out on a regular basis.

Discussion with staff demonstrated that they have a good understanding of the actions to be taken in the event of a medical emergency and the location of medical emergency medicines and equipment. The policy for the management of medical emergencies reflected best practice guidance. Protocols were available for staff reference outlining the local procedure for dealing with the various medical emergencies.

Infection prevention and control and decontamination procedures

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

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

Arrangements were in place to ensure the decontamination of equipment and reusable medical devices in line with manufacturer's instructions and current best practice. Ms Spellman and Mrs Caldwell confirmed single use equipment is used where possible.

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

Discussion with Ms Spellman and Mrs Caldwell confirmed they had a good knowledge and understanding of IPC measures.

A range of IPC audits has been carried out including:

- environmental
- infection prevention and control
- post treatment infection

There was a range of IPC policies and procedures in place.

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

Environment

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

Detailed cleaning schedules were in place and completed records of cleaning were displayed in various areas.

A carbon dioxide (CO₂) fire extinguisher was available which has been serviced within the last year.

Arrangements are in place for maintaining the environment. This included servicing of the patient lift, fire equipment, emergency lighting, fixed electrical wiring and portable appliance testing (PAT).

The fire risk assessment is reviewed annually and Ms Spellman and Mrs Caldwell confirmed fire training had been completed.

Patient and staff views

Ten patients submitted questionnaire responses to RQIA. One questionnaire was not fully completed. Review of the other nine questionnaires indicated that a similar number of respondents were either satisfied or unsatisfied with this aspect of the service.

No staff questionnaire responses were received by RQIA.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to: staff induction; training; supervision and appraisal; adult safeguarding; infection prevention and control; laser safety; management of emergencies; risk management and the environment.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

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

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

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

It was confirmed patients meet with their surgeon, on the day of surgery, to discuss their individual treatment and any concerns they may have. Arrangements can be made for the patient to meet with the surgeon earlier if necessary.

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

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

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

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

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

Observations made evidenced that patient records are securely stored.

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

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

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

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

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

Communication

As discussed, there is written information for patients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

Mrs Caldwell confirmed that management is approachable and staff views and opinions are listened to. Staff meetings are held on a quarterly basis and review of documentation demonstrated that minutes of staff meetings are retained. Daily team briefing meetings are also held, which are not recorded. Ms Spellman advised that she had made arrangements for the briefing meetings to be recorded from now on.

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

Patient and staff views

Review of the questionnaires submitted to RQIA indicated that a similar number of respondents were either satisfied or unsatisfied with this aspect of the service.

No staff questionnaire responses were received by RQIA.

Areas of good practice

There were examples of good practice found in relation to the completion of clinical records, the arrangements for records management and ensuring effective communication between patients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with Ms Spellman and Mrs Caldwell regarding the consultation and surgery confirmed that patients' modesty and dignity is respected at all times. The initial consultation is provided in a private room with the patient and the optometrist. The surgery is provided within a designated laser suite.

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

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

Appropriate measures are in place to maintain patient confidentiality and observations made evidenced that patient care records were stored securely in locked filing cabinets and electronic records are password protected. Arrangements are also in place for off-site secure archiving facilities.

Patient satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a summary report which is made available to patients and other interested parties. The survey includes patient's opinion on how their privacy and dignity was respected. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that patients were highly satisfied with the quality of treatment, information and care received.

Patient and staff views

Review of the patient questionnaires submitted to RQIA indicated that a similar number of respondents were either satisfied or unsatisfied with this aspect of the service.

No staff questionnaire responses were received by RQIA.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to maintaining patient's confidentiality, ensuring the core values of privacy and dignity were upheld and providing the relevant information to allow patients to make informed choices.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service operators in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Mrs Caldwell confirmed that there were good working relationships and the management were responsive to any suggestions or concerns raised. Arrangements were in place to facilitate annual staff appraisal.

Mrs Caldwell is the nominated individual with overall responsibility for the day to day management of the service. The registered person monitors the quality of services and undertakes a visit to the premises at least every six months in accordance with legislation. Reports of the unannounced monitoring visits were available for inspection.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a three yearly basis. Ms Spellman and Mrs Caldwell confirmed that staff were aware of the policies and how to access them.

Discussion with Ms Spellman demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the establishment. Discussion with Ms Spellman and Mrs Caldwell demonstrated good awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire and review of a random selection of complaints investigation records indicated that complaints have been managed in accordance with best practice.

Discussion with Ms Spellman confirmed that a system was in place to ensure that notifiable events were investigated and reported to RQIA or other relevant bodies as appropriate. A system was in place to ensure that urgent communications, safety alerts and notices are reviewed and where appropriate, made available to key staff in a timely manner.

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

The audit programme included the following:

- environment
- infection prevention and control
- cleaning schedules
- maintenance scheduling
- patient records
- post treatment infection
- patient satisfaction
- personnel files
- complaints
- incidents/accidents
- staff training

All consultant ophthalmologists are directly employed by Optical Express Limited and therefore do not require practising privileges agreements. Ms Spellman confirmed that all staff have contracts of employment.

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

Ms Spellman and Mrs Caldwell demonstrated a clear understanding of their roles and responsibilities in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. Ms Spellman confirmed that the Statement of Purpose and Patient Guide are kept under review, revised and updated when necessary and available on request.

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

Observation of insurance documentation confirmed that current insurance policies were in place.

Patient and staff views

Review of the patient questionnaires submitted to RQIA indicated that a similar number of respondents were either satisfied or unsatisfied with this aspect of the service.

No staff questionnaire responses were received by RQIA.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to the management of complaints and incidents, quality improvement and maintaining good working relationships.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Total number of areas for improvement	0	0

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a QIP is not required nor included as part of this inspection report.

13th December 2017

Ms Carmel McKeegan
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Carmel

Laser Protection Report

Optical Express Laser Eye Clinic, Donegal Place, Belfast BT28 6EA

Introduction

Further to the inspection of the above premises earlier today this report summarises the main laser protection aspects where improvement may be required. The findings are based on the requirements of current legislation, relevant guidance notes and European Standards.

Deficiencies / Comments

The laser Protection arrangements remain at a high standard.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix**Laser Systems***Optical Express Laser Eye Clinic, Donegal Place, Belfast BT28 6EA***Excimer Laser**

Manufacturer:	VisX
Model	Star 4
Product number	0030-4638
Serial Number:	5629
Output wavelength:	ArF (193nm)
Laser Class:	4

Intralase

Manufacturer:	Intralase
Model	FS
Serial Number:	0107-40185
Output wavelength:	Nd:Glass (1053nm)
Laser Class:	3B

Laser Protection Advisor

Dr Roy Henderson, Bioptica



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