

Announced Care Inspection Report 12 February 2019



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
RQIA's Medical Physics Advisor: Dr Ian Gillan

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):

- Mr Mike Regan

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 Klopper
- Mr Luca Antico

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	Registered Manager: Mrs Gail Caldwell
Responsible Individual: Ms Mary Spellman	
Person in charge at the time of inspection: Ms Mary Spellman	Date manager registered: 28 September 2012
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers (PD) Private Doctor	

4.0 Inspection summary

An announced inspection took place on 12 February 2019 from 10.30 to 12.30.

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

The inspection assessed progress with any areas for improvement identified 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.

No areas requiring improvement were identified during this inspection.

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, responsible individual 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 13 December 2017

No further actions were required to be taken following the most recent inspection on 13 December 2017.

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

Questionnaires were provided to patients prior to the inspection by the establishment on behalf of RQIA. Returned completed patient questionnaires were analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire prior to the inspection. One returned completed staff questionnaire was received prior to the inspection.

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

During the inspection the inspector met Ms Mary Spellman, responsible individual and Mrs Gail Caldwell, registered manager. A tour of the premises was also undertaken.

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

- staffing
- recruitment and selection
- 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 13 December 2017

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 13 December 2017

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 are 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 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.

A review of completed induction programmes evidenced that induction training is provided to 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 in keeping with the RQIA training guidance.

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 one consultant ophthalmic surgeon's 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

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

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policy 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 for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included. Ms Spellman and Mrs Caldwell were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

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 premises 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. Ms Spellman and Mrs Caldwell confirmed that systems are in place to ensure other authorised operators are aware who the LPS on duty is at any given time.

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 a key and digital codes which unauthorised staff do not have access to. Arrangements are in place for the safe custody of the laser key when not in use.

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 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 and concluded they 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 emergency medicines were provided in keeping with the British National Formulary (BNF), and that emergency equipment as recommended by the Resuscitation Council (UK) guidelines was retained. 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.

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. The establishment has a designated IPC lead nurse.

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. 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 have been carried out including:

- environmental
- hand hygiene
- post treatment infection

The compliance rate was noted to be very high and an action plan was in place for areas of non-compliance.

There were a range of IPC policies and procedures in place which are held within an IPC manual.

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 good 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.

A fire risk assessment had been undertaken and is reviewed annually. Mrs Caldwell confirmed fire training and fire drills had been completed and confirmed that all staff were aware of the action to take in the event of a fire.

Areas of good practice

There were examples of good practice found in relation to staff recruitment, induction, training, supervision and appraisal, safeguarding, management of medical emergencies, infection prevention control and decontamination procedures, radiology and the environment.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
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. This may be by direct face to face discussion or can be facilitated remotely by telephone or video link.

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.

Four 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 electronically.

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 in accordance with the General Data Protection Regulations (GDPR) that came into effect during May 2018 and where appropriate ICO regulations and Freedom of Information legislation. Optical Express Limited has employed a GDPR officer to oversee the management of records and ensure compliance with the GPDR.

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.

Staff meetings are held on a monthly basis in conjunction with colleagues in the Dublin Clinic and review of documentation demonstrated that minutes of staff meetings are retained.

Staff confirmed that there are good working relationships and there is an open and transparent culture within the practice.

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
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 the planned day 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 electronically and are password protected. Any paper records are stored in a locked cabinet within a locked room and there are arrangements 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. 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. Some comments from patients included:

Areas of good practice

There were examples of good practice found in 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
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 users 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. Ms Spellman monitors the quality of services and undertakes a visit to the premises at least every six months in accordance with legislation. Reports of previous unannounced monitoring visits were available for inspection which verified these were undertaken six monthly and had been conducted in a meaningful manner.

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. Mrs Caldwell confirmed that all staff were aware of the policies and how to access them.

Discussion with Ms Spellman and Mrs Caldwell 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.

It was 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 and Mrs Caldwell confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at

appropriate intervals. It was 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 includes the following;

- environment
- infection prevention and control
- cleaning schedules
- maintenance scheduling
- patient records
- post treatment infection
- patient satisfaction
- personnel files
- complaints
- incident/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 they were aware of who 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. It was confirmed that the Statement of Purpose and Client's 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.

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
Areas for improvement	0	0

6.8 Equality data

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 and Mrs Caldwell.

6.9 Patient and staff views

Eleven patients submitted questionnaire responses to RQIA. All 11 patients indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led. All patients indicated that they were very satisfied with each of these areas of their care. The following comments were provided in completed patient questionnaires;

- 'Staff are all very pleasant and helpful'
- 'Great results very happy. Lovely team who looked after me during my time.'
- 'I was completely satisfied with the level of care and service. I am delighted with the results. Thank you.'

One staff member submitted a questionnaire response to RQIA. The staff member indicated that they felt patient care was safe, effective, that patients were treated with compassion and that the service was well led and also indicated that they were very satisfied with each of these areas of patient care.

7.0 Quality improvement plan

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

12th February 2019

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 / Mike Regan
Date of last visit 27 April 2017



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