

# Announced Care Inspection Report 20 December 2016



## Optical Express

**Type of service: Independent Hospital (IH) - Refractive Eye Laser**

**Address: 32 Donegall Place, Belfast, BT1 5BB**

**Tel no: 028 9590 0234**

**Inspector: Emily Campbell**

[www.rqia.org.uk](http://www.rqia.org.uk)

Assurance, Challenge and Improvement in Health and Social Care

## 1.0 Summary

An unannounced inspection of Optical Express took place on 20 December 2016 from 09:50 to 13:10.

The inspection sought to determine if the refractive eye laser service was delivering safe, effective and compassionate care and if the service was well led. The inspector was accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor; the findings and report of Dr Gillan is appended to this report.

### **Is care safe?**

Observations made, review of documentation and discussion with Ms Mary Spellman, registered person and Mrs Gail Caldwell, registered manager, demonstrated that systems and processes were in place to ensure that care to patients was safe and avoid and prevents harm. Areas reviewed included, staffing, recruitment and selection, safeguarding, laser safety, management of medical emergencies, infection prevention control and decontamination and the general environment. No requirements or recommendations have been made.

### **Is care effective?**

Observations made, review of documentation and discussion with Ms Spellman and Mrs Caldwell demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included care pathway and communication. No requirements or recommendations have been made.

### **Is care compassionate?**

Observations made, review of documentation and discussion with Ms Spellman and Mrs Caldwell demonstrated that arrangements are in place to promote patients' dignity, respect and involvement in decision making. No requirements or recommendations have been made.

### **Is the service well led?**

Information gathered during the inspection evidenced that there was effective leadership and governance arrangements in place which creates a culture focused on the needs of patients in order to deliver safe, effective and compassionate care. Areas reviewed included organisational and staff working arrangements, the arrangements for policy and risk assessment reviews, the arrangements for dealing with complaints, incidents and alerts, insurance arrangements and the registered persons' understanding of their roles and responsibilities in accordance with legislation. No requirements or recommendations have been made.

This inspection was underpinned by 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 (DHSPPS) Minimum Care Standards for Independent Healthcare Establishments (July 2014).

## 1.1 Inspection outcome

|   | Requirements | Recommendations |
|---|--------------|-----------------|
| <b>Total number of requirements and recommendations made at this inspection</b> | 0            | 0               |

This inspection resulted in no requirements or recommendations being made. 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.

## 1.2 Actions/enforcement taken following the most recent care inspection

There were no further actions required to be taken following the most recent inspection on 11 August 2015.

## 2.0 Service details

|   |  |
|---|--|
| <b>Registered organisation/registered person:</b><br>Optical Express Limited<br>Ms Mary Spellman  | <b>Registered manager:</b><br>Mrs Gail Caldwell      |
| <b>Person in charge of the home at the time of inspection:</b><br>Ms Mary Spellman  | <b>Date manager registered:</b><br>28 September 2012 |
| <b>Categories of care:</b><br>AH (DS) – Acute Hospital Day Surgery,<br>PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers<br>PD Private Doctor (Other) |  |

### 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) –** Ms 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 Users –** Mr Stefan Kloppe  
 Mr Luca Antico  
 Mr Waseen Aziz  
 Mr Johnathan Carr

A further seven consultant ophthalmologists are included in the list of authorised users. 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 Users –** Mrs Gail Caldwell

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

### 3.0 Methods/processes

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of the RQIA. No questionnaire responses were submitted to RQIA. Prior to inspection we analysed the following records: notifiable events and complaints declaration.

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

Records were 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

## **4.0 The inspection**

### **4.1 Review of requirements and recommendations from the most recent inspection dated 11 August 2015**

The most recent inspection of the establishment was an announced care inspection. No requirements or recommendations were made during this inspection.

### **4.2 Review of requirements and recommendations from the last care inspection dated 11 August 2015**

As above.

## **4.3 Is care safe?**

### **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, 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 users. Mrs Caldwell is the only non-clinical authorised user currently working in the establishment. A register of clinical and non-clinical authorised users for the lasers is maintained and kept up to date.

No new staff have been recruited since the previous inspection, however, Ms Spellman and Mrs Caldwell confirmed that induction training is provided to new staff on commencement of employment. The four week induction programme is developed in accordance with the specific needs of the employee in relation to their role and responsibility and includes the identification of achievement goals at the end of each week.

A review of training records evidenced that all authorised users 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.

Ms Spellman confirmed by email on 22 December 2016 that laser safety awareness training has been scheduled to be provided on 22 and 23 December 2016 to all other staff employed at the establishment, but not directly involved in the use of the laser equipment.

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. Review of three appraisal records confirmed that appraisal is undertaken on an annual basis.

The personnel records of consultant ophthalmologists/ private doctors are retained by the Clinical Director in Scotland who acts as their line manager. Ms Spellman maintains a database which confirms the following records are retained:

- 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

It was suggested that copies of consultant ophthalmologists/ private doctors personnel files, including training records, are also retained in the establishment.

## **Recruitment and selection**

There have been no authorised users recruited since the previous inspection. During discussion Ms Spellman 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.

## **Safeguarding**

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.

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.

Ms Spellman and Mrs Caldwell were advised of the new regional guidance document 'Adult Safeguarding Prevention and Protection in Partnership (July 2015)' which should be used for policy review and staff awareness. The revised adult safeguarding gateway numbers, for referral in the event of a concern being identified, were provided to Ms Spellman during the inspection.

## **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 this expires on 16 April 2017.

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 on 16 April 2014, which expire on 16 April 2017 and no recommendations were made.

A list of clinical and non-clinical authorised users is maintained and authorised users 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 user 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 users 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 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 Ms Spellman and Mrs Caldwell 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 Ms Spellman and Mrs Caldwell 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.

### **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 have 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 (CO<sub>2</sub>) 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, and 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

Ms Spellman confirmed that questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of the RQIA. No questionnaire responses were submitted to RQIA.

## Areas for improvement

No areas for improvement were identified during the inspection.

|                               |          |                                  |          |
|-------------------------------|----------|----------------------------------|----------|
| <b>Number of requirements</b> | <b>0</b> | <b>Number of recommendations</b> | <b>0</b> |
|-------------------------------|----------|----------------------------------|----------|

## 4.4 Is care effective?

### 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.

Ms Spellman confirmed that in accordance to GMC 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 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.

Ms Spellman confirmed by email on 22 December 2016 that the establishment is registered with the Information Commissioner's Office (ICO) which is valid to 14 August 2017.

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. Ms Spellman confirmed by email on 22 December 2016 that the retention schedule had been amended to reflect that records would be retained for 10 years in keeping with The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011.

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**

As discussed previously, no patient or staff questionnaires were submitted to RQIA.

### **Areas for improvement**

No areas for improvement were identified during the inspection.

|                               |          |                                  |          |
|-------------------------------|----------|----------------------------------|----------|
| <b>Number of requirements</b> | <b>0</b> | <b>Number of recommendations</b> | <b>0</b> |
|-------------------------------|----------|----------------------------------|----------|

## **4.5 Is care compassionate?**

### **Dignity respect and involvement with decision making**

Discussion with Ms Spellman and Mrs Caldwell regarding 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 are also required to watch a video presentation on informed consent at their initial consultation with the optometrist, as part of the consent process.

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. An action plan is developed to inform and improve services provided, if appropriate.

## Patient and staff views

As discussed previously, no patient or staff questionnaires were submitted to RQIA.

## Areas for improvement

No areas for improvement were identified during the inspection.

|                               |          |                                  |          |
|-------------------------------|----------|----------------------------------|----------|
| <b>Number of requirements</b> | <b>0</b> | <b>Number of recommendations</b> | <b>0</b> |
|-------------------------------|----------|----------------------------------|----------|

### 4.6 Is the service well led?

## 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. Ms 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. There was a 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 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. 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**

As discussed previously, no patient or staff questionnaires were submitted to RQIA.

### **Areas for improvement**

No areas for improvement were identified during the inspection.

|                               |          |                                  |          |
|-------------------------------|----------|----------------------------------|----------|
| <b>Number of requirements</b> | <b>0</b> | <b>Number of recommendations</b> | <b>0</b> |
|-------------------------------|----------|----------------------------------|----------|

## **5.0 Quality improvement plan**

There were no issues identified during this inspection, and a QIP is neither required, nor included, as part of this inspection report.

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 registered provider from their responsibility for maintaining compliance with the regulations and standards.



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20<sup>th</sup> December 2016

Mrs E Campbell  
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BT1 3BT

Dear Mrs Campbell

## **Laser Protection Report**

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

### **Summary**


Laser protection arrangements continue to be of a high standard

### **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**

None



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**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

Date of most recent LPA visit - April 2014, next visit planned for April 2017