

Announced Care Inspection Report 19 October 2016



Optimax Laser Eye Clinic

**Type of service: Independent Hospital (IH) –
Refractive laser eye surgery**

Address: 7 Derryvolgie Avenue, Belfast, BT9 6FL

Tel no: 02890661118

Inspectors: Winnie Maguire accompanied by Liz Colgan

1.0 Summary

An announced inspection of Optimax Laser Eye Clinic took place on 19 October 2016 from 09.45 to 15.00.

The inspection sought to determine if the refractive laser eye surgery service was delivering safe, effective and compassionate care and if the service was well led. Dr Ian Gillan, RQIA's medical physics advisor carried out a visit to Optimax on 18 October 2016. Dr Gillan's findings and report is appended to this report.

Is care safe?

Observations made, review of documentation and discussion with Mr James Rowley registered person, Mrs Susan Moffatt, registered manager and staff demonstrated that systems and processes were in place to ensure that care to patients was safe and avoids 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 Mr Rowley, Mrs Moffatt, and staff 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 Mr Rowley, Mrs Moffatt and staff 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, arrangements for practising privileges, insurance arrangements and the registered persons' understanding of their role and responsibility 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
Total number of requirements and recommendations made at this inspection	0	0

This inspection resulted in no requirements or recommendations being made. Findings of the inspection were discussed with Mr James Rowley, registered person and Mrs Susan Moffatt 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.

2.0 Service details

Registered organisation/registered person: Optimax Laser Eye Clinic Mr James Rowley	Registered manager: Mrs Susan Moffatt
Person in charge of the home at the time of inspection: Mrs Susan Moffatt	Date manager registered: 30 March 2006
Categories of care: (IH) Independent Hospital PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PD private doctor	

Laser equipment

Manufacturer: Schwind
Model: 250
Serial Number: 5244
Laser Class: 4

Manufacturer: Intralase
Model: FS/F530
Serial Number: 0506-40039
Laser Class: 4

Laser protection advisor (LPA) - Dr Sandy Mosse

Laser protection supervisor (LPS) - Mrs Susan Moffatt

Medical support services - Clinical Director Optimax Ltd

Clinical authorised users - Dr S Mughal
Dr M Ghassan - Ayoubi

Non –clinical authorised users - Mrs Susan Moffatt
Ms Valerie Smyth
Ms Kelly Braniff
Ms Fiona Quinn

Types of treatment provided - Lasik, Lasek, Epi-lasek and Photorefractive Keratectomy

3.0 Methods/processes

Questionnaires were provided to patients and staff prior to the inspection by the establishment on behalf of the RQIA. Prior to inspection we analysed the following records: notifiable events, complaints declaration and returned completed staff and patient questionnaires.

During the inspection the inspectors met with Mr Rowley, registered person, Mrs Moffatt, registered manager and three non-clinical authorised users. 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 17 November 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 17 November 2015

As above

4.3 Is care safe?

Staffing

Discussion with Mr Rowley, Mrs Moffatt and staff confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and patients. This includes a team of ophthalmic surgeons, an optometrist, a nurse, laser technicians and counsellors who have evidence of specialist qualifications and skills in refractive laser eye surgery.

It was confirmed that refractive laser eye procedures are only carried out by ophthalmic surgeons acting as clinical authorised users. A register of clinical and non-clinical authorised users 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 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.

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

Discussion with Mrs Moffatt 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 two 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
- annual appraisal by a trained medical appraiser
- an appointed responsible officer
- arrangements for revalidation

Recruitment and selection

There have been no authorised users recruited since the previous inspection. During discussion Mrs Moffatt 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

Policies and procedures were in place for the safeguarding and protection of adults at risk of harm. The safeguarding policy was amended following inspection and an electronic copy forwarded to RQIA. The policy 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 expires on 1 January 2017.

Refractive laser eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by the clinical director of Optimax Ltd in March 2015. Systems are in place to review the medical treatment protocols on three yearly 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 in March 2015 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.

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 keys and passwords. Arrangements are in place for the safe custody of the laser keys 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 was available as outlined in the local rules for laser technicians 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. The most recent service report was reviewed as part of the inspection process.

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

Management of medical emergencies

A review of medical emergency arrangements evidenced that an anaphylaxis kit is in place, oxygen and an automated external defibrillator (AED) 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.

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. Staff confirmed single use equipment is used where possible.

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

Discussion with staff 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 very good standard of maintenance and décor.

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

Carbon dioxide (CO₂) fire extinguishers were available which have been serviced within the last year.

Arrangements are in place for maintaining the environment.

A legionella risk assessment was undertaken in October 2016 and water temperature is monitored and recorded as recommended.

A fire risk assessment had been undertaken in March 2016 and staff confirmed fire training and fire drills had been completed. Staff demonstrated that they were aware of the action to take in the event of a fire. Emergency lighting inspection had been carried out March 2016. Maintenance and servicing of the laser suite ventilation had been carried on 7 June 2016.

It was noted on review of incident reports and minutes of meetings that there had been difficulties with hot water temperatures at a number of hand washing sinks in the consultation rooms; this was despite remedial work by an engineer on a number of occasions. Mr Rowley and Mrs Moffatt confirmed during inspection that the affected hand washing sinks in the consultation rooms will be replaced in line with best practice and the hot water difficulties will be robustly investigated and resolved.

Patient and staff views

Seventeen patients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. Comments provided included the following :

- “The aftercare programme is super! I was advised to have extra appointments to ensure my eyes remained in good health – at no cost.”
- “Definitely.”
- “Staff extremely friendly and approachable, and took care to explain the risks.”
- “The clinic is very clean and relaxing for anyone getting treatment. Very friendly and appealing place.”
- “Very detailed consultation. Staff very professional and friendly.”
- “Lovely clinic and lovely staff.”
- “Care was really well explained. Team are very helpful and professional.”

Six staff submitted questionnaire responses. All indicated that they felt that patients are safe and protected from harm. Staff spoken with during the inspection concurred with this. The following comment was provided:

- “Robust recruitment, induction, appraisal and training measures in place. A series of weekly, monthly and bi-annual checks are in place to ensure the premises are well maintained.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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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.

It was 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 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.

Six 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.

It was confirmed 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 confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a regular basis. 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 establishment.

Patient and staff views

All patients who submitted questionnaire responses indicated that they get the right care, at the right time and with the best outcome for them. Comments provided included the following:

- “Had time to decide on treatment, everything fully explained.”
- “Very personal service.”
- “Great explanations given throughout. Always ensured we were well looked after.”
- “They constantly make you feel comfortable and feel important. Amazing people and service, never felt nervous or afraid because of how friendly staff were.”
- “Consultation was in-depth.”
- “Treatment was scheduled very quickly to ensure I had it before starting university. Optimax have been great at getting appointments to suit me.”

All submitted staff questionnaire responses indicated that they felt that patients get the right care, at the right time and with the best outcome for them. Staff spoken with during the inspection concurred with this. The following comment was provided:

- “Comprehensive auditing is in place to monitor all outcomes.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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4.5 Is care compassionate?

Dignity respect and involvement with decision making

Discussion with Mrs Moffatt and staff 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.

As stated previously, 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 meet the surgeon again on the day of surgery to complete the consent process for surgery.

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.

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.

Patient and staff views

All patients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care. Comments provided included the following:

- "Staff are so friendly."
- "Definitely."
- "Staff are extremely friendly and approachable, and took care to explain risks."
- "You don't feel pressured into anything and they make you feel comfortable with all the information you are given. Information wasn't confusing or long-winded which helped me understand what I was to expect. Very happy with my choice."
- "Everyone made the whole process very comfortable."
- "Treatment day was made easy considering I was very nervous. They put my mum at ease as well."
- "Staff extremely professional and friendly."

All submitted staff questionnaire responses indicated that they felt that patients are treated with dignity and respect and are involved in decision making affecting their care. Staff spoken with during the inspection concurred with this. The following comment was provided:

- "Detailed consultations take place. Excellent patient pathways to ensure confidentiality and all patients regularly complete satisfaction surveys."

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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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. Staff 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 Moffatt has overall responsibility for the day to day management of the service. Mr Rowley confirmed he has arrangements in place to monitor the quality of services and he or his appointee 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. Advice was given on the structure and content of the report.

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. Staff spoken with were aware of the policies and how to access them.

Discussion with Mrs Moffatt demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was displayed in the establishment. Discussion with Mrs Moffatt 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 indicated that complaints have been managed in accordance with best practice.

Discussion with Mrs Moffatt 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.

It was confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to patients at appropriate intervals. Mrs Moffatt and staff confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. Review of the audit programme noted the following audits are undertaken:

- asset register
- environmental
- patients notes
- drugs audit
- fire drill
- control of substances hazardous to health –COSHH
- multi-purpose task risk assessment
- IR1/IR2
- resuscitation drill
- infection control audit

Mrs Moffatt outlined the process for granting practising privileges and confirmed medical practitioners meet with clinical director of Optimax prior to privileges being granted.

Two medical practitioner’s personnel files reviewed confirmed that there was a written agreement between each medical practitioner and the establishment setting out the terms and conditions of practising privileges which has been signed by both parties.

There are systems in place to review practising privileges agreements every two years.

A policy and procedure was in place in place which outlined the arrangements for application, granting, maintenance, suspension and withdrawal of practising privileges.

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

Mr Rowley and Mrs Moffatt demonstrated a clear understanding of their role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. It was confirmed that the statement of purpose and patient’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.

Patient and staff views

All patients who submitted questionnaire responses indicated that they felt that the service is well managed. Comments provided included the following:

- “Staff were amazing, friendly and very caring. I really liked how I was treated throughout by every member that I met. Service was that good that I told all my friends/workmates about how good it is.”
- “Very impressed with the care given by the staff. Nothing was too much trouble.”
- “The atmosphere in the clinic was always friendly and helpful. Delighted I had the treatment.”
- “Changes were highlighted during consultation and prior to surgery.”
- “I’ve had no issues throughout the whole process - very happy.”

All submitted staff questionnaire responses indicated that they felt that the service is well led. Staff spoken with during the inspection concurred with this. The following comment was provided:

- “Clear guidelines and accessibility on all the above points. Regular auditing carried out and results discussed at staff meetings.”

Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements	0	Number of recommendations	0
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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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