Announced Care Inspection Report
25 February 2020

Optimax Laser Eye Clinic

Type of Service: Independent Hospital (IH) – Refractive Eye lasers
Address: 7 Derryvolgie Avenue, Belfast, BT9 6FL
Tel No: 028 9066 1118
Inspector: Emily Campbell
RQIA's Medical Physics Advisor: Dr Ian Gillan

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

Ophthalmology	–	Ar F Excimer laser
Manufacturer:		Schwind
Model:		250
Serial Number:		S244
Laser Class:		4

Ophthalmology – Nd YLF laser
Manufacturer: Intralase
Model: FS/F530
Serial Number: 0506-40039
Laser Class: 3B

Laser protection advisor (LPA):

- Ms Julie Robinson (University College London Hospitals Laser Protection Services)

Laser protection supervisor (LPS):

- Ms Fiona Quinn

Medical support services:

- Dr B Illango, Medical Director, A Sokwala, Head Optometrist, Dr M Stewart, Medical Director (Omtimax Ltd)

Clinical authorised operators:

- Dr M Ghassan - Ayoubi

Non–clinical authorised operators:

- Ms Fiona Quinn
- Ms Valerie Smyth
- Ms Kelly Braniff

Types of treatment provided:

- Lasik, Lasek, Epi-lasek and Photorefractive Keratectomy

3.0 Service details

Organisation/Registered Provider: Optimax Laser Eye Clinic **Responsible Individual:** Mr James Rowley	**Registered Manager:** Ms Fiona Quinn
Person in charge at the time of inspection: Ms Fiona Quinn	**Date manager registered:** 12 August 2019
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	

4.0 Inspection summary

An announced inspection took place on 25 February 2020 from 9:40 to 15:15.

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 included the arrangements for staffing, recruitment and selection, safeguarding, the management of medical emergencies, infection prevention and control and the environment. Other examples included the management of the patients' care pathway, communication, records management, the management and governance arrangements, practising privileges arrangements and engagement to enhance the patients' experience.

Three areas for improvement were identified. One area for improvement was made against the regulations in relation to reviewing the laser local rules and risk assessment. Two areas for improvement against the standards were made regarding the laser protection advisor (LPA) service level agreement and review of policies to identify that they relate to Optimax.

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	1	2

Details of the Quality Improvement Plan (QIP) were discussed with Mr James Rowley, responsible individual, and Ms Fiona Quinn, registered manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

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

4.2 Action/enforcement taken following the most recent care inspection dated 15 March 2019

No further actions were required to be taken following the most recent inspection on 15 March 2019.

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. Returned completed staff questionnaires were analysed prior to and following the inspection.

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

During the inspection the inspector met with Ms Fiona Quinn, registered manager and non-clinical authorised operator, and another non-clinical authorised operator. The inspector spoke briefly with Mr James Rowley, responsible individual, during the inspection and at the conclusion of the inspection. 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 Mr Rowley and Ms Quinn at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 15 March 2019

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 15 March 2019

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 Quinn 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 one consultant ophthalmologist, an optometrist, a nurse and laser technicians/surgical assistants 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 a trained medical practitioner acting as clinical authorised operator and laser technicians acting as non-clinical authorised operators. A register of clinical and non-clinical authorised operators for the laser is maintained and kept up to date.

No new staff have been recruited since the previous inspection, however, it was confirmed that an induction programme would be provided to any new staff recruited.

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. Some training records of one authorised operator were not available, however, these were provided to RQIA by email on 3 March 2020 and evidenced that all training was up to date and current. Ms Quinn provided assurance that all training records would be retained in the future.

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 to confirm that staff who have professional registration, undertake continuing professional development (CPD) in accordance with their professional body's recommendations. A review of records confirmed that there are arrangements in place for monitoring the professional body registration status of all clinical staff.

A review of a sample of records confirmed that arrangements are in place for monitoring the professional indemnity of all staff who require individual indemnity cover.

Discussion with Ms Quinn 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 ophthalmologist/private doctor's details confirmed there was evidence of the following:

- 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
- ongoing annual appraisal by a trained medical appraiser
- an appointed responsible officer (RO)
- arrangements for revalidation

Discussion with Ms Quinn confirmed that the private doctor/surgeon is aware of their responsibilities under GMC Good Medical Practice

Recruitment and selection

There have been no authorised operators recruited since the previous inspection. Ms Quinn confirmed that 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

It was confirmed that refractive laser eye procedures are not provided to persons under the age of 18 years.

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, including who the nominated safeguarding lead was.

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 policies included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

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 was in place. A number of issues were identified below which need to be addressed to ensure that it contains all of the relevant information in relation to laser equipment.

Dr Ian Gillan, RQIA’s Medical Physics Advisor, reviewed the laser protection arrangements of the establishment. Dr Gillan’s report is appended to this inspection report.

There was written confirmation of the appointment and duties of a certified LPA which covered the calendar year 2019. An area for improvement was made against the standards that evidence is provided in respect of the service level agreement between the establishment and the LPA for 2020. A copy should be retained in the laser safety file.

Refractive eye surgical procedures are carried out by trained medical practitioners in accordance with medical treatment protocols produced by the medical directors of Optimax in February 2019. Systems are in place to review the medical treatment protocols on an annual basis.

Since the previous inspection, a new LPA and a new laser protection supervisor (LPS) have been appointed. Two sets of local rules, one for each laser, were in place which had been developed by the previous LPA in March 2018. These had not been reviewed and updated to reflect a change in the LPA or the LPS. Dr Gillan identified the following issues in relation to protective eyewear:

- the Intralase local rules details the level of protection required for protective eyewear, however protective eyewear for this laser is not available in the clinic
- conversely the Schwind local rules do not detail the level of protection required for protective eyewear, however eyewear with protection level L7 against the output wavelength of 193nm is available in the clinic
- the action list within the risk assessment stated that the protective eyewear should be moved to outside the entrance door of the clinic, however the staff were unable to state which laser the available eyewear provided protection against
- both sets of local rules suggested that the protective eyewear would only be used by the engineer

The establishment's previous LPA completed a risk assessment of the premises on 4 April 2018. Two recommendations had been made; these had not been signed off as addressed and it was unclear if the recommendation in relation to additional signage to be put on the Control of Substances Hazardous to Health (COSHH) cupboard had been addressed, and staff could not advise on this matter. The second recommendation was in relation to protective eyewear; as discussed above further clarification by the LPA is required in this regard.

These matters were brought to the attention of Ms Quinn who confirmed she would contact the LPA in relation to these issues. On 2 March 2020 two new sets of local rules and a risk assessment were provided to RQIA which indicated that they had been reviewed by the current LPA on 26 February 2020. However, whilst the names of the LPA and LPS had been amended on the local rules, the detail regarding the eyewear remained unchanged and the risk assessment was unchanged. An area for improvement against the regulations was made that the LPA should review and clarify the arrangements regarding protective eyewear in the local rules and review the risk assessment to ensure it is current. Any recommendations made as a result of the revised risk assessment should be signed and dated on completion. Copies of the revised documents should be provided to RQIA.

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.

An optical radiation safety policy was retained in the laser safety file. However, the policy did not identify the name of the author, their designation or that it relates to Optimax. This matter is discussed further in section 6.7 of the report.

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 keypad doors to the laser suite are locked, when the laser equipment is in use but can be opened from the outside in the event of an emergency.

The laser equipment is operated using keys and passwords. Arrangements are in place for the safe custody of the laser keys when not in use.

A laser safety warning sign is displayed stating the laser room should not be entered when the warning light is on.

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 reports of 30 and 31 December 2019 were reviewed as part of the inspection process.

Dr Ian Gillan, RQIA's Medical Physics Advisor, reviewed the laser protection arrangements of the establishment. 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 is in place, consisting of one 300mcg adrenaline auto injector and adrenaline 1:1000 ampoules. It was suggested that as the service does not provide treatment to anyone under the age of 18 years, that on expiry, the auto injector should be replaced with the adult dose of adrenaline 500 mcg. Oxygen and an automated external defibrillator (AED) were 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. It was confirmed that resuscitation drills are undertaken on a regular basis, the most recent being carried out in January 2020.

There was a resuscitation policy in place.

Infection prevention and control and decontamination

The treatment room was clean and clutter free. Discussion with Ms Quinn evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided. As discussed previously, authorised operators have up to date training in infection prevention and control.

An IPC audit is carried out once or twice each year by the Optimax company IPC nurse and an action plan is generated as a result of this where applicable. Internal audits are also carried out including environmental and hand hygiene audits.

Risk management

Ms Quinn confirmed that risk management procedures are in place to ensure that risks are identified, assessed and managed and that arrangements were in place to review risk assessments. A review of documentation evidenced that risks, including near misses, have been identified and recorded detailing the measures to mitigate and control the risks and include any learning/findings implemented and assured.

Environment

The premises were maintained to a high standard of maintenance and décor. Cleaning schedules for the establishment were in place.

Arrangements were in place for maintaining the environment. This includes portable appliance testing (PAT), electrical installation, maintenance contracts for ventilation and cooling systems, boiler servicing and fire safety equipment servicing and checks.

A legionella risk assessment was in place and water temperature is monitored and recorded monthly.

A fire risk assessment had been undertaken 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. The most recent fire drill was undertaken in September 2019. As discussed previously, all authorised operators have up to date training in fire safety awareness.

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

Areas of good practice

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

Areas for improvement

Evidence should be provided in respect of the service level agreement between the establishment and the LPA for 2020. A copy should be retained in the laser safety file.

The LPA should review and clarify the arrangements regarding protective eyewear in the local rules and review the risk assessment to ensure it is current. Copies of the revised documents should be provided to RQIA.

	Regulations	Standards
Areas for improvement	1	1

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.

Ms Quinn confirmed patients meet with their surgeon, at least one week prior to surgery and on the day of surgery, to discuss their individual treatment and any concerns they may have.

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 the surgeon and/or 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 intervals of 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. 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 in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate Information Commissioner's Office (ICO) regulations and Freedom of Information legislation. The establishment is registered with the 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.

Audits

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

Arrangements are in place to escalate shortfalls identified during the audit process through the establishment's governance structure.

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 policy for advertising and marketing was not reviewed during the inspection. Ms Quinn advised that advertising is managed by the marketing department in the organisation's head office.

Staff confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis and 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 management of clinical records, the range and quality of audits 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 Quinn 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 establishment 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 at least one week prior to and 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 and electronic records are password protected.

Patient satisfaction surveys are carried out by the establishment and the results of these are collated on an annual basis 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. The summary report evidenced a high level of satisfaction with the service.

Areas of good practice

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

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. 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. There was a nominated individual with overall responsibility for the day to day management of the service.

A visit by the registered provider was undertaken as required under Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005; a report was produced and made available for patients, their representatives, staff, RQIA and any other interested parties to read. An action plan was developed to address any issues identified which include timescales and person responsible for completing the action.

A review of reports generated to document the findings of Regulation 26 visits evidenced that the visits were in keeping with the legislation.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a two yearly basis. It was noted that whilst the majority of policies identified the name and designation of the author, there was seldom reference to reflect that these related to Optimax. As discussed previously, the optical radiation safety policy did not identify the name of the author, their designation or that it relates to Optimax. An area for improvement was made against the standards to review policies and reflect that they relate to Optimax and where applicable, the name of the author and their designation.

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

There was a complaints policy and procedure in place which was in accordance with legislation and DoH guidance on complaints handling. Patients and/or their representatives were made aware of how to make a complaint by way of the patient's guide and information on display in the establishment. Discussion with staff confirmed that they were knowledgeable about how to respond to complaints.

There have been no complaints since the previous inspection, however, review of documentation and discussion with Ms Quinn confirmed that arrangements were in place to effectively manage complaints from patients, their representatives or any other interested party. It was confirmed that records of complaints would include details of any investigation undertaken, all communication with complainants, the outcome of the complaint and the complainant's level of satisfaction. Arrangements were in place to share information about complaints and compliments with staff. An audit of complaints on an organisational basis is used to identify trends, drive quality improvement and to enhance service provision.

The establishment retains compliments received, e.g. thank you letters and cards and there are systems in place to share these with staff.

Ms Quinn 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 Quinn confirmed that arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. If required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. Audits undertaken include the following:

- patient records
- medication
- IPC
- hand hygiene
- environmental
- incident reporting
- complaints
- surgical safety checklist

Ms Quinn outlined the process for granting practising privileges and confirmed medical practitioners meet with the medical directors prior to privileges being granted. The ophthalmic surgeon's details were reviewed and evidenced that there was a written agreement between him 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 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 Ms Quinn demonstrated a clear understanding of their roles and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. Ms Quinn 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.

Areas of good practice

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

Areas for improvement

Review policies and reflect that they relate to Optimax and where applicable, the name of the author and their designation.

	Regulations	Standards
Areas for improvement	0	1

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 Quinn and staff.

6.9 Patient and staff views

Ten patients submitted questionnaire responses to RQIA. All 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. One patient made a comment commending the clarity of information given, aftercare and staff.

Three staff submitted questionnaire responses to RQIA. All indicated that they felt patient care was safe, effective, that patients were treated with compassion and that the service was well led. All staff indicated that they were very satisfied with each of these areas of patient care. Two staff made positive comments about the services provided and working in the establishment.

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Mr James Rowley, responsible individual, and Ms Fiona Quinn, registered manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered provider/manager should note that if the action outlined in the QIP is not taken to comply with regulations and standards this may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered provider to ensure that all areas for improvement identified within the QIP are addressed within the specified timescales.

Matters to be addressed as a result of this inspection are set in the context of the current registration of a refractive laser eye surgery service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises RQIA would apply standards current at the time of that application.

7.1 Areas for improvement

Areas for improvement have been identified where action is required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005 and 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).

7.2 Actions to be taken by the service

The QIP should be completed and detail the actions taken to address the areas for improvement identified. The registered provider should confirm that these actions have been completed and return the completed QIP via Web Portal for assessment by the inspector.

Quality Improvement Plan

Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005

Area for improvement 1 **Ref**: Regulation 15 (1) (b) **Stated:** First time **To be completed by:** 9 April 2020	The registered person shall ensure that the laser protection advisor (LPA): • reviews and clarifies the arrangements regarding protective eyewear in the local rules • reviews the risk assessment to ensure it is current Any recommendations made as a result of the revised risk assessment should be signed and dated on completion. Copies of the revised documents should be provided to RQIA. Ref: 6.4
	Response by registered person detailing the actions taken: The Local rules and Risk assessment have been updated. An updated version was sent to our inspector Emily Campbell but these still contained an error; page 8 of the RA is dated 26th Feb 2019 and we have requested that this be changed to 26th Feb 2020, however our contact as UCLH has been on annual leave and only recently returned. With the developing situation with Covid 19 we are awaiting their response. Warning signs on the doors leading to the COSHH cupboard -Compliance Manager confirmed these were added and the RA needs to be updated. Again awaiting UCLH to update. Laser Goggles- Excimer goggles were on site and will now be labelled to show these are for the Excimer Laser. Intralase googles will be left on site the next time our Laser Engineer visits and will also been labelled to show this. LPA has been requested to update the RA and Local Rules to show this

Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (2014)

Area for improvement 1 **Ref**: Standard 48.6 **Stated:** First time **To be completed by:** 9 April 2020	The registered person shall obtain a copy of the service level agreement between the establishment and the laser protection advisor (LPA) for the calendar year 2020. A copy should be retained in the laser safety file. Ref: 6.4
	Response by registered person detailing the actions taken: The University College London Hospital 2020 contract was initally requested on the 22nd Jan 2020 however, UCLH proposed a different invoice and pricing structure that had to be appoved by our Senior Management Team. This has now been approved and we have requested the the updated contract. However, as above, our contact at UCLH has been on Annual Leave and has only recently returned and given the developing situaton with Covid 19 we are awaiting the

	updated contract
Area for improvement 2 **Ref**: Standard 19.5 **Stated:** First time	The registered person shall review policies to reflect that they relate to Optimax and where applicable the name of the author and their designation. Ref: 6.7
To be completed by: 25 May 2020	**Response by registered person detailing the actions taken:** The Policies have been amended to reflect that they relate to Optimax and where applicable the name of the author and their designation has been added

Please ensure this document is completed in full and returned via Web Portal

25th February 2020

Mrs Emily Campbell
Regulation & Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT

Dear Mrs Emily Campbell

Laser Protection Report

Optimax, 7 Derryvolgie Avenue, Belfast BT9 6 FL

Introduction

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

Comments

(1) The Laser Safety file should be reviewed and the documents updated where required. In particular the following points should be addressed:-

- The filed contract for a Laser Protection Advisory Service (LPA) from University College London Hospital covers the calendar year 2019. This should be replaced with information on the current 2020 contract.
- The filed Local Rules & Risk Assessment were signed by the previous LPA Sandy Moss with the Local Laser Protection Supervisor named as Susan Moffet. As the persons in both these positions have changed this represents a significant change in laser safety management requiring a review of these documents.
- The file contains a copy of the 'Optical Radiation Safety Policy'. There is no indication that the document relates to Optimax and neither the author nor person with responsibility for enforcing it are named. A more robust system of document control should be considered
- The risk assessment lists two action points to be carried out, however these have not be signed off, leaving it unclear whether the additional signage had been added to the COSHH cupboard. In addition staff were unable to confirm whether this action was completed.

(2) Local Rules & Protective Eyewear:- The LPA should clarify the arrangements regarding protective eyewear. The information currently contained in the Laser Safety file is summarised below:-

- The Intralase Local Rules details the level of protection required for protective eyewear, however protective eyewear for this laser is not available in the clinic
- Conversely, The Schwind Local Rules does not detail the level of protection required for protective eyewear, however eyewear with protection level L7 against the output wavelength of 193nm is available in the clinic.
- The action list within the Risk Assessment stated that the protective eyewear should be moved to outside the entrance door of the clinic, however the staff were unable to state which laser the available eyewear provided protection against.
- Both sets of Local Rules suggested that the protective eyewear would only be used by the engineer (so perhaps the Laser engineer may be able to bring their own appropriate eyewear)

RQIA should be informed when the deficiencies noted above have been corrected.

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