Announced Care Inspection Report
16 March 2021

Cathedral Eye Clinic

Type of Service: Independent Hospital (IH) –Laser Eye Surgery
Address: 89 - 91 Academy Street, Belfast, BT1 2LS
Tel No: 028 9032 2020
Inspectors: Carmel McKeegan and Winifred Maguire
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

In respect of refractive eye laser services for the 2020/21 inspection year we are moving to a more focused, shorter inspection which will concentrate on the following key patient safety areas:

- management of operations in response to COVID-19 pandemic;
- infection prevention and control (IPC);
- laser and intense pulse light (IPL) safety;
- organisational and medical governance:
- staff and client feedback; and
- review of areas for improvement identified during the previous care inspection.

2.0 Profile of service

This is a registered independent hospital providing laser eye surgery.

Laser equipment

Floor 1 YAG Room

Manufacturer: Quantel Medical
Model: Optimis Fusion
Serial Number: 62-07-0200
Output wavelength: 532 & 1064nm
Laser Class: 3B

Manufacturer: Quantel Medical
Model: Vitra 2
Serial Number: 3434
Output wavelength: 532nm
Laser Class: 4

Floor 2 Laser Suite

Manufacturer: Schwind-Amaris
Serial Number: A779
Output wavelength: ArF (193nm)
Laser Class: 4

Manufacturer: Zeiss
Model VISUMAX
Serial Number: 1048412
Output wavelength: 1043nm
Laser Class: 3B

Floor 2 Cataract Suite

Manufacturer: D.O.R.C
Model EVA
Serial Number: 2015000298
Output wavelength: 532nm
Laser Class: 4

Laser Protection Advisor (LPA)
Dr Anna Bass (Lasermet)

Laser Protection Supervisor (LPS)
Mr Andrew Spence

Clinical Authorised Operators -
Professor Jonathan Moore – All laser equipment (with the exception of the DORC EVA)
Mr Colin Willoughby – Quantel Fusion
Mr. Sri Kamalarajah - Quantel Fusion
Mr Richard Best - Quantel Fusion and DORC EVA

Mr Wing Chan - Quantel Fusion, Quantel Vitra 2 & DORC EVA
Ms Silva Madi – Quantel Fusion
Mr Murali Upendran – Quantel Fusion
Mr Stuart McGimpsey – Quantel Fusion
Mr Vasuki Jothi –DORC EVA

Non-clinical Authorised Operators -
Mr Andrew Spence – All laser equipment (with the exception of the Quantel Fusion)

Medical Support Services:
Professor Jonathan Moore
Mr Richard Best and Mr Wing Chan (vitrectomy procedures only)

Type of Treatments Provided:

Refractive eye laser and other vision correction treatments:

- LASEK
- LASIK
- Cross-Linking
- Presbymax
- VISUMAX SMILE
- SLT Laser treatments
- Transepi PTK
- Glaucoma
- Vitrectomy procedures
- Capsulotomy

3.0 Service details

Organisation/Registered Provider: Cathedral Eye Clinic Ltd **Responsible Individual:** Mr Jonathon Moore	**Registered Manager:** Mr Gary McArdle
Person in charge at the time of inspection: Mr Gary McArdle	**Date manager registered:** 18 July 2017
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

We undertook an announced inspection on 16 March 2021 from 10.00 to 17.00.

We were accompanied by Dr Ian Gillan, RQIA's Medical Physics Advisor. The findings and report of Dr Gillan are appended to this report.

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

The purpose of this inspection was to focus on the themes for the 2020/21 inspection year. A poster informing clients that an inspection was being conducted was displayed during the inspection.

We found evidence of good practice in relation to the management of operations in response to the COVID-19 pandemic; most aspects of laser safety; IPC procedures; and the organisational and medical governance arrangements.

One area of improvement made at the previous inspection in relation to the completion of mandatory training was assessed as partially met and has been stated for a second time.

We identified areas requiring improvement in relation to further developing infection prevention control (IPC) policies to reflect the current Covid -19 measures in place; aspects of laser safety arrangements including the local rules; the authorised operators role and training; displaying of laser warning signs; practising privileges agreements should clearly outline the scope of practice specific to the individual medical practitioner ; and to ensure all notifiable events are notified to RQIA in a timely manner.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	3	8

We discussed the details of the Quality Improvement Plan (QIP) with Mr Gary McArdle, Registered Manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

5.0 How we inspect

Prior to the inspection we reviewed a range of information relevant to the service. 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; and
- the returned QIP from the previous care inspection

We issued posters to the clinic prior to the inspection inviting patients and staff to complete an electronic questionnaire. Returned completed patient and staff questionnaires are discussed in section 6.9 of this report.

We undertook a tour of the premises, met with Mr McArdle and a nurse; and reviewed relevant records and documents in relation to the day to day operation of the establishment.

We reviewed areas for improvement identified at the last care inspection and assessment of compliance was recorded as met, partially met, or not met.

The findings of the inspection were provided to Mr McArdle at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 28 January 2020

The most recent inspection of the establishment was an announced care inspection. The completed QIP was returned and approved by the care inspector.

6.2 Review of areas for improvement from the last care inspection dated 28 January 2020

Areas for improvement from the last care inspection		
Action required to ensure compliance with The Independent Health Care Regulations (Northern Ireland) 2005		**Validation of compliance**
Area for improvement 1 **Ref**: Regulation19 **Stated:** First time	The registered person shall implement a robust system to ensure that the following records are retained in respect of each ophthalmologist/private doctor/anaesthetist: • confirmation of identity • current General Medical Council (GMC) registration	**Met**

	• 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 • each doctor/surgeon has an appointed responsible officer (RO) arrangements for revalidation	
	Action taken as confirmed during the inspection: We confirmed that there are 12 medical practitioners working in Cathedral Eye Clinic (CEC). We reviewed each medical practitioner's file and found that all required documentation was in place and that records were up to date.	
Area for improvement 2 **Ref**: Regulation19.(2) Schedule 2 **Stated:** First time	The registered person shall implement a robust system to ensure that all of the relevant information as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is sought and retained within the recruitment process. Records should be available for inspection.	**Met**
	Action taken as confirmed during the inspection: We reviewed the staff register and noted that eight staff had commenced employment since previous inspection. We selected three staff member's recruitment files and found that, in general, all required information as outlined on the Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 had been sought and were available for inspection. We found written references were not in place within two staff member's files. We discussed this Mr McArdle who stated he would follow this up. On 18 March 2021 we received correspondence which confirmed that the required written references were in place for both individuals and that these had been obtained prior to commencement of employment.	

Action required to ensure compliance with Minimum Care Standards for Independent Healthcare Establishments (July 2014)		Validation of compliance
Area for improvement 1 **Ref**: Standard 12.5 **Stated:** First time	The registered person shall ensure that the staff register is further developed to include the details of medical practitioners who have been granted practising privileges as outlined in Regulation 21(3) Schedule 3 Part II of The Independent Health Care Regulations (Northern Ireland) 2005.	**Met**
	Action taken as confirmed during the inspection: We confirmed that a staff register had been implemented which included details of medical practitioners who have been granted practising privileges as outlined in Regulation 21(3) Schedule 3 Part II of The Independent Health Care Regulations (Northern Ireland) 2005.	
Area for improvement 2 **Ref**: Standard 13.1 **Stated:** First time	The registered person shall ensure that a robust system is developed to ensure that all staff (including those with practising privileges) undertake mandatory training in keeping with the RQIA training guidance.	**Partially met**
	Action taken as confirmed during the inspection: We found that a training matrix was in place which recorded the completion dates of training undertaken for all staff members working in CEC (including those with practising privileges). We confirmed that all staff had completed mandatory training in keeping with RQIA guidance, with the exception of three Consultant Ophthalmologists for whom we could not evidence that they had completed safe application training in respect of the laser they had been authorised to use. This is further discussed in section 6.5 of this report. This area for improvement has been partially met and has been stated for a second time.	
Area for improvement 3 **Ref**: Standard 10.1	The registered person shall establish arrangements for monitoring and recording the professional body registration status of all clinical staff.	**Met**

Stated: First time	**Action taken as confirmed during the inspection**: Through discussion with Mr McArdle and review of records we established that arrangements were in place to ensure all clinical staff were registered with their affiliated professional body. Records were kept in relation to the General Optical Council; the Nursing and Midwifery Council and the General Medical Council. Mr McArdle informed us that a senior member of the administration team has been delegated responsibility to monitor the registration status of all clinicians.	
Area for improvement 4 **Ref: Standard 17.1** **Stated: First time**	The registered person shall implement a robust system to ensure that all incidents are recorded at the time of the event. Records of the incident investigation and outcome of the investigation including any action plan generated as a result of the investigation should be retained.	**Met**
	Action taken as confirmed during the inspection: Prior to this inspection we reviewed our records of notifications submitted by CEC since the previous care inspection and determined we had not received any notifications within this time frame. We reviewed the CEC record of incidents and found that three untoward events had been recorded since our previous inspection. We found that incidents had been recorded at the time of the event; a record of investigation had been documented and the outcome of the investigation including any action plan was also recorded. However we noted that two out of the three incidents were notifiable events and a notification should have been submitted to RQIA within 48 hours of each event occurring. We discussed this with Mr McArdle requested that these notification are submitted retrospectively. This area is further discussed in section 6.7 of this report.	

Area for improvement 5 **Ref:** Standard 11.5 **Stated:** First time	The registered person shall ensure that practising and privileges agreements are signed by both parties and reviewed at least every two years.	**Met**
	Action taken as confirmed during the inspection: As previously discussed we reviewed medical practitioners files which enabled us to evidence that a practising privileges agreement was in place which had been signed by both parties and reviewed with the last two years.	

6.3 Inspection findings

6.4 Management of operations in response to the COVID-19 pandemic

COVID-19 has been declared as a public health emergency and we all need to assess and manage the risks of COVID-19, and in particular businesses need consider the risks to their patients and staff.

We discussed the management of operations in response to the COVID-19 pandemic with Mr McArdle and a nurse who outlined the measures taken by CEC to ensure current best practice measures were in place. We determined that most appropriate actions had been taken in this regard.

There was evidence of collaborative work between CEC's management team, clinical staff and the lead nurse in the development of the COVID-19 environmental risk assessments. The risk assessments are used to support staff to recognise and manage the COVID-19 infection risk. Staff told us that risk assessments were undertaken to include all areas of the clinic. We heard how control measures were continuously being reviewed and updated to optimise solutions.

We reviewed the COVID-19 general risk assessment for CEC which included clinical and non-clinical areas, theatre/recovery area, waiting rooms and reception area and we were assured that the clinic had robust measures in place to protect patients and staff.

We noted Infection prevention and control (IPC) policies and procedures had been developed however we noted these policies and procedures needed to be updated to clearly reflect current Covid-19 best practice guidance and the measures in place within the clinic. We identified an area of improvement against the standards on this matter.

Areas of good practice: Management of operations in response to COVID-19 pandemic

We confirmed the establishment had identified a Covid-19 lead; Covid-19 risk assessments had been completed and staff demonstrated an understanding maintaining social distance; implement enhanced IPC measures; and the patient pathway.

Areas for improvement: **Management of operations in response to COVID-19 pandemic**

We identified an area for improvement regarding amending IPC policies and procedures to reflect Covid-19 best practice guidance.

	Regulations	Standards
Areas for improvement	0	1

6.5 Laser Safety

6.5.1 Laser safety

We reviewed the arrangements in respect of the safe use of the laser equipment.

We reviewed the five laser safety files and found that they contained most of the relevant information in relation to the lasers. We found 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 17 March 2021. We were informed by Mr McArdle that he had received an electronic updated LPA certificate which he will print and retain in the master laser safety file.

We noted due to Covid-19 restrictions the establishment's LPA completed a remote risk assessment of the premises on 3 February 2021. All recommendations made by the LPA have been addressed.

We evidenced that laser surgical eye procedures are carried out by Consultant Ophthalmologists, in accordance with medical treatment protocols produced by three Consultant Ophthalmologists. We confirmed systems were in place to review the medical treatment protocols on an annual basis.

We found up to date Local Rules in place which have been developed by the LPA and these contained the most of the relevant information pertaining to the laser equipment being used. We confirmed arrangements are in place to review the Local Rules on an annual basis. We reviewed the Local Rules and confirmed they included the following:

- the potential hazards associated with lasers;
- controlled and safe access;
- authorised operators' responsibilities;
- methods of safe working;
- safety checks;
- personal protective equipment;
- prevention of use by unauthorised persons; and
- adverse incident procedures.

We noted the Local Rules for the Quantel Fusion refer to the unit as a Class 4 laser; however the labels on the laser indicate that it is a Class 3b laser. This matter was highlighted on the inspection in January 2020 and had been confirmed as actioned immediately following the inspection. However it had not been and we identified an area of improvement against the standards on this matter.

We found that most identified authorised operators had signed the relevant Local Rules to confirm that they had read and understood them with the exception of one named authorised operator in respect of the DORC EVA laser. We noted that not all persons involved in the laser service had signed to indicate that they had read and understood the Local Rules to ensure that laser safety measures outlined are followed. We identified an area of improvement against the standards to ensure that all authorised operators and all persons involved in the laser service sign that they have read and understood the all relevant Local Rules.

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. We discussed the role of the LPS and their responsibilities. We identified an area of improvement under the standards to strengthen the LPS role with the full implementation of the responsibilities of the LPS to ensure robust laser safety arrangements.

We reviewed training records and found that authorised operators had up to date training in core of knowledge: safe application for the equipment in use: basic life support: infection prevention and control: fire safety awareness; and safeguarding adults at risk of harm in keeping with the RQIA training guidance.

We were informed that all other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

We confirmed that a laser surgical register is maintained for every time the lasers are operated and includes:

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

We reviewed the laser surgical registers during the inspection and found them to be comprehensively completed. However we noted the use of correction fluid on several entries. We highlighted this was not in keeping with best practice. We identified an area of improvement against the standards to ensure correction fluid is not used in records required under the regulations.

We cross referenced the laser surgical registers with the register of authorised operators for each laser. We identified that a Consultant Ophthalmologist recorded in the laser surgical register as operating the Schwind laser was not listed as an authorised operator for this laser. We found that two other Consultant Ophthalmologists were recorded in the laser surgical register as operating the Quantel Fusion laser were not listed as authorised operators for this laser. We reviewed training records for these Consultant Ophthalmologists and found that they did not have evidence of receiving application training for the use of these lasers. Application training is included in RQIA mandatory training for this service type and as previously discussed an area for improvement had been made in this regard at the previous inspection and has been stated for a second time.

We discussed the process for authorising operators; the role of the LPS in ensuring only authorised operators use the lasers and the general governance arrangements on use of the lasers. We found a lack of robustness on these matters. Mr McArdle gave assurances that the three identified Consultant Ophthalmologist s who were not authorised operators for Schwind and Quantel Fusion lasers would be stood down immediately from their use.

This was also confirmed in an email from Mr McArdle on 26 March 2021. We identified two new areas of improvements against the regulations on this matter.

We reviewed the laser suites and found the environment in which the laser equipment is used was safe and controlled to protect other persons while treatment is in progress.

We noted that the doors to the laser suites are locked when the laser equipment is in use but can be opened from the outside in the event of an emergency.

We confirmed that the laser suites are a controlled area that is clearly defined and not used for other purposes, or as access to areas when treatment is being carried out.

We observed that the lasers are operated using a key and passwords. We reviewed the arrangements in relation to the safe custody of the keys and confirmed the arrangements to be satisfactory.

We confirmed that protective eyewear is available as outlined in the local rules for laser technicians/surgical assistants if required.

We observed laser safety warning signs are displayed when the laser equipment is in use and removed when not in use, with the exception of Cataract Room on floor 1 where there was no evidence of the use of a laser safety warning sign in place and staff spoken to were unsure of the arrangements in relation to displaying the laser warning sign for this room. We identified an area of improvement against the standards to ensure laser warning signs are displayed when the laser is in use as outlined in the local rules.

We confirmed that arrangements have been established for all laser equipment to be serviced and maintained in line with the manufacturers' guidance. We reviewed the most recent service reports for all lasers and noted that all had been serviced in October or December 2020 with the exception of Zeiss Visumax laser. We noted that this laser had been serviced on 27 September 2019. Mr McArdle informed us that, due to Covid-19 restrictions, the service engineers who come from Germany have been unable to carry out a site visit. However Mr McArdle provided us with written correspondence from the company which confirmed the laser is safe to use and the engineers will arrange a visit as soon as Covid-19 restrictions are eased.

We observed carbon dioxide (CO2) fire extinguishers suitable for electrical fires were available in the establishment. We confirmed that arrangements were in place to ensure these fire extinguishers were serviced in keeping with manufacturer's instruction.

6.5.2 Laser Safety Care Pathway

We confirmed that all patients have an initial consultation with an optometrist who discusses their treatment options and the cost of the surgery.

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

We found 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.

We confirmed that in accordance to General Medical Council (GMC) and the Royal College of Ophthalmologists 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.

We found that 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 also provided with clear post-operative instructions along with contact details if they experience any concerns. We evidenced systems were in place to refer patients directly to the consultant ophthalmologist if necessary.

Staff informed us that systems were in place to review the patient following surgery at one day, one week, one month, three months and longer if necessary.

We reviewed four patient care records. We found the establishment retains hard copy care records which are supplemented with an electronic record system. We confirmed that 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; and
- review/follow up notes.

Areas of good practice: Laser safety

We reviewed the current arrangements with respect to laser safety and evidenced Local Rules were in place; the LPA has carried out a recent remote review of documentation and laser safety measures.

Areas for improvement: **Laser safety**

We identified eight areas for improvement in relation to laser safety:

- ensure the Local Rules for the Quantel Fusion refer to the unit's correct laser classification which is a Class 3b laser;
- ensure all authorised operators and persons involved in the laser service sign that they have read and understood the Local Rules;
- strengthen the LPS role with the full implementation of the responsibilities of the LPS to ensure robust laser safety arrangements;
- ensure correction fluid is not used in records required under the regulations;
- ensure that **only** authorised operators use the lasers;
- ensure there is evidence of application training on the use of the laser for authorised operators;
- formalise the authorising of operators and ensure it is carried out by a suitably qualified individual, such as the Clinical Director; and

- ensure that laser warning signs are displayed when the laser is in use as outlined in the Local Rules.

	Regulations	Standards
Areas for improvement	2	5

6.6 Infection prevention control (IPC)

We reviewed arrangements for IPC procedures throughout the establishment to evidence that the risk of infection transmission to clients, visitors and staff was minimised. We confirmed that the clinic had an overarching IPC policies and procedures in place. As stated previously we identified an area of improvement against the standards to amend the policy and procedures to reflect Covid-19 guidance.

We undertook a tour of the premises and noted that the establishment was clean, tidy and uncluttered. We found that all areas of the establishment were fully equipped to meet the needs of patients. We reviewed arrangements in relation to IPC procedures throughout the establishment and found that the risk of infection transmission to patients, visitors and staff was minimised. We noted that a hand dryer was operational in the toilets on the floor 1 and that chairs were situated close to each other in the waiting rooms on floor 1. Whilst we were informed the waiting rooms are not in use, we advised Mr McArdle that these arrangements are not in keeping with Covid-19 guidance. Following the inspection, RQIA received an email from Mr McArdle with photographic evidence that the hand dryer had been taken out of use and the number of the chairs had been reduced in the waiting rooms allowing for social distancing.

We found that arrangements were in place to ensure that staff received IPC and COVID-19 training commensurate with their roles and responsibilities. Staff who spoke with us demonstrated good knowledge and understanding of IPC procedures.

We found that cleaning schedules were in place. Staff described the arrangements to decontaminate the environment and equipment between patients and we found these to be satisfactory.

We confirmed that no reusable medical devices are used in the clinic. We established that personal protective equipment (PPE) was readily available in keeping with best practice guidance. We observed that there were social distancing screens in place at the reception desk and that hand sanitisers were readily available for staff and patient use throughout the clinic.

Staff told us that appointments are scheduled to minimise the number of patients in the waiting area and that following every appointment the seating in the waiting area and all touch points (door handles etc.) are decontaminated.

We confirmed waste management arrangements were in place and we observed clinical waste bins were pedal operated in keeping with best practice guidance.

We found that arrangements were in place to ensure that staff received IPC and COVID-19 training commensurate with their roles and responsibilities.

We noted that the laser suites provided dedicated hand washing facilities and were informed that hand sanitiser was available in each consultation room.

Areas of good practice: Infection prevention and control (IPC)

We reviewed the current arrangements with respect to IPC practice and evidenced good practice that was being actively reviewed.

Areas for improvement: Infection prevention and control (IPC)

We identified no areas for improvement regarding IPC practice.

	Regulations	Standards
Areas for improvement	0	0

6.7 Organisational and Medical governance

6.7.1 Organisational and medical governance

We examined various aspects of the organisational and medical governance systems in place and found there was a clear organisational structure within the clinic.

Where the business entity operating a laser eye surgery service is a corporate body or partnership or an individual owner who is not in day to day management of the service, unannounced quality monitoring visits by the Registered Provider must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. We established that Mr Jonathan Moore, Responsible Individual, was in day to day charge of the service, therefore the unannounced quality monitoring visits by the Registered Provider were not applicable.

Mr McArdle, Registered Manager oversees the day to day operation of services. Professor Jonathan Moore, Responsible Individual, is a consultant ophthalmologist and acts as the clinical director for the service. There are weekly clinic meetings with time limited actions and identifiable persons for these actions. Quarterly surgical governance meetings are held and are chaired by the clinical director and are attended by the consultant ophthalmologists and Mr McArdle. Policies and procedures were available for staff reference.

Discussion with Mr McArdle confirmed that there are sufficient staff in the various roles to fulfil the needs of the establishment and clients. This included a team of consultant ophthalmologists, optometrists, nurses, who have evidence of specialist qualifications and skills in laser eye surgery. Cathedral Eye Clinic also has a team of administration staff who undertake patient co-ordination roles to assist with enquires and appointment scheduling.

As previously stated were reviewed 12 medical practitioner's details and confirmed there was evidence of the following:

- confirmation of identity;
- current General Medical Council (GMC) registration;
- professional indemnity insurance;
- qualifications in line with services 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; and

- arrangements for revalidation with the GMC.

Discussion with Mr McArdle confirmed that all medical practitioners are aware of their responsibilities under GMC Good Medical Practice.

As previously stated we confirmed that there are arrangements are in place for monitoring the professional body registration status of all clinical staff with their relevant bodies. We also confirmed that arrangements are in place for monitoring the professional indemnity of all staff who require individual indemnity cover

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

Mr McArdle as the Registered Manager demonstrated a clear understanding of his role and responsibility in accordance with legislation. We confirmed that the statement of purpose and patient's guide are kept under review, revised and updated when necessary and available on request.

6.7.2 Practising privileges

In line with the legislation medical practitioners can only work in an independent hospital under a direct contract of employment or under a practising privileges agreement.

We reviewed the arrangements relating to the management of practising privileges for medical practitioners working within the hospital. We confirmed that a practising privileges policy and procedure was in place which outlined the arrangements for the application, granting, maintenance, suspension and withdrawal of practising privileges. Mr McArdle outlined the process for granting practising privileges and told us the medical practitioner would meet with Mr Moore prior to practising privileges being granted.

As previously discussed, we reviewed records and evidenced that there was a written agreement between each medical practitioner and CEC setting out the terms and conditions which had been signed by both parties. We found that all practising privileges agreements had been reviewed within the previous two years. We advised that the practising privileges agreement should clearly state each medical practitioner's scope of practice, this would further strengthen the governance arrangements of all laser authorised operators. An area for improvement has been made in this regard.

All medical practitioners working within the agency must have designated Responsible Officer (RO). In accordance with the requirements of registration with the GMC all doctors must revalidate every five years. The revalidation process requires doctors to collect examples of their work to understand what they are doing well and how they can improve. Experienced senior doctors called RO's work with the GMC to make sure doctors are reviewing their work. As part of the revalidation process, RO's make a revalidation recommendation to the GMC. Where concerns are raised regarding a doctor's practice information must be shared with their RO who then has the responsibility to share this information with all relevant stakeholders in all areas of the doctor's work. During our review of the medical practitioner's files we established that all medical practitioners working within the agency have a designated RO.

6.7.3 Notifiable events/incidents

As previously discussed we confirmed that a system was in place to ensure that notifiable events were contemporaneously recorded and investigated. We found that since our previous inspection three untoward events had been recorded. We identified that two out of the three incidents were notifiable events and should have been notified to RQIA within 24 hours of the event occurring.

We further discussed the investigative summary of one of the incidents and advised that further information was required to establish the root cause of this event occurring. Mr McArdle provided assurance that this would be followed up and any learning identified would be shared with all relevant staff. An area for improvement has been made that any notifiable event is notified to RQIA within 24 hours of the event occurring.

Areas of good practice: Organisation and medical governance

We found examples of good practice in relation to organisational and clinical governance arrangements; management of incidents; quality assurance and improvement; and complaints management.

Areas for improvement: Organisational and medical governance

We identified two areas for improvements; one was made against the standards to further develop the practising privileges agreement to clearly state each medical practitioner's scope of practice. The second area for improvement was made against the regulations to ensure that any notifiable event is notified to RQIA within 24 hours of the event occurring

	Regulations	Standards
Areas for improvement	1	1

6.8 Equality data

We discussed the arrangements in place regarding 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. Mr McArdle and staff demonstrated that equality data collected was managed in line with best practice.

6.9 Patient and staff views

We invited patients to complete an electronic questionnaire during the inspection. No patient questionnaires were received by RQIA during or following the inspection.

Due to social distancing practices and limited patient numbers in the clinic we did not have an opportunity to speak to patients/visitors during this inspection. We were informed visitors were not permitted unless for compassionate reasons and where appropriate arrangements would be discussed and agreed with the clinic prior to attending a pre-planned appointment.

As we were unable to meet with patients and/or visitors Mr McArdle made available the result of most recent patient consultation process which indicated patients who completed the survey completed a high level of satisfaction.

It was good to note that management recognised an area identified by patients where improvement could be made, in relation to patient waiting times in the clinic, with advice provided to staff on the importance of communicating with patients to offer reassurance should a clinic be running slightly behind schedule.

We invited staff to complete an electronic questionnaire and one response was received by RQIA, however the questionnaire was incomplete and did not provide any information other than it had been submitted by a staff member.

Total number of areas for improvement

	Regulations	Standards
Total number of areas for improvement	3	8

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 McArdle, 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 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 39 (2) **Stated:** First time **To be completed by:** 16 March 2021	The registered person shall ensure **only** authorised operators use the lasers. Ref: 6.5
	Response by registered person detailing the actions taken: Due to COVID-19 travel restrictions, the ability of OEM trainers from the UK / Europe to come to Northern Ireland to certify experienced consultants on laser equipment that the Consultants were extremely familiar with was impossible. Full and complete laser training and sign-off occurred internally with the Clinical Director for the additional consultants who completed very ad hoc, minimal numbers of procedures. With travel restrictions relaxing, this official certification will take place. No unauthorised operators will use lasers until this certification from the manufacturer has taken place.
Area for improvement 2 **Ref:** Regulation 39 (2) **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall formalise the authorising of operators and ensure it is carried out by a suitably qualified individual, such as the Clinical Director. Ref: 6.5
	Response by registered person detailing the actions taken: Following the inspection, each laser user will only be "authorised" when they have received: 1. OEM training and certification 2. Internal training & shadowing from the Clinical Director 3. Final sign-off by the Clinical Director Documentation of the 3 aspects above will be in place for each authorised user in order to allow them to use the laser.
Area for improvement 3 **Ref:** Regulation 28 (2) **Stated:** First time **To be completed by:** 16 April 2021	The registered person should ensure that any notifiable event is notified to RQIA within 24 hours of the event occurring. Ref: 6.7
	Response by registered person detailing the actions taken: Registered person and Clinic management now fully understand the definition of a notifiable event and those that need to be reported to RQIA. Two fully resolved incidents have since been retrospectively reported onto the RQIA portal along with one incident that has taken place since the inspection.
Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (2014)	

Area for improvement 1 **Ref**: Standard 13.1 **Stated:** Second time **To be completed by:** 16 April 2021	The registered person shall ensure that a robust system is developed to ensure that all staff (including those with practising privileges) undertake mandatory training in keeping with the RQIA training guidance. Ref: 6.2 and 6.5
	Response by registered person detailing the actions taken: A comprehensive training matrix was produced for the RQIA inspectors which shows that all staff, including those with practising privileges, have the requisite mandatory training in: Medical emergencies and resuscitation Infection Prevention and Control Safeguarding Adults, Children & Yound Adults Fire Safety Laser Safety Awareness Training Core of Knowledge Training A robust system is in place for tracking and recording training requirements across the growing team. The outstanding training relating to the use of individual particular lasers, as outlined in previous "Areas for Improvement". This OEM / manufacturer training is scheduled and will be completed as soon as the travel restrictions are relaxed.

Area for improvement 2 **Ref**: Standard 20.2 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall amend IPC policies and procedures to reflect Covid-19 best practice guidance Ref:6.4
	Response by registered person detailing the actions taken: Our Clinic's response to the pandemic has been exemplary. We produced a number of detailed documents that have been approved by the highly experienced Clinical Governance team including: 1. Our COVID-19 Protocols as we became more active in September 2020. 2. Our Demonstrating how we adhere to the latest Public Health Guidance (issued in March 2021) guidance and have considered each of the Recommendations, tailoring them to CEC activities, through an internal document entitled: "Maintaining Safe Services within Cathedral Eye Clinic through Infection Prevention & Control Adhering to Public Health Agency Guidance." March 2021 The entire CEC team is on board with the best practice protocols and they have been built into IPC policies and procedures.
Area for improvement 3 **Ref**: Standard 48.6 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall ensure the local rules for the Quantel Fusion refer to the unit's correct laser classification which is a Class 3b laser Ref:6.5
	Response by registered person detailing the actions taken: The typographical error on the part of the LPA and correct version of the laser has been placed in the relevant file.
Area for improvement 4 **Ref**: Standard 48.6 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall ensure all authorised operators and persons involved in the laser service sign that they have read and understood the local rules. Ref: 6.5
	Response by registered person detailing the actions taken: Due to the low frequency of visits by particular operators, the physical signing of the local rules was practically very difficult. All operators attended Laser Safety and Core of Knowledge training. With ease on movement, we will ensure all signatures are in place prior to laser usage from individual operators.
Area for improvement 5 **Ref**: Standard 48.15 **Stated:** First time	The registered person shall ensure the LPS role is strengthened with the full implementation of the responsibilities of the LPS to ensure robust laser safety arrangements. Ref: 6.5

To be completed by: 16 April 2021	**Response by registered person detailing the actions taken:** The LPS role will be taken on by one specific individual with the time and experience to ensure all aspects are adhered to and reported to the Registered Person, the LPA and RQIA.
Area for improvement 6 **Ref**: Standard 8 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall ensure correction fluid is not used in records required under the regulations Ref: 6.5
	Response by registered person detailing the actions taken: It is not Clinic practice to use correction fluid. This was used historically simply for "tidy presentation" purposes.
Area for improvement 7 **Ref**: Standard 48.16 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall ensure laser warning signs are displayed when the laser is in use as outlined in the Local Rules. Ref: 6.5
	Response by registered person detailing the actions taken: Sign frames have been installed for simple use of laser warning signs. The Clinic has moved from using velcro / blu-tack to inserting signs into the frames.
Area for improvement 8 **Ref**: Standard 11.4 **Stated:** First time **To be completed by:** 16 April 2021	The registered person shall further develop the practising privileges agreement to ensure each medical practitioner's specific scope of practice is documented. Ref: 6.7
	Response by registered person detailing the actions taken: The practising privileges agreement document has been further improved to outline each medical practitioners' specific scope of practice, including laser usage.

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

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