

Announced Follow-up Review of Vitrectomy Procedures Arrangements Inspection Report 12 December 2017



Cathedral Eye Clinic

Service Type: Independent Hospital (IH) – Laser Eye Surgery

Address: 89 - 91 Academy Street, Belfast BT1 2LS

Tel No: 0289032 2020

Inspector: Winifred Maguire

RQIA's Medical Physics Advisor: Dr Ian Gillan

www.rqia.org.uk

Assurance, Challenge and Improvement in Health and Social Care

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service provider 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 an independent hospital providing laser eye surgery.

Laser equipment

Ophthalmic Laser

| | |
|--------------------|----------|
| Manufacturer: | Zeiss |
| Model: | VISUMAX |
| Serial Number: | 1048412 |
| Laser Class: | Class 3b |
| Output Wavelength: | 1043nm |

Location Third Floor Treatment Room
(Not reviewed on this inspection)

YAG Photo disrupter

Manufacturer: NIDEX
 Model: YC 1600 Nd:Yag
 Serial Number: 60952
 Laser Class: 3B
 Output wavelength: 1064nm
 Location Second Floor Treatment Room
(Not reviewed on this inspection)

Excimer Laser

Manufacturer: Schwind-Amaris
 Serial Number: A779
 Laser Class: Class 4
 Output wavelength: ArF (193nm)
 Location Third Floor Treatment Room
(Not reviewed on this inspection)

Ophthalmic Laser

Manufacturer: Lumenis
 Model: Selecta II SLT
 Serial Number: 51883
 Laser Class: Class 3b
 Output wavelength: 532nm
 Location Second Floor Treatment Room
(Not reviewed on this inspection)

Vitrectomy laser

Model: D.O.R.C EVA
 Laser Class: Class 4
 Output wavelength: 532nm
 Location Second Floor theatre

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

Laser Protection Supervisor (LPS) Mr Andrew Spence

Authorised Operators - Professor Jonathan Moore – All laser equipment (with the exception of the DORC.EVA laser)
 Mr Andrew Spence - Schwind- Amaris Class 4 laser
 Mr Colin Willoughby - Lumenis Selecta II SLT Class 3b laser
 Mr. Sri Kamalarajah - Nd:Yag laser
 Mr Richard Best - DORC EVA laser
 Mr Wing Chan - DORC EVA laser

Medical Support Services: Professor Jonathan Moore
Mr Richard Best (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(reviewed on this inspection)

3.0 Service details

| | |
|---|---|
| Organisation: Cathedral Eye Clinic Ltd Responsible individual : Mr Jonathan Moore | Registered manager: Mr Gary McArdle |
| Person in charge of the establishment at the time of inspection: Mr Gary McArdle | Date manager registered: 18 July 2017 |
| Categories of care: Independent Hospital (IH) – AH (DS) Acute hospitals (day surgery only) PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PD Private Doctor | |

4.0 Inspection summary

An announced inspection took place on 12 December 2017 from 13.50 to 15.20.

The inspector was 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 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).

The inspection sought to assess progress with issues raised during an inspection focusing on arrangements for the provision of vitrectomy procedures on 8 November 2017. A significant number of areas of improvement had been identified as a result of the inspection on 8 November 2017. In light of the findings of the inspection on 8 November 2017, it was decided a further follow-up inspection would be undertaken.

The follow-up inspection was conducted on 12 December 2017 as above.

The findings of this report will provide the establishment with the necessary information to assist them to fulfil their responsibilities, enhance practice and patients' experience.

4.1 Inspection outcome

| | Regulations | Standards |
|--|-------------|-----------|
| Total number of areas for improvement | 0 | 0 |

This inspection resulted in no areas for improvement being identified. Findings of the inspection were discussed with Mr Gary McArdle, registered manager, as part of the inspection process and can be found in the main body of the report.

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

4.2 Action/enforcement taken following the most recent care inspection dated 8 November 2017

Other than those actions detailed in the QIP no further actions were required to be taken following the most recent inspection on 8 November 2017.

5.0 How we inspect

During the inspection the inspector met with Mr Gary McArdle, registered manager.

A range of laser documentation relating to the proposed vitrectomy service was examined during the inspection.

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

The findings of the inspection were provided to the person in charge at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 8 November 2017

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 8 November 2017

| 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: Regulation 18 (2) (a) Stated: First time | The registered person shall provide evidence that authorised operators have undertaken core of knowledge training within the last five years. | Met |
| | Action taken as confirmed during the inspection: It was confirmed one authorised operator had evidence of core of knowledge training in the last five years and the other authorised operator had arranged to undertake core of knowledge training in the coming weeks | |
| Area for improvement 2 Ref: Regulation 21 Schedule 3, part (II) 3 Stated: First time | The registered person shall establish a laser register in relation to use of the DORC EVA laser. | Met |
| | Action taken as confirmed during the inspection: A laser register had been established in relation to use of the DORC EVA laser. | |
| Area for improvement 3 Ref: Regulation 39 (2) Stated: First time | The registered person shall ensure that protective eyewear is provided in line with local rules and that they are labelled in accordance with the relevant laser machine for which they are to be used; and be available in sufficient numbers to provide eye protection for the authorised operator and associated laser staff. | Met |

| | | |
|---|---|---------------------------------|
| | <p>Action taken as confirmed during the inspection:</p> <p>It was confirmed protective eyewear had been ordered for use with the DORC EVA laser and in sufficient numbers to provide eye protection for the authorised operator and associated laser staff. All protective eyewear for all lasers in use in the establishment will be fully reviewed as part of the announced inspection in February 2018.</p> | |
| <p>Area for improvement 4</p> <p>Ref: Regulation 15 (2) (b)</p> <p>Stated: First time</p> | <p>The registered person shall ensure the installation certificate and servicing records for the DORC EVA laser are retained and available for inspection.</p> <p>Action taken as confirmed during the inspection:</p> <p>An installation certificate dated 22 November 2017 was in place for the DORC EVA laser. It was confirmed the DORC EVA laser had been included in the servicing and maintenance arrangements for the lasers within the establishment.</p> | Met |
| Action required to ensure compliance with The Minimum Care Standards for Independent Healthcare Establishments (July 2014) | | Validation of compliance |
| <p>Area for improvement 1</p> <p>Ref: Standard 16</p> <p>Stated: First time</p> | <p>The registered person shall amend the statement of purpose and patient guide to include details of the vitrectomy service.</p> <p>Action taken as confirmed during the inspection:</p> <p>The statement of purpose and the patient guide have been amended to include details of the vitrectomy service.</p> | Met |
| <p>Area for improvement 2</p> <p>Ref: Standard 10</p> <p>Stated: First time</p> | <p>The registered person shall ensure training and competency records for nurses in relation to the provision of the vitrectomy service are retained and are made available for inspection.</p> <p>Action taken as confirmed during the inspection:</p> <p>Nurses' training and competency records, dated 9 December 2017, in relation to the provision of the vitrectomy service, were available for inspection.</p> | Met |

| | | |
|--|---|------------|
| Area for improvement 3 Ref: Standard 1 Stated: First time | The registered person shall ensure written patient information leaflets in relation to vitrectomy procedures are devised. | Met |
| | Action taken as confirmed during the inspection: Written patient information leaflets in relation to vitrectomy procedures had been devised and were available for inspection | |
| Area for improvement 4 Ref: Standard 48 Stated: First time | The registered person shall ensure the medical treatment protocol produced by the consultant ophthalmologist includes his signature as the author, an issue and a review date; and are signed as read and understood by the relevant authorised operators. | Met |
| | Action taken as confirmed during the inspection: The medical treatment protocol produced by consultant ophthalmologists had been signed on 7 December 2017 by the authors who are the authorised operators. An issue and a review date are also included. | |
| Area for improvement 5 Ref: Standard 48.6 Stated: First time | The registered person shall ensure a current LPA verification certificate is retained and made available for inspection. | Met |
| | Action taken as confirmed during the inspection: A LPA verification certificate, issue date 31 March 2017, was available for inspection. | |
| Area for improvement 6 Ref: Standard 48.11 Stated: First time | The registered person shall ensure that the LPA is contacted and clarification is sought on the issues identified in the risk assessment and on any necessary action required to address them. | Met |
| | Action taken as confirmed during the inspection: It was confirmed the LPA had been contacted and clarification had been sought on the issues identified in the risk assessment and that any necessary action had been taken to address the issues. | |

| | | |
|---|---|------------|
| Area for improvement 7 Ref: Standard 48.6 Stated: First time | The registered person shall ensure the local rules are signed by the authorised operators. | Met |
| | Action taken as confirmed during the inspection: The local rules had been signed by the authorised operators on 7 December 2017. | |
| Area for improvement 8 Ref: Standard 48.7 Stated: First time | The registered person shall review the arrangements for the LPS in relation to the vitrectomy service and ensure the appointed LPS is in the position to fulfil the role and responsibilities of the LPS. | Met |
| | Action taken as confirmed during the inspection: The appointed LPS has been clarified and outlined in the local rules. | |
| Area for improvement 9 Ref: Standard 48.14 Stated: First time | The registered person shall ensure that there is controlled access to the theatre and that the doors can be locked during use of the laser and be opened from the outside in the event of an emergency. | Met |
| | Action taken as confirmed during the inspection: The theatre was in use during the inspection and it was not possible to directly observe the arrangements for controlled access to the theatre. However photographs were reviewed and Mr McArdle outlined the controlled access to the theatre and confirmed that the doors can be locked during use of the laser and be opened from the outside in the event of an emergency. | |
| Area for improvement 10 Ref: Standard 48.16 Stated: First time | The registered person shall ensure that the laser safety warning signs are made available for use as described within the local rules. | Met |
| | Action taken as confirmed during the inspection: Three laser safety warning signs were available for use as described within the local rules. | |

| | | |
|---|---|------------|
| Area for improvement 11 Ref: Standard 48.14 Stated: First time | The registered person shall ensure that the use of protective window and door blinds in the theatre area is discussed with the LPA and their use outlined in the local rules. | Met |
| | Action taken as confirmed during the inspection: Photographs confirmed that protective window and door blinds in the form a shutter has been fitted in the theatre area as outlined in the local rules. | |

6.3 Inspection findings

Areas of good practice

All previous areas of improvement had been addressed.

Areas for improvement

No areas for improvement were identified during the inspection.

| | Regulations | Standards |
|--|-------------|-----------|
| Total number of areas for improvement | 0 | 0 |

6.4 Conclusion

Information has been gathered throughout the inspection process. Scrutiny of this information means that this independent hospital is granted approval to provide vitrectomy procedures.

7.0 Quality improvement plan

There were no areas for improvement identified during this inspection, and a QIP is not required nor included as part of this inspection report.

13th December 2017

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

Dear Mrs Maguire

Laser Protection Report

*The Cathedral Eye Clinic
88 - 91 Academy Street, Belfast BT1 2LS*

Introduction

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

Findings and Comments

Protective Eyewear

As the clinic now has five different lasers systems, it is important that the correct eyewear is available for each laser. The options for introducing a system of labelling or colour coding the goggles to reduce the possibility of staff wearing incorrect protective eyewear was discussed. The clinic agreed to implement a system before the next RQIA inspection.

Laser Safety File

The file should be restructured to enable current versions of relevant documents to be easily viewed. Previous versions of documents should be placed in an archive file when documents are updated or superseded. It would be appropriate for the Hospital to seek advice from their LPA when reorganising the file.



Dr Ian Gillan
Laser Protection Adviser to RQIA

Appendix**Laser Systems***The Cathedral Eye Clinic, Academy Street, Belfast***Phaco-Vitrectomy System**

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

Ophthalmic Laser

Manufacturer: Zeiss
 Model: VISUMAX
 Serial Number: 1048412
 Output wavelength: 1043nm
 Laser Class: 3B
 Location: Third Floor Treatment Room

YAG Photo disrupter

Manufacturer: NIDEX
 Serial Number: 60952
 Output wavelength: 1064nm
 Laser Class: 3B
 Location: Second Floor Treatment Room

Excimer Laser

Manufacturer: Schwind-Amaris
 Serial Number: A779
 Output wavelength: ArF (193nm)
 Laser Class: 4
 Location: Third Floor Treatment Room

Ophthalmic Laser

Manufacturer: Lumenis
 Model: Selecta II SLT
 Serial Number: S1883
 Output wavelength: 532nm
 Laser Class: 3B
 Location: Second Floor Treatment Room

Laser Protection Advisor*Anna Bass, Lasernetmet**Date of last visit 14 July 2015*



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