

# Announced Care Inspection Report 9 August 2016



# **River Medical**

Type of Service: Independent Hospital (IH) – Cosmetic laser/IPL Service Address: 88 Lisburn Road, Belfast, BT9 6AF Tel No: 028 9560 7585 Inspector: Emily Campbell

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Assurance, Challenge and Improvement in Health and Social Care

# 1.0 Summary

An announced inspection of River Medical took place on 9 August from 10:05 to 13:15.

The inspection sought to determine if the cosmetic laser/intense pulse light (IPL) service was delivering safe, effective and compassionate care and if the service was well led.

### Is care safe?

Observations made, review of documentation and discussion with Ms Aoibhin Cronin, registered manager, and one staff member demonstrated that further development is needed to ensure that care provided to patients is safe and avoids and prevents harm. Areas reviewed included laser safety, staffing, recruitment and selection, safeguarding, management of medical emergencies, infection prevention control and decontamination and the general environment. One requirement was made in relation to the provision of protective eyewear as outlined in the local rules. Three recommendations were made in relation to safeguarding adults at risk of harm policy development and training, laser protection advisor (LPA) and medical support service agreements and management of a medical emergency.

### Is care effective?

Observations made, review of documentation and discussion with Ms Cronin and the staff member demonstrated that systems and processes were in place to ensure that care provided in the establishment was effective. Areas reviewed included care pathway, audits and communication. A strong emphasis is placed on auditing in this establishment. No requirements or recommendations have been made.

### Is care compassionate?

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

### Is the service well led?

Information gathered during the inspection evidenced that, in general, there was effective leadership and governance arrangements in place which creates a culture focused on the needs patients in order to deliver safe, effective and compassionate care. Areas reviewed included organisational and staff working arrangements, the arrangements for policy and risk assessment reviews, the arrangements for dealing with complaints, incidents and alerts, insurance arrangements and the registered person's understanding of their role and responsibility in accordance with legislation. However, during discussion it was identified that there may be a medical consultant working in the establishment who does not have any footfall in the NHS in Northern Ireland. A requirement was made that clarification should be sought on this matter and if appropriate an application for variation should be submitted to RQIA to include the private doctor (PD) category of care to the registration. As discussed previously, issues were identified in relation to protective eyewear, LPA and medical support service agreements and management of a medical emergency under the 'Is Care Safe' domain which all relate to quality assurance and good governance.

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 2014.

# 1.1 Inspection outcome

	Requirements	Recommendations
Total number of requirements and	2	2
recommendations made at this inspection	2	5

Details of the Quality Improvement Plan (QIP) within this report were discussed with Ms Aoibhin Cronin, 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.

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

There were no further actions required to be taken following the most recent inspection.

# 2.0 Service details

Registered organisation/registered provider: River Medical Mr John Canacott	Registered manager: Ms Aoibhin Cronin
Person in charge of the home at the time of inspection: Ms Aoibhin Cronin	Date manager registered: 15 July 2014

# Categories of care:

IH - PT(L) Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers and PT(IL) Prescribed techniques or prescribed technology: establishments using intense light sources

# Laser equipment

Manufacturer: Model: Serial Number: Laser Class: Wavelength:	Cynosure Elite Apogee ELMD 0610 Class 4 755nm – 1064nm	
Manufacturer:	Fraxel	

Model:	Dual
Serial Number:	J1021
Laser Class:	Class 4
Wavelength:	1550nm – 1927nm

### **IPL** equipment

Manufacturer:	Lumenis
Model:	Aculight Quantum
Model Number:	SA3 501 000
Serial Number:	007-04737

Manufacturer:	Asthera
Model:	Isolaz Pro
Serial Number:	Z201009008

Laser protection advisor (LPA) – Dr Anna Bass (Lasermet)

Laser protection supervisor (LPS) – Ms Aoibhin Cronin

Medical support services - Dr Paul Myers (Lasermet)

Authorised users - Ms Aoibhin Cronin and Ms Leanne McKee

**Types of treatment provided –** Hair removal, pigmented and vascular lesions, skin rejuvenation and acne scars.

### 3.0 Methods/processes

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

During the inspection the inspector met with Ms Aoibhin Cronin, registered manager, and Ms Leanne McKee, authorised user. A tour of the premises was also undertaken.

Records were examined during the inspection in relation to the following areas:

- staffing
- recruitment and selection
- safeguarding
- laser safety
- management of medical emergencies
- infection prevention and control
- information provision
- care pathway
- management and governance arrangements
- maintenance arrangements

# 4.0 The inspection

# 4.1 Review of requirements and recommendations from the most recent inspection dated 26 June 2015

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

# 4.2 Review of requirements and recommendations from the last care inspection dated 26 June 2015

As above.

### 4.3 Is care safe?

### Staffing

Discussion with Ms Cronin and Ms McKee who are the only authorised users and staff of the establishment confirmed that there is sufficient staff to fulfil the needs of the establishment and patients.

Ms Cronin and Ms McKee confirmed that laser and IPL treatments are only carried out by authorised users. A register of authorised users for the lasers and IPLs is maintained and kept up to date.

No new authorised users/staff have been appointed since the previous inspection, however, induction templates have been established should new staff be recruited.

A review of training records evidenced that authorised users have up to date training in core of knowledge training, application training for the equipment in use, basic life support, infection prevention and control and fire safety.

Ms Cronin confirmed that if staff are recruited in the future, who are not directly involved in the use of the laser/IPL equipment, laser safety awareness training would be provided.

Evidence was available that staff who have professional registration undertake continuing professional development (CPD) in accordance with their professional body's recommendations. Discussion with Ms Cronin and review of documentation confirmed that authorised users take part in appraisal on an annual basis.

# **Recruitment and selection**

There have been no authorised users recruited since the previous inspection. During discussion Ms Cronin confirmed that should staff be recruited in the future robust systems and processes have been developed to ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 would be sought and retained for inspection.

# Safeguarding

Ms Cronin was aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified. A recommendation was made that a safeguarding adults at risk of harm policy should be developed and training provided to staff based on the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015). The policy should include information regarding the types and indicators of abuse, referral pathway in the event of a safeguarding issue arising and the relevant contact details for onward referral to the local Health and Social Care Trust. A copy of adult safeguarding gateway numbers, for referral in the event of a concern being identified, was provided to Ms Cronin during the inspection.

Laser and IPL treatments are not provided to patients under the age of 18 years of age, therefore a safeguarding children policy is not required.

### Laser/IPL safety

A laser safety file was in place which contained all of the relevant information in relation to laser/IPL equipment.

There was written confirmation of the appointment and duties of a certified laser protection advisor (LPA). The service level agreement between the establishment and the LPA was reviewed and was noted to have expired in May 2016, although the LPA undertook a risk assessment of the premises on 2 August 2016.

Laser and IPL procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Paul Myers in May 2015. The medical treatment protocols contained the relevant information pertaining to the treatments being provided. Ms Cronin confirmed that systems are in place to review the medical treatment protocols on an annual basis, however, the medical support services certificate had also expired in May 2016.

A recommendation was made that documentary evidence is submitted to RQIA confirming that the service level agreement with the LPA and the medical support services certificate are current.

Up to date local rules are in place which have been developed by the LPA. The local rules contained the relevant information pertaining to the IPL/laser equipment being used.

The establishment's LPA completed a risk assessment of the premises on 2 August 2016. All recommendations made by the LPA have been addressed, with the exception of the provision of protective eyewear for the Fraxel and Cynosure lasers as outlined in the local rules. Ms Cronin confirmed these had been ordered. A requirement was made in this regard.

The laser protection supervisor (LPS) has overall responsibility for safety during laser treatments and a list of authorised users is maintained. Authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

When the laser/IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Arrangements are in place for the other authorised user to deputise for the LPS in their absence.

The environment in which the laser/IPL equipment is used was found to be safe and controlled to protect other persons while treatment is in progress. The door to the treatment room is locked when the laser/IPL equipment is in use but can be opened from the outside in the event of an emergency.

The laser/IPL equipment is operated using keys. Arrangements are in place for the safe custody of the laser/IPL keys when not in use. Protective eyewear is available for the patient and operator for each laser/IPL machine. As discussed protective eyewear as outlined in the local rules should be provided for use with the Fraxel and Cynosure lasers.

The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out. Laser safety warning signs are displayed when the laser equipment is in use and removed when not in use.

The establishment has laser and IPL registers which are 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

There are arrangements in place to service and maintain the laser/IPL equipment in line with the manufacturer's guidance. The Fraxel laser and Isolaz IPL machines were last serviced in April 2016. Arrangements had been established for the Cynosure laser and Quantum IPL machines to be serviced on 16 August 2016 and copies of the service reports were submitted to RQIA on the same date.

# Management of emergencies

As discussed, authorised users have up to date training in basic life support. Discussion with staff confirmed they were aware what action to take in the event of a medical emergency.

There was a resuscitation policy in place. Both authorised users are nurses registered with the Nursing and Midwifery Council and pre-filled syringes of adrenaline, for administration in the event of anaphylaxis, are provided in each laser/IPL treatment room. A recommendation was made that a written protocol should be developed for the administration of adrenaline in the event of anaphylaxis, including medical practitioner authorisation for administration by the nurses.

# Infection prevention and control and decontamination procedures

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

# Environment

The premises were maintained to a good standard of maintenance and décor. Cleaning schedules for the establishment were in place. A legionella risk assessment was carried out by an external contractor in July 2014 which indicated a low level of risk. Arrangements have been established for this to be reviewed again on the day following the inspection. Ms Cronin was advised that any recommendations made by the legionella risk assessor should be implemented. A copy of the service report confirming that the gas boiler had been serviced on 12 August 2016 was submitted to RQIA on 15 August 2016.

### Patient and staff views

Six patients submitted questionnaire responses to RQIA. All indicated that they felt safe and protected from harm. The following comment was provided:

• "The staff were very informative and friendly."

The only other staff member associated with laser/IPL treatments submitted a questionnaire response and indicated that they felt that patients are safe and protected from harm. This was confirmed by the staff member during the inspection.

### Areas for improvement

A safeguarding adults at risk of harm policy should be developed and training provided to staff.

Protective eyewear for the Fraxel and Cynosure lasers as outlined in the local rules should be provided.

Documentary evidence should be submitted to RQIA confirming that the service level agreement with the LPA and the medical support services certificate are current.

A written protocol should be developed for the administration of adrenaline in the event of anaphylaxis, including medical practitioner authorisation for administration by the nurses.

Number of requirements:	1	Number of recommendations:	3
4.4 Is care effective?			

### Care pathway

Patients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the patient pre and post treatment which outlines the treatment provided, any risks, complications and expected outcomes. The establishment has a list of fees available for each laser/IPL procedure.

Fees for treatments are agreed during the initial consultation and may vary depending on the type of treatment provided and the individual requirements of the patient.

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.

Three patient care records were reviewed. There is an accurate and up to date treatment record for every patient which includes:

- patient details
- medical history
- signed consent form
- skin assessment (where appropriate)
- patch test (where appropriate)
- record of treatment delivered including number of shots and fluence settings (where appropriate)

Observations made evidenced that patient records are securely stored.

The establishment is registered with the Information Commissioners Office (ICO)

# Communication

As discussed, there is written information for patients that provides a clear explanation of any treatment and includes effects, side-effects, risks, complications and expected outcomes. Information is jargon free, accurate, accessible, up-to-date and includes the cost of the treatment.

The establishment has a policy for advertising and marketing which is in line with legislation.

The other authorised user confirmed that management is approachable and their views and opinions are listened to. Staff meetings are held on a monthly basis and review of documentation demonstrated that minutes are retained.

# Audits

There were arrangements in place to monitor, audit and review the effectiveness and quality of care delivered to patients at appropriate intervals which included:

- patient satisfaction surveys
- clinical records
- laser safety file
- infection prevention and control
- hand hygiene
- environmental cleaning
- review of complaints/accidents/incidents

# Patient and staff views

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

• "I was fully informed on the procedure."

The staff questionnaire response indicated that they felt that patients get the right care, at the right time and with the best outcome for them. This was confirmed by the staff member during the inspection.

### Areas for improvement

No areas for improvement were identified during the inspection.

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

### Dignity respect and involvement with decision making

Discussion with Ms Cronin and the other authorised user, regarding the consultation and treatment process, confirmed that patients are treated with dignity and respect. The consultation and treatment is provided in private rooms with the patient and authorised user present. Information is provided to the patient in verbal and written form at the initial consultation and subsequent treatment sessions to allow the patient to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain patient confidentiality and observations made evidenced that patient care records were stored securely in a locked vault.

Patient satisfaction surveys are carried out by the establishment on an annual basis and the results of these are collated to provide a summary report which is made available to patients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

Review of the completed questionnaires found that patients were highly satisfied with the quality of treatment, information and care received. Some comments from patients included:

- "All staff are lovely, great experience and knowledge."
- "Easy access to clinic."
- "Staff are friendly."
- "Lovely building."

#### Patient and staff views

All patients who submitted questionnaire responses indicated that they are treated with dignity and respect and are involved in decision making affecting their care.

The submitted staff questionnaire response indicated that they felt that patients are treated with dignity and respect and are involved in decision making affecting their care. This was confirmed by the staff member during the inspection.

#### Areas for improvement

No areas for improvement were identified during the inspection.

Number of requirements:	0	Number of recommendations:	0
4.6 Is the service well led?			

### Management and governance

Since the previous inspection, Mr John Canacott submitted an application to RQIA to become the new registered person of River Medical. The relevant information, supporting documentation and appropriate fees accompanied the application. A fit person interview was held with Mr Canacott at the offices of RQIA on 14 March 2016.

Discussion with Mr Canacott evidenced that he had a clear understanding of his role and responsibilities as the registered person under the relevant legislation and minimum standards. The following issues were discussed:

- the statement of purpose and client guide;
- the management of complaints;
- notification of untoward incidents to RQIA and other relevant bodies;
- quality assurance measures to monitor and improve practice as appropriate;
- protection of vulnerable adults
- responsibilities under the Independent Health Care Regulations (Northern Ireland) 2005
- responsibilities under The Regulation and Improvement Authority (Independent Health Care) (Fees and Frequency of Inspections) (Amendment) Regulations (Northern Ireland) 2011
- responsibilities under the DHSSPS Minimum Standards for Independent Healthcare Establishments (July 2014)
- responsibilities under health and safety legislation.
- responsibilities for the safe use and operation of the lasers/IPLs
- any court cases pending/disciplinary cases with employers/professional regulatory bodies.

Registration of Mr Canacott with RQIA as the registered person was approved on 18 March 2016.

There was a clear organisational structure within the establishment and authorised users were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Authorised users 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. Ms Cronin is the nominated individual with overall responsibility for the day to day management of the service.

Mr Canacott had undertaken an unannounced visit to the premises, since his registration as the registered person, to monitor the quality of services in accordance with legislation. The report of the unannounced monitoring visit was available for inspection.

Policies and procedures were available for staff reference. Observations made confirmed that policies and procedures were indexed, dated and systematically reviewed on a yearly basis. Staff spoken with were aware of the policies and how to access them.

Discussion with Ms Cronin demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was available in the waiting area of the establishment. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The returned questionnaire indicated that no complaints have been received for the period 1 April 2015 to 31 March 2016 in respect of the laser/IPL service. Discussion with Ms Cronin demonstrated good awareness of complaints management and review of documentation evidenced that robust systems are in place for the management of complaints.

Ms Cronin 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.

Arrangements were in place to monitor, audit and review the effectiveness and quality of care delivered to service users at appropriate intervals. Ms Cronin confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process. However, issues were identified in relation to protective eyewear, LPA and medical support service agreements and management of a medical emergency under the Is Care Safe domain which all relate to quality assurance and good governance.

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

Ms Cronin demonstrated a clear understanding of her role and responsibility in accordance with legislation. Information requested by RQIA has been submitted within specified timeframes. The statement of purpose was observed to be up to date and Ms Cronin confirmed the patient guide is kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately. Medical consultants work in this establishment in a private basis and also work within the NHS in Northern Ireland. As such the establishment does not require to be registered with RQIA as a private doctor (PD) service. However, during discussion it was identified that there may be a medical consultant working in the establishment who does not have any footfall in the NHS in Northern Ireland. A requirement was made that clarification should be sought from the identified medical consultant and if they are working in a private capacity only, an application for variation should be submitted to RQIA to include the private doctor (PD) category of care to the registration.

Observation of insurance documentation confirmed that current insurance policies were in place.

### Patient and staff views

All patients who submitted questionnaire responses indicated that they felt that the service is well managed.

The submitted staff questionnaire response indicated that they felt that the service is well led. This was confirmed by the staff member during the inspection.

### Areas for improvement

Clarification should be sought from the identified medical consultant and if they are working in a private capacity only, an application for variation should be submitted to RQIA to include the private doctor (PD) category of care to the registration.

Number of requirements:1Number of recommendations:0
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# 5.0 Quality improvement plan

Any issues identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Ms Aoibhin Cronin, registered manager, as part of the inspection process. The timescales commence from the date of inspection.

The registered person/manager should note that failure to comply with regulations may lead to further enforcement action including possible prosecution for offences. It is the responsibility of the registered person/manager to ensure that all requirements and recommendations contained 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 the IH-Cosmetic Laser\Intense Pulsed Light service. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the RQIA would apply standards current at the time of that application.

# 5.1 Statutory requirements

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on 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

# 5.2 Recommendations

This section outlines the recommended actions based on research, recognised sources and The DHSSPS Minimum Care Standards for Independent Healthcare Establishments(July 2014). They promote current good practice and if adopted by the registered persons may enhance service, quality and delivery.

# 5.3 Actions taken by the registered provider

The QIP should be completed and detail the actions taken to meet the legislative requirements and recommendations stated. The registered provider should confirm that these actions have been completed and return the completed QIP to <u>Independent.Healthcare@rqia.org.uk</u> for assessment by the inspector

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the registered provider from their responsibility for maintaining compliance with the regulations and standards. It is expected that the requirements and recommendations outlined in this report will provide the registered provider with the necessary information to assist them to fulfil their responsibilities and enhance practice within the service.

	Quality Improvement Plan
Statutory requirements	
Requirement 1 Ref: Regulation 15 (1) (c)	The registered provider must ensure that protective eyewear for the Fraxel and Cynosure lasers as outlined in the local rules should be provided.
Stated: First lime	Response by registered provider detailing the actions taken: Connect protective eyewear for Filaxel
To be completed by: 20 September 2016	Connect protective eyescene for Filaxel and Cynosure lasers now in place, a per local rules.
Requirement 2 Ref: Regulation 12 (2) *Part IV The Regulation and Improvement	The registered provider must ensure that clarification is sought from the identified medical consultant and if they are working in a private capacity only, an application for variation should be submitted to RQIA to include the private doctor (PD) category of care to the registration.
Authority (Registration) Regulations (Northern Ireland) 2005	Response by registered provider detailing the actions taken: Ac Laboros Chatzis does not work
Stated: First time	Ac Laboros Chatzis does not work in NHS, private only currently. Application in progress and will be
To be completed by: 9 October 2016	Application in progress and will be submitted 5th October 116.
Recommendations	
Recommendation 1 Ref: Standard 3.1	A safeguarding adults at risk of harm policy should be developed and training provided to staff based on the new regional guidance Adult Safeguarding Prevention and Protection in Partnership (July 2015).
Stated: First time To be completed by: 9 November 2016	The policy should include information regarding the types and indicators of abuse, referral pathway in the event of a safeguarding issue arising and the relevant contact details for onward referral to the local Health and Social Care Trust.
	Response by registered provider detailing the actions taken: Policy developed and trauning provided

Recommendation 2	Documentary evidence should be submitted to RQIA, on submission of the OIP, confirming that the paneles level
Ref: Standard 48	the QIP, confirming that the service level agreement with the laser protection advisor (LPA) and the medical support services certificate are current.
Stated: First time	ounone
	Records should be retained in the laser safety file.
To be completed by: 9 October 2016	
	Response by registered provider detailing the actions taken: Certificates sconned to KaiA with QIP & also Retained in laser safety file
Recommendation 3	A written protocol should be developed for the administration of adrenaline in the event of anaphylaxis, including medical practitioner
Ref: Standard 18	authorisation for administration by the nurses.
Stated: First time	Response by registered provider detailing the actions taken:
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