Announced Care Inspection Report
2 October 2018

Bloomfield Laser & Cosmetic Surgery Centre

Type of Service: Independent Hospital (IH) – Cosmetic Laser Service
Address: "The Lodge", 1 Donaghadee Road, Groomsport, BT19 6LG
Tel No: 028 9127 5737
Inspector: Carmel McKeegan

It should be noted that this inspection report should not be regarded as a comprehensive review of all strengths and areas for improvement that exist in the service. The findings reported on are those which came to the attention of RQIA during the course of this inspection. The findings contained within this report do not exempt the service from their responsibility for maintaining compliance with legislation, standards and best practice.

1.0 What we look for

2.0 Profile of service

This is a cosmetic laser service providing treatments using Class 4 laser machines.

Laser Equipment Currently in Use

Manufacturer:	Sharplan
Model:	4020S
Serial Number:	14-001
Laser Class:	Class 4

Manufacturer:	Cynosure
Model:	Apogee Elite
Serial Number:	ELMD 2203
Laser Class:	Class 4

Manufacturer: Lumenis UltraPulse
Model: Encore
Serial Number: 014-76685
Laser Class: Class 4

It was confirmed that an intense pulse light (IPL) machine is not currently in use in the establishment.

Laser protection advisor (LPA):

- Mr Irfan Azam (Lasermet)

Laser protection supervisor (LPS):

- Dr Jules Handley

Medical support services:

- Dr Jules Handley

Authorised operators:

Sharplan 4020S – Dr Jules Handley, Mrs Beulah Morrow and Ms Amanda Houston

Cynosure Apogee Elite – Dr Jules Handley, Mrs Beulah Morrow, Ms Amanda Houston, MsJude Webb and Ms Jennifer Carson

Lumenis Ultra Pulse Encore – Dr Jules Handley, Mrs Beulah Morrow and Ms Amanda Houston

Types of treatment provided:

- Hair removal, laser skin resurfacing, acne scars treatment, photo rejuvenation and vascular treatments.

3.0 Service details

Organisation/Registered Provider: Bloomfield Laser and Cosmetic Surgery Centre **Responsible Individual:** Dr Jules Handley	**Registered Manager:** Dr Jules Handley
Person in charge at the time of inspection: Dr Robert Neill, clinic manager	**Date manager registered:** 15 September 2008
Categories of care: Independent Hospital (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	

4.0 Inspection summary

An announced inspection took place on 02 October 2018 from 10.30 to12.55.

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

The inspection assessed progress with any areas for improvement identified during and since the last care inspection and to determine if the establishment was delivering safe, effective and compassionate care and if the service was well led.

Examples of good practice were evidence in all four domains. These included the arrangements for managing medical emergencies; clinical records; the environment; maintaining client confidentiality; ensuring the core values of privacy and dignity were upheld; authorised operator training and providing the relevant information to allow clients to make informed choices.

Six areas of improvement were made against the standards to ensure the following areas are addressed. A record of induction should be completed for any new authorised operator; all required documentation should be provided for any new authorised operator prior to commencement of employment; an AccessNI enhanced disclosure check should be completed for any new authorised operator commencing employment in the future; all staff should complete mandatory training in keeping with best practice; confirmation of the service level agreement between the establishment and laser protection advisor (LPA) should be provided to the Regulation and Quality Improvement Authority (RQIA), and ensure that the LPA undertakes a review of the risk assessment at least every three years, and that if any recommendations are made within the risk assessment, that these are addressed.

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

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	6

Details of the Quality Improvement Plan (QIP) were discussed with Dr Robert Neill, clinic manager, as part of the inspection process. The timescales for completion commence from the date of inspection.

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

4.2 Action/enforcement taken following the most recent care inspection dated 17 January 2018

No further actions were required to be taken following the most recent inspection on 17 January 2018.

5.0 How we inspect

Prior to the inspection a range of information relevant to the service was reviewed. This included the following records:

- notifiable events since the previous care inspection
- the registration status of the establishment
- written and verbal communication received since the previous care inspection
- the previous care inspection report

Questionnaires were provided to clients prior to the inspection by the establishment on behalf of RQIA. Returned completed clients questionnaires were analysed prior to the inspection. RQIA invited staff to complete an electronic questionnaire prior to the inspection, no staff questionnaires were received by RQIA.

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

During the inspection the inspector met briefly with Dr Jules Handley, registered person and Dr Robert Neill, clinic manager, facilitated the inspection.

The following records were examined during the inspection:

- 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

The findings of the inspection were provided to Dr Neill at the conclusion of the inspection.

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 17 January 2018

The most recent inspection of the establishment was an announced care inspection on 17 January 2018.

6.2 Review of areas for improvement from the last care inspection dated 17 January 2018

There were no areas for improvement made as a result of the last care inspection.

6.3 Inspection findings

6.4 Is care safe?

Avoiding and preventing harm to patients and clients from the care, treatment and support that is intended to help them.

Staffing

Discussion with Dr Neill confirmed that there is sufficient staff in the various roles to fulfil the needs of the establishment and clients.

Dr Neill confirmed that laser treatments are only carried out by authorised operators. A register of authorised operators for the laser is maintained, it was noted that two new authorised operators had not signed this register. Dr Neill gave assurances that the identified authorised operators would sign this register at the earliest opportunity.

Dr Neill confirmed that both new authorised operators had completed a programme of induction however this had not been documented. An area of improvement has been made against the standards to ensure that a record of induction is completed for both new authorised operators and for any new authorised operator in the future.

A review of training records evidenced that all authorised operators have up to date safe application training for the equipment in use and protection of adults at risk of harm training. Training records did not show the date that the two new authorised operators had completed safe application for laser equipment training, Dr Neill stated that as Dr Handley had provided this training, Dr Handley would record the date this training was undertaken later that day.

It was identified that the two new authorised operators had not completed core of knowledge training or infection prevention and control (IPC) training, and one existing authorised operator was due refresher IPC training later in October 2018. Infection control training is discussed within the IPC section of this report. An area of improvement has been made against the standards to ensure that all staff complete training as outlined in the RQIA mandatory training guidance.

Dr Neill confirmed that fire safety awareness training and basic life support training are provided for all staff on an annual basis, and this will take place during January 2019.

All other staff employed at the establishment, but not directly involved in the use of the laser equipment, had received laser safety awareness training.

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

Recruitment and selection

As previously discussed, it was confirmed that since the previous inspections, two new authorised operators have been appointed. A review of both new authorised operators' personnel files confirmed that, in the main, they had been recruited as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005. However, two written references nor an employment history, showing the reasons for leaving previous employment or possible gaps in employment, had not been provided for either authorised operator. An area of improvement has been made against the standards in this regard.

It was identified that an AccessNI enhanced check had been undertaken for both new authorised operators however records retained showed that these checks had been completed after the commencement date as stated in their respective contracts of employment. Dr Neill stated that both staff members had previously been employed in the clinic in different roles and had subsequently been appointed as authorised operators. Dr Neill stated that an AccessNI enhanced check had been completed for each staff member for their previous positions and new AccessNI checks had been undertaken for each staff member on their appointment to the position of authorised operator. Dr Neill was advised to ensure that an AccessNI enhanced disclosure check is completed and the outcome recorded prior to any staff member commencing work as an authorised operator in the future. An area of improvement has been made against the standards in this regard.

A recruitment policy and procedure was in place which was comprehensive and reflected best practice guidance.

Safeguarding

Staff spoken with were aware of the types and indicators of abuse and the actions to be taken in the event of a safeguarding issue being identified, including who the nominated safeguarding lead was.

Review of records demonstrated that all staff in the establishment had received training in safeguarding children and adults as outlined in the Minimum Care Standards for Independent Healthcare Establishments July 2014. It was confirmed that the safeguarding lead has completed formal training in safeguarding adults in keeping with the Northern Ireland Adult Safeguarding Partnership (NIASP) training strategy (revised 2016).

Policies and procedures were in place for the safeguarding and protection of adults and children at risk of harm. The policy included the types and indicators of abuse and distinct referral pathways in the event of a safeguarding issue arising with an adult or child. The relevant contact details for onward referral to the local Health and Social Care Trust should a safeguarding issue arise were included.

It was confirmed that copies of the regional policy entitled 'Co-operating to Safeguard Children and Young People in Northern Ireland' (August 2017) and the regional guidance document entitled 'Adult Safeguarding Prevention and Protection in Partnership' (July 2015) were both available for staff reference.

Laser safety

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

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis. The service level agreement between the establishment and the LPA was reviewed and this had expired in June 2018. An area of improvement has been made against the standards has been made to provide RQIA with confirmation of the current service level agreement between the establishment and the appointed laser protection advisor (LPA).

Laser procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Jules Handley on 13 August 2016. Systems are in place to review the medical treatment protocols on an annual basis. The medical treatment protocols contained the relevant information pertaining to the treatments being provided.

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

The establishment's LPA completed a risk assessment of the premises on 18 June 2015 and all recommendations made by the LPA have been addressed. The LPA should undertake a risk assessment at least every three years. An area of improvement had been made against the standards in this regard.

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

When the laser equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS.

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

The laser equipment is operated using a keys. Arrangements are in place for the safe custody of the laser keys when not in use. Protective eyewear is available for the client and operator as outlined in the local rules.

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 a laser register which is completed every time the equipment is operated and includes:

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

There are arrangements in place to service and maintain the laser equipment in line with the manufacturer's guidance and the most recent service reports were available for inspection.

Management of emergencies

As discussed, authorised operators have up to date training in basic life support and refresher training will be provided in January 2019. Discussion with Dr Neill confirmed that all staff were aware of the action to take in the event of a medical emergency.

There was a resuscitation policy in place.

Infection prevention and control and decontamination procedures

There are two treatment rooms, both of which were clean and clutter free. It was evidenced that appropriate procedures were in place for the decontamination of equipment between use. Hand washing facilities were available and adequate supplies of personal protective equipment (PPE) were provided.

As discussed previously, it was identified that training records were not available to verify that the two new authorised operators had completed infection prevention and control (IPC) training, and one existing authorised operator was due refresher IPC training later in October 2018. An area of improvement has been made to ensure all authorised operators have completed IPC training in keeping with RQIA mandatory training guidance.

Environment

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

Observations made evidenced that a carbon dioxide (CO2) fire extinguisher is available which has been serviced within the last year.

Arrangements were in place for maintaining the environment. Review of records confirmed that up to date servicing and maintenance records were provided for the following areas:

- gas safety monitoring
- portable appliance testing (PAT) of electrical equipment
- the air conditioning system
- the security and alarm system
- the fire detection system

In addition a range of risk assessments and contingency arrangements were in place to guide and support staff, should an emergency situation occur. This is good practice.

A legionella risk assessment had been completed and monthly water temperatures were monitored and recorded and fire risk assessment was in place which has been reviewed annually.

Areas of good practice

There were examples of good practice found throughout the inspection in relation to staff appraisal, adult safeguarding, management of emergencies, risk management and the environment.

Areas for improvement

Ensure that a record of induction is completed for all new authorised operators.

All recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 should be provided for both new authorised operators and for any new authorised operators recruited in the future.

An AccessNI enhanced disclosure check should be completed and the outcome recorded prior to anyone commencing work as an authorised operator in the future.

Arrangements should be established to ensure that training is completed by authorised operators as outlined in the RQIA mandatory training guidance.

Confirmation of the current service level agreement between the establishment and the appointed laser protection advisor (LPA) should be provided to RQIA upon return of the QIP.

Ensure the LPA undertakes a review of the risk assessment at least every three years, and that if any recommendations are made within the risk assessment, that these are addressed.

	Regulations	Standards
Areas for improvement	0	6

6.5 Is care effective?

The right care, at the right time in the right place with the best outcome.

Care pathway

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. Written information is provided to the client 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 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 client.

During the initial consultation, clients are asked to complete a health questionnaire. There are systems in place to contact the client's general practitioner, with their consent, for further information if necessary.

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

- client 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 client records are securely stored. A policy and procedure is available which includes the creation, storage, recording, retention and disposal of records and data protection.

Discussion with Dr Neill and review of the management of records policy confirmed that patients have the right to apply for access to their clinical records in accordance with the General Data Protection Regulations that came into effect during May 2018 and where appropriate Information Commissioners Office (ICO) regulations and Freedom of Information legislation.

The establishment is registered with the ICO.

Communication

As discussed, there is written information for clients 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.

Dr Neill confirmed that staff meetings are held on a monthly basis. Review of documentation demonstrated that minutes of staff meetings are retained.

Areas of good practice

There were examples of good practice found in relation to the management of clinical records, the range and quality of audits, health promotion strategies and ensuring effective communication between clients and staff.

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.6 Is care compassionate?

Patients and clients are treated with dignity and respect and should be fully involved in decisions affecting their treatment, care and support.

Dignity respect and involvement with decision making

Discussion with Dr Neill regarding the consultation and treatment process, confirmed that clients are treated with dignity and respect. The consultation and treatment is provided in a private room with the client and authorised operator present. Information is provided to the client in verbal and written form at the initial consultation and subsequent treatment sessions to allow the client to make choices about their care and treatment and provide informed consent.

Appropriate measures are in place to maintain client confidentiality and observations made evidenced that client care records were stored securely in locked filing cabinets and electronic records are password protected.

Client 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 clients and other interested parties. An action plan is developed to inform and improve services provided, if appropriate.

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

- “Can’t fault treatment and aftercare. Very professional and well looked after.”
- “Staff have all been great and facilities very pleasant.”
- “An amazing clinic, with fantastic team.”
- “Excellent clinic.”

Areas of good practice

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

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.7 Is the service well led?

Effective leadership, management and governance which creates a culture focused on the needs and experience of service users in order to deliver safe, effective and compassionate care.

Management and governance

There was a clear organisational structure within the establishment and staff were able to describe their roles and responsibilities and were aware of who to speak to if they had a concern. Dr Neill 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.

Dr Neill is the nominated individual with overall responsibility for the day to day management of the service.

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

Discussion with Dr Neill demonstrated that arrangements were in place to review risk assessments.

A copy of the complaints procedure was displayed and available in the establishment. Discussion with Dr Neill demonstrated good awareness of complaints management. A complaints questionnaire was forwarded by RQIA to the establishment for completion. The evidence provided in the returned questionnaire indicated that complaints have been managed in accordance with best practice.

Discussion with Dr Neill 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 clients at appropriate intervals. Dr Neill confirmed that if required an action plan is developed and embedded into practice to address any shortfalls identified during the audit process.

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

Information requested by RQIA has been submitted within specified timeframes. The statement of purpose and client's guide are kept under review, revised and updated when necessary and available on request.

The RQIA certificate of registration was up to date and displayed appropriately.

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

Areas of good practice

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

Areas for improvement

No areas for improvement were identified during the inspection.

	Regulations	Standards
Areas for improvement	0	0

6.8 Equality data

Equality data

The arrangements in place in relation to the equality of opportunity for patients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of patients was discussed with Dr Neill.

6.9 Client and staff views

One client submitted a questionnaire response to RQIA. They indicated that they felt their care was safe and effective, that they were treated with compassion and that the service was well led and that they were very satisfied with each of these areas of their care.

RQIA also invited staff to complete an electronic questionnaire prior to the inspection. No completed staff questionnaires were received.

7.0 Quality improvement plan

Areas for improvement identified during this inspection are detailed in the QIP. Details of the QIP were discussed with Dr Robert Neill, clinic 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 the establishment. 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 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.

<table>
<tr><th colspan="2">Quality Improvement Plan</th></tr>
<tr><td colspan="2">Action required to ensure compliance with The Minimum Care Standards for Healthcare Establishments (July 2014)</td></tr>
<tr><td rowspan="2">Area for improvement 1

Ref: Standard 13.1

Stated: First time

To be completed by:
02 December 2018</td><td>The registered person shall ensure that a record of induction is completed for all new authorised operators.

Ref: 6.4</td></tr>
<tr><td>Response by registered person detailing the actions taken:
All staff must have record of induction completed, see Form 1 of hard copy posted to you.</td></tr>
<tr><td>Area for improvement 2

Ref: Standard 14.2

Stated: First time

To be completed by:
02 December 2018</td><td>The registered person shall ensure that all recruitment documentation as outlined in Schedule 2 of The Independent Health Care Regulations (Northern Ireland) 2005 is provided for both new authorised operators and for any new authorised operators recruited in the future.

Ref: 6.4</td></tr>
</table>

	Response by registered person detailing the actions taken: Recruitment documentation is completed in accordance with The Independent Health Care Regulations (Northern Ireland) 2005. See details on hard copy. Will be completed and on file for the two new Laser Operators.
Area for improvement 3 **Ref**: Standard 14.2 **Stated:** First time **To be completed by:** 02 December 2018	The registered person shall ensure that an AccessNI enhanced disclosure check is completed and the outcome recorded prior to anyone commencing work as an authorised operator in the future. Ref: 6.4
	Response by registered person detailing the actions taken: Any new Laser Operating Staff must have their Access NI Enhanced Disclosure confirmed before they start work.
Area for improvement 4 **Ref**: Standard 13.1 **Stated:** First time **To be completed by:** 02 December 2018	The registered person shall ensure that arrangements are established to ensure that training is completed by authorised operators as outlined in the RQIA mandatory training guidance. Ref: 6.4
	Response by registered person detailing the actions taken: All new Laser Operators must have satisfactory period of training, supervised, and written confirmation, and dated, and recorded in their personal file. This must be completed by Dr Jules Handley. Proof of "Core of Knowledge" training by Dr Jules Handley must be recorded in new Laser Operators personal files
Area for improvement 5 **Ref**: Standard 48.6 **Stated:** First time **To be completed by:** 02 December 2018	The registered person shall ensure that a copy of the current service level agreement between the establishment and the appointed laser protection advisor (LPA) is provided to RQIA upon return of the quality improvement plan (QIP). Ref: 6.4
	Response by registered person detailing the actions taken: Laser Protection Adisor did recent inspection, is enclosed in hard copy sent to you.
Area for improvement 6 **Ref**: Standard 48.11 **Stated:** First time **To be completed by:** 02 December 2018	The registered person shall ensure the LPA undertakes a review of the risk assessment at least every three years, and that if any recommendations are made within the risk assessment, that these are addressed. A copy of the most recent risk assessment undertaken by the LPA should be provided to RQIA upon return of this QIP. Ref: 6.4

	Response by registered person detailing the actions taken: Laser protection Advisor did recent risk assessment report, is enclosed with hard copy posted to you. All LPA reports have been placed in files in Treatment Room One and Two and are available for all Laser operators to read.

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

The Regulation and Quality Improvement Authority

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