

Announced Care Inspection Report 12 March 2021











Bloomfield Laser and Cosmetic Surgery Centre

Type of Service: Independent Hospital (IH) –
Cosmetic Laser and Intense Pulse Light (IPL) 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



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

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

2.0 Profile of service

Bloomfield Laser and Cosmetic Surgery Centre is registered as an Independent Hospital (IH) with the following categories of care: Prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers PT (L) and Prescribed techniques or prescribed technology: establishments using intense light sources PT (IL). The establishment provides a range of cosmetic/aesthetic treatments; this inspection focused solely on treatments provided using laser and intense pulse light (IPL) machines.

We were informed that Bloomfield Laser and Cosmetic Surgery Centre is only providing medically prescribed laser treatments, in keeping with the current restrictions applicable to close contact services, as directed by the Northern Ireland (NI) Executive in response to the COVID-19 pandemic.

Laser Equipment

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

Dr Handley 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, Ms Beulah Morrow and Ms Amanda Houston

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

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

Types of Treatment Provided – Hair removal, laser skin resurfacing, acne scars treatment, photo rejuvenation and vascular treatments

As previously discussed, we confirmed that only treatments prescribed by Dr Handley were offered at the time of this inspection.

3.0 Service details

Organisation/Registered Provider: Bloomfield Laser and Cosmetic Surgery Centre	Registered Manager: Dr Jules Handley
Responsible Individual: Dr Jules Handley	
Person in charge at the time of inspection: Dr Jules Handley	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

We undertook an announced inspection on 12 March 2021 from 10:30 to 13.20 hours.

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; laser safety; IPC procedures; and the organisational and governance arrangements.

An area for improvement made at the previous inspection in relation to completion of the laser registers has not been met and is stated for a second time.

No immediate concerns were identified regarding the delivery of front line client care.

4.1 Inspection outcome

	Regulations	Standards
Total number of areas for improvement	0	1

This inspection resulted in no new areas for improvement being identified. As previously stated an area for improvement made at the previous inspection, in relation to completion of the laser registers, has not been met and is stated for a second time. We discussed the findings of the inspection with Dr Jules Handley, Responsible Individual, as part of the inspection process and details 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 27 June 2019

Other than those action detailed in the QIP no further actions were required to be taken following the most recent inspection on 27 June 2019.

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 practice prior to the inspection inviting clients and staff to complete an electronic questionnaire. Returned completed client and staff questionnaires were analysed prior to the inspection and are discussed in section 6.8 of this report.

We undertook a tour of the premises, met with Dr Jules Handley, Responsible Individual, and an authorised operator; and reviewed relevant records and documents in relation to the day to day operation of the establishment.

A sample of records was examined during the inspection in relation to the following areas:

- information provided to clients;
- patient care records;
- policies and procedures;
- a medical practitioner personnel file;
- clinical records; and
- management and governance arrangements,

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

6.0 The inspection

6.1 Review of areas for improvement from the most recent inspection dated 27 June 2019

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 27June 2019

Areas for improvement from the last care inspection		
	e compliance with The Minimum Care nt Healthcare Establishments (July 2014)	Validation of compliance
Area for improvement 1 Ref: Standard 48.9	The registered person shall ensure that all laser registers record the precise exposure every time the laser is operated.	-
Stated: First time	Action taken as confirmed during the inspection: We confirmed that an individual register is retained in respect of each laser. We reviewed each laser register and found that the precise exposure detail had not been recorded in one of the laser registers. This was discussed with Dr Handley who confirmed the template in the identified laser register will be amended to include a column to enable recording of the precise exposure information. This area for improvement has not been met and has been stated for a second time.	Not met

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 resulting in the need for healthcare settings to assess and consider the risks to their clients and staff. We sought assurance of effective governance arrangements in the planning and delivery of IPC measures by reviewing the key areas of collaborative working, COVID-19 risk assessments, the monitoring of staff practices, work patterns and staff training.

We discussed the management of operations in response to the COVID-19 pandemic with Dr Handley and the authorised operator who outlined the measures taken, by Bloomfield Laser and Cosmetic Surgery Centre, to ensure current best practice measures were in place. We observed that the arrangements and staff practice, in relation to the management of COVID-19, was in line with best practice guidance. We determined that appropriate actions had been taken in this regard.

We reviewed a selection of documentation including minutes of meetings; COVID-19 risk assessments; audits of the environment and staff practices and training records. The records confirmed good governance measures were in place for the preparation and maintenance of a COVID-19 safe environment.

We found that COVID-19 policies and procedures were in place in keeping with best practice guidance.

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

We confirmed the establishment had identified a COVID-19 lead; had reviewed and amended policies and procedures in accordance with DoH guidance to include arrangements to maintain social distancing; prepare staff; implement enhanced IPC procedures; and the client pathway.

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

We identified no areas for improvement regarding the management of operations in response to the COVID-19 pandemic.

	Regulations	Standards
Areas for improvement	0	0

6.5 Laser Safety

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

We confirmed a laser safety file was in place. We reviewed this file and found that all of the relevant information in relation to the IPL equipment was retained and available for staff. We evidenced that a LPA had been appointed and that the LPA contract expires on 8 June 2021.

We confirmed that four authorised operators usually work in the clinic. However, as a result of a reduction in the treatments being provided, during the current period of NI Executive directed COVID-19 restrictions, only Dr Handley and one authorised operator were providing laser treatments.

In accordance with best practice guidance authorised operators must sign and date the authorised operator register. The purpose of signing the register is to confirm that they have read and understood the Local Rules and medical treatment protocols. We reviewed the authorised operator register and evidenced that it had been signed by all four authorised operators.

We reviewed the medical treatment protocols, produced by Dr Jules Handley, and confirmed that arrangements were in place to review the medical treatment protocols every year.

RQIA ID: 10631 Inspection ID: IN037241

We noted the medical treatment protocols set out the arrangements in relation to the following:

- contraindications;
- technique;
- pre-treatment tests;
- pre-treatment care;
- post-treatment care;
- recognition of treatment-related problems;
- procedure if anything goes wrong with treatment;
- permitted variation on machine variables; and
- procedure in the event of equipment failure.

We reviewed the LPA risk assessment of the premises undertaken on 19 October 2018 and noted the issues identified have been addressed by the LPS. Dr Handley confirmed that arrangements are being made for the LPA to undertake a fresh risk assessment later this year.

We found up to date Local Rules in place which have been developed by the LPA and these contained the relevant information pertaining to the laser equipment being used. We confirmed arrangements were 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 and intense light sources;
- 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 confirmed that Dr Handley is the LPS and has overall on-site responsibility for safety during laser treatments. The name of the LPS was recorded within the Local Rules. Dr Handley confirmed that arrangements are in place for another authorised operator, who is suitably skilled to fulfil the role, to deputise in his absence.

We reviewed training records and found that all 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 IPL equipment, had received laser safety awareness training.

We confirmed that an individual register is retained in respect of each laser, a review of the laser registers confirmed the following information was recorded:

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

As previously discussed, we found that the precise exposure detail had not been recorded in one of the laser registers. This was discussed with Dr Handley who confirmed the template in the identified laser register will be amended to include a column to enable recording of the precise exposure information. As previously discussed an area for improvement has been restated in this regard.

Dr Handley told us that an initial consultation is undertaken and clients are asked to complete a health questionnaire. Dr Handley confirmed that a process was in place to contact the client's general practitioner, with their consent, for further information if necessary.

We confirmed that client clinical records are retained in hard copy. We reviewed a selection of clinical records and found 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); and
- record of treatment delivered including number of shots and fluence settings (where appropriate).

There are two treatment rooms, one of which contains the Cynosure Apogee Elite laser and the other treatment room contains the Sharplan 4020S laser and the Lumenis Ultra Pulse Encore. Laser treatment rooms should be controlled to protect other persons while treatment is in progress. We reviewed both treatment rooms and noted the door to each treatment room can be locked when the laser machine is in use but can be opened from the outside in the event of an emergency. We confirmed that each treatment room is a controlled area that is clearly defined and not used for other purposes, or as access to areas when treatment is being carried out.

Dr Handley confirmed he was aware that when laser equipment is in use, the safety of all persons in the controlled area is his responsibility as the LPS.

We confirmed that protective eyewear is available for the client and operator, as outlined in the local rules, in respect of each laser machine.

We observed laser safety warning signs and confirmed these will be displayed when the lasers are in use and removed when not in use, as described within the Local Rules.

We observed that each laser machine is operated using a key. We reviewed the arrangements in relation to the safe custody of the keys and confirmed the arrangements to be satisfactory.

Arrangements have been established for the laser equipment to be serviced and maintained in line with the manufacturers' guidance. We were provided with a copy of previous service reports and of evidence that all the laser equipment is to be serviced on 16 April 2021.

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

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Areas of good practice: Laser safety

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

Areas for improvement: Laser safety

We identified one area for improvement made at the previous inspection has not been fully addressed and has been stated for a second time.

	Regulations	Standards
Areas for improvement	0	1

6.6 Infection prevention control (IPC)

We reviewed arrangements for IPC procedures throughout the clinic to evidence that the risk of infection transmission to clients, visitors and staff was minimised. We confirmed that the clinic had an overarching IPC policy and procedures in place.

We undertook a tour of the premises, which were maintained to a good standard of maintenance and decor.

As discussed we confirmed that staff had completed IPC training.

We found that cleaning schedules were in place. Dr Handley and the authorised operator described the arrangements to decontaminate the environment and equipment between clients and we found these to be satisfactory.

We noted that a dedicated hand washing basin and hand sanitiser was available in both treatment rooms.

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 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 an establishment registered with us is a corporate body, or partnership, or an individual owner, who is not in day to day management of the establishment, unannounced quality monitoring visits by the Responsible Individual must be undertaken and documented every six months; as required by Regulation 26 of The Independent Health Care Regulations (Northern Ireland) 2005. We confirmed that Dr Handley is in day to day charge of the establishment therefore Regulation 26 unannounced quality monitoring visits are not required.

We confirmed that Dr Handley is the only medical practitioner providing services within Bloomfield Laser and Cosmetic Surgery Centre. A review of Dr Handley's details confirmed that 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.

All medical practitioners working within the clinic must have a designated Responsible Officer, (RO) as per the requirements of registration with the GMC, and all medical practitioners must revalidate every five years. The revalidation process requires medical practitioners to collect examples of their work, to understand what they are doing well and how they can improve. Experienced senior doctors work as RO's 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. The RO then has the responsibility to share this information with all relevant stakeholders in all areas of the doctor's work.

Dr Handley informed us he is due to revalidate in June 2021 and has had discussions with the GMC in this regard. Dr Handley confirmed he is aware of his responsibilities under GMC Good Medical Practice.

We reviewed records and confirmed that Dr Handley had completed refresher training in keeping with RQIA training guidance.

We confirmed that the management of medical emergencies was included in the staff induction programme and that basic life support training was updated on an annual basis in keeping with best practice guidance. We reviewed training records and evidenced that staff completed basic life support training annually.

Dr Handley demonstrated a clear understanding of his role and responsibilities in accordance with legislation. Information requested by RQIA had been submitted within specified timeframes. Dr Handley told us that the Statement of Purpose and Patient's Guide were kept under review, revised and updated when necessary and were available to patients on request.

Areas of good practice: Organisational governance

We found examples of good practice regarding organisational governance.

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Areas for improvement: Organisational governance

We identified no areas for improvement in relation to organisational governance.

	Regulations	Standards
Areas for improvement	0	0

6.7 Equality data

We discussed the arrangements in place regarding the equality of opportunity for clients and the importance of staff being aware of equality legislation and recognising and responding to the diverse needs of clients. Dr Handley and staff demonstrated that equality data collected was managed in line with best practice.

6.8 Client and staff views

As discussed in section 5.0 of this report we invited clients and staff to complete an online questionnaire. Seven completed client questionnaires were submitted to RQIA. We found six clients felt their care was safe and effective, that they were treated with compassion and that the service was well led. These six clients also indicated that they were very satisfied with each of these areas of their care and two clients also included commentary which confirmed they were each very satisfied with care, treatment and services provided by Bloomfield Laser and Cosmetic Surgery Centre. They paid tribute the to the kindness and professionalism of all members of staff. One patient indicated they felt dissatisfied with the care and treatment provided by Dr Handley within a specified time frame and provided additional comments in this regard. We discussed this comment with Dr Handley who stated he had not received any complaints or expressions of dissatisfaction. We reviewed the complaints record and found that no complaints had been documented. Dr Handley confirmed that any comments or complaints received in the clinic would be shared with him.

We also invited staff to complete an electronic questionnaire. We received five staff questionnaire responses, which indicated that all staff members were very satisfied that care was safe, effective, that patients were treated with compassion and indicated they felt satisfied in response to the service being well led. One staff member provided an additional comment which confirmed they felt the clinic was a great place to work, and that they felt supported and valued.

6.10 Total number of areas for improvement

	Regulations	Standards
Total number of areas for improvement	0	1

7.0 Quality improvement plan

We identified an area for improvement made during the previous inspection had not been met, this area for improvement has been stated a second time and is included in the QIP. We discussed the detail of the QIP with Dr Handley, Responsible Individual, as part of the inspection process. The timescale commences from the date of inspection.

The Registered Person/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. It is the responsibility of the Registered Person 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

An area 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 action taken to address the area 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 Establishments (July 201	e compliance with The Minimum Care Standards for Healthcare	
Area for improvement 1	The registered person shall ensure that all laser registers record the precise exposure every time the laser is operated.	
Ref: Standard 48.9	Ref: 6.2	
Stated: Second time		
To be completed by: 13 March 2021	Response by registered person detailing the actions taken: I would like to report that following the inspection we have been recording the precise exposure every time the laserS are operated.	
	We have amended the template in the one laser register to enable us to record the exact settings.	
	Therefore all registers are now displaying the appropriate laser exposure used for each treatment.	

^{*}Please ensure this document is completed in full and returned via Web Portal*





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