



The Regulation and
Quality Improvement
Authority

THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
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VARIATION INSPECTION REPORT

Inspection No:	21201
Name of Establishment:	Fitzwilliam Clinic
Inspector's Name:	Jo Browne
Date of Inspection:	20 February 2015

1.0 General Information

Name of establishment:	Fitzwilliam Clinic
Address:	70-72 Lisburn Road Belfast BT9 6AF
Telephone number:	028 9032 3888
Registered Organisation/Registered Provider:	Fitzwilliam Partnership Mr James Small Mr Stephen Sinclair Mr James Kennedy
Registered Manager:	Ms Sheila Jordan
Person-in-charge of the establishment at the time of inspection:	Ms Sheila Jordan
Registration Categories:	AH (DS) – Acute Hospital Day Surgery PD – Private Doctor (Other)
Date and time of inspection:	20 February 2015 10.00 – 12.20
Name of inspector:	Jo Browne
Name of Medical Physics Advisor:	Dr Ian Gillan

2.0 Introduction

The Regulation and Quality Improvement Authority (RQIA) is empowered under the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to inspect independent health care establishments. A minimum of one inspection per year is required and this may be announced or unannounced.

3.0 Purpose of Variation Inspection

Fitzwilliam clinic have applied to RQIA to vary their category of registration to include PT(L) - prescribed techniques or prescribed technology: establishments using Class 3B or Class 4 lasers.

The purpose of the variation inspection is to determine compliance with:

- The Regulation and Improvement Authority (Registration) Regulations (Northern Ireland) 2005;
- 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.
- DHSPPS Independent Health Care Minimum Standards for Hospitals and Clinics.

4.0 Methods/Processes

The methods/process used in this inspection included the following:

- review of the submitted application forms and supported documentation
- discussion with Ms Sheila Jordan, registered manager;
- discussion with Miss Jenny Flanagan, authorised user;
- assessment of the environment;
- review of documentation required by legislation and good practice; and
- evaluation and feedback.

5.0 Profile of the Establishment

The Fitzwilliam Clinic is situated in a converted residential building located on the Lisburn Road in Belfast. The hospital offers a range of surgical and non-surgical procedures. The clinic has no overnight beds and all surgery is performed as day cases only.

The following procedures are available in the clinic:

Surgery

- Cutaneous surgery
- Oral surgery
- Breast surgery
- Hand surgery
- Aesthetic surgery
- General surgery
- Varicose Vein Treatments using radiofrequency ablation

All surgical procedures are undertaken by consultant surgeons and dental practitioners who have been granted practising privileges by the hospital.

The registered manager is Ms Sheila Jordan. Mr Stephen Sinclair is the medical director/responsible individual for the hospital. Mr Small and Mr Kennedy are also partners in the business and responsible individuals.

Laser Services

The hospital has applied to RQIA to vary their category of registration to provide laser treatments.

Laser Equipment

Manufacturer: Cynosure
Model: Apogee
Serial Number: APMD 1900
Laser Medium: Alexandrite (755nm)
Laser Class: Class 4

Cooler

Manufacturer: Cynosure
Model: Cryo 5
Serial Number: 727985

Laser Protection Advisor (LPA)

Alex Zarneh

Medical Support Services

Dr Tapan Patel

Laser Protection Supervisor (LPS)

Jenny Flanagan

Authorised Users

Jenny Flanagan

Type of Treatment Provided

Hair removal

6.0 Summary

A variation application was submitted to RQIA by Ms Sheila Jordan in respect of Fitzwilliam Clinic to include the PT (L) category of care in their registration. This report only refers to the provision of the laser services.

The application forms and supporting documentation was reviewed as part of the inspection process.

The inspection was carried out by Jo Browne accompanied by Dr Ian Gillan (Medical Physics Advisor for RQIA) on 20 February 2015 between the hours of 10.00 and 12.20.

Ms Jordan and Miss Flanagan were available during the inspection and for verbal feedback at the conclusion of the inspection.

During the course of the inspection the inspector discussed operational issues, examined a selection of records and carried out a general inspection of the establishment.

A Statement of Purpose and Patient Guide were in place for the hospital and a further Statement of Purpose and Client Guide had been developed for the laser service. It is recommended that the information from both sets of documents is merged into one overall Statement of Purpose and Patient Guide.

Systems will be in place to obtain the views of clients using a satisfaction questionnaire. A summary report will be completed and made available to clients and other interested parties after the service is operational.

The establishment had a complaints policy and procedure in place which was found to be in line with the DHSSPS guidance on the management of complaints within regulated establishments and agencies. Systems were in place to effectively document and manage complaints.

Fitzwilliam Clinic has an existing policy and procedure in place which outlines the arrangements for application, granting, maintenance and withdrawal of practising privileges. A recommendation was made to amend this policy to include granting practising privileges to authorised users of the laser equipment.

A requirement was made to ensure all information required by legislation is retained for the authorised user prior to granting practising privileges, as outlined in the main body of the report.

A review of training records confirmed that authorised users had completed the required mandatory training. Arrangements are in place for staff not involved in the use of the laser to receive laser safety awareness training.

There was a policy and procedure in place for infection prevention and control. The inspector undertook a tour of the premises, which were maintained to a high standard of

maintenance and décor. Staff have received training in infection prevention and control. Cleaning schedules were in place and arrangements for the decontamination of equipment between clients.

The treatment to be provided, fees, risks, complications and expected outcomes are discussed with the client during the initial consultation. Written aftercare instructions are provided following treatment.

The proposed client care records were reviewed and found to contain a health questionnaire, consent form and record of treatment.

The establishment has medical treatment protocols in place written by Dr Patel in July 2013. A recommendation was made to confirm that these were the latest version.

The establishment has local rules developed by their LPA and written in December 2014.

A risk assessment of the premises was undertaken by the LPA in December 2014 and any issues identified have been addressed by the LPS.

There was list of authorised users in place.

The environment in which the laser was used was found to be safe and controlled. Protective eyewear was available for the client and operator as outlined in the local rules. The inspector advised including the total blocking shields in the local rules. Laser safety warning signs are displayed when the laser is in use as described within the local rules.

A recommendation was made to ensure that arrangements are in place to open the locked laser treatment room from the outside in the event of an emergency.

Arrangements are in place to ensure that the laser key is stored safely and securely when the equipment is not in use.

A laser protection report prepared by Dr Ian Gillan, RQIA's medical physics advisor has been appended to this report and also outlines any deficits in laser safety arrangements within the establishment.

One requirement and three recommendations were made as a result of the variation inspection, details can be found in the main body of the report and the attached Quality Improvement Plan (QIP).

Overall the establishment was found to be providing a safe and effective service; laser safety arrangements are generally of a high standard.

The inspector wishes to thank Ms Sheila Jordan and Miss Jenny Flanagan for their helpful discussions, assistance and hospitality throughout the inspection process.

7.0 Inspection Findings

7.1 Statement of purpose

A statement of purpose was in place in a recognised format which covered the key areas and themes outlined in regulation 7, schedule 1 of The Independent Health Care Regulations (Northern Ireland) 2005 for Fitzwilliam Clinic. A further Statement of Purpose had been developed solely for the provision of the laser service. It is recommended that the information contained within the documents is merged into one Statement of Purpose that reflects all services provided by the hospital, including the laser treatments.

7.2 Patient Guide

A Patient Guide was in place in a recognised format which covered the key areas and themes specified in regulation 8 of The Independent Health Care Regulations (Northern Ireland) 2005. A further Client Guide had been developed solely for the provision of the laser service. It is recommended that the information contained within the documents is merged into one Patient Guide that reflects all services provided by the hospital, including the laser treatments.

7.3 Client Partnerships

The establishment intends to obtain the views of clients, availing of laser treatments, on the quality of treatment, information and care received using a questionnaire.

The registered manager confirmed that the information obtained from clients will be collated into an anonymised format, summarised and used by the establishment to make improvements to the services.

A copy of the summary report will be made available to clients and other interested parties.

7.4 Complaints

The establishment operates a complaints policy and procedure in accordance with the Department of Health, Social Services and Public Safety (DHSSPS) guidance on complaints handling in regulated establishments and agencies (April 2009) and the Independent Health Care Regulations (Northern Ireland) 2005. Staff spoken with demonstrated an understanding of complaints management.

Systems are in place to effectively document and manage complaints.

7.5 Practising Privileges

Fitzwilliam Clinic has an existing policy and procedure in place which outlines the arrangements for application, granting, maintenance and withdrawal of practising

privileges. It is recommended that this is amended to include granting practising privileges to authorised users of the laser equipment.

It is required that the following information is retained for all authorised users who are granted practising privileges at Fitzwilliam Clinic for laser treatments:

- A written agreement between the authorised user and the establishment setting out the terms and conditions of the practising privileges;
- Evidence that all mandatory training is completed as outlined in the RQIA guidance;
- Proof of identity including a recent photograph;
- Enhanced AccessNI disclosure;
- Two written references, including a reference from the person's present or most recent employer;
- Evidence of any relevant qualifications or accredited training;
- A full employment history, together with a satisfactory written explanation of any gaps in employment;
- Details of any criminal offences;
- Confirmation that they are physically and mentally fit to fulfil their duties and responsibilities.

There are systems in place to review practising privilege agreements every two years.

7.6 Staff Training and Development and Training for Staff using Lasers and Intense Light Sources

A record of training was available for the authorised user.

Core of knowledge training was undertaken in September 2013.

The safe use and application of the laser training was undertaken in August 2014.

A review of the training records confirmed that all mandatory training outlined in the RQIA guidance had been completed.

Laser safety awareness training will be provided for staff not directly involved in the use the laser by the LPS. The inspector reviewed the content of the training programme as part of the inspection process.

7.7 Infection Prevention and Control

The establishment has policies and procedures in place for infection prevention and control.

The inspector undertook a tour of the premises, which were maintained to a high standard of maintenance and décor.

Staff have received training in infection prevention and control.

Cleaning schedules are in place and arrangements for the decontamination of equipment between clients.

The establishment had hand washing facilities available within the treatment room.

There were adequate supplies of personal protective equipment, liquid soap, alcohol based hand gels and disposable hand towels available.

7.8 Client Information and Laser Procedures

The establishment has policies and procedures for advertising and marketing which are factual and not misleading.

Clients are provided with written information on the specific laser procedures that explains the risks, complications and expected outcomes of the treatment.

Clients are provided with an initial consultation to discuss their treatment and any concerns they may have. The establishment has a list of fees available for each laser procedure. Fees for treatment are agreed during the initial consultation and may vary depending on the treatment provided and the individual requirements of the client.

Clients are asked to complete a health questionnaire. There are systems in place to contact the client's GP, with their consent, for further information if necessary.

7.9 Procedures for the User of Lasers and Intense Light Sources

Laser procedures will be carried out by trained operators in accordance with medical treatment protocols produced by Dr Tapan Patel on 29 July 2013. It was recommended that Dr Patel is contacted to confirm that the treatment protocols provided are the most recent version as systems should be in place to review the medical treatment protocols annually.

The medical treatment protocols sets out:

- 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
- Procedure in the event of equipment failure.

There was written confirmation of the appointment and duties of a certified LPA which is reviewed on an annual basis.

The establishment has local rules in place which have been developed by their LPA in December 2014.

Systems are in place to review the local rules every annually.

The local rules cover:

- 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
- Adverse incident procedures

The name of the person who has overall on-site responsibility for safety during laser treatments is recorded within the local rules.

The laser operator is authorised to use the equipment and a register of authorised users is maintained.

The authorised user has signed to state that they have read and understood the local rules and medical treatment protocols.

A register is maintained for every time the laser is operated and includes:

- The name of the person treated
- The date
- The operator
- The treatment given
- The precise exposure
- Any accident or adverse incidents

The laser register was reviewed and found to contain all of the information required by legislation.

The proposed client care records were reviewed and found to contain a health questionnaire, consent form and record of treatment.

7.10 Safe Operation of Lasers and Intense Light Sources

The environment in which the laser is used was found to be controlled to protect other persons while treatment is in progress. The controlled area is clearly defined and not used for other purposes, or as access to areas, when treatment is being carried out.

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

The LPA had completed a risk assessment of the premises in December 2014 and any issues identified had been addressed.

Laser safety warning signs are displayed when the laser is in use and removed when not in use as described within the local rules.

Protective eyewear was available for the client and operator as outlined in the local rules. The inspector advised including the total blocking shields available within the local rules.

The door to the laser treatment room is locked when treatments are being provided and it is recommended that arrangements are in place to open the door from the outside in the event of an emergency. The inspector suggested placing a key for the door in a 'break glass' box outside the room.

There are formal written arrangements in place for the safe custody of the laser key. The laser key was observed to be stored safely and securely during the inspection.

There is a laser safety file in place.

Equipment is serviced and maintained in line with the manufacturers' guidance. The most recent service reports were reviewed as part of the inspection process.

The inspector reviewed the incident policy and discussed the reporting of adverse incidents in line with the RQIA reporting procedure.

8.0 Laser Protection Report

A laser protection report prepared by Dr Ian Gillan, RQIA's medical physics expert has been appended to this report and outlines any deficits in laser safety arrangements within the establishment.

9.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Ms Sheila Jordan and Miss Jenny Flanagan as part of the inspection process.

The timescales commence from the date of inspection.

Requirements are based on 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

Recommendations are based on the Department of Health, Social Services and Public Minimum Care Standards for Independent Healthcare Establishments, July 2014, promote good practice and should be considered by the management of the establishment to improve the quality of service experienced by clients.

The registered provider/manager is required to record comments on the Quality Improvement Plan.

Matters to be addressed as a result of this inspection are set in the context of the current registration of your premises. The registration is not transferable so that in the event of any future application to alter, extend or to sell the premises the Authority would apply standards current at the time of that application.

Enquiries relating to this report should be addressed to:

**Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
Belfast
BT1 3BT**



Quality Improvement Plan

Variation Inspection

Fitzwilliam Clinic

20 February 2015

The areas where the service needs to improve, as identified during this inspection visit, are detailed in the inspection report and Quality Improvement Plan.

The specific actions set out in the Quality Improvement Plan were discussed with Ms Sheila Jordan and Miss Jenny Flanagan during the inspection visit.

Any matters that require completion within 28 days of the inspection visit have also been set out in separate correspondence to the registered persons.

Registered providers / managers should note that failure to comply with regulations may lead to further enforcement and/ or prosecution action as set out in The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003.

It is the responsibility of the registered provider / manager to ensure that all requirements and recommendations contained within the Quality Improvement Plan 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 your premises. 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.

STATUTORY REQUIREMENT

This section outlines the actions which must be taken so that the registered person/s meets legislative requirements based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, 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.

NO.	REGULATION REFERENCE	REQUIREMENT	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	19 (2) (d)	<p>The registered manager must ensure that all information required by legislation is retained before granting practising privileges as outlined in the main body of the report.</p> <p>Ref: 7.5</p>	One	<p>All required information has been sited and retained.</p> <p>The Enhanced Disclosure form has been sent off with completed payment.</p> <p>Awaiting Disclosure confirmation and Hep B and C status results, prior to operational laser procedures.</p> <p>A Practising and Privileges contract has been drawn up to include the independent laser contractor. (See attached)</p>	Within one month

RECOMMENDATIONS

These recommendations are based on the DHSSPS draft Independent Health Care Minimum Standards for Hospitals and Clinics, research or recognised sources. They promote current good practice and if adopted by the registered person/manager may enhance service, quality and delivery.

NO.	MINIMUM STANDARD REFERENCE	RECOMMENDATIONS	NUMBER OF TIMES STATED	DETAILS OF ACTION TAKEN BY REGISTERED PERSON(S)	TIMESCALE
1	16.6 & 16.8	The registered manager should ensure that one Statement of Purpose and Patient Guide is in place that reflects all of the services available within the hospital, including laser treatments. Ref: 7.1 & 7.2	One	Both Jenny's and the FWC's Statement of purpose and Patients Guide have been carefully combined. (please see attached)	Within one month
2	48.4	The registered manager should ensure that Dr Patel is contacted to confirm that the medical treatment protocols provided are the most recent version. Ref: 7.9	One	Confirmation has been received to state the medical treatment protocols are the most recent version and are updated every three years. (please see attached confirmation emails and a signed copy from Dr. Patel)	Within one month
3	48.18	The registered manager should ensure that systems are in place to unlock the laser treatment room from the outside in the case of an emergency. Ref: 7.10	One	A code secured key, lock box will be installed outside the laser room door. All staff members will be alerted of the code. (please see attached photos)	Immediately and ongoing

Please complete the following table to demonstrate that this Quality Improvement Plan has been completed by the registered manager and approved by the responsible person / identified responsible person and return to independent.healthcare@rqia.org.uk

Name of Registered Manager Completing QIP	Sheila Jordan
Name of Responsible Person / Identified Responsible Person Approving QIP	

QIP Position Based on Comments from Registered Persons	Yes	Inspector	Date
Response assessed by inspector as acceptable		Jo Browne	08/14/15
Further information requested from provider			