

Announced Inspection

Name of Establishment: Woodford Medical Ltd

Establishment ID No: 10799

Date of Inspection: 19 February 2015

Inspector's Name: Winnie Maguire

Inspection No: 17404

The Regulation and Quality Improvement Authority
9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501

1.0 General Information

Name of establishment:	Woodford Medical Ltd	
Address:	Unit 1B Marlborough House 348 Lisburn Road Belfast BT9 6AL	
Telephone number:	08456021161	
Registered organisation/ registered provider:	Woodford Medical Ltd Dr Hilary Frances Allan	
Registered manager:	Dr Hilary Frances Allan	
Person in charge of the establishment at the time of inspection:	Dr Mervyn Patterson	
Registration category:	PT(IL) - Prescribed techniques or prescribed technology, establishments using intense light sources, PD Private Doctor	
Date and time of inspection:	19 February 2015 10:00- 12:00	
Date and type of previous inspection:	Announced 4 February 2014	
Name of inspector:	Winnie Maguire	

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.

This is a report of the announced inspection to assess the quality of services being provided. The report details the extent to which the regulations and DHSPPS Minimum Care Standards for Healthcare Establishments, July 2014, measured during the inspection were met.

2.1 Purpose of the Inspection

The purpose of this inspection was to ensure that the service is compliant with relevant regulations, the minimum standards and to consider whether the service provided to clients was in accordance with their assessed needs and preferences. This was achieved through a process of analysis and evaluation of available evidence.

RQIA not only seeks to ensure that compliance with regulations and standards is met but also aims to use inspection to support providers in improving the quality of services. For this reason, inspection involves in-depth examination of an identified number of aspects of service provision.

The aims of the inspection were to examine the policies, procedures, practices and monitoring arrangements for the provision of IPL services, and to determine the provider's compliance with the following:

- The HPSS (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
- The Department of Health, Social Services and Public Safety's (DHSPPS)
 Minimum Care Standards for Healthcare Establishments

Other published standards which guide best practice may also be referenced during the inspection process.

2.2 Method/Process

Committed to a culture of learning, RQIA has developed an approach which uses self-assessment, a critical tool for learning. The self-assessment was forwarded to the provider prior to the inspection and was reviewed by the inspector prior to the inspection. The inspection process has three key parts; self-assessment, pre-inspection analysis and the visit undertaken by the inspector.

Specific methods/processes used in this inspection include the following:

- Analysis of pre-inspection information and self-assessment
- Discussion with Dr Mervyn Patterson
- Examination of records
- Tour of the premises
- Evaluation and feedback

Any other information received by RQIA about this registered provider and its service delivery has also been considered by the inspector in preparing for this inspection.

The completed self- assessment is appended to this report.

2.3 Consultation Process

During the course of the inspection, the inspector:

Reviewed client feedback questionnaires, issued by the establishment	50
Spoke with staff	2

2.4 Inspection Focus

The inspection sought to establish the level of compliance being achieved with respect to the following DHSPPS Minimum Care Standards for Healthcare Establishments and to assess progress with the issues raised during and since the previous inspection.

- Standard 5 Patient and Client Partnerships
- Standard 7 Complaints
- Standard 9 Clinical Governance
- Standard 10 Qualifications Practitioners, Staff and Indemnity
- Standard 16 Management and Control of Operations
- Standard 48 Laser and Intense Light Sources

3.0 Profile of Service

Woodford Medical Ltd is registered with RQIA since 2009 for the use of intense pulsed light (IPL) and the provision of private medical services. Dr Hilary Allan has been the registered provider/manager since the initial registration. Dr Patterson informed the inspector that Dr Allan has not been providing private medical or IPL services in the clinic for some time. Dr Patterson informed the inspector he continued to provide private medical and IPL services at least once a month in the clinic. The inspector recommended Dr Patterson contact the registration team at RQIA to clarify his registration status with RQIA and with a view to undertaking the registered manager's role.

Woodford Medical Ltd has a number other clinics in England.

The Woodford Medical Ltd situated on the Lisburn Road, close to local amenities and transport routes.

The establishment is not accessible for patients with a disability as the clinic is located on the first floor of the building. There is an extensive reception, waiting area and toilet facilities available for patient use.

IPL Equipment

Manufacturer: Palomar

Model: Starlux 500 IPL

Serial Number: 55-0209

Treatments provided

- Hair removal
- Photo rejuvenation
- Acne treatments

Authorised User

Dr Mervyn Patterson

Authorised user in training

Ms Kerry Blein (under Dr Patterson's supervision only at present)

Laser Protection Supervisor (LPS)

Dr Mervyn Patterson (is to undertake the role of LPS following a recommendation as a result of inspection).

Laser Protector Advisor (LPA)

Mr Godfrey Town

The Private Doctor Service includes:

- IPL services
- Consultation on range of skin conditions
- Botox injections
- Derma fillers provision

4.0 Summary of Inspection

An announced inspection was undertaken by Winnie Maguire on 19 February 2015 from 10:00 to12:00. The inspection sought to establish the compliance being achieved with respect to 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, the DHSSPS Minimum Care Standards for Independent Healthcare Establishments and to assess the progress made to address the issues raised during the previous inspection.

There was one recommendation made as a result of the previous annual announced inspection on 4 February 2014. This recommendation has been fully addressed.

The inspection focused on the DHSSPS Minimum Care Standards for Independent Healthcare Establishments outlined in section 2.4 of this report.

Dr Patterson was 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.

The establishment has robust systems in place to obtain the views of patients on a formal and informal basis. The inspector reviewed the completed patient feedback questionnaires and found that patients were highly satisfied with the care and treatment provided. Some of the comments received can be viewed in the main body of the report. Senior management collates the information from the questionnaires into a summary report which is made available to patients and other interested parties in patient information folder in the waiting area.

Woodford Medical Ltd has a complaints policy and procedure in place which was found to be line with the DHSSPS guidance and legislation. No complaints have been received by the establishment, however, systems are in place to effectively document, manage and audit complaints. Dr Patterson displayed a good understanding of complaints management.

There is a defined management structure within the establishment and clear lines of accountability.

The inspector recommended Dr Patterson contact the registration team at RQIA to clarify his registration status with RQIA and with a view to undertaking the registered manager's role. Dr Patterson is one of the medical directors in the organisation.

Dr Patterson is presently responsible for the day to day running of the establishment and ensuring compliance with the legislation and standards.

The establishment has systems in place to audit the quality of service provided as outlined in the main body of the report.

The inspector also reviewed incident management and found this to be line with legislation and best practice. No incidents have been recorded by the establishment however systems are in place to document, manage and report incidents in line with the legislation.

The inspector reviewed the policy and procedures in relation to the absence of the registered manager and whistleblowing. They were found to be in line with legislation and best practice.

A Statement of Purpose and Patient Guide were in place which reflected legislative and best practice guidance.

The inspector reviewed the insurance arrangements for the establishment and found that current insurance policies were in place.

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

There were clear medical treatment protocols and local rules in place. Systems are in place to review the medical treatment protocols and local rules on an annual basis. A service level agreement was in place between the establishment and the LPA. A recommendation was made to amend the local rules to include Dr Patterson as the LPS.

The establishment has an IPL register which is completed every time the equipment is operated.

Six patient treatment records were examined and found to be generally well completed. The records contained the patients personal details, a completed health questionnaire, signed consent form, evidence of patch test and treatment provided. The clinic carries out a regular patient record audit.

A risk assessment had been undertaken by the establishment's LPA on 13 January 2015 and no issues were identified.

Review of the training records confirmed that mandatory training was up to date and the authorised user had received appropriate training in the safe use and operation of the IPL equipment. A further member of staff has been recruited who has received training in the safe use and operation of the IPL equipment and core of knowledge. On the completion of a period of supervised practice with Dr Patterson and written evidence of mandatory training she will become an authorised user.

The environment in which the IPL equipment is used was found to be safe and controlled. Protective eyewear was available for the patient and operator as outlined in the local rules.

Laser safety warning signs are displayed when the IPL equipment is in use. The IPL equipment is operated using a key control system. Arrangements are in place for the safe custody of the IPL key when not in use.

Systems were in place to service and maintain the IPL equipment in line with the manufacturers' guidance. The most recent service report was reviewed by the inspector. A laser safety file was in place.

The private doctor details reviewed found the GMC (General Medical Council) registration was up to date, professional indemnity insurance was in place and the medical practitioner had the appropriate qualifications to carry out the services outlined in the establishment's Statement of purpose. There was evidence of appraisal in place.

The certificate of registration was clearly displayed in the waiting area of the establishment.

Two recommendations were made as a result of this inspection. These are discussed fully in the main body of the report and in the appended Quality Improvement Plan.

Overall, on the day of inspection, the establishment was found to be providing a safe and effective service.

The inspector would like to extend her gratitude to Dr Patterson and the staff of Woodford Medical Ltd for their hospitality and contribution to the inspection process.

5.0 Follow up on Previous Issues

No.	Minimum Standard Ref.	Recommendations	Action taken as confirmed during this inspection	Number of times stated	Inspector's validation of compliance
1	P4	The registered person should review arrangements for opening the IPL room door for the outside in the event of an emergency	A lock has been fitted and arrangements are in place to ensure the door can be opened in the event of an emergency.	One	Complaint

6.0 Inspection Findings

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Woodford Medical Ltd obtains the views of patients on a formal and informal basis as an integral part of the service they deliver.

The establishment completed a patient satisfaction survey of fifty patients in 2014. The results of the survey are reviewed by the management team within the organisation and an action plan is developed and implemented if any issues are identified. However no issues were identified as requiring to be addressed.

The inspector reviewed the completed survey and found that patients were highly satisfied with the quality of care and treatment provided by the clinic. Some comments received from patients included:

- "Very friendly"
- "A very personal service"
- "Great service"
- "Great experience"
- "Very informed consultation and great result"

The information received from the patient survey is collated into an annual summary report which is made available to patients and other interested parties to read.

Evidenced by:

Review of patient satisfaction surveys
Review of summary report of patient satisfaction surveys
Summary report made available to patients and other interested parties

STANDARD 7	
Complaints:	All complaints are taken seriously and dealt with appropriately and promptly.

The establishment operates a complaints policy and procedure in accordance with the DHSSPS guidance on complaints handling in regulated establishments and agencies and the legislation. Dr Patterson demonstrated a good understanding of complaints management.

All patients are provided with a copy of the complaints procedure, which is contained within the Patient Guide.

The inspector reviewed the complaints register and found that no complaints had been received by the establishment; however systems are in place to effectively document and manage complaints.

There are systems in place to carry an audit of complaints as when required as part of the establishment's quality assurance mechanisms.

Evidenced by:

Review of complaints procedure Complaint procedure made available to patients and other interested parties Review of complaints records

Clinical Governance: Patients and clients are provided with safe and effective treatment and care based on best practice guidance, demonstrated by procedures for recording and audit.

The registered manager ensures the establishment delivers a safe and effective service in line with the legislation, other professional guidance and minimum standards.

The establishment has systems in place to audit the quality of service provided. The inspector reviewed the following audits as part of the inspection process:

- Clinical audit
- Adverse reaction audit
- Complaints audit
- · Policies and procedures audit
- Consent audit
- Patient record audit
- Patient satisfaction survey

Dr Patterson informed the inspector that the registered person/manager Dr Hilary Allan has not provided medical or IPL services in the establishment for some time.

The inspector recommended Dr Patterson should contact the registration team at RQIA to clarify;

- his registration status with RQIA;
- and undertaking the registered manager's role.

Dr Patterson is one of the medical directors of the organisation.

The establishment has an incident policy and procedure in place which includes reporting arrangements to RQIA. No incidents have occurred within the establishment since registration; however systems are in place to document and manage incidents appropriately.

Dr Patterson confirmed that no research is currently being undertaken within the establishment.

Evidenced by:

Review of policies and procedures Review of audits Review of incident management Review of research arrangements

STANDARD 10	
Qualified	Staff are educated, trained and qualified for their role
Practitioners, Staff	and responsibilities and maintain their training and
and Indemnity	qualifications.

The inspector reviewed the details of the medical practitioner and confirmed that:

- There was evidence of current registration with the General Medical Council (GMC)
- The medical practitioner is covered by the appropriate professional indemnity insurance
- There was evidence of ongoing professional development and continuing medical education that meet the requirements of the Royal Colleges and GMC
- There was evidence of ongoing annual appraisal by a trained medical appraiser

The inspector confirmed that the medical practitioner has an appointed responsible officer.

Arrangements are in place for dealing with professional alert letters, managing identified lack of competence and poor performance for all staff and reporting incompetence in line with guidelines issues by the DHSSPS and professional regulatory bodies.

Discussion with Dr Patterson confirmed that he is aware of his responsibilities under GMC Good Medical Practice.

Evidenced by:

Review of staff personnel files for verification of registration status with professional bodies
Review of professional indemnity insurance
Review of specialist qualifications
Review of arrangements for dealing with alert letter/competency
Review of training records

STANDARD 16	
Management and	Management systems and arrangements are in place
Control of	that ensure the delivery of quality treatment and care.
Operations:	

There is a defined organisational and management structure that identifies the lines of accountability, specific roles and details responsibilities for all areas of the service.

The establishment has a policy and procedure in place to ensure that RQIA is notified if the registered manager is absent for more than 28 days. The policy includes the interim management arrangements for the establishment.

The inspector reviewed the establishment's Patient Guide and Statement of Purpose and found them to be in line with the legislation.

There is a written policy on workers concerns ("Whistle Blowing") and written procedures that identify to whom staff report concerns about poor practice and the support mechanisms available to those staff.

The inspector discussed the insurance arrangements within the establishment and confirmed current insurance policies were in place. The certificates of registration and insurance were clearly displayed in the waiting area of the premises.

Evidenced by:

Review of policies and procedures Review of training records Review of Patient Guide Review of Statement of Purpose Review of insurance arrangements

STANDARD 48	
Laser and Intense	Laser and intense light source procedures are carried
Light Sources:	out by appropriately trained staff in accordance with
_	best practice.

Patients 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 IPL procedure. Fees for treatments are agreed during the initial consultation and may vary depending on the treatment provided and the individual requirements of the client.

Patients are asked to complete a health questionnaire.

Patients are provided with written information on the specific IPL procedure to be provided that explains the risks, complications and expected outcomes of the treatment.

IPL procedures are carried out by trained operators in accordance with medical treatment protocols produced by Dr Hilary Allan on 20 January 2015. Systems are in place to review the medical treatment protocols on an annual basis.

The medical treatment protocols set out:

- Indications
- Contraindications
- Technique
- Pre-treatment tests
- Pre-treatment care
- Post-treatment care
- Recognition of treatment related problems
- Procedure if anything goes wrong with the 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 inspector reviewed the service level agreement between the establishment and the LPA which expires on 12 January 2016.

The establishment has local rules in place which have been developed by their LPA on 13 January 2015

The local rules cover:

- The potential hazards associated with lasers
- Controlled and safe access
- Authorised operator's responsibilities
- Methods of safe working
- Safety checks

- Personal protective equipment
- Prevention of use by unauthorised persons
- Adverse incidents procedures

A recommendation was made to include Dr Patterson as the laser protection supervisor with overall responsibility for safety during IPL treatments within the local rules.

A list of authorised users is maintained and authorised users have signed to state that they have read and understood the local rules and medical treatment protocols.

The establishment has an IPL 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

Six patient treatment records were reviewed and found to contain information regarding the patients 's personal details, a completed health questionnaire, signed consent form, record of treatment and evidence of a patch test being undertaken(if appropriate).

Patients are provided with written aftercare instructions following treatment.

The establishment's LPA completed a risk assessment of the premises in 13 January 2015 and no recommendations were made

The authorised user has completed training in core of knowledge and the safe use and operation of the IPL equipment.

Review of the training records confirmed that the authorised user had also undertaken the following required mandatory training in line with RQIA guidance:

- Basic life support annually
- Fire safety annually
- Infection prevention and control annually
- Protection of vulnerable adults within the last three years

A further member of staff has been recruited who has received training in the safe use and operation of the IPL equipment and core of knowledge. On the completion of a period of supervised practice with Dr Patterson and written evidence of mandatory training she will become an authorised user.

The environment in which the IPL equipment is used was found to be safe and 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 IPL equipment is in use, the safety of all persons in the controlled area is the responsibility of the LPS. Dr Patterson is to undertake this role.

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

Protective eyewear is available for the client and operator as outlined in the local rules. The inspector reviewed the protective eyewear available as part of the inspection process.

The door to the treatment room is locked when the IPL equipment is in use but can be opened from the outside in the event of an emergency.

The IPL equipment is operated using a key. Arrangements are in place for the safe custody of the IPL key when not in use.

There are arrangements in place to service and maintain the IPL equipment in line with the manufacturer's guidance. The most recent service report dated 15 April 2014 was reviewed as part of the inspection process.

There is a laser safety file in place that contains all of the relevant information relating to the IPL equipment.

Evidenced by:

Discussion with staff
Review of policies and procedures patients
Review of local rules
Review of medical treatment protocols
Review of IPL register
Review of client care records
Review of LPA's risk assessment
Review of training records
Review of premises and controlled area
Review of maintenance records
Review of Laser safety file

7.0 Quality Improvement Plan

The details of the Quality Improvement Plan appended to this report were discussed with Dr Patterson as part of the inspection process.

The timescales for completion commence from the date of inspection.

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 RQIA would apply standards current at the time of that application.

Enquiries relating to this report should be addressed to:

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



Quality Improvement Plan

Announced Inspection

Woodford Medical Ltd

19 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 Dr Patterson either during or after 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.

RECOMMENDATIONS

These recommendations are based on the DHSPPS Minimum Care Standards for Independent Healthcare Establishments, 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	Standard 48	The registered person should ensure the local rules are amended to include Dr Patterson as the LPS. Ref standard 48	One	Rules have been amended.	One month
2	Standard 9	Dr Patterson should contact the registration team at RQIA to clarify: • his registration status with RQIA; • and undertaking the registered manager's role. Ref standard 9	One	Ongoing with Mark Lynch	One month

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@rgia.org.uk

Name of Registered Manager Completing QIP	Dr Hilary Allan
Name of Responsible Person / Identified Responsible Person Approving QIP	Dr Mervyn Patterson

QIP Position Based on Comments from Registered Persons	Yes	Inspector	Date
Response assessed by inspector as acceptable	Х	Winnie Maguire	15 July 2015
Further information requested from provider			