



Independent Healthcare Inspection (Announced)

Laser Clinic North Wales

08 March 2016

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

In writing:

**Communications Manager
Healthcare Inspectorate Wales
Welsh Government
Rhydycar Business Park
Merthyr Tydfil
CF48 1UZ**

Or via

Phone: 0300 062 8163
Email: hiw@wales.gsi.gov.uk
Fax: 0300 062 8387
Website: www.hiw.org.uk

Contents

1.	Introduction	2
2.	Methodology.....	3
3.	Context.....	4
4.	Summary.....	5
5.	Findings	6
	Quality of patient experience	6
	Delivery of safe and effective care	9
	Quality of management and leadership	11
6.	Next Steps	13
	Appendix A	14

1. Introduction

Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of all health care in Wales.

HIW's primary focus is on:

- Making a contribution to improving the safety and quality of healthcare services in Wales
- Improving citizens' experience of healthcare in Wales whether as a patient, service user, carer, relative or employee
- Strengthening the voice of patients and the public in the way health services are reviewed
- Ensuring that timely, useful, accessible and relevant information about the safety and quality of healthcare in Wales is made available to all.

HIW inspections of independent healthcare services seek to ensure services comply with the Care Standards Act 2000 and requirements of the Independent Health Care (Wales) Regulations 2011 and establish how services meet the National Minimum Standards (NMS) for Independent Health Care Services in Wales¹.

This report details our findings following the inspection of an independent health care service. HIW is responsible for the registration and inspection of independent healthcare services in Wales. This includes independent hospitals, independent clinics and independent medical agencies.

We publish our findings within our inspection reports under three themes:

- Quality of patient experience
- Delivery of safe and effective care
- Quality of management and leadership.

¹ The National Minimum Standards (NMS) for Independent Health Care Services in Wales were published in April 2011. The intention of the NMS is to ensure patients and people who choose private healthcare are assured of safe, quality services. <http://www.hiw.org.uk/regulate-healthcare-1>

2. Methodology

During the inspection we gather information from a number of sources including:

- Information held by HIW
- Interviews with staff (where appropriate) and registered manager of the service
- Conversations with patients and relatives (where appropriate)
- Examination of a sample of patient records
- Examination of policies and procedures
- Examination of equipment and the environment
- Information within the service's statement of purpose, patient's guide and website (where applicable)
- HIW patient questionnaires completed prior to inspection.

At the end of each inspection, we provide an overview of our main findings to representatives of the service to ensure that they receive appropriate feedback.

Any urgent concerns that may arise from an inspection will be notified to the registered provider of the service via a non-compliance notice². Any such findings will be detailed, along with any other improvements needed, within Appendix A of the inspection report.

Inspections capture a snapshot on the day of the inspection of the extent to which services are meeting essential safety and quality standards and regulations.

² As part of HIW's non-compliance and enforcement process for independent healthcare, a non compliance notice will be issued where regulatory non-compliance is more serious and relates to poor outcomes and systemic failing. This is where there are poor outcomes for people (adults or children) using the service, and where failures lead to people's rights being compromised. A copy of HIW's compliance process is available upon request.

3. Context

Laser Clinic North Wales is registered as an independent hospital because it provides Class 3B/4 laser and Intense Pulsed Light Technology (IPL)³ treatments at Telford Road, Menai Bridge, Angelsey. The service was first registered in 2013.

The service has a staff team which includes the registered manager and one laser/IPL operator. The service is registered to provide the following treatments to patients over the age of 18 years:

Lumia machine including IPL, fractional laser, Nd YAG and Q-switched laser for the following treatments:

- Skin rejuvenation
- Hair removal
- Vascular lesions
- Pigmented lesions
- Acne and acne scarring
- Tattoo removal
- Congested skin
- Sun damage
- Stretch marks.

³ IPL is a broad spectrum light source technology and is used by cosmetic and medical practitioners to perform various skin treatments for aesthetic and therapeutic uses.

4. Summary

We identified some areas for improvement and regulatory breaches during this inspection. Further details of these improvements are provided in Appendix A.

This is what we found the service did well:

- Patients were provided with enough information to make an informed decision about their treatment
- The service is committed to providing a positive experience for patients
- Feedback from patients who completed the HIW questionnaire was very positive
- Staff had undertaken additional qualifications in IPL and laser therapy.

This is what we found the service needed to improve:

- Updates to the patient's guide and statement of purpose
- Arrangements for safeguarding vulnerable adults
- Updates to policies and procedures.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service to ensure compliance with the regulations and standards. This is important to ensure the safety and effectiveness of the service provided.

Whilst this has not resulted in the issue of a non compliance notice, there is an expectation that the registered manager takes meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with regulations.

Services registered with HIW are only entitled to provide treatments in accordance with their conditions of registration. However, on the day of inspection, we found that treatments/equipment were not consistent with these conditions. This is because the service was using another laser machine for which they were not registered. Arrangements were made for the clinic to vary their conditions of registration following the inspection.

Failure to comply with any condition of registration is an offence under Section 24 of the Care Standards Act 2000. While this has not resulted in further action on this occasion, in future the registered manager must ensure that an application to vary or remove an existing condition of registration is made to HIW at least six weeks before any change is to take effect.

5. Findings

Quality of patient experience

Patient information and consent (Standard 9)

We found evidence to indicate that patients were provided with enough information to make an informed decision about their treatment.

Staff told us that patients were provided with a verbal consultation prior to treatment, which included discussion of the risks and benefits. Patients were asked to provide written consent to treatment and we saw examples of information and aftercare guidance given to patients.

We saw that patients were asked to complete medical history forms prior to treatment. A treatment register was maintained for each machine and treatment information was also recorded within individual patient files. While the treatment register was up-to-date, we noticed that this did not include space to record any adverse effects.

Improvement needed

Details of any adverse effects should be included within the treatment registers.

Communicating effectively (Standard 18)

A patient's guide document was available, but the following updates were needed in accordance with the regulations:

- Details of how patients can access the latest HIW inspection report (i.e. by providing HIW's website address)
- A summary of the latest patient feedback
- Contact details for HIW.

Improvement needed

The patient's guide must be updated in accordance with the regulations.

We found that a statement of purpose was available, but the following updates were needed:

- Remove duplicated information in the aims and objectives and qualifications sections
- Clear descriptions of which laser/IPL machines are used for each treatment and the age range of patients treated
- Details of all relevant training and qualifications completed by staff, including Core of Knowledge⁴ training
- In relation to the arrangements for dealing with concerns, incorrect references to the General Medical Council National Care Standards should be replaced with the Independent Health Care (Wales) Regulations 2011
- Arrangements for patient chaperones are needed
- Date the statement was created and revised.

Improvement needed

The statement of purpose must be updated in accordance with the regulations.

A copy of the statement of purpose must be sent to HIW.

Citizen engagement and feedback (Standard 5)

Before the inspection, the clinic was asked to give out HIW questionnaires to obtain patient views of the services provided. Twenty seven patient questionnaires were completed prior to the date of inspection. The questionnaires were unanimously positive and all patients strongly agreed or agreed with statements that the clinic was clean, tidy and that staff were polite, caring, listened and provided enough information about their treatment. The majority of patients rated the care and treatment received at the service as excellent. Patient comments included the following:

“Amazing service, amazing treatment!”

⁴ Core of Knowledge training is intended for operators using lasers and IPL systems for various skin treatments. The training includes information and guidance on the safe use of lasers and IPL systems.

“I am extremely pleased with the care and treatment I have at the clinic. The staff are always very professional and informative. I highly recommend all the treatments and service.”

“Professional and friendly environment. Very informative about treatment and aftercare. Feel very relaxed. Highly recommended to all friends and family. Experts in treatment.”

Staff told us that patients could provide feedback through their website which is reviewed by the registered manager. The registered manager confirmed they had started seeking patient feedback through conducting questionnaires, but we discussed the importance of tailoring these questionnaires specifically to the service. We also advised the service to formalise a system for regularly analysing this feedback, as a way of monitoring the quality of the service provided.

Delivery of safe and effective care

Safe and clinically effective care (Standard 7) and medical devices, equipment and diagnostic systems (Standard 16)

We saw certificates showing that the registered manager and IPL/laser operator had completed Core of Knowledge training within the last three years training and training in the use of the IPL/laser machines. Both the registered manager and laser operator had also completed additional qualifications in laser and IPL therapy.

We looked at the local rules, which detail the safe operation of the equipment. There were separate local rules for each IPL/laser machine which were up-to-date and had been recently reviewed by a Laser Protection Advisor. We saw this included the names of the registered manager and IPL/laser operator to indicate their awareness and agreement to follow these rules. However, we noticed that signatures were missing and we told the clinic to address this.

We saw that a current contract with a Laser Protection Advisor was in place and there were records to show they had visited the service within the last year. We discussed the latest visit by the Laser Protection Advisor and staff confirmed that all recommended actions had been addressed. This meant that the safety of the environment and use of the IPL/laser equipment had been appropriately reviewed.

We saw that eye protection was available and appeared in visibly suitable condition. Staff confirmed that glasses were checked regularly for any damage. We found there was a contract in place for the servicing for both IPL/laser machines and we saw recent servicing records, to help ensure they were safe for use. There was a warning sign outside the treatment room to indicate when the machines are in use. We were told that the activation keys for the IPL/laser machines were removed and stored securely when not in use, to help prevent unauthorised access.

Safeguarding children and vulnerable adults (Standard 11)

The service is registered to treat patients over the age of 18 year only. The registered manager confirmed that this condition was complied with.

We found that improvements were needed to the arrangements for safeguarding vulnerable adults. We were unclear if a safeguarding policy was in place, as we could not see this on the day of inspection. Training in the protection of vulnerable adults needed to be completed by staff.

Improvement needed

Robust processes must be in place to ensure the welfare and safety of vulnerable adults who may use the service, including a safeguarding policy and training for staff.

Infection prevention and control and decontamination (Standard 13)

We saw the service was visibly clean and tidy. An infection control policy was in place and was sufficiently detailed.

Managing risk and health and safety (Standard 22)

We looked at maintenance arrangements at the service. We saw servicing certificates showing that a wiring check of the building and a recent gas safety check had been conducted. No lifts were present at the clinic. We saw evidence that Portable Appliance Testing (PAT) testing, to help ensure that small electrical appliances were safe to use, had been recently conducted.

We looked at some of the arrangements for fire safety. The registered manager confirmed they had conducted fire safety training. Fire extinguishers were serviced annually and fire exits had been signposted. We saw a fire risk assessment had been completed by the registered manager, but as the building had treatment rooms over three floors and the registered manager was unsure if additional fire exit routes were needed, we recommended the service seek advice from a fire safety expert or relevant guidance from a fire authority.

Improvement needed

The registered manager must ensure that all appropriate measures and precautions must be in place to protect the health and safety of patients and staff at this service. Specifically, the service should seek additional fire safety guidance from an appropriate source regarding the fire safety arrangements and update the fire risk assessment accordingly.

Quality of management and leadership

Governance and accountability framework (Standard 1)

Laser Clinic North Wales is run by the registered manager.

On the day of inspection, we saw that a limited number of policies and procedures were available. The registered manager told us that they believed they had created the other policies required by the regulations, but were unsure of their location and had not been updated within the last three years. It is important that policies are regularly reviewed and updated.

Improvement needed

The registered manager must ensure that all required policies and procedures are in place and regularly updated in accordance with the regulations.

Dealing with concerns and managing incidents (Standard 23)

We saw that the arrangements for dealing with concerns and complaints had been noted within the statement of purpose document, but a complaints policy was not available in accordance with regulatory requirements.

Improvement needed

A complaints policy must be created.

We were told that the service had not received a formal complaint, but we were shown a log that would be used for recording any complaint correspondence. We advised the service to record any informal and verbal complaints in order to help identify any emerging themes as a way of monitoring the quality of the service provided.

Records management (Standard 20)

We found that patient information was kept securely at the service. Paper records were kept in locked filing cabinets within treatment rooms and the registered manager confirmed they were locked when not in use.

Workforce recruitment and employment practices (Standard 24)

At the time of our inspection, the registered manager had a Disclosure and Barring Service (DBS) certificate dated within the last three years, but we saw that a new certificate would soon be required. We also found that an updated DBS check was needed for the laser operator.

Improvement needed

All staff must have a DBS certificate dated within the last three years.

The registered manager confirmed that any new staff would receive an induction and we were told that annual staff appraisals were conducted. Appraisals are important to ensure that staff have the right knowledge and skills to carry out their role and any training needs are identified. We were told that regular staff meetings also take place.

Given the findings from this inspection, improvements are needed in the quality assurance and governance arrangements of this service to ensure compliance with the relevant regulations and standards. It was also evident that the registered manager needed to improve their knowledge and understanding of these requirements.

The operation of sound quality assurance and governance arrangements and timely response to remedy issues of concern are important indicators of a registered manager's ability to run their service with sufficient care, competence and skill. There is an expectation, therefore, that the registered manager take meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with regulations.

Improvement needed

There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.

6. Next Steps

This inspection has resulted in the need for the service to complete an improvement plan in respect of improvements identified in this report. The details of this can be seen within Appendix A of this report.

The improvement plan should clearly state how the improvement identified at Laser Clinic North Wales will be addressed, including timescales.

The improvement plan, once agreed, will be published on HIW's website and will be evaluated as part of the ongoing inspection process.

Appendix A

Improvement Plan

Service: Laser Clinic North Wales

Date of Inspection: 08 March 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
6	Details of any adverse effects should be included within the treatment registers.	Regulation 23 (1) & 45 (2)	An extra column has now been added to the treatment log book to include adverse effects.	Ruth Brockley	09/03/16
6	The patient's guide must be updated in accordance with the regulations.	Regulation 7	Patient guide has been updated in accordance with the regulations.	Ruth Brockley	11/03/16
7	The statement of purpose must be updated in accordance with the regulations. A copy of the statement of purpose must be sent to HIW.	Regulation 6 (1) and Schedule 1	Our statement of purpose is being updated and will be sent to HIW this month.	Ruth Brockley	30/04/16
Delivery of Safe and Effective Care					
10	Robust processes must be in place to	Regulation	The registered manager will update	Ruth	30/04/16

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	ensure the welfare and safety of vulnerable adults who may use the service, including a safeguarding policy and training for staff.	16 Standard 11	Safeguarding Of Vulnerable Adults (SOVA) training. Staff will complete SOVA training.	Brockley	
10	The registered manager must ensure that all appropriate measures and precautions must be in place to protect the health and safety of patients and staff at this service. Specifically, the service should seek additional fire safety guidance from an appropriate source regarding the fire safety arrangements and update the fire risk assessment accordingly.	Regulation 15 (1),(2); 19(1); 26(5)(b) Standard 22	An updated Fire Safety Assessment has been carried out by Snowdonia Fire & Security.	Ruth Brockley	20/03/16
Quality of Management and Leadership					
11	The registered manager must ensure that all required policies and procedures are in place and regularly updated in accordance with the regulations.	Regulation 9	All policies and procedures have been updated in accordance with regulations.	Ruth Brockley	30/03/16
11	A complaints policy must be created.	Regulation 24	A new complaints policy has been created.	Ruth Brockley	03/04/16
12	All staff must have a DBS certificate dated within the last three years.	Regulation 12(2) (c)	Although the registered manager's DBS was in date at the time of	Ruth	08/04/16

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
		and Schedule 2	inspection, forms have been sent to HIW to update the certificate. Staff members have also completed and sent forms to HIW to update their DBS certificate.	Brockley	
12	There must be effective management and quality assurance systems in place to ensure compliance with the standards and regulations, as a means to meeting the legal obligations to provide safe and effective laser treatments to patients.	Regulation 19 Standard 1	New management and quality assurance systems have been put in place in compliance with standards and regulations.	Ruth Brockley	30/03/16

Service Representative:

Name (print): Ruth Brockley

Title: Director

Date: 12/04/16