

Independent Healthcare Inspection (Announced)

Facial and Cosmetic
Enhancement (FACE)
Clinic, Cardiff

30 June 2015

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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 staffing, 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

Facial and Cosmetic Enhancement (FACE) Clinic is registered with HIW as an independent hospital to provide treatments using Intense Pulsed Light Technology (IPL)³ and a Class 4 laser at 27 Castle Arcade, Cardiff. The service was registered February 2014.

In relation to the registered service, only one member of staff (the registered manager) provides IPL/laser treatments. The clinic is registered to provide the following treatments to patients over the age of 18 years:

- Hair removal
- Skin rejuvenation
- Vascular lesions
- Tattoo removal.

HIW completed an announced inspection to the service on 30 June 2015.

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

A patient's guide was available for patients to view, but this required updating. Sufficient information was provided to patients before and after treatment to ensure they were fully informed. This included a consultation, a detailed written consent form and aftercare information. The clinic encouraged patients to provide feedback via their website, but as limited feedback was received, we recommended that feedback questionnaires should be given to patients in order to monitor the quality of the service provided.

In general, we found evidence that the IPL and laser treatments were provided safely to patients and equipment had been maintained appropriately. The clinic was visibly clean and tidy. However, an infection control policy needed to be developed. We identified some concerns regarding the fire safety arrangements at the clinic and highlighted this to the registered manager on the day of inspection. We also shared these findings with the appropriate fire authority.

People who use this service cannot be assured that it is meeting the relevant national minimum standards and complying with regulations. This is because it was evident from discussions with the registered provider that they lacked awareness and understanding of the particular standards and regulations that concern the provision of Class 3B and Class 4 laser services. We have made a formal recommendation in this regard. A statement of purpose was available, but some of the information was unclear, misleading and needed to be updated to comply with the regulations. The complaints policy also needed to be updated and followed.

We identified the following areas for improvement during this inspection regarding – statement of purpose, patient's guide, fitness of premises, staff training, policies and procedures and monitoring the quality of service. Further details of required improvements are provided in Appendix A. Whilst this has not resulted in the issue of a non compliance notice, there is an expectation that the registered provider takes meaningful action to address these matters, as a failure to do so could result in non-compliance with regulations.

5. Findings

Quality of patient experience

We found that sufficient information was provided to patients before and after treatment to ensure they were fully informed. This included a consultation, a detailed written consent form and aftercare information. A patient's guide was available for patients to view, but this required updating. The clinic encouraged patients to provide feedback via their website, but as limited feedback was received, we recommended that feedback questionnaires should be given to patients in order to monitor the quality of the service provided.

A copy of the patient's guide was available to patients in the reception area. However, this did not include all the required information, specifically:

- Summary of the statement of purpose
- Summary of the complaints procedure
- Summary of the views/feedback on the service from patients
- Address of HIW
- The most recent HIW inspection report or information on how patients could obtain a copy (e.g. a link to the HIW website).

Improvement needed

The patient's guide must be updated to include all required information.

We saw the clinic had a patient questionnaire, but the registered manager told us this had not been used in the last year. Instead, patients were given a comments card with their treatment information, requesting feedback through the clinic's website. However, this was not consistent with the patient feedback arrangements detailed in the clinic's statement of purpose. The registered manager confirmed that limited feedback had been received on the website from patients having IPL and laser treatments. We therefore advised the clinic to use patient questionnaires, so that the responses could be analysed as a way of monitoring the quality of the service provided.

Improvement needed

The views of patients should be regularly sought, in accordance with the arrangements detailed in the statement of purpose. This should be analysed regularly and a summary of views should be included within the patient's guide.

We saw that appropriate patient and treatment information was recorded. We also saw examples of records which showed that patients had completed medical history forms and signed a written consent to treatment. A separate treatment register was maintained for the IPL and laser machines and included the relevant patient/treatment information. However, this did not include details of any adverse effects and we advised the clinic to add this.

The registered manager told us that all patients were provided with a consultation prior to treatment and were given information about the possible risks and benefits. Post treatment information was also provided to patients with aftercare advice.

The registered manager demonstrated they understood the need to respect and observe patient's privacy and dignity. There were arrangements for patients to change in private, doors were kept closed during treatment and cover-up towels were provided to maintain patients' dignity.

We noticed a HIW registration certificate was not on display and arrangements were made following the inspection for the clinic to be sent a new HIW certificate.

Delivery of safe and effective care

In general, we found evidence that the IPL and laser treatments were provided safely to patients and equipment had been maintained appropriately. The clinic was visibly clean and tidy. However, an infection control policy needed to be developed. We identified concerns regarding the fire safety arrangements at the clinic and highlighted this to the registered manager on the day of inspection. We also shared these findings with the appropriate fire authority.

We looked at the arrangements and documents relating to the IPL and laser machines. We found evidence that the relevant IPL/laser training had been undertaken by the registered manager and updated Core of Knowledge⁴ training was completed in January 2014.

The Laser Protection Advisor, who provides expert guidance in relation to IPL/laser equipment, last visited the premises in August 2014 and provided a visit report. The registered manager confirmed that areas identified in the report had been addressed. However, we noticed that updates were needed to the local rules, which detail the safe operation of the equipment, including signatures and details of the eye protection to be used during treatments. Following the inspection, we saw another copy of the local rules with updated information regarding eye protection, but it was unclear if the Laser Protection Advisor had signed off these changes as their signature was missing.

Improvement needed

The local rules must be reviewed annually, updated as appropriate and signed by both the Laser Protection Advisor and Laser Protection Supervisor.

We saw certificates which indicated that both the IPL and laser machine had been recently serviced to help ensure they were safe to use.

We were told that during treatment, the door was locked and a sign placed on the door to indicate the IPL/laser machine was in use and protective eyewear worn. The registered manager confirmed the designated activation keys for the IPL/laser

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.

machines were removed when not in use and stored securely to prevent unauthorised use of the IPL/laser machines.

We looked at maintenance certificates for the premises and saw that Portable Appliance Testing (PAT) testing to check that small electrical appliances were fit for purpose and safe to use, had been conducted. A five yearly wiring check was last completed in June 2015. No gas or lifts were provided at the premises.

We saw records which showed fire drills were conducted weekly, fire extinguishers had been recently inspected and we saw fire exits were signposted. The basement level had a fire exit through the laser/IPL treatment room. However, we found this exit was obstructed by a large curtain that had been installed above the fire exit, partially covering the sign, latch for the door and the 'break glass' alarm system. The fire exit was also obstructed by a draft excluder, which could cause a tripping hazard. The fire exit opened inwards towards the room and due to equipment in the room, it was difficult to open the door fully. We also found that no fire risk assessment had been conducted for the premises and no fire training had been completed by staff. We highlighted this to the registered manager on the day of inspection, who agreed to take action to address these issues. Following inspection the registered manager confirmed the curtain above the fire exit had been removed. Due to the nature of these fire safety concerns, we shared this information with the appropriate fire authority – South Wales Fire Service.

Improvement needed

All appropriate measures and precautions must be in place to protect patients and staff from the risk of fire, specifically:

- ***All fire exits must be kept clear at all times***
- ***A fire risk assessment must be conducted***
- ***Fire training must be completed.***

We looked at the health and safety risk assessment at the clinic and found this did not include all potential risks to staff and patients and it was missing details of how these risks could be reduced.

Improvement needed

The health and safety risk assessment must be updated to identify, assess and manage risks relating to the health, welfare and safety of patients and others, including how these risks could be reduced.

We found the clinic was visibly clean and tidy. We saw evidence that a waste contract was in place for the disposal of hygiene waste and non-hazardous sharps.

There were also records of cleaning schedules at the clinic. However, the clinic did not have a policy to detail arrangements for infection control.

Improvement needed

An infection control policy must be developed.

We discussed the emergency arrangements with the registered manager who confirmed they were aware of the procedure to follow in the event of fire or medical emergency. We saw there was a first aid kit outside the treatment room, but we found some materials (dressings) were out of date.

Improvement needed

Patients and service users must be provided with safe, effective treatment and care. Specifically, that any materials and equipment intended to be used for first aid must be suitable for use.

Quality of management and leadership

People who use this service cannot be assured that it is meeting the relevant national minimum standards and complying with regulations. This is because it was evident from discussions with the registered provider that they lacked awareness and understanding of the particular standards and regulations that concern the provision of Class 3B and Class 4 laser services. We have made a formal recommendation in this regard. A statement of purpose was available, but some of the information was unclear, misleading and needed to be updated to comply with the regulations. The complaints policy also needed to be updated and followed.

Face clinic is owned by the registered manager who is the sole operator of the registered IPL and laser machines. Because the registered manager was the only staff member involved in IPL/laser treatments, information relating to other staff at the clinic did not form part of this inspection

There was a statement of purpose in place, but this needed to be updated to comply with the Independent Health Care (Wales) Regulations 2011. Specifically, the statement of purpose was missing the qualifications and experience of the registered manager and full details of the arrangements for dealing with complaints. We noticed there were incorrect references to “*regulations of the Healthcare Inspectorate for Wales*” rather than the Independent Health Care Regulations. There was also incorrect information about the role of HIW as an inspectorate of “*early years and social services*”, rather than healthcare. In general, there were statements included throughout the first page of the statement of purpose which were unclear and misleading.

Improvement needed

The statement of purpose must be updated to include all required information.

Clear information must be provided to patients about the clinic’s responsibilities under the regulations and the treatments and services provided.

References to the regulations and the role of HIW must be updated.

A revised copy (addressing the above improvements) of the statement of purpose must be provided to HIW.

We saw some evidence that the service had reviewed the policies and procedures within the last three years. However, as mentioned in the previous section, the service did not have an infection control policy in place.

The registered manager confirmed they had not attended training in the Protection of Vulnerable Adults (POVA). We were told that children were not seen at the clinic.

Improvement needed

POVA training should be completed by the registered manager.

We looked at the arrangements for ensuring the confidentiality of patient information. We saw that patient records and information relating to laser treatments were kept confidential and secure in a locked filing cabinet and we were told that electronic records were kept on a password protected computer.

At the time of our inspection, the registered manager had a Disclosure and Barring Service (DBS) certificate dated within the last three years in line with the regulations.

The clinic had a complaints policy, but this needed to be updated to include details of how patients could contact HIW. The complaints policy stated that responses to complaints would be provided by letter, but the registered manager told us this was mainly done by email. We reminded the clinic to ensure they were following their complaints procedure and update this as necessary. We also advised the clinic to be careful when corresponding with patients by email, as this could contain sensitive and personal information relating to patients which is not secure when sending by email, unless encrypted.

Improvement needed

The complaints policy must be updated to include details of how patients can contact HIW in the event they had a complaint.

The complaints policy must be followed when dealing with complaints.

We were told the service had received a complaint regarding laser treatment, but all information had been sent to the clinic's insurance company and was not available on the day of inspection. We were shown a book where complaints were recorded, including verbal complaints. However, we advised the clinic to create a clearer filing method for complaint correspondence to ensure that all information was kept together.

People who use this service cannot be assured that it is meeting the relevant national minimum standards and complying with regulations. This is because it was evident from discussions with the registered provider that they lacked awareness and understanding of the particular standards and regulations that concern the provision of Class 3B and Class 4 laser services.

Improvement needed

Knowledge and awareness of the Independent Health Care Regulations must be improved.

The registered manager must ensure that there are systems and processes in place to assure, patients, service users, regulators and other stakeholders, that they are meeting the relevant national minimum standards and complying with regulations.

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 Facial and Cosmetic Enhancement Clinic 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: Facial and Cosmetic Enhancement (FACE) Clinic

Date of Inspection: 30 June 2015

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
6	The patient's guide must be updated to include all required information.	Regulation 7	Patient Guide has been updated	Eileen Strong	Completed
7	The views of patients should be regularly sought, in accordance with the arrangements detailed in the statement of purpose. This should be analysed regularly and a summary of views should be included within the patient's guide.	Regulations 7(1)(e) 19(2)(e)	Questionnaires have been updated and are given to patients also written on the Statement of Purpose and in the patient guide with HIW address tel and email included.	Eileen Strong	Completed
Delivery of Safe and Effective Care					
8	The local rules must be reviewed annually, updated as appropriate and signed by both the Laser Protection	Standard 16 NMS	Both are signed by LPA and LPS and updated annually	Eileen Strong	Completed

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	Advisor and Laser Protection Supervisor.				
9	<p>All appropriate measures and precautions must be in place to protect patients and staff from the risk of fire, specifically:</p> <ul style="list-style-type: none"> • All fire exits must be kept clear at all times • A fire risk assessment must be conducted • Fire training must be completed 	Regulation 26(5)(b)	<p>All fire exits are clear</p> <p>Fire Risk assessment is being carried out by Fire-Rite Ltd. visiting fire officer Report will be available.</p> <p>Fire training Completed with Certificate from High Speed Training.</p>	Eileen Strong	<p>Completed</p> <p>Fire Risk Assessment in 3 days</p> <p>Completed</p>
9	The health and safety risk assessment must be updated to identify, assess and manage risks relating to the health, welfare and safety of patients and others, including how these risks could be reduced.	Regulation 19 (1)(b)	<p>Risk Assessment has been updated and identifying risks to patients and others</p> <p>Also how risks could be reduced</p>	Eileen Strong	Completed
10	An infection control policy must be developed.	Regulation 9 (n)	Infection Control Policy has been developed	Eileen Strong	Completed
10	Patients and service users must be	Regulation	A new first aid kit has been bought	Eileen Strong	Completed

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	provided with safe, effective treatment and care. Specifically, that any materials and equipment intended to be used for first aid must be suitable for use.	15(1)(b) Standard 7 NMS	and a note made of the expiry dates of materials.		
Quality of Staffing, Management and Leadership					
11	<p>The statement of purpose must be updated to include all required information.</p> <p>Clear information must be provided to patients about the clinic's responsibilities under the regulations and the treatments and services provided.</p> <p>References to the regulations and the role of HIW must be updated.</p> <p>A revised copy (addressing the above improvements) of the statement of purpose must be provided to HIW.</p>	Regulation 6 (1) and Schedule 1	<p>Statement of Purpose has been updated to include the required information.</p> <p>This includes now includes information about the clinics responsibilities and the treatment and services provided.</p> <p>The references to the role of HIW updated</p> <p>This will be provided to HIW immediately</p>	<p>Eileen Strong</p> <p>Eileen Strong</p>	<p>Completed</p> <p>Copy to be provided by 14/08/2015</p>
12	POVA training should be completed by the registered manager.	Regulation 16 Standard 11 NMS	Pova Course booked for 17/08/2015	Eileen Strong	Completed by 17/08/2015

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
12	<p>The complaints policy must be updated to include details of how patients can contact HIW in the event they had a complaint.</p> <p>The complaints policy must be followed when dealing with complaints.</p>	Regulation 24 (4)(a-b)	<p>To include Address of HIW address, tel Number, Email, website.</p> <p>The complaints policy will be followed when dealing with all complaints.</p>	Eileen Strong	Completed
13	<p>Knowledge and awareness of the Independent Health Care Regulations must be improved.</p> <p>The registered manager must ensure that there are systems and processes in place to assure, patients, service users, regulators and other stakeholders, that they are meeting the relevant national minimum standards and complying with regulations.</p>	Regulation 19 (1)(a)	<p>Copies of the regulations and standards will be obtained and read.</p> <p>The registered manager will use the knowledge and awareness gained from the above to regularly review how the clinic complies with the regulations and meets the standards.</p>	<p>Eileen Strong</p> <p>Eileen Strong</p>	<p>by 21/08/2015</p> <p>On-going</p>

Service Representative:

Name (print): EILEEN STRONG

Title: Registered Manager

Date: 03 August 2015