

Independent Healthcare Inspection (Announced)

Complexion Medispa Ltd

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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 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

Complexion Medispa Limited is registered as an independent hospital because it provides Intense Pulsed Light Technology (IPL)³ treatments at Complexion Mediaspa & Laser Clinic, 24 High Street, Caerleon, Newport, NP18 1AG. The service was first registered in February 2016.

At the time of inspection, the staff team included the registered manager and the operator of the IPL machine. The service is registered to provide the following treatments to patients over the age of 18 years:

Luxor Versalles HKS801 IPL for the following treatments:

- Hair removal
- Skin rejuvenation
- Wrinkle removal
- Acne treatments
- Pigmentation.

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 looked at how the service complied with the requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards.

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
- We saw evidence that patients were satisfied with their treatment and the service provided.

This is what we found the service needed to improve:

- Updates to the patient's guide and statement of purpose
- Documentation of training completed by the IPL operator
- Medical protocols to be reviewed to ensure only one set is adhered too

Further details of these improvements are provided in Appendix A.

Given the findings from this inspection, some improvements are needed in the quality assurance and governance arrangements of this service to ensure compliance with the relevant 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 take meaningful action to address these matters, as a failure to do so could result in HIW taking action for non-compliance with the regulations.

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.

We were told 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 conditions and medication forms. Any changes to medical histories are verbally checked at each appointment and the patient signs to confirm.

Complexion Medispa maintains paper copies of patient information and treatments. We saw examples of some records and noted the appropriate information recorded. An electronic diary is used to record when treatments are provided.

Communicating effectively (Standard 18)

We found that a statement of purpose was available, but updates were needed to comply with the regulations, including:

- The arrangements for chaperones

Improvement needed

The statement of purpose must be updated in accordance with the regulations and a copy of the updated statement of purpose must be sent to HIW.

There was no separate copy of a patients guide and we were told the statement of purpose was an all in one guide. Good practice would be to have two separate documents. Therefore it is recommended that the statement of purpose is updated to also include in the heading patients guide.

It was recommended that the following updates are made in accordance with the regulations:

- The patient guide to be updated to reflect the current staff providing IPL treatments

- 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, including the telephone number
- Arrangements for obtaining consent.

Improvement needed

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

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. Ten patient questionnaires were completed prior to the date of inspection.

The questionnaires showed that all patients strongly 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 their care and treatment as 'excellent'.

The registered manager told us that the service conducted their own patient questionnaires on an annual basis. There were customer comment cards available at reception and feedback was mainly obtained from the settings Facebook and Twitter pages. We were told that patient feedback was collated and analysed and the results would inform the forward business plan of the business. In the reception area, a book was available displaying customer comments. All these avenues for feedback meant that the service had a suitable method of regularly gaining patient 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)

The registered manager explained that only one IPL operator provided IPL treatments to patients. We saw a certificate to show that the IPL operator had completed Core of Knowledge⁴ training. We were told that the IPL operator had received training on how to use the IPL machine, but no certificate or record of this training was available. The registered manager agreed to arrange for a training certificate to be obtained and sent to HIW.

Improvement needed

There must be evidence to document that all IPL operators have received training on how to use the IPL machine.

We saw that there was a current contract in place with a Laser Protection Adviser and there were local rules detailing the safe operation the machine. We advised the registered manager to update the local rules to ensure they referenced the correct regulations and included HIW contact details for adverse incident reporting in accordance with regulatory requirements.

The registered manager confirmed that the Laser Protection Adviser visited the service annually and reviewed the local rules and environmental risk assessments. We were told that the last LPA visit was conducted in October 2015 and a letter outlining the findings was provided to the registered manager.

We saw a certificate to evidence that the IPL machine had been serviced, however, the certificate said it was valid for six months indicating that the servicing of the IPL machine was due in April 2016 based on the six month timeframe. This issue was discussed with the registered manager and it was agreed that confirmation would be sought and HIW updated once clarified.

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.

Improvement needed

The registered manager must clarify the guidance given regarding the servicing of the IPL machine, including the six month timescale on the servicing certificate, to ensure that the machine is maintained in a safe and good condition.

A copy of this guidance must be sent to HIW once clarified.

We saw that eye protection was available for patients and the IPL operators. The eye protection appeared in visibly suitable condition and we were told this was checked by the IPL operator before any treatment.

The IPL machine was made secure when not in use, with staff removing the key after use. We were told that the key was locked in the safe at the end of the day.

We reviewed the documentation relating to the environmental risk assessment. We saw that a letter had been provided by the Laser Protection Adviser, in which control measures had been briefly outlined. We were told that the Laser Protection Adviser had communicated other findings verbally. We saw that the service had a document including an environmental risk assessment they had conducted, but this did not include the hazards and control measures relating to the IPL. As a comprehensive assessment of all hazards was not recorded, it was difficult to ascertain the full extent of the environmental risk assessment and progress to date. We advised the registered manager to refer to the Health and Safety Executive's five steps to risk assessment.

Improvement needed

The registered manager must ensure that all risks, including risks relating to the IPL, are clearly identified, assessed, managed, recorded and reviewed. Specifically, that hazards and control measures relating to the IPL are included in the environmental risk assessment.

There was a sign on the outside of the treatment room to indicate when the room was being used, as well as the door being closed. There were no safety warning signs used. Although safety warning signs were not specifically identified as needed in the local rules, the last LPA report did include an action for additional signage. Therefore, clarification is required from the LPA regarding this action from the last report. In addition, British Safety Standards should be followed regarding signs to warn the public of the risk inside the treatment room.

Improvement needed

There must be appropriate warning signs displayed outside the treatment room when the IPL machine is being used to prevent any accidental access which could cause harm.

There were two differing treatment protocols in place for the IPL machine. One was signed by the LPA adviser, but it did not list his medical qualification. The other set of treatment protocols was signed by a medical practitioner but we could not identify an expiry/review date. We compared these two protocols and found they contained contradictory information. Therefore, it is essential that the registered manager address this issue to ensure that one consistent set of medical protocols is in place. In addition, the registered manager agreed to contact the medical practitioner and check the date of expiry of the protocols provided.

Improvement needed

In accordance with regulatory requirements, the registered manager must ensure that there is a treatment protocol written by an expert medical or dental practitioner and that treatment is provided in accordance with it. Specifically, the registered manager must ensure there are consistent treatment protocols in place which are signed by a trained and experienced medical practitioner or dentist from the relevant discipline.

Safeguarding children and vulnerable adults (Standard 11)

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

There was a safeguarding policy and procedure in place, providing a clear route to follow in the event of a safeguarding concern. The registered manager told us that she provided in-house training to staff on how they would deal with any safeguarding issues, however there were no certificates in place to evidence the training completed.

Improvement needed

Copies of training certificates, specifically safeguarding must be provided to HIW to evidence that the IPL operator has received appropriate training.

Infection prevention and control and decontamination (Standard 13)

We saw the service was visibly clean and tidy. There was a control of infection and cleaning policy in place, which covered hand hygiene and cleaning the treatment area and equipment between patients.

We were told of the arrangements for ensuring the service is cleaned appropriately which consisted of a cleaning rota that was divided between the staff.

Managing risk and health and safety (Standard 22)

We saw evidence that Portable Appliance Testing (PAT) had been conducted, to help ensure that small electrical appliances were safe to use. We also saw evidence that there had been a building wiring check within the last five years.

We looked at some of the arrangements for fire safety. Servicing of fire extinguishers take place annually and the service conducted their own fire drills.

There was a first aid kit available and the registered manager was trained in first aid.

Quality of management and leadership

Governance and accountability framework (Standard 1)

Complexion Medispa limited is run by the registered manager. IPL treatments are provided by the IPL operator.

We saw the service had a range of policies in place and that policies had a review date and version date on the front of the policy folder. Staff are informed of changes to policies by the registered manager and there was a sheet for staff to sign in the staff room to confirm they had read update policies.

We were told that the registered manager undertakes audits and spot checks of patient records, amongst others. However, these audits were not documented. While the completion of audits is good practice, we advised the registered manager of the importance of recording this as a way of monitoring the quality of the service provided.

Dealing with concerns and managing incidents (Standard 23)

A complaints policy was available and details of the complaints procedure had been included within the statement of purpose.

The registered manager told us that they had not received any complaints. Any concerns or issues were captured in a diary. We discussed the need to record both written and verbal complaints if they are received, so that any common themes or issues identified could be addressed.

Records management (Standard 20)

We found that patient information was kept securely at the service. This is because paper records were kept in filing cabinets and the registered manager confirmed they were locked when not in use.

Workforce recruitment and employment practices (Standard 24)

The registered manager and IPL operator had an enhanced Disclosure Barring Service (DBS) check in place.

We were shown an example of the induction programme in place for new staff and we saw examples of annual appraisals and reviews. Appraisals are important to ensure that the staff have the right knowledge and skills to carry out their role and any training needs are identified. It was advised during the visit to ensure all reviews and appraisals are signed and dated.

Given the findings from this inspection, some improvements are needed in the quality assurance and governance arrangements of this service to ensure ongoing compliance with the relevant regulations and standards.

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

Date of Inspection: 18 August 2016

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
Quality of Patient Experience					
6	The statement of purpose must be updated in accordance with the regulations and a copy of the updated statement of purpose must be sent to HIW.	Regulation 6 (1) (2)	We have always provided our clients with a Statement of purpose complying with regulations which was submitted on Registration. I have updated the Statement of purpose and sent another copy to HIW	Manager	Completed
7	The patient's guide must be updated in accordance with the regulations. A copy of the updated statement of purpose must be sent to HIW.	Regulation 7 (1) (a) – (g) & (2)	This has been updated and sent to HIW	Manager	Completed
Delivery of Safe and Effective Care					

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
8	There must be evidence to document that all IPL operators have received training on how to use the IPL machine.	Regulation 20 (1) (a) & 45 (3)	A letter has been sent to HIW Confirming the Training had taken place on how to use the IPL Machine	Manager	Completed
9	The registered manager must clarify the guidance given regarding the servicing of the IPL machine, including the six month timescale on the servicing certificate, to ensure that the machine is maintained in a safe and good condition. A copy of this guidance must be sent to HIW once clarified.	Regulation 15(2)	I'm awaiting a response to the Company who are currently out of the country.	Manager	8 weeks
9	The registered manager must ensure that all risks, including risks relating to the IPL, are clearly identified, assessed, managed, recorded and reviewed. Specifically, that hazards and control measures relating to the IPL are included in the environmental risk assessment.	Regulation 19(1)(a)(b)	We have a LPA advisory who annual completes and reviews our risk assessment which was given on inspection. We also Risk assess our Clients during our Thorough consultation with comprehensive forms and Questionnaire's and Patch testing. We also risk asses every IPL treatment by ensuring Clients have not changed or started	Manager	Done

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
			taking any new medication. They sign and the Therapist a consent forms on every treatment.		
10	A warning sign should be displayed on the door of the IPL room when the machine is being used to prevent any accidental access which could cause harm.	Health & Safety Executive (HSE) Guidance for Employers on the Control of Artificial Optical Radiation at Work Regulations (AOR) 2010	An additional sign requested by yourselves and not our LPA has now been put upon the laser door.	Manager	Completed
10	In accordance with regulatory requirements, the registered manager must ensure that there is a treatment protocol written by an expert medical or dental practitioner and that treatment is provided in accordance with it. Specifically, the registered	Regulation 15 (1)(b)(c) &(10)	It's been confirmed that the Treatment Protocol used at Complexion is the one signed by the Doctor and was shown during inspection. Please advise us under the regulations when it has to be updated by a Doctor or Dentist..	Manager	Completed

Page Number	Improvement Needed	Regulation / Standard	Service Action	Responsible Officer	Timescale
	manager must ensure there are consistent treatment protocols in place which are signed by a trained and experienced medical practitioner or dentist from the relevant discipline.				
10	Copies of training certificates, specifically safeguarding must be provided to HIW to evidence that the IPL operator has received appropriate training.	Regulation 20(1)(a)	A copy of this Certificate has been sent to HIW.	Manager	Completed
Quality of Staffing, Management and Leadership					

Service Representative: Clare Sawkins Name (print):

Title: Manager

Date: 8/9/16