

Independent Healthcare Inspection (Announced)

Complexion Medispa and Laser
Clinic

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2019

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In writing:

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

Or via

**Phone: 0300 062 8163
Email: hiw@gov.wales
Website: www.hiw.org.uk**

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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that people in Wales receive good quality healthcare

Our values

We place patients at the heart of what we do. We are:

- **Independent**
- **Objective**
- **Caring**
- **Collaborative**
- **Authoritative**

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care

Promote improvement:

Encourage improvement through reporting and sharing of good practice

Influence policy and standards:

Use what we find to influence policy, standards and practice

1. What we did

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Complexion Medispa and Laser Clinic on the 27 November 2019.

Our team for the inspection comprised of two HIW inspectors, one of whom led the inspection.

HIW explored how the service complied with the Care Standards Act 2000, requirements of the Independent Health Care (Wales) Regulations 2011 and met the National Minimum Standards for Independent Health Care Services in Wales.

Further details about how we conduct independent service inspections can be found in Section 5 and on our website.

2. Summary of our inspection

We found that Complexion Medispa and Laser Clinic was providing an effective service to patients in an environment that was conducive to providing Intense Pulsed Light (IPL) treatments.

Clinical staff had undertaken the training required to help deliver safe treatment to patients.

Patients were provided with detailed information to help them make an informed decision about their treatment.

Suitable arrangements were in place to protect the privacy and dignity of patients during consultation and treatments.

This is what we found the service did well:

- The environment was clean and well maintained
- Patient notes and records were being maintained to a good standard
- The clinic was committed to improving services and actively sought feedback from patients about their experiences
- Documentation was available to show that the IPL machine had been serviced and maintained in line with manufacturer's guidelines.

This is what we recommend the service could improve:

- A new first aid kit must be purchased and checked regularly by staff to ensure all items are present and remain in date and fit to use
- The IPL operator and registered manager must undertake appropriate adult protection training.

There were no areas of non compliance identified at this inspection.

3. What we found

Background of the service

Complexion Medispa and Laser Clinic is registered to provide an independent hospital at 24 High Street, Caerleon, Newport, NP18 1AG.

The service employs a staff team of four, which includes one IPL operator.

The service was first registered on 22 February 2016 and provides a range of services which include:

- Hair removal
- Skin rejuvenation
- Wrinkle removal
- Acne
- Pigmentation
- Thread vein removal.

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

We were assured that the clinic was providing a positive experience for patients.

Patients received detailed information to help them make an informed decision about their treatment.

Suitable arrangements were in place to protect the privacy and dignity of patients during consultation and treatments.

Patients could provide feedback about their experiences of the care and treatment received at the clinic.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of two were completed. One patient commented:

"It's great, would highly recommend to friends!"

Health promotion, protection and improvement

We were told that patients must complete a medical history form at their initial consultation which is signed by the patient and countersigned by the IPL operator prior to receiving treatment. Patients sign a record card at each subsequent treatment session confirming that there have or have not been any changes in their medical history. This follows best practice guidance and helps to ensure treatment is safe and suitable for each patient.

We saw evidence of completed and signed medical history forms within patient records to confirm this approach.

Dignity and respect

The registered manager told us that patients are provided with towels to change in the lockable treatment room if necessary and confirmed that the door is locked during treatments in order to maintain the patient's privacy, dignity and modesty at all times. Consultations with patients take place in private to ensure

that confidential and personal information can be disclosed without being overheard.

The registered manager confirmed that patients are entitled to have a family member, friend or a formal chaperone present for support during consultations and treatment sessions.

Patient information and consent

We were assured that patients were able to make an informed decision about their treatment. This is because patients are provided with a face-to-face consultation prior to receiving treatment to help them understand the treatment options available to them and the risks and benefits associated with each treatment option. Patients are required to sign a consent form that also details the risks and benefits as a final reminder before receiving treatment.

During the inspection we looked at a sample of patient records and saw that consent forms were being stored appropriately and noted that each form had been signed by the patient and countersigned by the IPL operator.

Communicating effectively

A patients' guide and a statement of purpose¹ were available for patients in a patient information folder in the reception area. We noted that both documents contained the information required by the regulations, such as the aims and objectives of the clinic and the arrangements for dealing with complaints.

Both patients who completed a HIW questionnaire said that they felt listened to during their appointments and felt that they had been involved as much as they wanted to be in decisions about their treatment.

Care planning and provision

The registered manager described suitable pre-treatment checks that are performed on patients to help determine a safe and effective setting of the IPL machine for their skin and hair type. Patients are required to undergo a patch

¹ A statement of purpose is a legally required document that includes a standard set of information about a provider's service.

test a week before receiving treatment, the results of which are documented in their patient records.

Both patients who completed a HIW questionnaire told us that they had been given aftercare instructions about how to prevent infection and aid healing after their treatment.

The sample of patient records we examined were being maintained to a high standard and we were assured that care was being planned and delivered with patients' safety, wellbeing and individual needs in mind.

Equality, diversity and human rights

The clinic is located on the main road and no parking is available for patients at the premises. The facilities are spread over three floors and the IPL treatment room is only accessible via some steep winding stairs. Therefore the premises are not suitable for patients with mobility issues.

We recommended to the registered manager that these accessibility issues are made clear to patients in the patients' guide and statement of purpose and we received evidence shortly after the inspection that these changes had been made.

Citizen engagement and feedback

We found that the clinic had a system in place for seeking patient feedback as a way of monitoring the quality of service provided. Questionnaires are issued annually to patients but patients could also complete comment cards or complete an online review about their experience at the clinic all year round.

We were told that all patient feedback is reviewed and summarised to identify any themes. A summary of patient feedback was also included in a customer testimonial book that was available in the reception area. This helps to inform current and prospective patients about the quality of care being delivered by the clinic.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

We found evidence that patients were receiving focussed individualised care that was documented in well maintained patient records.

Clinical facilities were in good condition and the IPL machine had been regularly serviced to help ensure patients were being treated as safely as possible.

Staff needed to undertake more advanced training in the safeguarding of vulnerable adults to ensure they have the relevant knowledge and awareness to recognise and act on any safeguarding concerns.

Managing risk and health and safety

Overall, we found suitable maintenance arrangements were in place to protect the safety and well-being of staff and people visiting the premises.

We saw certification that confirmed an electrical wiring and a gas safety check had recently been undertaken. Portable Appliance Testing (PAT) had also been carried out to help ensure small electrical appliances were fit for purpose and safe to use.

The clinic had arrangements in place to provide adequate protection in the event of a fire. Fire extinguishers throughout the clinic had been serviced within the last 12 months to ensure they worked properly and fire exits were appropriately signposted. The clinic did not have a fire alarm but a whistle was available to sound the alarm in the event of a fire. We noted that regular fire drills had been carried out and recorded in a logbook.

The registered manager described suitable procedures to follow in the event of an emergency such as patient collapse and we saw evidence that the IPL operator had been trained in first aid to treat minor injuries. However, we recommend that the clinic purchases a new first aid kit because we found the first aid kit at the practice to be incomplete and contained some items that had

exceeded their expiry date; in future, the first aid kit must be monitored by staff to ensure all items are present and in date.

Improvement needed

A new first aid kit must be purchased and subsequently checked regularly by staff to ensure all items are present and in date.

Infection prevention and control (IPC) and decontamination

We found the premises to be in good condition and the treatment rooms were clean and clutter free.

The registered manager described suitable infection control arrangements at the clinic which included ensuring good hand hygiene and the completion of cleaning schedule checklists to document the cleaning undertaken of the treatment rooms and IPL equipment. We found these arrangements were consistent with those outlined in the clinic's infection control policy.

Safeguarding children and safeguarding vulnerable adults

The registered manager confirmed that the service complies with their condition of registration to only treat patients over the age of 18 years old. Any children accompanying adults at appointments are not permitted into the treatment room when treatment is taking place for their safety.

The procedures for staff to follow in the event of any safeguarding concerns were detailed in a policy for the safeguarding of vulnerable adults. We recommended to the registered manager that the policy should be updated to include the contact details of relevant local adult safeguarding agencies to ensure any concerns can be reported appropriately and in a timely manner. We received evidence immediately after the inspection that the policy had been updated accordingly.

We saw certification that the registered manager and the IPL operator had recently undertaken level 1 safeguarding training to improve their knowledge and awareness relating to the protection of vulnerable adults. However, we recommend that undertaking more advanced safeguarding training would be more appropriate to fully ensure staff are aware of how to safeguard patients against the risk of abuse and neglect.

Improvement needed

The registered manager and IPL operator must undertake level 2 training in safeguarding vulnerable adults.

Medical devices, equipment and diagnostic systems

Overall, we found suitable arrangements were in place to protect the safety of patients when using the IPL machine at the clinic. This is because:

- The IPL machine had been regularly serviced and calibrated in line with the manufacturer's guidelines to help ensure it performs consistently and as expected
- A treatment protocol setting out the procedures to follow to ensure treatment is delivered safely to patients was in place which had been overseen by an expert medical practitioner as required by the regulations
- A contract was in place with a Laser Protection Adviser (LPA) to provide expert advice on the safety of the IPL machine installation and day to day operational use
- Comprehensive local rules² developed by the LPA that detailed the safe operation of the IPL machine were in place and had been signed by the IPL operator to evidence their awareness and agreement to follow these rules.

Safe and clinically effective care

We saw evidence that the IPL operator met Medicines and Healthcare products Regulatory Agency (MHRA) requirements³ to be a competent user of the IPL

² Local rules (or safe working procedures) should reflect safe working practices and relate to the day-to-day safety management of lasers, IPL systems and LEDs. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/474136/Laser_guidance_Oct_2015.pdf.

³ [Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices](#).

machine having completed both Core of Knowledge⁴ training and training by the IPL machine manufacturer on how to operate it safely.

A range of protective eyewear was available for patients and the IPL operator. We saw that the glasses and goggles had been kept in good condition and the registered manager confirmed that they were checked regularly for any damage.

No patients received treatment on the day of the inspection, but the registered manager described the safety precautions taken when treatment is in progress; a warning sign on the outside of the treatment room door indicates that the IPL machine is in use and the treatment room is locked to prevent any unauthorised persons from entering during treatments. We were told that the key to the IPL machine is locked away after each appointment to ensure it is kept secure when not in use.

We saw evidence that the LPA had regularly visited the clinic to undertake environmental risk assessments to identify and mitigate for any hazards associated with the use of the IPL machine and the environment of the treatment room.

Participating in quality improvement activities

We found evidence that the service had suitable systems in place to regularly assess and monitor the quality of service provided. For example, we noted earlier in the report that the clinic provided the opportunity for patients to provide feedback through questionnaires and comment cards.

The registered manager also explained the importance of post treatment observations and discussions with patients to help provide improved individualised care throughout a course of treatment.

We saw certificates of various relevant training courses undertaken by the IPL operator to ensure they had the skills and knowledge necessary to help provide quality patient care.

⁴ Training in the basics of the safe use of IPL/laser machines.

The registered manager described how they undertook random audits of patient records and patient notes to check the quality and ensure that the relevant information is being documented.

Records management

We saw evidence that patient records were being maintained in line with best practice and professional guidelines and supported the service to deliver good quality patient care. Patient notes were detailed and of good quality and print outs from the IPL machine were attached to each record to document the parameters used for each treatment session.

We found that patient information was kept securely. The clinic had a records and information management policy in place that set out appropriate procedures to protect patient information and safely manage patient records in compliance with the General Data Protection Regulations (GDPR). Paper patient records were kept in a locked cabinet to prevent unauthorised access.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care. We also considered how the service review and monitor their own performance against the Independent Health Care Regulations and National Minimum Standards.

Effective governance arrangements had been implemented by the registered manager to support staff working at the clinic.

The authorised IPL operator had the relevant skills and knowledge to help deliver safe treatment to patients.

A range of policies and procedures were in place for the safety of staff and patients which were all updated on an annual basis. However, we required further evidence that indicated staff had read and understood each policy.

Governance and accountability framework

Complexion Medispa and Laser Clinic is owned by the registered manager. There are four other members of staff, which includes one IPL operator.

We found that the clinic had a number of policies in place which were accessible and updated annually by the registered manager. However, we could not be assured that all staff had read and understood each policy and any updates. We spoke to the registered manager who agreed to implement a new system to monitor this, and we received evidence after the inspection that staff had subsequently read each policy and that the new system had been put in place to document this.

We saw that the clinic had an up to date liability insurance certificate in place to protect against compensation claims and associated legal costs.

Dealing with concerns and managing incidents

The clinic had an appropriate complaints procedure which included the correct contact details for HIW in line with regulatory requirements. A summary of the complaints procedure was included within the statement of purpose and in the

patients' guide. We advised the registered manager to also consider putting a copy of the procedure within the patient information folder.

We saw that suitable systems were in place to record and manage any formal or informal complaints and concerns received by the clinic.

Workforce planning, training and organisational development

We were assured that the IPL operator at the clinic had the appropriate knowledge, skills and experience to provide safe and effective care to patients. As mentioned earlier within the report, they had completed the Core of Knowledge training and had also completed training on how to use the IPL machine safely. They were also committed to keeping their skills and knowledge up to date through continuing professional development⁵ (CPD).

The registered manager told us that they hold regular catch ups with all members of staff which allow staff to hear feedback about their performance and to identify future training opportunities.

Workforce recruitment and employment practices

We saw evidence that the IPL operator had an appropriate Disclosure and Barring Service⁶ (DBS) certificate to help protect patients against the risk of inappropriate, or unsafe, care and treatment and to help the service comply with the regulatory requirements that staff are of good character.

The registered manager described an appropriate process for recruitment and induction of any new IPL operators. This included pre-employment checks to ensure they are fit to work and a period of mentoring and supervision to ensure they had the skills and knowledge to undertake the role.

⁵ Continuing professional development (CPD) is the process of documenting skills, knowledge and experience gained formally and informally to help improve the safety and quality of care provided to patients.

⁶ The Disclosure and Barring Service (DBS) helps employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups. It replaces the Criminal Records Bureau (CRB) and Independent Safeguarding Authority (ISA).

4. What next?

Where we have identified improvements and immediate concerns during our inspection which require the service to take action, these are detailed in the following ways within the appendices of this report (where these apply):

- Appendix A: Includes a summary of any concerns regarding patient safety which were escalated and resolved during the inspection
- Appendix B: Includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Where we identify any serious regulatory breaches and concerns about the safety and wellbeing of patients using the service, the registered provider of the service will be notified via a [non-compliance notice](#). The issuing of a non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

The improvement plans should:

- Clearly state when and how the findings identified will be addressed, including timescales
- Ensure actions taken in response to the issues identified are specific, measurable, achievable, realistic and timed
- Include enough detail to provide HIW and the public with assurance that the findings identified will be sufficiently addressed.

As a result of the findings from this inspection the service should:

- Ensure that findings are not systemic across other areas within the wider organisation
- Provide HIW with updates where actions remain outstanding and/or in progress, to confirm when these have been addressed.

The improvement plan, once agreed, will be published on HIW's website.

5. How we inspect independent services

Our inspections of independent services may be announced or unannounced. We will always seek to conduct unannounced inspections because this allows us to see services in the way they usually operate. The service does not receive any advance warning of an unannounced inspection. In some circumstances, we will decide to undertake an announced inspection, meaning that the service will be given up to 12 weeks' notice of the inspection.

Feedback is made available to service representatives at the end of the inspection, in a way which supports learning, development and improvement at both operational and strategic levels.

HIW inspections of independent healthcare services will look at how services:

- Comply with the [Care Standards Act 2000](#)
- Comply with the [Independent Health Care \(Wales\) Regulations 2011](#)
- Meet the [National Minimum Standards](#) for Independent Health Care Services in Wales.

We also consider other professional standards and guidance as applicable.

These inspections capture a snapshot of the standards of care within independent services.

Further detail about [how HIW inspects independent services](#) can be found on our website.

Appendix A – Summary of concerns resolved during the inspection

The table below summaries the concerns identified and escalated during our inspection. Due to the impact/potential impact on patient care and treatment these concerns needed to be addressed straight away, during the inspection.

Immediate concerns identified	Impact/potential impact on patient care and treatment	How HIW escalated the concern	How the concern was resolved
No immediate concerns were identified on this inspection.			

Appendix B – Improvement plan

Service: Complexion Medispa and Laser Clinic

Date of inspection: 27 November 2019

The table below includes any other improvements identified during the inspection where we require the service to complete an improvement plan telling us about the actions they are taking to address these areas.

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of the patient experience				
No recommendations made.				
Delivery of safe and effective care				
A new first aid kit must be purchased and subsequently checked regularly by staff to ensure all items are present and in date.	National Minimum Standards for Independent Health Care Services in Wales Standard 22	This has now been purchased.	Clare Sawkins	Completed

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
	Health and Safety (First-Aid) Regulations 1981			
The registered manager and IPL operator must undertake level 2 training in safeguarding vulnerable adults.	The Independent Health Care (Wales) Regulations 2011 Regulation 16 National Minimum Standards for Independent Health Care Services in Wales Standard 11	Safeguarding Adults level 2 CPD accredited has been purchased via REED online training company.	Clare Sawkins	Complete by March 2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of management and leadership				
No recommendations made.				

The following section must be completed by a representative of the service who has overall responsibility and accountability for ensuring the improvement plan is actioned.

Service representative

Name (print): Clare Sawkins
Job role: Registered Manager
Date: 23 January 2020