

Independent Healthcare Inspection (Announced)

Vale Laser Ltd

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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 Vale Laser Ltd on the 30 April 2019.

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

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

Overall, we found that Vale Laser Ltd was committed to providing a positive service to its patients, in an environment that was clean, tidy and pleasant.

The registered manager had a wide range of policies and procedures in place to ensure the safety and dignity of patients and staff. We also found that there were comprehensive arrangements in place to discuss treatment options with patients and obtain consent prior to treatment.

This is what we found the service did well:

- The environment was clean and well maintained.
- Processes were in place to ensure the privacy and dignity of patients.
- Patients were provided with detailed information to help them make an informed decision about their treatment.
- Appropriate arrangements were in place for infection prevention and control.

This is what we recommend the service could improve:

- The patients' guide should be updated and provided on the website along with the statement of purpose.
- The registered manager should undertake appropriate safeguarding training.
- The registered manager must ensure that there are medical treatment protocols in place for the Energist ePulse machine.

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

3. What we found

Background of the service

Vale Laser Ltd is registered to provide a range of independent treatments, mainly cosmetic based.

The service was first registered on 09 February 2015 and employs one laser operator, who is also the registered manager.

The clinic is registered to provide the following treatments to patients over the age of 18 years:

Energist MedArt Varimed 435 laser

- Hair removal
- Pigmentation treatment
- Thread Veins
- Acne

Energist ePulse System

- Hair 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 found that patients were very happy with the service provided and the registered manager was committed to providing a positive experience for patients.

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

The service ensures that patients are provided with detailed information pre and post treatment, to help them make an informed decision about their treatment.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of 14 were completed.

Overall, patient feedback was very positive, and the majority of patients who completed a questionnaire rated the care and treatment that they were provided with as 'excellent'. Patient comments included the following:

"Very professional service but made to feel so at ease at the same time"

"I found the clinic knowledgeable and helpful. Eager to help and listened to my feedback when working on sensitive areas of my face"

Health promotion, protection and improvement

We were told that patients complete a medical history form at their initial consultation. They must also sign a form at each subsequent treatment confirming whether there has been any changes in their medical history, to help ensure treatment is provided in a safe way.

We saw evidence of completed medical history forms within patient records to confirm this approach. All but one of the patients who completed a

questionnaire confirmed that they had completed a medical history form, or had had their medical history checked, before undertaking any treatment.

Dignity and respect

The registered manager told us that patients could change in the treatment room, and screens were provided to give suitable levels of privacy. Consultations with patients took place in the treatment room to ensure that any confidential and personal information could be disclosed without being overheard.

The registered manager confirmed that chaperones are welcome to attend with patients and can stay in the treatment room for the duration of the treatment.

Every patient who completed a questionnaire agreed that they had been treated with dignity and respect by the staff at the clinic, and felt that they were always able to maintain their own privacy, dignity and modesty during their appointments.

Patient information and consent

We found that patients were provided with enough information to make an informed decision about their treatment. This is because all patients were provided with a face-to-face consultation prior to laser treatment. This discussion includes the risks, benefits and likely outcome of the treatment offered. Patients were also directed to the website where written information about their laser treatment was also available.

All patients who completed a questionnaire agreed that they had been given enough information to help them understand the treatment options available to them, and to understand the risks and benefits associated with each treatment option. All but one of the patients also told us that the cost of any treatment was always made clear to them before they received the treatment.

Where applicable, all of the patients who completed a questionnaire confirmed that they had signed a consent form before receiving any new treatment and all but one of the patients told us that they had been given aftercare instructions about how to prevent infection and aid healing after their treatment.

Communicating effectively

A detailed statement of purpose¹ was provided to us by the registered manager that contained the essential information as required by the regulations. A patients' guide² was not available online or in the waiting areas, and we advised that this should be easily accessible to patients. The patients' guide needs to be updated, to include details on how patients can provide feedback to the service and a summary of the views of patients. As the service has a website, we recommend that both the statement of purpose and patients' guide are made available to patients via the website.

We noticed that both the statement of purpose and patients' guide had been reviewed in 2018, however a relevant date for the next review date was missing from these documents. We advised that both documents should include review dates.

All of the patients who completed a questionnaire said that they were always able to speak to staff in their preferred language.

Every patient who completed a questionnaire also said that staff listened to them during their appointment and felt that they had been involved, as much as they wanted to be, in decisions about their treatment.

Improvement needed

The service must ensure that the patients' guide includes all of the relevant information required by the Independent Health Care (Wales) Regulations 2011.

The service must make the statement of purpose and patients' guide available to patients on their website,

Care planning and provision

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

² A patients' guide is required to inform patients about vital information relating to a service, such as how to access services, provide feedback and a raise a complaint.

The registered manager told us that prior to treatment, patients must agree to undergo a patch test to determine a safe and effective setting of the laser for their skin and hair type. Where applicable, all of the patients who completed a questionnaire agreed that they had been given a patch test before they received treatment.

We saw evidence of good record keeping processes in place at the service, including complete patient notes and a comprehensive patient treatment register³.

Equality, diversity and human rights

The service is located within a privately owned clinic, and is based on the first floor. The service is not accessible to individuals with mobility difficulties.

Citizen engagement and feedback

We found that the service had a system in place for seeking patient feedback as a way of monitoring the quality of service provided. Questionnaires were available, and patients were also encouraged to complete a review about their experience at the service via their website or Facebook page. We advised the registered manager to display outcomes from the questionnaires and online reviews to demonstrate to patients that their feedback is listened to and used to improve the service.

Just under a third of the patients who completed a questionnaire said that they were not aware of being asked for their views about the service provided at the clinic, for example, through patient questionnaires. The practice may wish to consider how to ensure that this information is clear and available to patients.

³ A treatment register is a comprehensive log of every treatment undertaken for each machine, to log details of how and when the machine was used and any adverse effects that have been noted either during or immediately following treatment.

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 the service to be well run and meeting the relevant regulations to ensure the health, safety and welfare of staff and patients.

Systems were in place to ensure patients were being treated as safely as possible. The laser machines were maintained in accordance with the manufacturer's guidelines, and the registered manager had up to date training on the use of the machines.

The treatment room was well equipped and visibly very clean and tidy.

The service needs to ensure that there are appropriate and up to date medical treatment protocols in place for the Energist ePulse machine.

Managing risk and health and safety

We found suitable maintenance arrangements were in place to protect the safety and well-being of the registered manager and people visiting the premises.

We saw evidence that a building electrical wiring check had been undertaken within the last five years, and that regular Portable Appliance Testing (PAT) testing is carried out to ensure equipment is maintained in a safe and suitable condition.

The service shared a building with a number of other businesses, overseen by a building manager. We looked at the arrangements in place with regard to fire safety within the building. We found the fire policy was agreed between all of the businesses within the clinic; it was readily available in reception and we saw that all staff within the clinic were aware of this policy. However, we saw that the fire extinguishers were overdue for a service. We were provided with evidence on the day that servicing was booked in for the following week. We also saw that fire exits were signposted. However, we did not see evidence on

the day of fire training being provided for staff. We therefore recommend that the registered manager undertakes training to ensure the safety of herself and her patients within the service.

There was an emergency first aid kit available within the wider clinic, however we found upon inspection that numerous items were out of date. We recommended that the service should ensure that there is a complete, in date first aid kit available to them at all times. We also found that the registered manager had not undertaken first aid training, and advised that this was undertaken to ensure she could appropriately deal with injuries to herself or patients.

Improvement needed

The registered manager must undertake fire safety training.

The service should ensure that there is an appropriate first aid kit available at all times.

Infection prevention and control (IPC) and decontamination

We found the premises to be visibly clean and tidy. There were no concerns given by patients over the cleanliness of the setting. All of the patients who completed a questionnaire felt that, in their opinion, the premises were very clean.

The registered manager described the infection control arrangements at the service which we found to be consistent with the procedures outlined in their infection control policy. We also saw that a cleaning schedule was in place.

We found there were suitable arrangements in place for the storage and collection of waste.

Safeguarding children and safeguarding vulnerable adults

The service is registered to provide treatments to people over the age of 18, and the registered manager confirmed that this was complied with. We were told that any children accompanying adults who were receiving treatment would not be permitted into the treatment rooms.

We found that the registered manager had not received safeguarding training since first registering with HIW in 2014. The registered manager must undertake appropriate training in the protection of vulnerable adults to ensure their safeguarding knowledge is kept up to date.

We saw that a policy for safeguarding of adults was in place, however this did not include specific procedures for staff to follow in the event of any safeguarding concerns. We recommended that the safeguarding policy be updated to include details of actions to be taken in the event of a safeguarding concern, and details of the local safeguarding contacts.

Improvement needed

The registered manager must undertake appropriate safeguarding training.

The safeguarding policy should be updated to include details of the procedures to be followed, as well as details of the local safeguarding authorities.

Medical devices, equipment and diagnostic systems

We saw evidence that both the Energist MedArt Varimed 435 laser and Energist ePulse System had been regularly serviced and calibrated⁴ in line with the manufacturer's guidelines.

We saw that there was a medical treatment protocol in place for the safe use of the Energist MedArt Varimed 435 laser machine. However, on the day of the inspection we did not see evidence of an updated protocol for the Energist ePulse System machine. The registered manager must ensure that there are appropriate medical protocols in place for both laser machines. The registered manager told us that the treatment protocols were produced by a suitable expert medical practitioner.

We saw that there was a contract in place with a Laser Protection Adviser⁵ (LPA) and a set of local rules⁶ were in place detailing the safe operation of the

⁴ Regular calibration can help insure the laser machine's performance stays consistent over time, ensuring top performance and output quality.

⁵ The Laser Protection Advisor is contracted to a practice to determine the safety controls and procedures that are necessary, and in providing safety training to staff, identify additional and specialised expertise will be needed.

⁶ 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.

laser machine. The rules had been reviewed by the LPA and we saw they had also been signed by the registered manager, indicating their awareness and agreement to follow these rules.

Improvement needed

The registered manager must ensure that there is an appropriate medical treatment protocol in place for the Energist ePulse machine.

Safe and clinically effective care

We saw evidence that the registered manager had received training on how to use the laser machine via the manufacturer.

We saw that eye protection was available for patients and the laser operator, with enough spare sets for any chaperones. The eye protection was visibly in good condition and the registered manager confirmed that glasses were checked daily for any damage.

No patients were being treated on the day of the inspection, but the registered manager described the treatment process in detail. A warning sign is placed on the outside of the treatment room door, indicating that the laser machine is in use. We were told that the machine is kept secure at all times by removing the keys and keeping them in locked areas separate to the machines. The keys for the locked key storage are removed from the service daily.

We reviewed documentation in place relating to various risk assessments undertaken by the service. We saw evidence that the LPA had completed a recent risk assessment which confirmed no improvements or changes were required.

Participating in quality improvement activities

We saw evidence that the registered manager regularly met with and had ongoing peer reviews with another laser operator, who operated from the same

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/474136/Laser_guidance_Oct_2015.pdf.

private clinic. This enabled both operators to discuss cases, provide an environment for problem solving and drive quality improvement.

Records management

We found that patient information was kept securely. Paper patient records were kept in a locked cabinet in the treatment room, and keys to the cabinet were taken away with the registered manager every night.

We examined a sample of patient records and found evidence that patient notes were maintained to a high standard, demonstrating that care was being planned and delivered with patients' safety and wellbeing in mind.

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.

The registered manager had the appropriate training and relevant knowledge to deliver safe treatment to patients.

The service had a wide range of policies and procedures which were all updated on an annual basis.

A comprehensive complaints procedure was in place to ensure any complaints are responded to efficiently and effectively.

Governance and accountability framework

Vale Laser Ltd is run by the registered manager who is responsible for the day to day management of the service and is the only laser operator.

We found that the service had a number of policies in place which were updated regularly and were accessible.

We saw that the service had an up to date liability insurance certificate in place.

Dealing with concerns and managing incidents

The service had an appropriate complaints procedure which included the correct contact details of HIW in line with regulatory requirements. A summary of the complaints procedure is included within the statement of purpose and in the patients' guide.

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

Workforce planning, training and organisational development

We saw certificates showing that the registered manager, as the only authorised operator of the laser machine, had completed the Core of

Knowledge⁷ training within the last five years and had also completed training on how to use the laser machine.

We advise that in order to ensure that the laser operator was regularly kept up to date, and to support continual professional development, the registered manager should undertake Core of Knowledge training every three years.

Improvement needed

Workforce recruitment and employment practices

We saw evidence that the registered manager had an appropriate Disclosure and Barring Service (DBS) certificate in place to satisfy Regulation 19, which requires that patients must be protected against the risks of inappropriate or unsafe care and treatment.

⁷ Training in the basics of the safe use of lasers and IPL systems

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: Vale Laser Ltd

Date of inspection: 30 April 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				
The service must ensure that the patients' guide includes all of the relevant information required by the Independent Health Care (Wales) Regulations 2011 The service must make the statement of purpose and patients' guide available to patients on their website	18. Communicatin g effectively	Yes uploaded on website today.	Mandy Davies	04/07/2019
Delivery of safe and effective care				
The registered manager must undertake fire	22. Managing risk and health	Yes first aid kit in the clinic room.	Mandy Davies	04/07/2019

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
safety training. The service should ensure that there is an appropriate first aid kit available at all times.	and safety	SANDS are arranging fire training with the next fire inspection.		
The registered manager must undertake appropriate safeguarding training. The safeguarding policy should be updated to include details of the procedures to be followed, as well as details of the local safeguarding authorities.	11. Safeguarding children and safeguarding vulnerable adults	Yes updated policy.	Mandy Davies	04/07/2019
The registered manager must ensure that there are appropriate medical protocols in place for the Energist ePulse machine.	16. Medical devices, equipment and diagnostic systems	Yes	Mandy Davies	04/7/2019

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): Mandy Davies

Job role: Registered Manager

Date: 04/07/2019