Independent Healthcare Inspection Report (Announced)

Studio 9 Advanced Treatments, Tredegar

Inspection date: 21 May 2024

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

Our purpose

To check that healthcare services are provided in a way which maximises the health and wellbeing of people

Our values

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

- Independent we are impartial, deciding what work we do and where we do it
- Objective we are reasoned, fair and evidence driven
- Decisive we make clear judgements and take action to improve poor standards and highlight the good practice we find
- Inclusive we value and encourage equality and diversity through our work
- Proportionate we are agile and we carry out our work where it matters most

Our goal

To be a trusted voice which influences and drives improvement in healthcare

Our priorities

- We will focus on the quality of healthcare provided to people and communities as they access, use and move between services.
- We will adapt our approach to ensure we are responsive to emerging risks to patient safety
- We will work collaboratively to drive system and service improvement within healthcare
- We will support and develop our workforce to enable them, and the organisation, to deliver our priorities.



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1. What we did

Full details on how we inspect the NHS and regulate independent healthcare providers in Wales can be found on our website.

Healthcare Inspectorate Wales (HIW) completed an announced inspection of Studio 9 Advanced Treatments, 99 Commercial Street, Tredegar, NP22 3DW on 21 May 2024.

The inspection was conducted by a HIW healthcare inspector.

During the inspection we invited patients or their carers to complete a questionnaire to tell us about their experience of using the service. None were completed. Feedback and some of the comments we received appear throughout the report.

Where present, quotes in this publication may have been translated from their original language.

Note the inspection findings relate to the point in time that the inspection was undertaken.

2. Summary of inspection

Quality of Patient Experience

Overall summary:

We found Studio 9 Advanced Treatments was committed to providing a positive experience for their patients in a pleasant environment with friendly and professional staff. We found systems and processes in place to ensure patients were being treated with dignity and professionalism.

Patients were provided with adequate information, including the risks and benefits of treatment, to enable them to make an informed decision. Information was in English only, although access to Welsh translation was available on request.

We were assured that the clinic was an inclusive environment and that all staff and patients would be treated equally. However, we saw no evidence of an equality and diversity policy or that training in this subject had been completed by staff.

We found patient feedback was obtained and acted upon when received, however there was no system for anonymous patient feedback to be obtained at the clinic.

This is what we recommend the service can improve:

- Patient records are completed fully, and signed by both the patient and laser and Intense Pulsed Light (IPL) operator
- Ensure all patients have a patch test prior to commencing a course of treatment
- Maintain treatment registers which are specific to each machine.

This is what the service did well:

- Treating patients with dignity and respect
- Enthusiastic and friendly staff.

Delivery of Safe and Effective Care

Overall summary:

In general, the premises appeared to be well maintained and equipped to provide the services and treatments they are registered to deliver. All areas were clean and free from visible hazards, and we saw cleaning schedules were being maintained throughout. Whilst there was an appropriate risk assessment in place for the use of the laser and IPL machines, there was no contract in place with a Laser Protection Advisor (LPA).

We found there were good arrangements in place to ensure that the laser machine was used appropriately and safely. However, maintenance records for the IPL machine could not be provided during the inspection. We also found one pair of IPL protective eyewear was damaged and needed to be replaced. We were told that the clinic was planning to cease IPL treatments and sell this machine.

We found the fire safety arrangements needed some immediate attention and some first aid kit items were out of date and needed to be replaced.

Safeguarding policy and procedures were in place although there was no evidence that staff had completed safeguarding training.

Immediate assurances:

- Up to date version of the local rules are obtained prior to providing further treatments
- Fire extinguishers in the building to be serviced and relevant inspection labels put in place
- All staff to complete appropriate fire safety training
- Fire safety risk assessment to be conducted.

This is what we recommend the service can improve:

- Ensure that an up-to-date gas safety certificate is available for the premises
- Fire drills to be recorded in a fire safety logbook
- Implement a system to ensure the first aid kit is checked regularly
- All staff to complete safeguarding training
- Remove and replace damaged IPL glasses
- Implement a documented process to regularly assess and monitor the quality of the services provided.

This is what the service did well:

- Premises clean and appeared well maintained
- Patient records were kept safe and secure.

Quality of Management and Leadership

Overall summary:

Studio 9 Advanced Treatments has a small but dedicated team with clear lines of accountability. The day-to-day management of the clinic was the responsibility of

the owner/ registered manager, who we found to be committed to providing good quality patient care.

We found a range of policies and procedures which were reviewed within the last year, although we found staff had not countersigned the latest versions.

We were told that the laser and IPL operator had recently left the clinic and that the service had suspended these treatments while they trained the new operator.

This is what we recommend the service can improve:

- Staff to countersign policy documents to confirm they have read and understood them.
- Disclosure and Barring Service (DBS) checks to be completed for all staff.

This is what the service did well:

• Suitable complaints policy in place to deal with patient concerns.

3. What we found

Quality of Patient Experience

Patient Feedback

Before our inspection we invited the practice to hand out HIW questionnaires to patients to obtain their views on the service provided at the practice. As the clinic had no laser or IPL customers during this period, there were no completed questionnaires.

Dignity and respect

We saw that Studio 9 Advanced Treatments had one treatment room located on the ground floor. We found the room to be clean, tidy, and well organised. The treatment room had a lockable door so that patients could change in privacy. Towels were provided for patients to use throughout treatments to protect dignity.

Chaperones were not typically offered by the service, however chaperones were permitted to attend if patients requested.

Communicating effectively

We reviewed the patient guide and the statement of purpose provided to us by the registered manager. We found the statement of purpose to be compliant with the regulations. Whilst the patient guide contained a summary of the statement of purpose, client feedback and terms and conditions of treatment, there was no telephone number or email contact details for the clinic. Although we found documentation only available in English, the registered manager told us they had access to a Welsh translation service if required. However, there was no indication of this provision within their documentation.

We recommend the registered manager reviews the patient guide:

- To include the full contact details of the clinic
- To indicate to patients the availability of Welsh translation service
- Provide a copy to HIW once complete.

Appointments could be arranged via the clinic's social media pages, by telephone or in person. This enabled patients without digital access to book treatments.

Patient information and consent

We reviewed a sample of five patient records during the inspection. The notes included patient identifiers and the parameter settings for the machine used. However, there were several omissions across the notes including a missing date, area treated and missing operator signatures on several records.

The registered manager must ensure that all required entries on patient records are completed fully, and are signed by both the patient and operator as correct.

Additionally, all records contained a signed patch test waiver form. This indicated that all patients we reviewed had either been advised or chose to not have a test that would help determine the likelihood of any adverse reactions.

The registered manager must ensure all patients have a patch test to help determine the most effective parameters and identify possible adverse reactions prior to commencing a course of treatment.

We saw evidence that patients were asked to provide signed consent before each treatment.

Care planning and provision

We were told that patients were asked to provide a comprehensive medical history during their initial consultation. We were told that these discussions included the risks, benefits and the likely outcome of the treatment offered along with aftercare guidance. We were told that patients were asked about changes to their medical history prior to all subsequent treatments which was documented using a treatment continuation form.

We asked to see the laser and IPL treatment registers as required by the regulations. The registered manager informed us that they did not have one as it was contained within the individual patient's records.

We recommend that the registered manager maintains treatment registers recording each occasion laser or IPL treatments are provided, which are specific to each machine rather than being separated into individual patient files.

Equality, diversity and human rights

The doorways and corridor were wide enough for wheelchairs and there was a ramp from the street to the reception door, although there was a lip created by the lower part of the door frame that would hinder wheelchair access.

We did not see an equality and diversity policy in place, and did not see any evidence that staff had received equality and diversity training.

We recommend the registered manager:

- Put in place an equality and diversity policy
- Ensure all staff complete equality and diversity training.

We were assured that the clinic was an inclusive environment irrespective of any protected characteristic, and that all staff and patients would be treated fairly and equally. We were told that the human rights of transgender patients would be actively upheld with preferred names and pronouns used as requested.

Citizen engagement and feedback

We were told that patient feedback could be provided either in person, by email or via social media. However, we found there was no facility for patients to provide anonymous feedback in person. We discussed the option of putting in place a suggestions box.

We recommend the registered manager puts in place a suggestions box and make anonymous feedback forms available within the treatment room and/or reception area.

The registered manager advised that feedback is monitored and assessed on an ongoing basis. This has led to the clinic remaining open on two evenings in the week. A summary of customer feedback was included in the patient guide.

Delivery of Safe and Effective Care

Managing risk and health and safety

We saw that Portable Appliance Testing (PAT) had been conducted recently and that the premises had a five yearly electrical system inspection in 2022, which provided assurance that it was safe to use electrical appliances within the clinic. However, the annual gas safety certificate we were provided was dated July 2022.

The registered manager must ensure that an up-to-date gas safety certificate is available for the premises and provide evidence of this to HIW.

We found that a comprehensive risk assessment had been conducted by the Laser Protection Advisor in March 2024 and an up-to-date risk management policy was in place.

We inspected the clinic fire safety arrangements. We were told that fire drills were conducted every six months. However, there was no record made to evidence on what dates these had taken place.

The registered manager must ensure that fire drills are conducted on a regular basis and that these are recorded in the fire safety logbook.

We found the fire risk assessment consisted of a basic checklist document which was undated and lacked key details including address of the premises, which areas were assessed and any evaluation of risks and actions or mitigation to reduce those risks. Furthermore, we found a fire extinguisher which did not have an inspection label and that staff had not completed any fire safety awareness training. Our concerns regarding this were dealt with under our non-compliance notice process.

This meant that we wrote to the service immediately following the inspection requiring that urgent remedial actions were taken. Further information on the issues we identified, and the actions taken by the service, are provided in Appendix B.

We inspected the first aid kit and numerous first aid items were out of date. This was raised with the registered manager at the time of the inspection, and replacement items were ordered during the inspection.

The registered manager must implement a system to ensure the first aid kit is checked regularly to ensure expiry dates are not exceeded and all items are present or replaced.

Infection prevention and control (IPC) and decontamination

We saw that the clinic was visibly clean and tidy. Furniture, equipment and fittings were of materials that were easy to wipe down. We discussed the infection control arrangements with the registered manager and considered these to be appropriate to protect patients from cross infection.

We saw an infection prevention and control policy was in place which had been recently reviewed. Hand sanitizer was available in the patient areas and appropriate cleaning schedules were being used.

A current contract for clinical waste collections was in place and we were told that this was collected quarterly.

Safeguarding children and safeguarding vulnerable adults

The service is registered to treat patients aged 18 years and over. The registered manager confirmed that this was complied with.

We saw an up-to-date safeguarding policy was in place for vulnerable adults and children, with clear procedures to follow in the event of any safeguarding concerns which included the local safeguarding team contact details. The registered manager described how capacity to consent was assessed as part of the consultation process. We were told that children were permitted on the premises, and that they would have to stay in the waiting area with the receptionist during treatment. However, staff had not completed safeguarding training.

The registered manager must ensure all staff working at the clinic complete relevant safeguarding training and provide evidence to HIW when complete. As children are permitted to attend the premises, this must include safeguarding of children training.

Medical devices, equipment and diagnostic systems

We saw that the laser and IPL machines were the same as registered with HIW. We were told that the clinic was not currently providing treatments as the operator had recently left. We were also told that they were not planning to recommence IPL treatments and that this machine was now in storage, awaiting sale. We also saw that the previously registered laser machine was still in the treatment room, although we saw no evidence this was still being used to provide treatments. We were told this was also awaiting sale. The registered manager should consider storing the deregistered laser machine in a location other than a treatment room.

We saw the service and calibration checks for the laser were up-to-date and in line with the manufacturer's guidelines. However, the records for the IPL machine were not seen. Whilst the clinic may be planning to sell this equipment, it is still

registered and should therefore be serviced and maintained in accordance with the manufacturer's guidelines.

The registered manager must provide HIW with copies of up-to-date service and calibration records for the IPL machine prior to recommencing any IPL treatments.

There were treatment protocols in place for the use of the laser and IPL machine and these had been approved by an expert medical practitioner. We also saw copies of local rules detailing the safe operation of the machines. However, these were found to be last reviewed in 2022 and therefore had not been reviewed annually in accordance with the conditions of registration. Failure to review and update the local rules could mean that patients and staff are put at risk of serious and avoidable harm as a result of treatment not being provided to the appropriate standard.

This meant that we wrote to the service immediately following the inspection requiring that urgent remedial actions were taken. Further information on the issues we identified, and the actions taken by the service, are provided in Appendix B.

We saw no current contract in place with a Laser Protection Adviser (LPA).

The registered manager must have in place a current contract with a laser protection advisor prior to recommencing laser and/or IPL treatments and provide a copy to HIW.

Safe and clinically effective care

Eye protection was available for both patients and the operators. This was found to be clean and consistent with the requirements specified in the local rules. Whilst the laser eyewear was in good condition, we found one pair of the IPL eyewear to be cracked and needed to be replaced.

The registered manager must replace damaged IPL glasses in compliance with the local rules. The registered manager should consider removing damaged glasses from the clinic to avoid any mistaken use.

There were signs on the outside of the treatment room to indicate the presence of the laser and IPL machine. We saw that the machines and their keys were kept secure when not in use.

Participating in quality improvement activities

We found no documented systems in place to regularly assess and monitor the quality of service provided. We found that the provider does not seek the views of

patients as a way of informing care, conduct audits of records to ensure consistency of information and assess risks in relation to health and safety.

We recommend the registered manager puts in place a system to regularly assess and monitor the quality of the services provided in accordance with the regulations.

Records management

The clinic had a records and information management policy in place outlining the clinic's obligations and procedures for maintaining data security and client confidentiality. This had been reviewed in March 2024. We found patient records were kept securely at the service.

Quality of Management and Leadership

Governance and accountability framework

Studio 9 Advanced Treatments is owned and run by the registered manager with a small, dedicated team of staff.

We found a range of policies and protocols that had been reviewed and signed by the registered manager within the last year. However, we found that the policies had not been countersigned by the staff, so we were unable to confirm if they had been read and understood.

We recommend the registered manager arranges for staff to countersign the policy documents as confirmation that they have read and understood them.

Dealing with concerns and managing incidents

There was a suitable complaints policy in place covering both written and verbal complaints. This identified the person responsible for handling any complaints, expected timeframe for acknowledgement and resolution, and included further contact details should the patient wish to escalate an issue.

A summary of the complaint procedure was included within the statement of purpose and patients' guide. We saw the comments and complaints file for the clinic, although to date, there have been no formal complaints recorded.

Workforce planning, training and organisational development

We saw certificates showing that the operator of the laser machine had completed Core of Knowledge training and received device specific instruction from the manufacturer on how to use the laser machine. However, this person had now ceased employment. The clinic was currently in the process of training another member of staff to carry out laser/ IPL treatments.

The registered manager must ensure any staff appointed to provide laser/IPL treatments completes core of knowledge and device specific training prior to providing laser and/or IPL treatments.

Workforce recruitment and employment practices

We were provided with a current Disclosure and Barring Service (DBS) check for the registered manager. We saw no current DBS check in place for the other staff.

The registered must ensure a DBS check is conducted for all staff and provide HIW with copies once complete.

4. Next steps

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 immediate concerns regarding patient safety where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking
- Appendix C: 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.

The improvement plans should:

- Clearly state how the findings identified will be addressed
- 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
- Ensure required evidence against stated actions is provided to HIW within three months of the inspection.

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.

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 - Immediate improvement plan

Service: Studio 9 Advanced Treatments

Date of inspection: 21 May 2024

The table below includes any immediate non-compliance concerns about patient safety identified during the inspection where we require the service to complete an immediate improvement plan telling us about the urgent actions they are taking.

Improvement needed	Standard/ Regulation	Service action	Responsible officer	Timescale
An up-to-date copy of the general laser/ IPL safety procedures (Local Rules) was not available during the inspection which meant we could not be assured that treatment had been provided in accordance with current professional guidelines. The registered manager must provide written assurance to HIW that:	Act 2000,	Have contacted our LPA for an up to date copy of Local Rules.	Lynette Whittaker	Approx 4 weeks
 Up to date version of the local rules are obtained prior to providing further treatments to patients. 				

There was no evidence that the large 6kg fire extinguisher located adjacent to the treatment room had undergone any required annual maintenance inspection. The registered manager must provide written assurance to HIW that: • All fire extinguishers in the building to be serviced and relevant inspection labels put in place prior to providing further treatments to patients.	The Independent Health Care (Wales) Regulations 2011, Regulation 26(4)(a)	The 6kg fire extinguisher was placed temporarily in the clinic by the owner of the building (my son) who is renovating the property upstairs. This has now been removed as we have already got a fully serviced extinguisher in the clinic.	Lynette Whittaker	Completed
There was no evidence available that any fire safety training had been completed by staff. This was confirmed by the registered manager. The registered manager must provide written assurance to HIW that:	The Independent Health Care (Wales) Regulations 2011, Regulation 26(4)(c)	A more detailed risk assessment has been completed and staff have been informed the correct procedure to follow. A fire action notice has also been placed in the clinic for staff and clients to follow in the event of a fire. 07/06/2024 - In response to the notice that was provided to us on 04/06/24 required us to give a more detailed fire	Lynette Whittaker	Completed

 All staff to complete appropriate fire safety training prior to providing further treatments to patients. 		safety procedure. All staff has completed fire safety training which included a fire drill and details on what needs to be done on an event of a fire. A fire safety training document has been uploaded to the portal which shows what was covered. Also, our fire drill protocol that is within our policies and procedures has also been uploaded. A fire extinguisher guide has also been placed next to the fire extinguisher.		
The fire safety risk assessment was considered inadequate. We were provided with a basic checklist document which was undated and lacked key details and assessments. The registered manager must provide written assurance to HIW that: • A robust fire safety risk assessment to be conducted by a competent person prior to providing further treatments to patients.	Independent Health Care (Wales) Regulations 2011, Regulation	A more detailed risk assessment has been completed. 07/06/24 We have provided a further risk assessment that shows more detail as requested.	Lynette Whittaker	Completed

Appendix C - Improvement plan

Service: Studio 9 Advanced Treatments

Date of inspection: 21 May 2024

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	Standard/ Regulation	Service action	Responsible officer	Timescale
 We recommend the registered manager reviews the patient guide: To include the full contact details of the clinic To indicate to patients the availability of Welsh translation service Provide a copy to HIW once complete. 	Regulation 7 of The Independent Health Care (Wales) Regulations 2011	An updated patient guide as required has been provided to HIW.	Lynette Whittaker	Completed
The registered manager must provide written assurance to HIW that in the future, all required entries on patient records are completed fully, and are signed by	Regulation 23(1)(a)	Signed written assurance has been issued to HIW.	Lynette Whittaker	Completed

both the patient and operator as correct.				
The registered manager must ensure all patients have a patch test to help determine the most effective parameters and identify possible adverse reactions prior to commencing a course of treatment.	Regulation 15(1)(a) & (b)	Signed written assurance has been issued to HIW.	Lynette Whittaker	Completed
We recommend that the registered manager maintains treatment registers recording each occasion laser or IPL treatments are provided, which are specific to each machine rather than being separated into individual patient files.	Regulation 45(2)	We have now implemented a laser register that records when each laser treatment has been carried out. IPL is no longer applicable.	Lynette Whittaker	Completed
We recommend the registered manager: • Put in place an equality and diversity policy • Ensure all staff complete equality and diversity training.	Regulation 18(1) Regulation 20(2)(a)	Equality and diversity policy has now been written and put in place. Equality and diversity training has been completed by the required staff. Certificates provided to HIW.	Lynette Whittaker	Completed

We recommend the registered manager puts in place a suggestions box and make anonymous feedback forms available within the treatment room and/ or reception area.	Regulation 19(2)(e)	Anonymous feedback forms are now available in the reception area.	Lynette Whittaker	Completed
The registered manager must ensure that an up-to-date gas safety certificate is available for the premises and provide evidence of this to HIW.	Regulation 26(2)(a)	There are no gas facilities situated within the clinic currently, the landlord Is looking to fit one by the end of the year if this occurs, we will provide a gas safety certificate.	Lynette Whittaker	Completed
The registered manager must ensure that fire drills are conducted on a regular basis and that these are recorded in the fire safety logbook.	Regulation 26(4)(d)	A fire drill record is now available which will be filled out every 6 months by all staff.	Lynette Whittaker	Completed
The registered manager must implement a system to ensure the first aid kit is checked regularly to ensure expiry dates are not exceeded and all items are present or replaced.	National Minimum Standards for Independent Health Care Services in Wales, Standard 22	A first aid kit record is now available which will be updated and checked every 6 months.	Lynette Whittaker	Completed

	Health and Safety (First Aid) Regulations 1981			
The registered manager must ensure all staff working at the clinic complete relevant safeguarding training and provide evidence to HIW when complete. As children are permitted to attend the premises, this must include safeguarding of children training.	Regulation 20(2)(a)	Relevant staff have now completed safeguarding training for children and adults. Certificates provided to HIW.	Lynette Whittaker	Completed
The registered manager must provide HIW with copies of up-to-date service and calibration records for the IPL machine prior to recommencing any IPL treatments.	Regulation 15(2)	As explained on inspection, we no longer carry out IPL treatments. The machine has been removed from the clinic.	Lynette Whittaker	Completed
The registered manager must have in place a current contract with a laser protection advisor prior to recommencing laser and/ or IPL treatments and provide a copy to HIW.	Regulation 19(2)(a)	A contract is now in place with our LPA. Documents have been provided to HIW.	Lynette Whittaker	Completed

The registered manager must replace damaged IPL glasses in compliance with the local rules. The registered manager should consider removing damaged glasses from the clinic to avoid any mistaken use.	Regulation 15(2)	All IPL glasses have been removed from the clinic as we no longer carry out IPL treatments. The IPL equipment has been removed from the clinic.	Lynette Whittaker	Completed
We recommend the registered manager puts in place a system to regularly assess and monitor the quality of the services provided in accordance with the regulations.	Regulation 19	The quality of our services are regularly reviewed to help us maintain the best service to our clients. One-to-one meetings with the laser operator are carried out every 3 months.	Lynette Whittaker	Completed
We require the registered manager to provide HIW with evidence that staff have countersigned the policy documents as confirmation that they have read and understood them.	Regulation 9	The policy documents have been reviewed and signed by relevant staff and sent to HIW.	Lynette Whittaker	Completed
The registered manager must ensure any staff appointed to provide laser/IPL treatments	Regulation 45(3)	The laser operator has completed core of knowledge and laser training.	Lynette Whittaker	completed

completes core of knowledge and device specific training prior to providing laser and/ or IPL treatments.		Certificate and documents have been provided to HIW.		
The registered must ensure a DBS check is conducted for all staff prior to recommencing laser and/ or IPL treatments and provide HIW with copies once complete.	Regulation 21(2)(d) & Schedule 2, Para 3	A DBS application has been completed. Once arrived will send to HIW.	Lynette Whittaker	Approx 2-3 weeks

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): Lynette Whittaker

Job role: Registered Manager

Date: 07/08/2024