



Independent Healthcare Inspection (Announced)

The ME Clinic

Inspection date: 19 February
2018

Publication date: 21 May 2018

This publication and other HIW information can be provided in alternative formats or languages on request. There will be a short delay as alternative languages and formats are produced when requested to meet individual needs. Please contact us for assistance.

Copies of all reports, when published, will be available on our website or by contacting us:

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
Fax: 0300 062 8387
Website: www.hiw.org.uk**

Contents

1.	What we did	5
2.	Summary of our inspection	6
3.	What we found	8
	Quality of patient experience	10
	Delivery of safe and effective care	13
	Quality of management and leadership	17
4.	What next?	20
5.	How we inspect independent services	21
	Appendix A – Summary of concerns resolved during the inspection	22
	Appendix B – Improvement plan	23

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

Our purpose

To check that people in Wales are receiving good care.

Our values

- **Patient-centred:** we place patients, service users and public experience at the heart of what we do
- **Integrity:** we are open and honest in the way we operate
- **Independent:** we act and make objective judgements based on what we see
- **Collaborative:** we build effective partnerships internally and externally
- **Professional:** we act efficiently, effectively and proportionately in our approach.

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 the ME Clinic on the 19 February 2018.

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 the ME Clinic was committed to providing an effective service to its patients in an environment that was conducive to providing laser and intense pulse light (IPL) treatments.

This is what we found the service did well:

- Patients were provided with sufficient and detailed information pre and post treatment
- The service is committed to providing a positive experience for patients, regularly seeking feedback to improve services where applicable
- The service was clean, tidy and well maintained
- There were contracts in place to ensure the premises and equipment were maintained and serviced to ensure the health and safety of all staff and visitors
- Patient records were stored securely
- Staff received regular training in a number of areas and were often monitored in their use of the laser and IPL machines to ensure their techniques, skills and knowledge were inline with the services expectations.

This is what we recommend the service could improve:

- Updates to the complaints policy and Statement of Purpose¹ as well as any other documentation, to reflect HIW's email address

¹ Every service provider is required by law to have a Statement of Purpose and it should include specific details about the service, what treatments are provided, to who (age), by whom and any equipment used. For more information visit hiw.org.uk

- Ensure that the two laser/IPL machines no longer used by the service are removed from the table of services and facilities within the Patient Guide and Statement of Purpose.

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

3. What we found

Background of the service

The ME Clinic is registered with HIW as an independent hospital at 8 Churchill Way, Cardiff, CF10 2DX.

The service was first registered on 3 September 2015.

The service employs a staff team which includes two therapists and a Registered Manager who is also a laser/IPL operator.

A range of services can only be provided to persons over the age of 18 years using the following:

Alba 355 Laser system for the following treatments:

- Improvement in the symptoms of Psoriasis
- Improvement in the symptoms of Eczema

Asset tattoo removal Laser system for the following treatments:

- Tattoo removal

Epsilon Laser / IPL system for the following treatments:

- Thread vein removal
- Hair removal
- Skin rejuvenation
- Acne clearance

Superbium system for the following treatments:

- Hair removal
- Vein removal
- Photo rejuvenation
- Acne clearance
- Tattoo removal

- Pigmentation removal
- Nail fungi

Square Epil system for the following treatments:

- Hair removal
- Vein removal
- Pigmentation removal
- Nail fungi

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 staff committed to providing a positive experience for patients.

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

The service had appropriate processes in place to ensure that consultations with patients were held in a dignified and private manner.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain their views on the services provided. A total of seven questionnaires were completed. Patient comments included the following:

"All staff at the ME Clinic are extremely professional and welcoming. Great service"

[Named member of staff] "has been brilliant with me - completely understands what I'm after from the treatment, is very knowledgeable about the procedure. Couldn't fault the service provided"

"Any issues I have had have been respected and rectified, every staff member I have met has been incredibly friendly and polite, I would definitely recommend".

Health promotion, protection and improvement

We saw that patients were asked to complete a medical history form prior to initial treatment, which was signed by both the patient and operator. Patients' medical history/condition(s) were checked at each subsequent appointment to

ensure that treatment was provided in a safe way and recorded on the patient record.

Dignity and respect

The clinic is situated in a large, four-storey building. It has an intercom system at the main entrance which has to be opened by staff to allow visitors access to the reception.

Each treatment room has a coded key pad door which prevents unauthorised access. Prior to any treatment, discussions with patients take place to ensure they understand how the treatment will be performed.

The premises had sufficient space for conversations to be conducted in private and personal information could be discussed without being overheard.

Patient information and consent

All patients receive a consultation before starting any treatment so the process and outcome/s can be fully explained. In addition, risks and aftercare advice is also discussed before a patient is asked to sign the consent form confirming their understanding and agreement to treatment. We saw evidence of completed consent forms, ensuring all areas were covered and signatures of patients and staff were present.

We found that patients were provided with sufficient information to make an informed decision about their treatment. This is because patients were provided with a face to face consultation prior to any treatment with a laser/ILP operator. Discussions with patients included the risks, benefits and likely outcome of the treatment offered. Patients who completed a HIW questionnaire agreed that they had been given enough information about their treatment. We were told that all patients were given a patch test prior to treatment and were given after care advice following treatment. We saw examples of detailed written information provided to patients.

Communicating effectively

A client information folder was available in the reception area which included a Patient Guide and Statement of Purpose. These documents contained all the information required by the regulations, however the email address in the Statement of Purpose should be updated to reflect HIW's new address. In addition, both the Patient Guide and Statement of Purpose needs to be updated to reflect that two laser/IPL machines are no longer being used by the service (Omniyag and Unilite Diode laser).

Improvement needed

Updates to both the Patient Guide and Statement of Purpose are required to ensure HIW's new email address is listed and that the two laser/IPL machines no longer used by the service are removed from the table of services and facilities.

Care planning and provision

All patients received a consultation appointment prior to treatment, which included a skin type assessment. We saw that the outcome of this assessment was documented and used to assist with treatments. We saw examples of information and aftercare documents, which included the risks and benefits of treatment.

We saw examples of patient records, which were detailed and updated by the patient and practitioner at each appointment.

We found the service maintained an overall treatment register specific to each IPL/laser machine. The records were detailed and thorough as required by the regulations.

Equality, diversity and human rights

The treatment rooms which contained the laser and IPL machines were situated on the first and basement floors of the building. All rooms were accessible via stairs. Handrails were in place to provide patients with some assistance should this be required.

Staff told us that prior to any appointments being made, patients were informed of the building's accessibility (via stairs), both internally and externally. This is also documented in the Statement of Purpose.

Citizen engagement and feedback

The ME Clinic had systems in place to obtain patient feedback. Questionnaires were regularly given and/or sent to patients to enable them to submit feedback following the completion of their treatment.

Regular analysis of any feedback takes place and staff follow up any issues identified. Results are displayed in the patient information available in reception.

Delivery of safe and effective care

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

There were systems in place which ensured that patients were being treated as safely as possible. We found the laser/IPL machines were maintained in accordance with the manufacturer's guidelines and staff had up to date training on the use of the machines.

The treatment rooms were visibly clean and tidy and staff were aware of the cleaning tasks required to ensure cleanliness standards remained high.

We found the service had taken steps to protect the health, safety and welfare of staff and patients.

Managing risk and health and safety

We found arrangements were in place to protect the safety and well being of staff working at, and people visiting, the premises.

We looked at a selection of maintenance arrangements for the premises. We saw evidence that Portable Appliance Testing (PAT) was up to date, to help ensure that small electrical appliances were fit for purpose and safe to use.

Certification was provided to show gas safety and five yearly electrical wiring checks for the building were up to date.

We looked at some of the arrangements in place with regard to fire safety. Elements of fire risks had been assessed via the setting's own risk assessment and the laser protection adviser; but we were told that the company responsible for maintaining fire safety and equipment at the premises would be undertaking a full risk assessment in 2018. The registered manager confirmed that fire training for staff was included at induction and yearly thereafter, with regular fire drills taking place, which were documented, to ensure staff are aware of what to do in an emergency situation.

Labels on the fire extinguishers showed they were serviced annually and fire exits were signposted.

Staff were trained in first aid. A first aid kit was available and monthly checks carried out to ensure the materials were in-date and fit for purpose.

Infection prevention and control (IPC) and decontamination

We found the premises to be visibly clean and tidy. There were no concerns raised by patients over the cleanliness of the setting. In addition, all of the patients who completed a HIW questionnaire strongly agreed that the environment was clean and tidy.

Staff described in detail, the infection control arrangements at the service and the policy was consistent with those arrangements. Cleaning schedules were in place, which staff signed once the tasks had been completed. The tasks included the cleaning of the equipment and treatment areas between patients.

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

Safeguarding children and safeguarding vulnerable adults

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

A policy for the safeguarding of adults was in place which contained a clear procedure for staff to follow in the event of any safeguarding concerns.

Staff described how they would deal with any safeguarding issues. The staff had been trained in the protection of vulnerable adults and children.

Medical devices, equipment and diagnostic systems

We saw evidence that the laser and IPL machines had been regularly calibrated² and serviced in line with the manufacturers' guidelines.

² Regular calibration can help insure the laser machine's performance stays consistent over time, ensuring top performance and output quality.

We saw that there were treatment protocols in place for the laser/IPL machines and these had been overseen by an expert medical practitioner.

We saw that there was a contract in place with a Laser Protection Adviser (LPA) and there were local rules³ detailing the safe operation of the machines. These rules had been reviewed by the LPA and we saw that they had been signed by staff who operated the laser machines which indicated their awareness and agreement to follow these rules.

Safe and clinically effective care

We saw certificates to evidence that all the laser/IPL operators had completed Core of Knowledge⁴ training.

We saw that eye protection was available for patients and the operator of the laser and IPL machines. The eye protection appeared in visibly good condition and staff confirmed that glasses were checked regularly for any damage.

There were signs on the outside of the treatment rooms which indicated when the laser machine was in use. We were told that the machines are kept secure at all times. The activation keys for all machines were stored securely when not in use, preventing unauthorised access.

We reviewed the documentation relating to the environmental risk assessment. We saw that the LPA had completed an updated risk assessment which had no improvements identified.

Participating in quality improvement activities

We found that the service was undertaking a number of quality improvement activities. For example, the service regularly sought the views of patients as a

³ 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

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.

way of informing care and conducted audits of patient records to ensure consistency of information and assessed risks in relation to health and safety matters. However, we found that not all of these areas were formally recorded and we recommended that written evidence is available in the future to verify audit outcomes.

Records management

We found that patient information was kept securely, in a lockable cabinet. We examined a sample of patient records and found evidence that patient notes were maintained to a high standard.

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.

We found the ME Clinic to have a small, but effective team in place. This was supported by a management structure within which staff clearly understood their roles and responsibilities.

Systems were in place to ensure policies and procedures were updated and communicated to staff on a regular basis. The service had systems in place to ensure any complaints were logged, and responded to, in a timely way.

There were established systems in place to undertake pre-employment checks and support staff to remain up to date with their skills and knowledge.

Governance and accountability framework

The ME Clinic is managed on a day to day basis by the Registered Manager and supported by the Responsible Individual. The service has two laser/IPL operators, as well as the Registered Manager.

We saw the service had a number of policies in place, which were regularly reviewed to ensure they remain up to date and relevant. Any changes to policies and/or procedures are communicated to staff, who are required to sign and demonstrate that they had read and understood any changes.

We were told that team meetings were held regularly, and we saw evidence of recent minutes of the meetings. Notes and specific agenda items ensure they can be understood and shared among staff members unable to attend.

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

Dealing with concerns and managing incidents

We saw that the service had a complaints policy in place, but the policy needed to be updated to include HIW's contact details. The Patient Guide included a process for patients to follow should they need to make a complaint which included details for HIW.

The service had a system in place to log complaints and concerns. At the point of inspection, no complaints had been received.

All of the patients who completed a HIW questionnaire told us that they knew how to make a complaint if they needed to do so.

Improvement needed

The complaints policy needs to be updated to include HIW's contact details.

Workforce planning, training and organisational development

We saw certificates showing that all authorised users who operated the laser and IPL machines had completed the Core of Knowledge training and had also completed training on how to use the laser and IPL via the manufacturer.

All staff had a mandatory training programme in place which ensured they maintained their skills and knowledge in a number of areas including first aid and safeguarding. In addition, staff regularly undertook shadowing and peer reviews of each other's work to ensure standards were maintained when operating the laser and IPL machines.

Workforce recruitment and employment practices

We were told about the recruitment and employment practices in place to ensure appropriate employment checks are undertaken in respect of new staff.

This included a disclosure and barring service (DBS) check⁵ which we were told will be renewed every three years for all staff. We recognised this as good practice because it enables the service to make and maintain safer recruitment choices.

An induction programme was in place to support new starters, the completion of which is documented.

We were told that a programme of annual appraisals was in place for staff, which covers performance and development.

⁵ 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, measureable, 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: The ME Clinic

Date of inspection: 19 February 2018

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				
Updates to both the Patient Guide and Statement of Purpose are required to ensure HIW's new email address is listed and that the two laser/IPL machines no longer used by the service are removed from the table of services and facilities.	Regulation 6 (1) (2) & 7(1) (f)	Changes already actioned with updated copies within Patient guide for viewing. Copies for HIW to review are available upon request	Registered Manager	N/A Already Completed
Delivery of safe and effective care				
No improvements identified				
Quality of management and leadership				

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
The complaints policy needs to be updated to include HIW's contact details	Regulation 24 (4) (a)	Changes already actioned with updated copies printed and filed. Copies for HIW to review are available upon request	Registered Manager	N/A Already Completed

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): Philippa Lunn

Job role: General Manager

Date: 12.03.18