

Independent Healthcare Inspection (Announced)

Ultralase, Cardiff

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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 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 Ultralase on the 12 April 2018.

Our team, for the inspection comprised of one HIW inspector and HIW's clinical director.

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.

The focus of the inspection was to review the safe provision of laser eye care treatments and ensure that the environment is fit for purpose. The general safe running of the service forms part of the inspection but HIW are unable to comment of the quality of individual surgical techniques or outcomes.

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 evidence that the service provided safe and effective care to its patients.

The service was organised, well managed and had appropriate processes in place to help ensure treatment was provided in a patient focussed and safe way.

This is what we found the service did well:

- Patients were provided with detailed information to help them make an informed decision about their treatment
- The service had detailed patient records that evidenced medical histories, consent to treatment and discussions with patients
- The service is committed to providing a positive experience for patients
- The service was clean and tidy
- The service had a range of quality improvement activities to help identify areas for improvement.

This is what we recommend the service could improve:

- Details of adverse reactions needed to be included in the overall treatment register
- One staff member is required to sign a copy of the local rules.

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

3. What we found

Background of the service

Ultralase is registered as an independent hospital because it provides class 3B/4 laser treatments at Northgate House, Kingsway, Cardiff, CF10 3FD.

The service was first registered on the 28 April 2014.

The service employs a staff team which includes the registered manager, two laser technicians, a nurse and a patient adviser. The service also employs two optometrists and two ophthalmic surgeons, all of whom are employed on a sessional, part-time basis.

The service is registered to provide eye surgery to patients over the age of 18 years including the use of:

- a) Nidek Quest Argon Fluoride Excimer Laser.
- b) IntraLase Model II FS60 Femtosecond 60 Hz Laser.

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 staff were committed to providing a positive experience for 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 treatments.

Consideration should be given to implementing patient information in more accessible formats.

Prior to the inspection, we invited the service to distribute HIW questionnaires to patients to obtain views on the services provided. A total of 16 questionnaires were completed. Patient comments included the following:

"Very good service, good results so happy!"

"First class facilities and care."

"Very friendly and responsible. They make you aware of the risks and the potential hazards of the surgery and they will support your decision either way. Couldn't recommend them enough."

"Excellent service and treatment made me feel very at ease."

"Treated 10 years ago, vision still perfect. Back now with my son. Lovely new clinic. Staff very friendly and knowledgeable."

Health promotion, protection and improvement

We found that patients were asked to complete a medical history form prior to treatment, and we saw documentation to show that patient answers had been assessed by the ophthalmic surgeons. On the day of treatment, we found that

the patient's medical history was checked to confirm whether there had been any changes, to help ensure that treatment is provided in a safe way.

Dignity and respect

Without exception, all patients who completed a questionnaire told us that they either agreed or strongly agreed that staff were always polite, kind and sensitive when carrying out care and treatment. We found that the patient journey was carried out in a dignified and respectful manner. We were told that all patient consultations were carried out in individual consultation and/or assessment rooms, allowing for patients to discuss private and confidential information with staff without being overheard.

We were told that on the day of treatment patients would be supported through the treatment process by staff to help ensure they were comfortable throughout the process.

Patient information and consent

We found that patients were provided with comprehensive information prior to and post treatment, to help them make an informed decision about whether treatment was suitable for themselves. An initial appointment was held with an optometrist to assess whether a patient was suitable for treatment. This appointment also included a discussion about the risks and benefits of treatment, the treatment procedure and potential outcomes. Patients would also be provided at this stage with a consent form, which also included detail about the risks and benefits of treatment. Patients were also given an information pack, which included a profile of the surgeon, a patient guide and aftercare guidance.

Patients would also be required to attend a subsequent appointment with the ophthalmic surgeon prior to treatment, which included a surgical assessment and a further opportunity to discuss the treatment process and procedure. At this stage patients would be asked to confirm in writing that they consented to treatment. In line with professional standards, treatment would not be offered on the same day that patients signed consent. The service allowed for a seven day cooling off period between patients signing consent and starting treatment. This helped to ensure that patients had the time and opportunity to make an informed decision.

All patients that completed a questionnaire also agreed that they felt they had been given enough information about their treatment, including the risks, different treatment options available, the costs for services and after care

services. Patients confirmed in completed questionnaires that staff listened to them during their appointment.

Detailed information about treatments was also available on the service's website to help patients make an informed decision about their care.

Communicating effectively

A patients' guide and statement of purpose were available, and we found they contained all relevant information as required by the regulations. These were both displayed in the patient reception area for patients to peruse at their convenience.

Care planning and provision

We found that the service had a comprehensive consultation programme, which resulted in an effective care planning process for patients. All patients received an initial appointment with an ophthalmologist, which helped to determine a patient's suitability for treatment. This was followed by an appointment with the ophthalmic surgeon and finally an appointment with a patient adviser, to help provide any additional support and guidance to patients. We saw examples of information, guidance, consent forms and aftercare documents and we discussed the guidance shared verbally with patients at all stages of the consultation process, which also included discussions about the risks and benefits.

We found that the service maintained detailed individual patient records, which also demonstrated the above processes. The service maintained an overall treatment register, as required by the regulations and we advised that adverse reactions also needed to be included. The registered manager agreed to implement this change.

Improvement needed

The service should ensure that details of adverse reactions are included in the overall treatment register.

Equality, diversity and human rights

The service was located on the ground floor and was accessible to patients using wheelchairs and those with mobility difficulties; accessible toilets were also available. There was a hearing loop in reception for patients with hearing

difficulties, and we were told that the service is also able to arrange translation services for those patients whose first language is not English.

We were unable to see, however, that information for patients was available in large print. Given the potential for patients having reduced visual acuity we recommended that the service consider making large print information available.

Improvement needed

The service should consider making arrangements for patient information to be available in large print.

Citizen engagement and feedback

We found that the service had a range of processes in place for obtaining patient feedback about the care and treatment they received. After each appointment patients would be asked to complete an electronic questionnaire. We were told that any negative responses would be automatically highlighted to the registered manager to deal with and resolve any issues. There was a comments book available in reception for patients to complete providing their views on the services received. The comments book was left for new and /or returning patients to view. The service completed an overall assessment of patient feedback on an annual basis, and results were available for patients to read. We recommended that the service should also consider telling patients about any improvements made as a result of feedback provided. The registered manager agreed to do this.

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 that arrangements were in place to provide laser treatments in a safe and effective way.

Patient records were detailed and demonstrated the care and treatment provided.

The service had good arrangements in place to maintain hygiene standards.

There was an effective programme of audit activity to help ensure the service was meeting relevant standards.

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 practice.

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 safe to use.

We looked at some of the arrangements for fire safety. Servicing labels on the fire extinguishers showed they were serviced annually. Fire exits were signposted and we saw that fire risk assessments were carried out on an annual basis. We also saw certificates to show that staff had received fire safety training.

We saw that the service had equipment and drugs available for use in a patient emergency. We found that the service had processes in place to ensure that the equipment and drugs remained safe to use. We saw certificates to show that staff had received first aid training, with some staff having attended advanced life support training in addition.

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; without exception all of the

patients who completed a questionnaire strongly agreed that the environment was clean and tidy.

There were suitable facilities in place to allow for effective hand hygiene, and the service demonstrated a clear process for cleaning treatment areas and equipment between patients. We saw that there was an infection control policy in place and cleaning schedules were maintained to help evidence the cleaning undertaken. The registered manager told us that an annual audit is undertaken of the infection control arrangements with a view to identifying any practice improvement areas.

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

Safeguarding children and safeguarding vulnerable adults

The service is registered to treat patients from the age of 18 years; we were told that no children were allowed in the treatment rooms.

The service had an adult safeguarding policy in place, which provided all the relevant information and guidance for staff to use in the event of need. We saw certificates to show that staff receive training in adult safeguarding on an annual basis.

Medical devices, equipment and diagnostic systems

We saw certificates to show that all laser operators had received training on the use of the laser machines. We also saw certificates to show that all laser operators had completed the Core of Knowledge¹ training within the last three years.

We saw that there was a contract in place with a Laser Protection Adviser (LPA) and there were local rules detailing the safe operation of the machines, which had recently been reviewed. One member of staff was required to sign the local rules to ensure that they had read and understood them.

¹ Training in the basics of the safe use of lasers and IPL systems

The service had the support of a laser engineer employed by the company. We saw certificates to show that the laser machines had been serviced on a regular basis to help ensure they were safe to use. The registered manager described that daily testing and calibration of one laser machine is also carried out, and the records are sent to the laser engineer to check. The other laser machine is calibrated seven days prior to each treatment session, to again help ensure it is safe to use.

We saw that there were treatment protocols in place for the use of the laser machines that had been provided by a medical professional.

Improvement needed

The service must ensure that all staff sign a copy of the local rules to evidence that they have read and understood them.

Safe and clinically effective care

We saw that the treatment room had a lock on the inside of the door, which was used when treatment was ongoing. We also saw warning signs on the outside of the door to indicate when the machines were in use. We found that there were arrangements in place to securely store the keys to operate the machines, to help prevent unauthorised use.

We reviewed the documentation relating to the environmental risk assessment. We saw that the LPA had recently completed an updated risk assessment.

Participating in quality improvement activities

We saw that the service had a detailed audit programme in place to ensure that it was meeting relevant standards. We saw documentation to show that quality improvement activities included checks on the emergency equipment, treatment rooms, patient records, infection control arrangements, environmental hazards, staff training amongst others. An annual audit, overseen by the medical director, is undertaken to review the work of each surgeon to ensure that the treatments they provide are effective and safe.

Records management

We observed that there was good provision for safeguarding patient notes and data, which were being kept securely within 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.

We found that there was a clear and supportive management structure in place.

The service had a process in place to ensure that policies and procedures were updated on a regular basis and communicated to staff.

Staff had access to a wider range of training opportunities.

Governance and accountability framework

Ultralase Cardiff, is part of a larger group that provides eye care services across England and Wales. The registered manager is supported on a day to day basis by a small team of both clinical and non clinical staff. Senior management support is provided from the service's head office.

We saw that the service had a number of policies in place, which all had evidence of regular review. The service had a good system in place to ensure that staff would be informed of any changes to policies and procedures to keep them up to date.

We saw that team meetings were held on a monthly basis, and minutes produced as an outcome. We were also told that the service receives minutes from a number of senior management meetings, to help them keep informed about a wider range of issues.

The service had an up to date liability insurance certificate in place which was displayed in the patient waiting area.

We found that the service had a process in place to help ensure they were providing safe and effective treatment. We found that the service conducted six monthly audits of the ophthalmic surgeons as well as reviewing any complications or incidents through their compliance team. We were told that the

audit was based upon clinical guidelines outlined by the Royal College of Ophthalmology.

Dealing with concerns and managing incidents

We found that the service had a complaints procedure in place. We saw evidence that the service had a suitable process in place for dealing with, and recording complaints appropriately and demonstrated learning from any concerns or complaints raised.

We found that the service had a system in place for recording and managing any incidents, which would be reviewed accordingly and actions taken where appropriate.

Workforce planning, training and organisational development

We saw certificates to show that all laser operators had completed training in a number of areas, including the Core of Knowledge, and operator training for the laser machines. The service also had a comprehensive training programme in place to help ensure that staff have the right skills and knowledge to carry out their roles.

We saw evidence that staff receive regular appraisals, and personal development and training identified as a result of the discussions.

Workforce recruitment and employment practices

Whilst the service had not needed to recruit any new staff recently, the registered manager was able to describe a detailed induction programme should it be required. The registered manager also described a suitable recruitment process including appropriate pre-employment checks, should they need to recruit in the future. We found that all relevant staff had an up to date Disclosure and Barring Service (DBS) check in place.

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: Ultralase

Date of inspection: 12 April 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				
The service should ensure that details of adverse reactions are included in the overall treatment register.	8. Care planning and provision Regulation 23 (1)(a)	Further to the recommendation by HIW, we have added an addition comment column to our laser log book. This will enable us to document any issues in the treatment room when and if they happen. This will ensure no information is missed and the information can then be easily audited as it will be in one place as well as on individual patient files	Andrea Flowers – Registered Manager	In place
The service should consider making arrangements for patient information to be	2. Equality, diversity and	The Company has discussed this recommendation and has decided that it	Andrea Flowers – Registered	On going, available at

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
available in large print.	human rights Regulation 15(1)(a)	would not be cost effective as a business to reproduce our paperwork in large font. However, we do have an interpretation and translation policy in place to combat any communication issues we may encounter. Also we can allow patients to view our literature on a PC where the font can be increased, this can be in a private room	Manager	patient request
Delivery of safe and effective care				
The service must ensure that all staff sign a copy of the local rules to evidence that they have read and understood them.	16. Medical devices, equipment and diagnostic systems	We had overlooked one member of staff when signing the new Laser local rules. This has been rectified and the clinic records are complete, and our Compliance Department also has a copy	Andrea Flowers – Registered Manager	In place
Quality of management and leadership				
No improvements identified during this inspection.				

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): Andrea Flowers

Job role: Registered Clinic Manager - Cardiff

Date: 10 May 2018