

Independent Healthcare Inspection (announced)

Optical Express

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2019

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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 Optical Express on the 10 December 2019.

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

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

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

2. Summary of our inspection

We were assured that Optical Express was providing an effective service to its patients in an environment suitable for providing laser eye procedures.

The staff had appropriate skills and relevant knowledge to deliver safe procedures to patients.

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

Patient feedback was very positive with the majority of the patients rating the care and treatment that they were provided with as excellent or very good.

This is what we found the service did well:

- Patients were able to make informed decisions about their treatment due to the processes patients go through before the procedure is agreed by all parties
- Systems were in place to ensure patients were being treated as safely as possible
- Patient notes and records were maintained to a high standard
- All staff had up to date training, including on how to use the laser machines appropriately
- Effective arrangements were in place for infection prevention and control.

This is what we recommend the service could improve:

- To review policies and procedures to ensure they are relevant to Wales, citing Welsh regulations and standards, where applicable.

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

3. What we found

Background of the service

Optical Express is registered as an independent hospital to provide eye surgery using a laser at 24 Windsor Place, Cardiff, CF10 3BY.

The service was first registered with HIW on 21 June 2018.

The service employs a staff team which includes three employees; one of whom is the laser operator.

A range of services are provided to persons aged 18 - 70 years, which include:

- Class 3b Intralase FS Nd: Glass Laser for treatment of:
 - Corneal Flap creation
- Class 4 VISX Star IR Laser for the treatment of:
 - Laser Vision Correction.

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 the staff at Optical Express were committed to providing a positive experience for their patients. Patient feedback from HIW questionnaires rated the service as excellent or very good.

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

The service had appropriate arrangements in place to protect the privacy and dignity of patients during their consultation and procedure.

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.

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 or very good. Patient comments on the questionnaires included the following:

"Excellent customer service. Friendly staff, informative and helpful. Good aftercare and great facilities. Good biscuits and coffee!"

"Everything before the laser eye surgery helped reassure me that I was in very safe hands"

"The service I have received is excellent. Staff are always helpful and friendly. Facilities are excellent. I am always put at ease".

Health promotion, protection and improvement

Patients complete and sign a medical history form at their initial consultation and this is reviewed and discussed with the patient by an optometrist¹. Medical history is checked again at the preparation stage, before the patient receives their surgery.

We saw evidence of completed and signed medical history forms within patient records to confirm this approach. The majority of patients that completed a questionnaire also confirmed that they always complete a medical history form, or have their medical history checked, before undertaking any treatment. This follows best practice guidance and helps ensure treatment is safe and suitable for each patient.

Dignity and respect

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

Staff told us consultations with patients take place in private rooms to ensure that confidential and personal information can be disclosed without being overheard.

Staff confirmed that patients can have a chaperone attend their consultation, but they are reminded that personal information will be asked at this stage. Chaperones are not allowed in the treatment room.

Staff told us that they endeavour at all times to keep post and pre-treatment patients away from each other as much as possible to protect their confidentiality and dignity.

Patient information and consent

We were assured that patients were able to make an informed decision about their treatment. This is because patients are provided with face-to-face

¹ Optometrists are trained in the care of eye and visual system, including refraction, detection, and diagnosis and in some cases management of disease.

consultations and written information prior to any laser procedure taking place. All of the patients that completed a questionnaire agreed that they had been given enough information to help them understand the treatment options available to them and the risks and benefits associated with each treatment option. The majority of patients also told us that the cost of any treatment was always made clear to them before they undertook the procedure.

Every patient who completed a questionnaire confirmed that they were required to sign a consent form to evidence that they understood the associated benefits and risks before undertaking any treatment.

During the visit staff showed us the stages a patient has to complete and consent to before any laser procedure is agreed. Firstly, during the initial consultation there is a patient consent video which describes the risks and benefits of the procedure. Patients sign a declaration form to say they have seen the video.

Secondly, patients are provided with written information which they take home to read. The information covers the terms and conditions of the procedure and needs to be signed by the patient to evidence their acceptance of the terms and conditions.

A consent appointment is undertaken prior to surgery, which is carried out by the surgeon. The surgeon signs the relevant form to say they have discussed the information with the patient.

On the day of the surgery, both the patient and surgeon sign consent documentation.

Staff obtain patient consent at different stages throughout the process, but made it clear that a patient can withdraw their consent at any time.

Communicating effectively

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

All patients who completed a questionnaire also told us that the 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.

A detailed statement of purpose² was provided to us by the registered manager which we found contained the essential information as required by the regulations.

A patients' guide was available providing information about the service and included the areas required by the regulations.

Care planning and provision

As highlighted in the above sections, patients are provided with lots of information that they need to agree to before any procedure will be undertaken. This information is collected and used by the service to determine the most appropriate procedure for each patient.

All of the patients that completed a questionnaire told us that they had been given aftercare instructions about how to prevent infection and aid healing after the procedure. In addition, patients are provided with a face to face follow up appointment to ensure appropriate aftercare.

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

Equality, diversity and human rights

Optical Express occupies a number of floors in a building. The main entrance has a step to access the reception area, however, a side entrance provides access for anyone unable to climb the step. A lift ensures accessibility to all floors and all areas were accessible to anyone with a mobility difficulty and/or using a mobility aid.

² A statement of purpose is a legally required document that includes a standard set of information about a provider's service.

Citizen engagement and feedback

Patient feedback is obtained by the service through the completion of patient satisfaction questionnaires and via Google reviews. This ensures that current and prospective patients are informed about the quality of care being delivered by the clinic.

The majority of the patients who completed a questionnaire said that they were aware of being asked for their views about the service provided at Optical Express, for example, through patient questionnaires.

We saw that regular analysis of completed questionnaires (by the service) had been undertaken. This demonstrated that the provider had reviewed all comments and was using the analysis as a means to identify the areas that were working well, as well as using the data to highlight where changes may be required to improve the service.

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 met the relevant standards and regulations to ensure the health, safety and welfare of patients and people visiting the clinic. This was supported by a regular programme of audits and risk assessments, with any identified improvements used to improve the service.

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 staff had up to date training on the use of the machines.

The service was committed to providing safe and reliable care. The treatment room was visibly clean and tidy and staff were aware of the cleaning tasks required on a daily, weekly and monthly basis to ensure infection prevention and control standards remained high.

Managing risk and health and safety

Overall, we found suitable maintenance arrangements were in place to protect the safety and well-being of the staff and people visiting the premises. A building electrical wiring check had been undertaken within the last five years and Portable Appliance Testing (PAT) had been carried out to help ensure small electrical appliances were fit for purpose and safe to use.

Appropriate arrangements were in place to adequately protect the staff and people visiting the clinic in the event of a fire:

- A fire risk assessment had been undertaken
- Fire extinguishers were available throughout the premises and had been serviced within the last twelve months to ensure that the equipment worked properly
- Fire drills were carried out regularly and recorded in a logbook
- Fire exits were appropriately signposted.

Emergency equipment, including an Automated External Defibrillator, was available and regular checks were undertaken and recorded to ensure the equipment was in date and effective for use.

Staff told us that all staff were trained in basic and/or immediate life support and described the procedures staff will follow in the event of an emergency such as patient collapse.

Infection prevention and control (IPC) and decontamination

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

Staff described the infection control arrangements at the clinic which we found to be in line with best practice guidance and consistent with the procedures outlined in their infection control policies.

Staff told us of the procedures in place for the safe transfer and disposal of any hazardous (clinical) waste. Hazardous waste was being stored appropriately.

Safeguarding children and safeguarding vulnerable adults

Staff confirmed that the service complies with their conditions of registration to only treat patients aged 18 - 70 years.

We saw that a policy for the safeguarding of children and adults was in place which outlined the procedures to follow in the event of any safeguarding concerns. The policy folder also included the contact details of relevant local children and adult safeguarding agencies to ensure concerns are reported appropriately.

We saw certificates to confirm that all staff had received training in the protection of vulnerable adults and children.

Medical devices, equipment and diagnostic systems

Overall, we found suitable arrangements were in place to protect the safety of patients when receiving treatment from the laser machine/s at the service. This is because:

- The laser machines had been regularly serviced and calibrated in line with the manufacturer's guidelines to help ensure they perform consistently and as expected

- A treatment protocol setting out the procedures to follow to ensure treatment is delivered safely to patients was in place and had been overseen by an expert medical practitioner as required by the regulations
- A contract was in place with a Laser Protection Adviser (LPA) to provide expert advice on the safety of the laser installation and day to day operational use
- Comprehensive local rules³ developed by the LPA that detailed the safe operation of the laser machine were in place and had been signed by all staff including the laser operator to evidence their awareness and agreement to follow these rules.

Safe and clinically effective care

We saw evidence that the laser operator met the Medicines and Healthcare products Regulatory Agency (MHRA) requirements⁴ to be a competent user of the laser machine having completed the Core of Knowledge⁵ training and training by the laser machine's manufacturer on how to operate them safely.

We saw that eye protection glasses specific to the strength of the laser machines were available, but in line with the local rules, eyewear was not required for the procedures carried out by the service. Staff told us that the glasses, despite not being used were checked regularly for any damage.

No patients were being treated on the day of the inspection, but staff described the safety precautions taken when treatment is in progress; a warning sign on the outside of the treatment room door informs staff and/or the public of the risk of lasers being used inside the treatment room. A sign stating do not enter is illuminated when the room is being used for the procedures. The public do not

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

⁵ Training in the basics of the safe use of laser machines

have free access to the clinical areas without being accompanied by a member of staff due to the key coded doors. In addition, the laser machines are kept secure at all times to prevent unauthorised usage.

We saw evidence that the LPA had completed a risk assessment to identify any hazards associated with the use of the laser machines and the environment of the treatment room. The risk assessment had been reviewed by staff and the actions identified had been completed.

Participating in quality improvement activities

Optical Express had a programme of internal audits and assessments which they undertake to enable themselves to demonstrate best practice in providing vision correction procedures. Completed audits are submitted to head office and any improvements highlighted as a result of these are shared with the surgery manager to take forward and implement. Regular completion of audits and assessments contributes to the quality and safety of the care provided to patients.

Staff told us they had recently completed an audit tool in order to gain accreditation from The Association for Perioperative Practice (AfPP)⁶. Undertaking this work and on receipt of their accreditation, will provide assurance that the organisation are demonstrating their commitment to high standards of perioperative care.

Records management

We found that patient information was kept securely. Paper patient records were kept in a locked cabinet to prevent unauthorised access. Electronic notes were accessible via a member of staff's individual login details.

We saw evidence of comprehensive record keeping processes in place at the clinic, including detailed patient notes that were of good quality and a

⁶ The Association for Perioperative Practice is a British professional body for healthcare workers. Its stated aims include "the promotion of high standards of perioperative care, the exchange of professional information between members and co-operation with other professional bodies". It is a registered charity. <https://www.afpp.org.uk/home>

comprehensive patient treatment register, which supported the service to deliver quality patient care.

All records relating to the laser machines and environment of the building were well organised and easily accessible.

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.

Staff had the appropriate training and relevant knowledge to deliver safe treatment to patients.

The service had a wide range of policies and procedures in place. We have recommended that they are reviewed to ensure they are applicable to the Welsh standards and regulations.

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

Governance and accountability framework

Optical Express is owned by Optical Express Ltd. The day to day running of the practice is led by a surgery manager who is supported by a wider team of clinical and non clinical staff. We found the clinic to have clear lines of accountability and staff told us they understood their roles and responsibilities.

We found that the service had a number of policies in place which were accessible to staff and had been reviewed and updated regularly. In reviewing some policies, we noticed that they included references to organisations applicable in England. We recommended that they are reviewed and updated so Welsh regulations and standards are made clear for staff.

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

Improvement needed

The registered provider must review the policies and procedures to ensure they are appropriate and applicable for Wales and that the Welsh regulations and standards are clearly reflected.

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 was included within the statement of purpose and in the patients' guide. The complaints procedure was also displayed in the reception/waiting area of Optical Express.

Formal complaints are dealt with by head office and are regularly reviewed to help identify any themes that could be used to improve services.

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

Workforce planning, training and organisational development

Staff had a mandatory training programme in place which ensured they maintained their skills and knowledge in a number of areas including safeguarding.

As mentioned earlier within the report, we saw certificates showing that the operator/s of the laser machines, had completed the Core of Knowledge training and had also completed training on how to use the laser machines.

Head office provides a central service to support the surgery manager in ensuring all workforce planning, training and organisational development activities are delivered.

Staff attend daily team briefings so everyone is aware of the forthcoming day's events. In addition, there are regional staff meetings. These all contribute to ensuring staff are kept up to date with local and corporate information.

Workforce recruitment and employment practices

Staff confirmed that the head office recruitment team are responsible for all recruitment and employment practices. Staff told us the information that is obtained for new starters which includes references.

We saw evidence that all staff 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. Staff told us DBS certificates would be renewed every three years, which we recognise as good practise.

All new starters receive an induction and we saw evidence of completed induction check sheets. Staff are inducted in various areas and are provided with shadowing opportunities before staff sign them off as competent in that area.

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: Optical Express

Date of inspection: 10 December 2019

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

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
Quality of the patient experience				
No areas of improvement identified at this inspection				
Delivery of safe and effective care				
No areas of improvement identified at this inspection				
Quality of management and leadership				
The registered provider must review the policies and procedures to ensure they are appropriate and applicable for Wales and that the Welsh	Regulation 19 (1) (a)	Review policies to ensure references and procedures reflect Welsh regulations. One policy affected.	Mary Spellman	31/01/2020

Improvement needed	Regulation/ Standard	Service action	Responsible officer	Timescale
regulations and standards are clearly reflected.				

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): Mary Spellman

Job role:

Date: 23/01/2020