

Visualase Laser Eye Clinic

Quality Report

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Bolton

Lancashire

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Date of inspection visit: 1 May 2019, 8 May 2019

Date of publication: 17/07/2019

This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Good



Are services safe?

Good



Are services effective?

Good



Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Good



Overall summary

Visualase Laser Eye Clinic is operated by Visualase Laser Limited and provides refractive eye surgery for self-funded patients over the age of 18 years. The clinic was established in September 2001 and uses laser technology to correct refractive errors such as myopia, hyperopia and astigmatism to reduce patients' need to use visual aids to see clearly.

The facilities included a reception area, two assessment rooms, a consultation room, a theatre suite and recovery room. In addition to these rooms there was an

administration office and toilet facilities that were designed for use for people with disabilities. There were no inpatient facilities and no children were treated at the clinic.

We inspected this service using our comprehensive inspection methodology. We carried out a short-announced inspection on 1 and 8 May 2019.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services:

Summary of findings

are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

At the previous inspection in 2017, we had a legal duty to regulate refractive eye surgery services, but we did not have a legal duty to rate these services. However, we now have the powers to rate services provided and continue to highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- Staff were 100% compliant with their appraisals and competency checks.
- The service used the World Health Organisation safer surgery checklist to reduce the risk to patients during refractive eye surgery procedures.
- Staff spoke to patients throughout their procedures as recommended by the Royal College of Ophthalmology professional standards for refractive eye surgery.
- Staff kept comprehensive records, and these were stored securely.
- There were systems in place to ensure that the laser was used safely. Local rules were displayed and adhered to by all staff.
- There were systems for the maintenance of equipment. Service level agreements were in place and in date with external organisations.

- Medicines were stored safely, and staff followed infection control protocols when handling cytotoxic medications.
- All patients were assessed for their suitability for refractive eye surgery.
- There was a clear procedure for obtaining patient consent.
- All patients, their families and friends were treated with privacy, dignity and respect. We observed that staff were kind and compassionate whilst delivering care and treatment.
- Patients we spoke with were happy with the service provided and the care received. Patient feedback was always positive about their experience and patients would recommend friends and family to receive care and treatment at the clinic.

However, we found the following issues that the service provider needs to improve:

- Hand hygiene was not audited at the time of inspection.
- Not all theatre staff were trained in the process of aseptic non-touch technique.
- There was no approval process or review process of the risk register by any other member of the team than the registered nurse.

Following this inspection, we told the provider that it should make other improvements, even though a regulation had not been breached, to help the service improve.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating

Good



Summary of each main service

Refractive eye surgery was the main activity of the service. We rated the service as good overall because it was safe, effective, caring, responsive and well-led.

Summary of findings

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Good 

Location name here

Services we looked at:

Refractive eye surgery

Summary of this inspection

Background to Visualase Laser Eye Clinic

Visualase Laser Eye Clinic is operated by Visualase Laser Limited. The clinic primarily served the communities of Bolton in Lancashire; however, patients were accepted from outside of this area for laser refractive eye surgery.

The service provided refractive eye surgery for adult patients who self-funded their care and treatment. No NHS funded work was completed at the clinic.

Regulated activities for the service were diagnostic and screening procedures; surgical procedures and treatment of disease, disorder and injury.

The service had a registered manager in post since 2011 and they had also been employed with the service since 2001.

The service was inspected in 2017 and during this inspection we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We were assured that all the improvements that we told the provider should be completed were actioned.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and another CQC inspector. The inspection team was overseen by Judith Connor, Head of Hospital Inspection.

Information about Visualase Laser Eye Clinic

Visualase Laser Eye Clinic is a private independent clinic based in Bolton town centre providing laser-assisted in situ keratomileusis (LASIK), laser-assisted sub-epithelial keratectomy (LASEK) and transepithelial photorefractive keratectomy (TransPRK) refractive surgery for the correction of myopia, hyperopia and astigmatism. The location of the clinic was served well by public transport and there was ample car parking close to the facility.

During the inspection we spoke to the registered manager, receptionist, optometrist, theatre assistant, registered general nurse and the consultant surgeon. We also spoke to three patients and reviewed six sets of patient records.

There were no special reviews or investigations of the service ongoing by the Care Quality Commission at any time during the 12 months before this inspection. The service was last inspected in 2017.

In the 12 months preceding the inspection, there had been no never events or serious incidents reported. Never

events are serious, largely preventable patient safety incidents which should not occur if available preventative measures have been put into place by healthcare providers.

In the 12 months preceding our inspection, there was one complaint which had been investigated and resolved at the time of inspection.

There were six permanent members of staff, including the registered manager, employed in the clinic. In addition to this, there was one consultant who was employed under practising privileges and one consultant had recently retired in December 2018. Practising privileges is a well-established process within independent private practice, or within the provision of community services.

The registered general nurse was accountable for medicines management. There were no controlled drugs on the premises.

Activity

Summary of this inspection

- In the period January to December 2018. There were 209 Laser-Assisted in Situ Keratomileusis (LASIK) treatments, 24 Laser-Assisted Subepithelial Keratomileusis (LASEK) treatments and 36 transepithelial photorefractive keratectomy (TransPRK) treatments.
- In LASIK procedures a cut is made across the cornea by either a special machine (microkeratome) or a special laser (ferntosecond) to raise a flap of the cornea. The exposed surface is then sculpted using the laser and the flap is replaced. This results in tissue being removed from the middle layers of the cornea (stroma).
- In LASEK procedures the surface layer (epithelium) of the cornea is retained as a flap. A special soft contact lens is kept on the eye for three to four days to allow the surface to heal. Retaining the epithelium is thought to prevent later complications of haze and speed up healing.

- In TransPRK procedures the eye is not touched with any instrument. The laser removes the epithelium, without suction, flap or blade.

Services accredited by a national body:

- None of the services were accredited by a national body

Services provided at the clinic under service level agreement:

- Clinical and or non-clinical waste removal
- Laser protection services
- Sterilisation of surgical equipment
- Maintenance of laser equipment
- Air conditioning and humidity
- Uninterrupted power supply
- Fire prevention

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated it as **good**.

Good



We found the following areas of good practice:

- Staff knew how to report incidents and safeguarding concerns. Incidents were investigated thoroughly.
- Staff used the five steps to safer surgery outlined by the World Health Organisations safer surgery checklist for all procedures. This was an improvement since the last inspection.
- Staff followed infection prevention and control guidance. We saw that staff washed their hands and cleaned equipment thoroughly.
- Staff kept comprehensive records regarding patient care and these were stored securely.
- Staff followed best practice when handling medications, including cytotoxic medicines. All medicines were stored securely, and the stock managed safely.
- Patients were assessed for their suitability for treatment using the Royal College of Ophthalmology standards.

However, we found the following issues that the provider needs to improve:

- Although we observed staff washing their hands, there was no documented audit to state that this was a continual process.
- Although theatre staff underwent scrub competencies, there was no training for the process of aseptic non-touch technique for clinical procedures.

Are services effective?

We rated it as **good**.

Good



We found the following areas of good practice:

- The service provided care and treatment based on national guidance and evidence-based practice.
- Staff ensured that patients undergoing laser refractive eye surgery had an appropriate pre-operative assessment and opportunity for discussion regarding their care and treatment as set out in the General Medical Council guidance for doctors who offer cosmetic surgery.

Summary of this inspection

- Staff participated in appraisals and competency checks.
- Treatments given, and enhancements carried out by the ophthalmologists were monitored by the registered manager to measure their performance.
- Staff empowered patients to manage their own health and to take responsibility for their aftercare treatment.

Are services caring?

We rated it as **good**.

We found the following areas of good practice:

- The consultant ophthalmologist and staff spoke to patients throughout the procedures as recommended in the Royal College of Ophthalmology professional standards for refractive eye surgery.
- We observed that staff were highly motivated to deliver good care to patients and their families consistently. We observed staff talking and listening to patients with dignity and respect.
- We observed staff explaining treatment options, including benefits and risks to patients. In addition to this, we observed staff ensuring that the patient demonstrated their understanding of the explanations given. This was in line with the Royal College of Ophthalmology professional standards for refractive eye surgery and the National Institute for Health and Care Excellence (NICE) Quality Statement 15, statement five.

Good



Are services responsive?

We rated it as **good**.

We found the following areas of good practice:

- The service planned and provided care in a way that met the needs of local people and the communities served. The clinic was easily accessible from the town centre and close to public transport links.
- The waiting areas within the clinic were bright, spacious and comfortable. Treatment areas were arranged so that the patient journey from admission in reception to discharge from the consultant flowed with ease.
- People could access the service when they needed it and received the right care promptly.

Good



Summary of this inspection

- It was easy for people to give feedback and raise concerns about care received. Staff learned from complaints and shared this learning via discussion and emails.

Are services well-led?

We rated it as **good**.

We found the following areas of good practice:

- There was a clearly defined leadership structure.
- Staff we spoke with told us that they felt supported and valued. All staff were proud of the service and many had worked for the service for a long time.
- The safety and quality of the patient pathway was monitored by the registered manager.

However, we found the following issue that the provider needs to improve:

- The risk register was reviewed annually by the registered general nurse, but we saw no approval process or review by any other member of the team.

Good



Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Refractive eye surgery	Good	Good	Good	Good	Good	Good
Overall	Good	Good	Good	Good	Good	Good

Refractive eye surgery

Safe	Good 
Effective	Good 
Caring	Good 
Responsive	Good 
Well-led	Good 

Are refractive eye surgery services safe?

Good 

Mandatory training

- The service provided mandatory training in key skills to all staff and made sure everyone completed it. All staff were 100% compliant in all areas, for example basic life support, anaphylaxis, fire safety, core of knowledge (laser training) and safeguarding (see safeguarding section). The completion rate of basic life support training had improved since the last inspection.
- Staff told us that they were aware of what training was available and when they needed to complete it by. They told us that the registered manager was supportive and encouraged them to complete the training and remain up to date with their training needs.

Safeguarding

- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff told us that they knew who to contact if they had any concerns.
- All staff in the service were trained to safeguarding level one and the registered manager, nominated individual, optometrist and the ophthalmologist were trained to safeguarding level two. This met with intercollegiate guidance (2019) which states all staff working in healthcare services require training at level one and all non-clinical and clinical staff who may have contact with adults, children and young people must hold level two training. This was an improvement since the last inspection.

- No patients in the service were treated under the age of 18 years.
- There were systems and processes in place to keep patients safe immediately following their procedure. The registered general nurse and the theatre assistant looked after the patient in the recovery area.

Cleanliness, infection control and hygiene

- The service controlled infection risk well. Staff kept equipment and the premises clean. They used control measures to prevent the spread of infection.
- The service had an infection control policy that was in date and incorporated the code of practice from the Health and Social Care Act 2008. This was an improvement since the last inspection.
- A register of post-operative infections was maintained by the registered manager that included patient details, the treatment date, the infections and action taken. There had been no incidences of infection since 2011 and since the clinic opened in 2001 there had only been four incidences in total.
- There had been no healthcare acquired infections in the 12 months prior to the inspection.
- There were no incidences of methicillin-resistant *Staphylococcus aureus* (MRSA) or methicillin-sensitive *Staphylococcus aureus* (MSSA) for the 12 months prior to the inspection.
- There were systems in place to ensure that the environment and equipment used for patient care were clean. We reviewed cleaning schedules which demonstrated that all areas were cleaned daily. Chairs in the reception area and recovery room were wiped clean with a detergent wipe.
- Clinical areas had flooring which was washable and compliant with the Department of Health and Social Care Health Building Note (HBN 00-10).

Refractive eye surgery

- Surgical instruments were sent to an external company for decontamination and sterilisation. We saw a service level agreement in place for this. Accessory items marked as single use were used in accordance with the Medicines and Healthcare products Regulatory Agency (MHRA 2013). We checked a sample of five single use items and found them to be within the manufacturers' expiry dates and stored in chronological order.
- We observed staff following the service infection control guidelines regarding the cleaning of diagnostic equipment between patients use. Personal protective equipment was used and disposed of following single use.
- We observed staff with arms bare below the elbow during each patient's treatment.
- We observed staff using effective hand washing techniques which was in line with the National Institute of Health and Care Excellence, Quality Standard 61, Quality Statement 3. However, hand hygiene was not audited at the time of inspection. We raised this with management and were told that unannounced observations of each other would now be implemented to ensure good practice was maintained.
- We observed the theatre assistant and the registered general nurse preparing the treatment trolley for the surgical procedure. We observed good aseptic non-touch technique being used. However, we did not see evidence of this procedure in the training records we reviewed. We raised this with management and were told that theatre staff undergo theatre scrub competencies but other staff who occasionally help in theatres do not. We were told by the registered manager that aseptic non-touch technique training would be implemented post-inspection to ensure best practice was maintained. Aseptic non-touch technique is used during clinical procedures to identify and prevent microbial contamination of aseptic parts and sites by ensuring that they are not touched either directly or indirectly.
- There were hand gel sanitisers available in the all areas of the clinic environment.
- Laser refractive eye surgery was performed in a theatre suite with an airflow system that minimised the spread of airborne infection. Humidity conditions in the operating theatre were maintained consistently within range and we saw evidence of this on each of the patient records we reviewed.

Environment and equipment

- The design, maintenance and use of facilities, premises and equipment kept people safe. Prior to refractive eye surgery commencing we observed the registered general nurse set up and calibrated the equipment according to the manufacturer's instructions. This ensured that the laser was in the expected ranges prior to usage.
- The service had a tracker system for monitoring when services and maintenance was due. For example, air conditioning, uninterrupted power supply, fire alarm and public and employer's liability. All were serviced and in date.
- The service had recently purchased a new laser and we saw a contract for the services of a laser protection advisor who was responsible for compiling the local rules for the service.
- The registered general nurse was the laser protection supervisor for the service and attended every surgical list. We were told that in her absence a deputy would step in to ensure that all local rules were followed. Because the service had a small team, all staff in the clinic were trained on the use of the laser so that they could attend the theatre in the absence of the registered general nurse.
- The theatre suite was set up to mitigate the safety risks associated with laser treatment and complied with guidance issued by the Medicines and Healthcare products Regulatory Agency. The laser-controlled area was clearly defined, and warning notices were clearly visible when in operation.
- The temperature and humidity in the theatre suite was recorded on the nursing record treatment sheet at the time of the patient's procedure. All the records we reviewed demonstrated that the temperatures and humidity were in the safe ranges in accordance with the manufacturer's guidance. In addition to this, the laser fluence parameters were in range in all the records that we looked at. These parameters were recorded to monitor the functioning of the laser.
- The clinic included a reception area, two assessment rooms, a consultation room, a theatre suite and recovery room. Toilet facilities were available and were designed for patients with a disability. The toilet had an emergency cord button which was working. In addition to these areas, there was an office and storage areas on the first floor which could only be accessed by staff.

Refractive eye surgery

- Fire exits were clearly signposted and fire extinguishers had been serviced and were in date. We saw that there was a service level agreement in place for fire prevention to check alarms and equipment.
- The service had agreements with external companies for the sterilisation of equipment, maintenance of laser equipment, air conditioning and humidity and uninterrupted power supply (UPS). All were in date.
- The theatre suite had separate bins for the disposal of clinical and domestic waste. This was in line with the control of substances hazardous to health (COSHH) regulations 2002.
- Cytotoxic removal was carried out quarterly via an external party. We reviewed the service level agreement with the external party for this process. Cytotoxic drugs are a group of medicines that contain chemicals which are toxic to cells, preventing their replication or growth.
- Sharps bins were labelled, signed and dated which was in line with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013.

Assessing and responding to patient risk

- Staff completed and updated risk assessments for each patient and removed or minimised risks. They kept clear records and asked for support where necessary.
- The patient's initial assessment was completed by the optometrist who examined the patient's eye, or eyes, to detect defects in vision, signs of injury, ocular disease or abnormality. Within the assessment general health was explored and questions were asked if there were any health problems, such as diabetic retinopathy, epilepsy or high blood pressure.
- Following the initial assessment, a consultation took place with an ophthalmologist. We reviewed six consultations in patients' records and noted that a thorough assessment was completed that included past ocular history, family ocular history, past medical history and allergies.
- The admissions form was completed by a patient advisor on the patient's arrival to the clinic. Details were confirmed with the patient on which eye, or eyes, were to be treated and what procedure was due to be undertaken. This was reconfirmed with the patient by the treating ophthalmologist during the pre-surgical assessment.
- Prior to the patient entering the theatre suite, the consultant ophthalmologist, registered general nurse

and theatre assistant completed verbal checks against the theatre list for the day and the patient's admissions record as recommended by the Royal College of Ophthalmologists standards for refractive eye surgery.

- The service had a marking the surgical site policy which was adhered to for every surgical procedure. We were told by the consultant ophthalmologist that surgical sites were only marked when carrying out procedures on one eye. During bi-lateral eye procedures the areas were not marked but it was standard practice to treat the right eye first. The laser machine defaulted to the right eye first which was an additional safety check for staff before carrying out refractive eye procedures.
- We observed that once the patient was made comfortable on the theatre trolley, all details were again confirmed by the surgical team. The service used a sign in and a sign out checklist which was in line with the five steps to safe surgery World Health Organisation checklist. This was an improvement since the last inspection.
- Following surgery, patients were escorted to the recovery room. The recovery room was dimly lit and decorated so that the patients felt comfortable. Armchairs were available as the patients had to remain in the room for approximately 30 minutes following the procedure. Patients were asked if they wanted their family member or friend for company in the room. An emergency call bell was in the recovery room; this was tested at the time of inspection and was working.
- From the recovery room, patients were seen in the adjacent consultation room where the ophthalmologist checked their eye, or eyes, before discharge. Aftercare advice was given by the ophthalmologist and a full explanation of how and when to use the prescribed eye drop medication. Written information was also given that included contact details for advice if required, a 'dos and don'ts' list for general guidance (for example, do administer your eye drops as prescribed and don't rub your eyes). Twenty-four-hour contact details were given to the patients in case of emergencies for any concerns they may have. All patients were seen in clinic for a review by the consultant the following day.
- The service had a first aid kit located in the administration office. Resuscitation equipment was not available; if there was an emergency, staff would dial

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999 for the emergency services. The service had an anaphylaxis kit to treat a patient should they have an allergy. This was an improvement since the last inspection.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service had planned staffing levels to keep patients safe. The team was small and did not need the use of a staffing tool to plan staffing numbers. The registered manager and the nominated individual worked at the clinic full-time.
- There was always an optometrist and a patient advisor on-site during clinic hours.
- There was an ophthalmologist on-site two to three times per week. One ophthalmologist retired in December 2018 and there were plans to recruit to their post.
- There had been no sickness for staff in the three months prior to the inspection.
- There were no bank or agency staff used at the clinic. All staff had been employed for many years, the majority since the opening of the clinic in 2001.
- There were no locum staff used at the clinic.
- There was a service level agreement for the laser protection service. A laser protection advisor visited the clinic every three years to complete a risk assessment. Staff could telephone the laser protection advisor for advice when required.

Records

- Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.
- Patient records were paper based and stored securely in a locked cabinet in the administration office. Access could only be gained by staff.
- Patient records were completed in accordance with the General Medical Council guidance for services that offer cosmetic surgery. We reviewed six patient records and all included consultation forms, pre-operative assessments, consent forms, treatment records and post-operative follow up correspondence.
- The service had a records management policy which outlined details on the implementation and storage of

patient records. In addition to this, it outlined that the notes would be available to the patient in accordance with the request for information outlined by the Data Protection Act 2018. A patient handout about this was available on request.

- We reviewed a records audit for the period up to April 2019 which highlighted that mitomycin had not been recorded on some patient treatment sheets. This was addressed by the registered manager and actioned by email and discussion with all staff in the service.
- It was standard practice that all patients treated had a letter sent to their GP detailing the procedure that they had undergone; what eye drops they had been issued with and what was the routine aftercare review intervals. The patient had the option to have no correspondence sent to their GP which they had to indicate on their consent form.

Medicines

- The service used systems and processes to safely prescribe, administer, record and store medicines.
- There had been no reported medicine incidents in the 12 months before the inspection. Medicines management was audited by the registered manager and no notable concerns had been identified. We reviewed the service medicines policy which was in date.
- There were processes for managing and storing medicines in the theatre areas. We reviewed the storage process of the drug 'diazepam'. This was locked in a lockable tin within the locked medicines cabinet. We observed that a signing in and signing out book was used to record the dispensing and ordering of this medication. All were checked and correct at the time of inspection.
- We checked an anaphylaxis kit that was in the theatre environment. The box had a checklist to ensure all sundries were present and a crib sheet for staff to follow when making up the adrenaline medication. We checked the box against the list and all items were present and within the manufacturer's' expiry dates. Two 2ml syringes were missing and one vial of adrenaline; these items were re-stocked at the time of inspection.
- We checked the fridge temperatures and observed that these were checked daily to ensure that the temperatures were maintained between two and eight degrees Celsius. The range was not recorded, only the

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temperature at the time of checking. Staff told us that if the temperature was out of range then the medicines would be destroyed. We observed that only eye drops, and topical anaesthetic eye drops were stored in the fridge and that the fridge was locked securely with a padlock and the key kept in a locked cupboard. An emergency storage of medicines was held in an adjacent storage room and if these were unavailable due to unforeseen circumstances then the medicines could be obtained from the local pharmacy on a private prescription signed by the ophthalmologist.

- The service had a strong link with the local pharmacy and had used their services for numerous years.
- The service did not use intravenous sedation and treatments only used local anaesthetic drops. Prior to laser treatment, anaesthetic drops were administered. These were prescribed by the ophthalmologist and administered by the theatre assistant under supervision of the registered general nurse.
- The service had a discarding drugs policy which set out the procedure for storing the drugs until they were ready for collection from an external party. A log of disposed drugs was evident, and all were signed and dated.
- The use of cytotoxic medicines was well managed. There was a protocol for the preparation of mitomycin and we observed that all staff had signed and dated it to demonstrate that they had read and understood the guidance.
- Medicines were given to patients to take home following their procedure. Labels with the patients details and the name of the eye drops being given were written out by the administration staff as per the prescription written by the consultant. The medications were then dispensed by the registered general nurse and checked by the consultant prior to them being given to the patient on discharge from the service.

Incidents

- The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team.
- There had been no serious incidents and no never events during the 12 months prior to our inspection. A never event is a serious incident that is largely preventable, and of concern to both the public and health care providers for public accountability.

- We were told that three incidents had occurred in the period February 2018 to April 2019. We reviewed the incidents and their outcomes and noted that lessons learnt had been shared between the whole team.
- The registered manager and staff were aware of the duty of candour and their responsibilities for this. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or their relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. There had been no incidents that met the threshold for the duty of candour in the 12 months prior to our inspection.
- The registered manager reviewed all National Patient Safety Alerts (NPSA) and Medicines and Healthcare products Regulatory Agency (MHRA) alerts. These were emailed and discussed verbally with all staff.

Are refractive eye surgery services effective?

Good 

Evidence-based care and treatment

- The service provided care and treatment based on national guidance and evidence-based practice.
- Policies were reviewed every three years unless changes were required within the review period.
- The consultant ophthalmologist cascaded any training learnt from external parties to staff in the service. In addition to this, we were told that any changes or new practices within the field of ophthalmology would be brought into the service to ensure patient and staff safety was maintained.
- Patients were supported by staff to understand the various treatment options available to them, including the risks and benefits of the procedures. This was in line with the National Institute of Health and Care Excellence (NICE) Quality Statement 15, statement five on understanding treatment options and the Royal College of Ophthalmologists professional standards for refractive eye surgery.
- Health and Safety Executive guidance was followed on the control of artificial optical radiation at work regulations 2010. This was evident in the operating procedures we reviewed within the theatre suite.

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- Staff ensured that patients undergoing laser refractive eye surgery had an appropriate pre-operative assessment and opportunity for discussion on their care and treatment as set out in the General Medical Council guidance for doctors who offer cosmetic surgery.
- Policies and protocols were stored in a file in the administration office. These were easily accessible for all staff. We observed a sign-off process to ensure that staff had read the latest document.

Nutrition and hydration

- Staff gave patients hot or cold drinks following their surgery.

Pain relief

- Staff assessed and monitored patients regularly to see if they were in pain during the procedure.
- Staff informed patients that they may feel uncomfortable following the procedure. The ophthalmologist and the registered general nurse advised the patients to take their preferred choice of simple analgesia if they had some pain when they got home.

Patient outcomes

- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieve good outcomes for patients.
- The registered manager monitored the individual performance of the ophthalmologists, for example, the total number of treatments given, treatment types and enhancement rates. Enhancements are follow up procedures that are sometimes performed if the outcome of the original vision correction surgery is unsatisfactory or the patient's vision has changed significantly over time. Of the 257 eyes treated in the year 2018, 18 eyes, which equated to 7% of the procedures required enhancement surgery.
- The service carried out an audit for flap complications. The LASIK procedure involves the creation of a hinged flap on the front surface of the cornea. This is lifted during surgery for laser reshaping of the eye. For the period April 2018 to April 2019, there had been one flap complication which was due a patient rubbing their eye in the post-operative period.
- There had been no infections for the period April 2018 to April 2019.

- We reviewed an audit that had been completed by the consultant ophthalmologist on refractive and visual outcomes. However, this audit was not recent, but we were told that a prospective audit was to be carried out on myopia and hyperopia separately to look at the accuracy, healing response and regression rates. This would be carried out following the inspection.

Competent staff

- The service made sure staff were competent for their roles. Managers appraised staff's work performance and the registered general nurse held supervision meetings with the theatre assistant to provide support and monitor the effectiveness of the service.
- Appraisals and validation of professional registration had been completed for all staff within the service.
- All staff had completed core of knowledge training delivered by the laser protection advisor. This had been carried out in March 2018 and was valid for three years. We saw certificates awarded to staff to demonstrate that the training had been completed. Staff had signed a statement sheet to demonstrate that they had read and understood the local rules compiled by the laser protection advisor.
- We observed up-to-date certificates held by the laser protection advisor on the safe use of the laser.
- Two ophthalmologists held certificates from the Royal College of Ophthalmology in laser refractive surgery.
- Competencies for both surgeons were completed as part of their continuing professional development and were monitored by the Royal College of Ophthalmology.
- We reviewed both personnel files of the consultant surgeons and all documentation was available to review, including certificates and passport details. Both consultants were registered on the General Medical Council Specialist Register in Ophthalmology and held the CertLRS exit level qualification as per the Royal College of Ophthalmology guidance for surgeons.
- The two optometrists were registered with the General Optical Council and were members of the Northern Optometric Society. All competencies were completed and up-to-date.
- The optometrists were required to complete continuous education training annually within their field of expertise. Without completion of this they were not be able to register with the General Optical Council.
- We reviewed the theatre assistant's personnel file and saw a competency checklist for assisting as a scrub

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nurse during procedures. This enabled the theatre assistant to assist the surgeon during procedures if the registered general nurse was off sick. These competencies were reviewed annually.

- All staff had been employed in excess of ten years within the service. However, should any new staff be employed we were told that an induction programme would be carried out.

Multidisciplinary working

- Doctors, nurses and other healthcare professionals worked together as a team to benefit patients.
- GP details were taken from patient's with their consent, when they proceeded to treatment. This allowed the sharing of information and also ensured that the service was in line with the General Data Protection Regulation (GDPR) 2018.
- During our observations in the theatre suite, we observed that staff worked well together, and all were appreciative of each other's roles.

Seven-day services

- The clinic was open six days per week. Monday, Tuesday, Thursday and Friday from 9am to 5.30pm; Wednesday 9am to 8pm and Saturday 9am to 3pm.
- There was an out of hours telephone number for the on-call optometrist. In addition to this, every patient was given the mobile telephone number of their ophthalmologist in case of emergencies.
- The service had a 24-hour contact number for the ophthalmologist so that they could be called upon at any time for advice from either of the patient advisors or optometrists. This was outlined in the urgent/emergency treatment and adverse reactions to drugs policies.

Health promotion

- The clinic provided a service for refractive eye laser surgery only. This service did not include general health promotion based upon the national priorities to improve the health of the population.
- Staff empowered patients to manage their own health and to take responsibility for their aftercare treatment.
- The consultant ophthalmologist and nursing staff supported patients to be independent by teaching them to administer their own medicines following the procedure.

- Advice was given to every patient on how they could achieve the best outcome during and after the procedure, as recommended in the Royal College of Ophthalmology standards for refractive eye surgery.

Consent and Mental Capacity Act

- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. Only patients who could give informed consent for the procedure were accepted for refractive eye surgery.
- Patients were given opportunities to change their mind throughout the patient pathway. Written information about the treatment options and a paper copy of the consent form were given to each patient to take home to read.
- A cooling off period of seven days or more was given to patients between the procedure recommendation and surgery. This adhered to guidelines published by the Royal College of Ophthalmology. No patients were ever consented on the day of treatment.
- Staff gave detailed verbal and written information about all risks, benefits, realistic outcomes and costs of treatments. The consent forms clearly explained the risks of using cytotoxic medicines in refractive eye surgery.
- The consultant ophthalmologist ensured that patients had capacity to consent for refractive eye surgery. In the pre-assessment patient questionnaire, patients were asked if they had any medical conditions or were taking any regular medication.
- Patients were offered a range of options for treatment as alternatives to refractive eye surgery. During the initial consultation, the optometrist offered patients treatments such as corrective eye wear.

Are refractive eye surgery services caring?

Good 

Compassionate care

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

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- Feedback from patients in the patient feedback questionnaire was all positive with comments that staff were great, caring and reassuring. All patients said that staff made them feel at ease and that staff were always friendly and approachable.
- We observed that staff were highly motivated to deliver good care to patients and their families consistently. We saw that staff introduced themselves to the patient and continually used eye contact when speaking to them. This was in line with guidance from the National Institute for Health and Care Excellence (NICE) Quality Statements one, two and three.
- We observed the consultant ophthalmologist talking with patients during the surgical procedure and explaining what sensations they may feel. This complied with the Royal College of Ophthalmology professional standards for refractive eye surgery.
- We reviewed feedback from patients about staff; all comments were positive and stated that staff were great, caring and reassuring.
- We also reviewed feedback on the surgeons, all of which ranged from good to very good.

Emotional support

- Staff provided emotional support to patients. When patients expressed anxiety regarding their surgery, we observed staff giving verbal reassurance in a kind and gentle manner.
- We observed that the theatre assistant stood by the patient during the procedure and with prior consent from the patient to their surgery, the assistant would hold their hand if they became anxious.

Understanding and involvement of patients and those close to them

- Staff supported and involved patients to understand their condition and make decisions about their care and treatment.
- We observed staff explaining treatment options, including benefits and risks. This was in line with the Royal College of Ophthalmology professional standards for refractive eye surgery and the National Institute for Health and Care Excellence (NICE) Quality Statement 15, statement five.

- Patients told us that they felt comfortable asking questions and staff were always very helpful. In addition to this, patients told us that if they attended with their family, staff always spoke to them and made them feel comfortable.
- We observed patients being given transparent and accurate information about all the costs involved for the procedure. This was in line with regulation 19 of the Care Quality Commission (CQC) registration regulations 2009.

Are refractive eye surgery services responsive to people's needs?

Good 

Service delivery to meet the needs of local people

- The service planned and provided care in a way that met the needs of local people and the communities served. The clinic was easily accessible from the town centre and close to public transport links.
- We were given an example of how changes were implemented quickly. For example, one of the ophthalmologists changed the artificial tears they prescribed to patients to a product that was preservative free. This was provided to patients within less than two weeks of the request.
- The service ensured that all patients received the necessary information and clear explanations of what to expect before the day of surgery. Patient information leaflets were given with instructions on what to do before, during and following treatment.
- The recovery room had four comfortable chairs for patients to relax on following their surgery. The room had low lighting as patients would be sensitive to light following the procedures. The room had home comforts; for example, music if required and pictures on the wall to make it feel homely.

Meeting people's individual needs

- The service was inclusive and took account of patients' individual needs and preferences.
- We saw in patient records that each patient was treated individually. The consultations were performed by the ophthalmologist and the treatment was tailored towards the patient's refractive needs and desired

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outcome. For example, we saw a patient record of a patient who had presbyopia. Presbyopia is a condition associated with the ageing of the eye that results in progressively worsening ability to focus clearly on close objects. The patient record demonstrated that their treatment needed was tailored individually to the patient's prescription, age and near vision requirements.

- The waiting areas within the clinic were bright, spacious and comfortable. Treatment areas were arranged so that the patient journey from admission in reception to discharge from the consultant flowed with ease.
- The reception area was accessible for patients with a disability by a ramp. The room was bright and the décor pleasant.
- An external interpreter service was available to patients' whose first language was not English. Patients had to pay for this service if required.
- We observed that in the patients' pre-operative information guide they were advised to bring in a pair of sunglasses on the day of treatment to wear when they go home as often patients were sensitive to light immediately following the procedure. However, even though this was advised, many patients forgot so the service stocked a supply of sunglasses. We observed this happening during inspection and the patient was very grateful that these were given to them on discharge.

Access and flow

- People could access the service when they needed it and received the right care promptly.
- Access to the service was timely and flexible. There were currently 12 people on the service waiting list for refractive eye surgery.
- The service had three long-serving patient advisors dealing with new enquiries. If a consultation was booked, it was confirmed in writing to the patient and a text alert message sent as reminder the day before their appointment.
- In the year 2018, there were 293 enquiries for treatment. Referrals came from a variety of sources; for example, social media, people passing the clinic and the optician adjacent to the clinic. Of the 293 enquiries, 278 went on to have consultations making the conversion rate of enquiry to consultation 94%. In addition to this, of the 278 consultations, 33 were unsuitable for treatment which left 490 eyes to treat.

- There had been no unplanned admissions within the service and no cancellations in the 12 months prior to the inspection.
- Appointments were available during the week, evenings and at weekends to ensure that the service was accessible to all current and perspective clientele.
- Staff minimised waiting times for patients in the clinic. Appointments were staggered to coincide with their allotted surgery time.

Learning from complaints and concerns

- It was easy for people to give feedback and raise concerns about care received. Staff learned from complaints and shared this learning via discussion and emails.
- We reviewed one written complaint that the service had received in the 12 months prior to the inspection. The complaint was withdrawn later by the complainant with a written letter to confirm.
- We reviewed a verbal complaints and dissatisfaction policy that was in date and staff had signed to state that they had read and understood it. Within the document it stated that all complaints were to be made in writing which would ensure that the service insurance team were duly notified. Written acknowledgement would be given in two working days and a full response within a further 18 working days.

Are refractive eye surgery services well-led?

Good 

Leadership

- There was a clearly defined system of leadership for all staff working in the clinic. All staff we spoke to in the clinic were clear how the leadership structure worked.
- The service had a small team and the registered manager, and the nominated individual worked in the clinic full-time. We were told by the registered manager that she and the nominated individual met daily with the patient advisors and optometrists. In addition to this they would meet with the ophthalmologist who attended the clinic two or three times per week.

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- Clinical leadership of the optometrists was provided by completion of competencies outlined by the General Optical Council. These were checked annually by the registered manager of the service.
- We observed good leadership that was visible and approachable. Staff in the service told us that they had confidence and trust in the leadership of the whole service.

Vision and strategy

- The service had a vision. We were told by the consultant ophthalmologist that the staff in the service wanted to grow and develop the organisation and to continue to provide the highest quality service to enhance peoples' lives. In addition to this we were provided with a document that demonstrated their vision and strategy for the service.
- There was a clear vision regarding quality and sustainability. We were told by the consultant ophthalmologist that the service had recently reduced their prices for treatments due to the competitiveness of refractive eye surgery nationwide. The new prices and the services offered were advertised via social media and by word of mouth to increase the footfall of the service.

Culture

- Staff told us that they felt supported and valued. All staff were proud of the service and many had worked at the service for a long time.
- The culture of the service was focused on working together as a team and providing the best possible care to patients and their families.
- The patient experience was extremely important to all the team and this was evident when we spoke to staff. A summary of the patient questionnaire was circulated to all staff via email and discussed verbally to ensure that all the team were aware of the feedback given about the service.

Governance

- The safety and quality of the patient pathway was monitored by the registered manager.
- Following each procedure, the registered manager would look at the patient documentation to ensure that all surgical ophthalmic procedures had been followed for the treatment provided.

- We reviewed a policy and procedure file that incorporated various policies that were all in date. For example, urgent and emergency treatment, resuscitation, sharps injury, marking the surgical site policy and infection and prevention control policy. Within the infection, prevention and control policy it stated that staff undertaking procedures must be trained in aseptic techniques; however, we did not see evidence of this being undertaken. We raised this with management at the time of inspection and was assured that both the registered general nurse and consultant were trained scrub practitioners and we saw evidence of this in their competency files.
- The service had a safeguarding policy that was in date and we checked a sample of staff personnel files and saw that all relevant documentation, such as professional registration, qualifications and disclosure and barring checks were in place.
- We were told by the registered manager and the consultant ophthalmologist that risks were discussed on an informal basis as they arose. These would then be documented in the official team meetings that were held on a quarterly basis. We reviewed the team meeting minutes and saw structured agenda items for discussion.
- The two consultants (one of whom had recently retired) worked under practising privileges and both held an appropriate level of professional indemnity insurance. This was checked annually by the registered manager.

Managing risks, issues and performance

- We reviewed a risk to service policy which was in date. This policy covered the potential risk to the service functioning as normal; for example, mobility to source supplies or long-term sickness. All staff had signed and dated the policy to demonstrate that they had understood it.
- We saw a risk assessment log that had been reviewed in January 2019. This was an improvement since the last inspection. Examples of risk assessments were; clinic corridors in which patients could potentially fall on as all patients wear overshoes on entering the theatre suite; patients receiving refractive treatment would have reduced vision due to receiving eye drops and wearing eye shields to protect the eyes; theatre room laser

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equipment which could produce injury to staff from deflected laser beam and the use of mitomycin which is a cytotoxic drug which could come into contact with staff when mixing the solution.

- We saw on the risk register that a notification had been received in May 2018 from the external party that was used to decontaminate the instruments. The external party would no longer be providing services at their current site and would be moving to alternative premises. This had now been resolved at the time of inspection.
- The risk register was reviewed annually by the registered general nurse, but we saw no approval process or review by any other member of the team. We raised this on inspection and was told that this would now be discussed in team meetings and approval shared between the ophthalmologist and the registered manager of the service.
- Laser treatment was not compromised if power failed mid-treatment. The equipment was fitted with an uninterruptible power supply to complete a surgical procedure, as recommended by the Royal College of Ophthalmologists 2017. We reviewed a policy to guide staff in the event of a mains service failure and this was in date.
- The registered general nurse was the laser protection supervisor for the service. If there were any concerns regarding the laser equipment, the procedures would be cancelled until it was reviewed by the external laser protection advisor.

Managing information

- Staff had the information they needed to provide care and treatment to patients. All information was accessible to staff in paper or electronic format.
- The General Data Protection Regulation (2018) was followed by the service to ensure fairness and transparency, data minimisation and integrity and confidentiality.

- The registered manager documented every consultation and treatment given so that revenue could be monitored.

Engagement

- The service proactively acted upon the views and experiences of patients gained from the feedback from the patient questionnaires.
- The service collected patient feedback and monitored the results. The patient survey results for the 233 patients treated in the year 2018 were all positive. For example, a question was asked on how patient's rate the information provided on the website; 100% of respondents stated it was excellent. Another question was asked on the cleanliness of the clinic; again 100% of the respondents stated that it was excellent.
- We were given examples of feedback that patients had given to the clinic. One example, that a patient had written, said that 'they had chosen the clinic as they knew that the surgeons were of excellent standards and the clinic was the only choice for them'. Another example given stated that 'from the initial consultation and advice provided they did not consider going anywhere else'.
- We were shown an example of a patient questionnaire that had been completed. The patient had queried the question "Expectation of Outcome?". The service subsequently changed the wording of the choice of answers so that patients found this easier to understand. The patient welcomed this change as they felt it was a better phrase and made the question easier to understand.

Learning, continuous improvement and innovation

- There had been no internal or external reviews of the service during the 12 months prior to our inspection.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The service should make sure consider auditing hand hygiene to ensure good compliance.

This is in relation to part of Regulation 12 (2h) on safe care and treatment. Care and treatment must be provided in a safe way for service users. The registered person must comply with assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated.

- The service should review the training for aseptic non-touch technique to ensure good practice is maintained during surgical procedures.

This is in relation to part of Regulation 12 (2h) on safe care and treatment. Care and treatment must be provided in a safe way for service users. The registered person must comply with assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated.

- The service should consider checking the emergency anaphylaxis kit on a daily or weekly basis to ensure items are available within the box.

This is in relation to part of Regulation 12 (2b) on safe care and treatment. Care and treatment must be provided in a safe way for service users by doing all that is reasonably practicable to mitigate any such risks.

- The service should review the process for reviewing the risk register and include a structured process on governance in their team meetings for the systems and processes of the service.

This is in relation to part of Regulation 17 (2e) on good governance. Systems or processes must enable the registered provider to seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services. This section is primarily information for the provider