Visualase Laser Eye Clinic

Quality Report

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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

Overall summary

Visualase Laser Eye Clinic is operated by Visualase Limited.

The service provides refractive eye surgery for self-funded patients over 18 years old. Facilities include a reception area, two assessment rooms, a consultation room, disabled toilet, a theatre suite and recovery room.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 25 July 2017, along with an unannounced visit to the clinic on 3 August 2017.

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

We regulate refractive eye surgery services but we do not currently have a legal duty to rate them when they are provided as a single specialty service. We 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:

- Patient's records were stored securely, legible, completed and updated appropriately.
- There were robust systems in place for the maintenance of equipment including service level agreements with external organisations.
- Registered staff had been employed for several years with consultant-led medical cover.
- Outcomes of laser surgery were monitored via a computerised software system and benchmarked against other providers with the same equipment.
- Ninety per cent of staff had received an annual appraisal.
- There was effective multi-disciplinary working at the clinic.
- Patients were seen by the consultant at each stage with a comprehensive consent process.
- All patients, and those close to them, were treated with privacy dignity and respect. We saw that staff were kind and compassionate whilst delivering care and treatment.
- Patients we spoke with were happy with the service that they had received.
- The provider's annual patient feedback survey was overwhelmingly positive about their experiences with the provider.

Summary of findings

- Consultations took place in individual consultation rooms before and after procedures.
- Patients were encouraged to be accompanied by someone close to them.
- Patients were self-referred with appointments made individually and flexibly.
- The clinic was open six days a week and on Sundays, as required, for post-operative check-ups.
- Patients were given access to 24 hour helpline services for the duration of the post – operative treatment and after-care was available as long as was needed.
- The clinic was accessible for patients with reduced mobility.
- A hearing loop was available for patients with a hearing impairment.
- There had been no written complaints and any concerns were dealt with promptly.
- There was clear leadership with supportive team working.
- Recruitment checks had been completed for all staff employed.
- There was a positive culture, with staff working there for many years.
- Alternative treatments were being introduced to offer more patient choice.

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

- There was a paper incident reporting system, however; records showed that these only recorded complications of the treatment.
- There was no mandatory training programme in place, following the initial induction, with only the clinic manager having received current life support training.
- The safeguarding policy only listed the contact details of the local safeguarding boards and records showed that only two of the staff had completed safeguarding training for adults.
- The processes for the management of specialised medicines were not robust with no evidence of a policy or risk assessment in place.
- The systems in place for infection prevention and control did not follow current national guidance.
- There were no systems in place for the recognition or treatment of anaphylaxis (an extreme and severe allergic reaction) or sepsis (a serious complication of an infection).
- Newly-appointed staff followed an induction programme, however; competencies were not re-assessed following initial training.
- Staff had not received training about the Mental Capacity Act (2005).
- The consent form for Laser-Assisted Subepithelial Keratomileusis (LASEK) did not include that the drug Mitomycin was unlicensed for use in ophthalmic surgery.
- There was no interpreter service or information available in languages other than English.
- There was no vision or strategy for the service.
- There was no overall management of organisational risks or formal governance arrangements and no formal minuted meetings.
- There was no audit programme in place.
- We were told the appraisal process reviewed training needs, however; did not include all development needs of staff.
- Policies had been reviewed, and shared with all staff, at least every three years, however; did not always reference guidance.

Following 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 also issued the provider with requirement notices. Details are at the end of the report.

Name of signatory

Edward Baker

Chief Inspector of Hospitals

Summary of findings

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Visualase Laser Eye Clinic

Service we looked at
: Refractive eye surgery

Summary of this inspection

Background to Visualase Laser Eye Clinic

Visualase Laser Eye Clinic is operated by Visualase Limited and the service opened in 2001. It is a private clinic in Bolton, Lancashire that primarily serves the communities of the Bolton area. It also accepts patient referrals from outside this area for laser refractive eye surgery.

The clinic has had a registered manager in post since 2011, and has been employed since 2001.

Our inspection team

The team that inspected the service comprised a CQC inspection manager, and three CQC inspectors. The inspection team was overseen by Lorraine Bolam, Head of Hospital Inspection.

Information about Visualase Laser Eye Clinic

The clinic is registered to provide the following regulated activities:

- Diagnostic and Screening Procedures
- Surgical Procedures
- Treatment of disease, disorder or injury.

During the inspection, we visited each area of the clinic. We spoke with seven out of ten members of staff including; the clinic manager, an ophthalmic surgeon, two optometrists (one is the owner of the business), a registered nurse, a health care assistant and the receptionist. We spoke with five patients and also received 15 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed eight sets of patient records.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected six times, and the most recent inspection took place in December 2013 which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (May 2016 to April 2017)

- In the reporting period (May 2016 to April 2017), there were 344 Laser-Assisted in Situ Keratomileusis (LASIK) treatments and 31 Laser-Assisted Subepithelial Keratomileusis (LASEK) treatments that were all self-funded. 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 3-4 days to allow the surface to heal. Retaining the epithelium is thought to prevent later complications of haze and speed up healing. In LASIK, a cut is made across the cornea by either a special machine (microkeratome) or a special laser (femtosecond) to raise a flap of the cornea. The exposed surface is then sculpted using the excimer laser and the flap is replaced. This results in tissue being removed from the middle layers of the cornea (stroma).
- The two ophthalmic surgeons worked at the clinic under practising privileges. Practising privilegesis a well-established process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic, in independent private practice, or within the provision of community services.
- Visualase employed two registered nurses, two care assistants and a receptionist. The two optometrists were also employed at the adjoining opticians that was owned by the provider.

Summary of this inspection

Track record on safety

- There were no never events
- There were no serious injuries
- There were two incidents recorded related to the treatment

-No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA)

-No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)

-No incidences of hospital acquired Clostridium difficile (c.diff)

-No incidences of hospital acquired E-Coli

-No complaints

Services provided at the clinic under service level agreement:

- Clinical and non-clinical waste removal
- Laser protection service
- Surgical equipment
- Maintenance of laser equipment
- Air conditioning and humidity
- Uninterrupted Power Supply (UPS)
- Fire Prevention
- Decontamination of Instruments

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 do not currently have a legal duty to rate refractive eye surgery services where these services are provided as an independent healthcare single speciality service.

We found the following issues that the service provider needs to improve:

- There was a paper incident reporting system, however; records showed that these were only used for complications of treatment rather than other organisational incidents.
- There was no mandatory training programme in place, following the initial induction, with only the clinic manager having received current life support training.
- The safeguarding policy only included contact details of the local safeguarding boards and records showed that only two of the staff had completed safeguarding training for adults.
- The processes for the management of specialised medicines were not robust, with no evidence of a policy or risk assessment in place.
- The systems in place for infection prevention and control did not follow current national guidance.
- There were no systems in place for the recognition or treatment of anaphylaxis or sepsis.

However, we also found the following areas of good practice:

- Patient's records were stored securely, legible, completed and updated appropriately.
- There were robust systems in place for the maintenance of equipment including service level agreements with external organisations.
- Registered staff had been employed for several years with consultant-led medical cover.

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Are services effective?

We do not currently have a legal duty to rate refractive eye surgery services where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Outcomes of laser surgery were monitored via a computerised software system and benchmarked against other providers with the same equipment.

Summary of this inspection

- There were 90% of staff that had received an annual appraisal.
- There was effective multi-disciplinary working at the clinic.
- Patients were seen by the consultant at each stage with a comprehensive consent process.

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

- There were no audits and policies reviewed did not always reference guidance.
- Newly-appointed staff followed an induction programme, however; competencies were not re-assessed following initial training.
- Staff had not received training about the Mental Capacity Act (2005).
- The consent form for LASEK did not include that it was unlicensed for use in ophthalmic surgery.

Are services caring?

We do not currently have a legal duty to rate refractive eye surgery services where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- All patients, and those close to them, were treated with privacy dignity and respect. We saw that staff were kind and compassionate whilst delivering care and treatment.
- Patients we spoke to were happy with the service that they had received.
- The provider's annual patient feedback survey was consistently positive about their experiences with the provider.
- Consultations took place in individual consultation rooms before and after procedures.
- Patients were encouraged to be accompanied by someone close to them.

Are services responsive?

We do not currently have a legal duty to rate refractive eye surgery services where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Patients were self-referred with appointments made individually and flexibly.
- The clinic was open six days a week.

Summary of this inspection

- Patients were given access to 24 hour helpline services for the duration of the post – operative treatment and after-care was available as long as was needed.
- The clinic was accessible for patients with reduced mobility.
- A hearing loop was available for patients with a hearing impairment.
- There had been no written complaints and any concerns were dealt with promptly.

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

- There was no interpreter service or information available in languages other than English.

Are services well-led?

We do not currently have a legal duty to rate refractive eye surgery services where these services are provided as an independent healthcare single speciality service.

We found the following issues that the service provider needs to improve:

- There was no vision or strategy for the service.
- There was no overall management of organisational risks or formal governance arrangements and no formal minuted meetings.
- There was no audit programme in place.
- We were told the appraisal process reviewed training needs, however; did not include all development needs of staff.
- Policies had been reviewed, and shared with all staff, at least every three years, however; some were missing or not complete.

However, we also found the following areas of good practice:

- There was clear leadership with supportive team working.
- There was a positive culture with staff working there for many years.
- Alternative treatments were being introduced to offer more patient choice.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

Incidents and safety monitoring

- Staff reported incidents that occurred in the theatre room in an incident and accident book stored in the theatre area. This included details of the patient, nature of the incident and recommendations or actions. In addition, paper-records of patient specific incidents were also stored in the management office as well as being recorded in patients' individual paper records. However, the service did not have a system to record and investigate other incidents across the service. This meant that there was no system for monitoring trends in the organisation.
- There were a total of two incidents reported between May 2016 to April 2017; these were not graded according to their severity. There was no formal root cause analysis (RCA) or investigation process, although; each incident and subsequent treatment or contact with the patients was recorded in their individual patient record. Each incident was reviewed by the consultants on an individual basis.
- There was no formal written process for sharing learning from incidents, however; we were told that this was done verbally. An example was given about a historical incident where there was a mechanical fault with the laser. The list of patients was cancelled immediately for that day until the fault was rectified. Another example reported included difficulties in inserting the clip prior to the treatment; it was found that the patient had undergone recent 'Botox' treatment. As a result, this has now been added to the pre-assessment questionnaire.
- There were no never events or serious incidents. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. They have the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.
- There was a duty of candour policy in place. 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 other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person. Staff we spoke to were aware of the requirement to be open and honest with patients. The service had not had any incidents which triggered the duty of candour requirements.

Mandatory training

- There was no formal mandatory training programme or update process in place. Newly appointed staff completed an induction programme that included fire procedures and infection control and prevention as well as laser specific local rules; however, there was no evidence of updates of mandatory training or training in life support training in records, except for the clinic manager, seen on-site. We were told that registered staff had received training in other locations, however; there was no evidence.
- There were no staff, at the clinic that had received current life support training, except for the clinic manager who was the nominated first aider. This meant that we were not assured that all staff had the skills to treat patients in the event of an emergency.
- Following the inspection, the clinic manager told us that one of the consultants has provided evidence of current basic life support training and all other staff are booked on to a course.

Safeguarding

Refractive eye surgery

- The clinic did not treat any patient under the age of 18 years old.
- There was a policy for protection of vulnerable adults, although; this only included the contact details for the local safeguarding boards either for adults or children. This meant that staff may not recognise if a patient was at risk of harm or actions to take if a concern as there was no information available to refer to.
- Staff knew who to contact, in the event of a safeguarding concern, although; we were told that for this type of self-referring independent service, it was unusual for a patient to present as vulnerable.
- Patients were seen in individual consulting rooms and were encouraged to be accompanied by someone close to them particularly post treatment.
- The two optometrists that were employed for the clinic and the adjoining opticians had received training for safeguarding adults and children to level two in February 2016, however; no other staff had received current safeguarding training and there was no nominated safeguarding lead. Intercollegiate Guidance (2014) includes that the minimum level required for non-clinical and clinical staff who have some degree of contact with children and young people and/or parents/carers is level two.

Cleanliness, infection control and hygiene

- There was an infection control policy, however; this did not reference the Health and Social Care Act 2008 guidance 'Code of Practice on the prevention and control of infections'. This meant we were not assurance that staff were following current guidance.
- There was hand sanitiser available in the patient reception area and disabled toilet. There were liquid soap dispensers, however; these were not wall-mounted and there was no hand washing instructions in any area. There were no infection control environmental audits carried out, or audit of hand hygiene compliance.
- We observed the surgeon and registered nurse using appropriate hand washing techniques before the first treatment. Following the surgery, the sterile gloves were removed. The scrub team washed hands before the next patient, however; did not wash hands following removal of gloves as per national guidance.
- The theatre area had separate bins for the disposal of clinical, domestic waste and sharps. We observed staff appropriately disposing of clinical and domestic waste.
- All areas of the clinic were visibly clean. In the reception and recovery areas, chair seats were covered with fabric. Staff told us that these were cleaned with alcohol wipes.
- Staff told us the nurses cleaned the theatre prior to each scheduled treatment list, following a cleaning schedule, and at the completion of the list, however; this was not recorded. A bucket, with liquid was observed, in the room adjoining the theatre, that had not been discarded prior to a patient undergoing treatment. Following the inspection we were told that this liquid was cleaning solution. A bin for waste was uncovered, although following the inspection we were told that this was only used for packing discarded during the treatments. A routine deep clean took place in the clinic annually, however; there was no evidence seen during the inspection.
- The domestic cleaner for the adjoining optician, cleaned the clinic on a daily basis and as required in the general non-clinical areas.
- Staff followed 'arms bare below the elbow' guidelines in the theatre areas and wore personal protective equipment (PPE) when treating patients in the theatre area. Gloves and aprons were available.
- Patients wore theatre gowns, plastic over shoes and hats during treatments.
- There were no incidences of Meticillin-resistant Staphylococcus aureus (MRSA), Meticillin-sensitive staphylococcus aureus (MSSA). MRSA and MSSA are infections that have the capability of causing harm to patients. MRSA is a type of bacterial infection and is resistant to many antibiotics. MSSA is a type of bacteria in the same family as MRSA but is more easily treated.
- A register of infections was maintained that included patient details, the treatment date, the infection and the action taken. Since the clinic opened in 2001, there had been four incidences of an infection with the most recent in 2011.
- There were service level agreements (SLA's) in place for the decontamination of instruments and clinical and non-clinical waste removal.

Environment and equipment

- The clinic included a reception area, two assessment rooms, a consultation room, a disabled toilet (with

emergency pull cord), a theatre area and recovery room that were all on the ground floor. On the first floor, there were offices, storage areas and facilities accessed only by staff.

- There was firefighting instructions, alarms and equipment in place as well as a fire exit at the rear of the building on the ground floor. There was an SLA in place for fire prevention to check alarms and equipment.
- The reception area was accessible for all, with a ramp at the optician entrance, and was light and bright.
- There was a maintenance schedule in place for monitoring the equipment. All electrical equipment had clear stickers to indicate safety checks had taken place with renewal dates of April 2018.
- There were SLA's in place, with external companies, for surgical equipment, maintenance of laser equipment, air conditioning and humidity and Uninterrupted Power Supply (UPS) that were all up-to-date
- There was a plume extractor built into the laser that used nitrogen gas.
- We were told that there was no optical radiation policy or optical radiation committee which was not in line Medicines and Healthcare Products Regulatory Agency (MHRA) (2015) guidance. The provider followed the guidance of the external laser protection advisor (LPA). There was a risk assessment in place for the use of the optical laser. This was last reviewed by the LPA in 2012. The LPA contacted the provider annually to review any changes and was scheduled to visit the clinic later this year for the agreed five year review.
- A register of authorised users was maintained in accordance with the Local Rules as provided by the LPA. The name of the business owner for the rules was in the process of being amended due to a transfer of ownership. There were clear signs to indicate a controlled area and patients accessed this area only with staff present.
- There was routine checks of the laser equipment with daily calibration as well as prior to treatments that were recorded.
- Staff had no access to monitoring equipment in theatres or emergency equipment on site except for a first aid box, in the staff area. This meant that in the event of an emergency, there could be a risk of a delay in treatment.
- If a patient presented with reduced mobility, it was a requirement that the patient needed to transfer on to the theatre bed independently; there was no hoist available.
- A sample of sundry items was checked. A role of surgical tape was found to have expired in 2012. This was highlighted with the provider who explained this was no longer used and was, therefore; disposed of.

Medicines

- There were processes in place for managing and storage of medicines in the clinic and theatre areas and medicines alerts were received electronically from the Medicines and Healthcare products Regulatory Agency (MHRA).
- There was storage of drugs policy, however; when a sample of medicines were checked, it was found that the three remaining bottles of alcohol and water mixture used in the treatment of LASEK had expired. These were subsequently discarded.
- LASEK treatment included the use of a drug Mitomycin C (MMC) which is a cytotoxic Medicine, (Cytotoxic drugs describe a group of medicines that contain chemicals which are toxic to cells). We had concerns there was no written policy / protocol or risk assessment for the use of cytotoxic medicine which may mean staff and patients were exposed to risks in the preparation and administration of Mitomycin. Staff told us that the drug was prepared by either the ophthalmologist or the registered nurse only. The surgeon had initially trained the registered nurse in the preparation and disposal of the Mitomycin, however; there was no evidence of re-assessment of competencies. We were told that all staff were aware that it was a cytotoxic drug and could only be handled by the senior medical team.
- We were told that Mitomycin was prepared in a designated clean area that included an air filtration system, wearing gloves and goggles. It was disposed of in a dedicated disposal bin that was coloured purple to distinguish it from other sharps bins. There was a process in place for the disposal of this bin. We were told that, the use of the cytotoxic drug was well recognised for LASEK and, therefore; well established off-licence use. The patient consent form included information about the Mitomycin, however;
- We requested assurances from the provider that processes were put in place to mitigate risks to patients and staff. We raised our concerns with the owner, who was the nominated individual, post inspection and action was taken to address concerns. The provider

initially suspended the service. Following further discussions, we were provided with a draft written policy and risk assessments for the management of Mitomycin.

- There had been an SLA agreement for the supply of an alcohol and water mixture, used in LASEK treatment, with a local pharmacy, however; this had now stopped. We were told this was due to pharmacy licence restrictions. There was a concern that this may affect future treatments as this was specific to the treatment. The service was seeking advice from other sources.
- During the initial consultation, patients completed a form that included details of any drug allergies. There was a policy for adverse reactions to drugs, however; this did not include management of any anaphylaxis (a serious allergic reaction and medical emergency). There were no emergency medicines to manage any anaphylaxis. This meant that if a patient had a severe allergic reaction, to medicines given at the clinic, they would not be able to be treated immediately.
- For LASEK treatments, the consent form included a section about Mitomycin-C, however; did not include that it was not licensed for this purpose or that there was a risk of systemic absorption.
- There were no controlled drugs stored on – site or used at the clinic.
- Medicines that needed to be refrigerated to ensure their effectiveness were stored in a locked fridge on the first floor. The temperatures were recorded and checked daily to ensure that the temperatures maintained between two and eight degrees.The range, however; was not recorded, only the temperature at the time of the check.
- The temperature of the fridge in the theatre area was not checked, although; only salt solution sachets and topical voltarol (anti-inflammatory medicines) were stored as cooling on the eyes post treatment, as part of a trial in progress.
- We were told that oral sedation, of diazepam, could be used if a patient presented as nervous immediately prior to the treatment.
- Prior to the laser treatment, anaesthetic drops were administered. These were prescribed by the ophthalmologist and administered by the health care assistant who acted as a runner for the surgeon and registered nurse who were 'scrubbed' for theatre.
- In the reporting period May 2016 to April 2017, there were no medicines errors reported or recorded.
- Medicines were given, to patients, to take home. Stickers with the patients' name, date of birth and name of eye drop was attached to the medicines. The manufacturer's information leaflet was also included. The medicines was prescribed by the consultant and dispensed by them at time of discharge. The patient was also given written instructions about how to administer the eye drops as well as the list of do's and don'ts and 24 hour contact details. The batch numbers of the medicines were recorded in theatre and in the patient records.

Records

- Patient records were paper-based and securely stored in locked filing cabinets in the staff-only area on the first floor.
- There was a policy in place for the confidential management of patient records in accordance with the Data Protection Act 1998 and information given to patients included how the service used their records.
- We reviewed care records for eight patients. Paper records were organised in forms that were completed by relevant health professionals. They were all complete and legible including pre- operative assessments, consultation records, consent forms, treatment and prescriptions and post- operative consultations. There were no audits of records.
- Some records, including prescription sheets did not have patient names on the top of every page, although; the provider demonstrated that if that page became separated it was traceable by matching the drug batch numbers and the dates of treatment.
- The temperature and humidity, in the theatre were recorded in patient records at the time of their laser treatment.

Assessing and responding to patient risk

- We observed staff at the clinic confirming the identity of patients on arrival. Patients were asked to complete a form that included a pre-assessment health questionnaire. This included details specific to eye health, including details of any allergies. A patient's medical history was recorded by the surgeon in the consultation notes in line with current NICE guidelines.
- The initial assessment, following an enquiry, was with an optometrist. This was followed by an initial consultation by the ophthalmologist. They assessed if the patient was suitable for refractive eye surgery by

ensuring a stable eye prescription and that they did not have certain medical conditions or were pregnant. Patients were given information about the procedure that included the consent form to take home.

- On the day of treatment, a pre-operative assessment was completed. This included confirming any allergies. This occurred at least one week following the initial consultation. The consent form was then checked and completed with the consultant surgeon.
- There was no policy for the recognition or management of any anaphylaxis or sepsis. There was no monitoring of vital signs at any time in the patient journey, although; a verbal check was made that the patient was fit and well at the time of treatment. In the event of an emergency, a patient would be transferred to the local NHS hospital.
- If a patient was consented for treatment to one eye, rather than both, the service did not mark the site or use the safer surgery checklist or an adapted version of the checklist. This meant there was a risk of treating the wrong eye.Verbal checks only, of eye to be treated were confirmed with the surgeon and patient prior to the surgery. The paper nursing record in the patients notes included an instrument check and check of swabs and spears before and after treatment.
- Following surgery, patients were escorted to the recovery room; this was dimly lit, to help eye recovery, with armchairs. They remained there for about thirty minutes. Patients were encouraged to be accompanied by someone close to them in this room. If alone, we were told that patients were asked to knock on the theatre door if they felt unwell or in need of clinical support. There was no call bell in the recovery room.
- Patients were escorted from the recovery room and back into the consultation room where their eyes were checked prior to discharge; they were give verbal and written instructions and medicines to take home.
- On discharge, each patient was provided with contact details of the clinic, optometrists and ophthalmologists. These could be contacted 24 hours a day post-operative, for as long as required.
- The clinic was open six days per week. If treatments took place on a Saturday, the ophthalmologist visited the clinic on a Sunday solely to review the post-operative patients.
- In the event of an emergency situation that required further treatment outside of the clinic, the escalation policy in place had a requirement to dial 999 to transfer a patient to the local NHS trust. The service did not have any emergency equipment, such as a defibrillator, on site and there were no staff that had evidence of current life support training, except the registered manager who was the nominated first aider.
- Between May 2016 to April 2017, there was one incidence where a patient contacted the clinic following discharge as one eye was uncomfortable. The patient required further surgery on the same day and then was subsequently routinely monitored.

Nursing and medical staffing

- Medical staffing was provided by two ophthalmic surgeons that had worked at the clinic for several years via practising privileges arrangements. (Authority granted to a physician or dentist to provide patient care in an independent health care setting).
- One consultant was on the General Medical Council (GMC) Specialist Register in ophthalmology and held the CertLRS exit level qualification as per Royal College of Ophthalmology guidance for surgeons; the other consultant had Grandfather Rights as a founder member of the British Society for Refractive Surgery (BSRS). Grandfather rights refer to the arrangements by which individuals or organisations undertaking a particular activity are exempted from new rules relating to that activity, either for a limited period or indefinitely. It is a recognised feature of implementing major system changes which is intended to enable someone to continue to practise under their existing rights after new rules for that activity have been introduced. There was no medical advisory committee (MAC) as there were only two consultants.
- The clinic employed two registered trained nurses and two nursing assistants. The registered manager was not a nurse, however; supported staff with patients if needed. A registered nurse and a health care assistant were present with one of the ophthalmologists during treatments in theatre. If the full team were not available, the treatments were cancelled, however; there were no reports that this had occurred.
- The theatre team included the ophthalmic surgeon, a registered nurse and a healthcare assistant. Treatments included the use of local anaesthetic drops only with patients awake throughout the procedure.
- There were no bank, agency or locum staff used at the clinic. All staff had been employed for many years, the majority since opening of the clinic in 2001.

Refractive eye surgery

Major incident awareness and training

- There was a 'major plant failure protocol' and a service level agreement (SLA) for uninterrupted power supply (UPS).
- There was a back-up generator in place and gave an example when power had failed once since opening in 2001, in the surrounding locality, and the back-up system activated without interruption to a laser treatment that was in progress.
- Monthly fire drills took place and inspections occurred annually.

Are refractive eye surgery effective? (for example, treatment is effective)

Evidence-based care and treatment

- Policies, procedures, assessments and treatment were not aligned with the latest recognised national standards and guidance including Royal College of Ophthalmology Standards for Laser Refractive Surgery and guidance on photorefractive surgery.
- All policies and procedures were easily accessible for all staff. Policies had been reviewed at least every three years, more if deemed necessary, however; the policies we reviewed did not always reference the relevant guidance such as the code of practice for infection prevention and control. There were also some policies not in place, during the inspection, such as management of cytotoxic medicines and the recognition and treatment of sepsis.
- Patients were supported by staff to understand relevant treatment options, including risks, benefits and potential consequences, as per NICE QS15 statement 5 and RCOphth professional standards for refractive surgery.
- Medical staff had identified concerns about an increase in diagnosed numbers of diffuse lamellar keratitis (DLK) between 2015 and 2016. DLK is a recognised inflammatory reaction seen in corneas that have undergone LASIK treatment. In 2015 there were six cases (previous years were two and three cases), however; the number rose to 16 from April 2016. There were no initial trends that could be identified, although; the investigations found that since eliminating a swab used in the procedure, in August 2016, there have been no further cases identified.

Pain relief

- We observed that observed that staff confirmed patients patients were comfortable during the treatment.
- Patients were routinely prescribed analgesia post LASEK treatment and given to take home.

Patient outcomes

- Refractive and visual outcomes were monitored via a specialist computerised software programme. We were told that the provider benchmarked the service against other providers who operate the same laser, however; they did not currently submit any data externally.
- In the reporting period (May 2016 to April 2017), there were 344 Laser-Assisted in Situ Keratomileusis (LASIK) treatments and 31 Laser-Assisted Subepithelial Keratomileusis (LASEK) treatments that were all self-funded.
- The copies of data, provided on site showed that 84% of patients' corrected vision, following surgery, had remained stable when reviewed at routine checks.
- Between May 2016 to April 2017, there were four patients that required further enhancement surgery due to over correction and one for under correction. These were identified as part of the routine post procedure appointments.
- We were told that surgical refractive procedures were benchmarked against other services with the same laser equipment, however; there was no evidence provided.
- One of the ophthalmologists had attended international laser user meetings, or virtual forums, where results were discussed with other providers.
- In August 2016, one of the surgeons carried out a retrospective audit of 70 eyes, in 38 patients, that had undergone treatments between April 2014 and April 2015. It was concluded that the laser surgery was an effective procedure to correct vision for myopia (short-sightedness) and hyperopia (farsightedness). Following monitoring post – operatively, it was found that 85% of patient corrections were stable close to target refraction after 11 months. Following the inspection we were told that less than 2% of others went on to require further corrective surgery. In addition between 85% and 97% of patients had positive outcomes which we were told is comparable to current research.

Competent staff

- Newly appointed staff had an induction and their competency assessed before working unsupervised. Staff received training in the Core of Knowledge (nationally recognised training for laser safety). There was a nominated Laser Protection Supervisor (LPS), although; other staff were trained and could adopt the role in the absence of the LPS. Staff were scheduled to renew the training later this year when the Laser Protection Advisor visits the service. Local rules were read and understood by staff.
- All staff had received an annual appraisal with the exception of the manager who was waiting for the owner to complete an appraiser's course. There was no evidence, however; of current training, supervision or professional development.
- The consultants received appraisals and revalidation with their Responsible Officers. Staff files, for the surgeons, included details of qualifications, registration checks and indemnity insurance. One consultant was on the GMC Specialist Register in ophthalmology and held the CertLRS exit level qualification as per Royal College of Ophthalmology guidance for surgeons; the other consultant had Grandfather Rights as a founder member of the British Society for Refractive Surgery (BSRS).
- One of the consultants told us that he attended international laser unit meetings and also met with the laser company when needed.
- Both surgeons were trained, skilled and experienced in providing laser refractive eye services.
- There were no records to show that, staff had completed any life support training, except for the clinic manager.
- The ophthalmologist had trained and assessed one of the registered nurses as competent in the preparation and administration of the cytotoxic medicines, however; there was no evidence that any competencies had been re-assessed.

Multidisciplinary working

- We observed, the staff that included surgeons, optometrists, nurses and administrative staff worked effectively together during informal verbal meetings.
- All the staff worked well together as a team.
- There was good multididciplinary working with the adjoining optician where the optometrists and health care assistant also worked.

Access to information

- All pre-operative tests and assessments were carried out at the clinic and, therefore; results were easily accessible.
- Medical records were all stored securely at the clinic and available for the staff involved in the care and treatment of patients.
- There was a file containing copies of all the latest policies and procedures which was accessible for all staff.
- Patients were given a choice of informing their General Practitioner (GP) of their surgery personally or the clinic could forward the discharge summaries directly.

Consent and Mental Capacity Act

- Staff had the appropriate skills and knowledge to seek consent from patients. Staff were clear about how they sought informed verbal consent and written consent before providing care or treatment.
- Patients' records confirmed that written consent had been obtained, by the consultant surgeon, from patients before planned care was delivered. We observed a consultation and observed that patients were provided with written information about risks, benefits, realistic outcomes and costs following the initial consultation.
- Possible risks and complications were discussed openly and honestly with patients. They were encouraged to ask questions and were given time to ensure they understood what was being said to them. The consent form for LASEK, however; did not include that it was unlicensed for this purpose or that there was a risk of systemic absorption.
- There was a cooling off period, of at least one week, between a patient agreeing to go ahead with procedure and surgery being performed.
- Staff told us that they did not accept consent from any third party. This meant that if a patient was considered to lack the mental capacity to provide informed consent, then they would not accept the patient for treatment.
- There was no training for Mental Capacity Act 2005 (MCA) or Deprivation of Liberty Safeguards (DOL's), although; staff understood capacity and could explain the meaning.

Are refractive eye surgery caring?

Compassionate care

Refractive eye surgery

- We observed compassionate care and very positive interactions by all staff.
- Staff treated patients, and those close to them, with respect and dignity. They were aware of patients care needs and communicated in an appropriate and professional manner.
- We spoke to five patients and reviewed 15 comment cards. They described care as exemplary with excellent care from all staff. This included doctors, optometrists, nurses and administrative staff.
- Other comments from patients included, "amazing service", "would definitely recommend them", "nothing is too much trouble", "staff are very warm, friendly, attentive and patient."
- We observed an initial consultation that included assessments with the optometrist followed by the consultation with the surgeon. Staff were friendly and warm with a reassuring manner. Each procedure was talked through, in detail, after discussions about the completed forms. The patient was given a tour of the theatre and had opportunities to ask any immediate questions.
- We also observed a patient on a treatment day, with their verbal consent. Initially the patient was welcomed by both the reception staff and the consultant surgeon. The patient was required to complete, assessment forms and then attended a pre-operative assessment in a private consultation room with the consultant.
- We observed the surgery and recovery period. Finally the patient attended a post-operative consultation with the surgeon prior to discharge. Staff were compassionate throughout the process.
- All staff introduced themselves and communicated well to ensure patients fully understood. Staff were open with patients about all aspects of care and treatment with positive relationships and trust clear between them.
- Staff were proud to share individual examples of providing care above and beyond for patients to have a positive experience at the clinic, such as more than one member of a family attending for surgery or regular social visits from former patients.
- The clinic carried out an annual survey, in January 2016, for patients to complete and provide feedback. The results showed that 99% of patients would recommend the provider to family and friends. The response rate was 38%. The results from previous annual surveys were displayed on the provider's website showing consistently positive feedback since 2009.
- Possible risks and complications were discussed openly and honestly with patients. They were encouraged to ask questions and were given time to ensure they understood what was being said to them.
- Privacy and dignity was maintained by patient consultations in individual consulting and treatment areas. During treatment days, a one-way flow system was in operation. This meant that patients moved through the clinic from admission to discharge privately without crossing other patients. There was no policy for chaperones, although; patients were encouraged to be accompanied by someone close to them.
- Staff gave us several examples of how they had treated each patient as an individual. This included post discharge. We were told that past patients often call into the clinic and join staff for a hot drink.

Understanding and involvement of patients and those close to them

- Patients were supported by staff to understand relevant treatment options, including risks, benefits and potential consequences, as per NICE QS15 statement 5 and Royal College of Ophthalmologists (RCOphth) professional standards for refractive surgery.
- Patients were provided with the brochure and other patient information documents. Information was also available on the provider's website.
- Patients and those close to them were encouraged to ask staff about care and treatment during consultations.

Emotional support

- Patients were actively encouraged to be accompanied by a relative or someone close to them, particularly on the treatment day.
- Feedback from a patient included feeling vulnerable in the post-operative recovery room when alone. The patient information recommended that patients are accompanied and as a result of the feedback, this is now repeated verbally to patients.

Are refractive eye surgery responsive to people's needs?

(for example, to feedback?)

Service planning and delivery to meet the needs of local people

- The clinic provided services to the patients in the local area but could also see patients from further afield.
- The clinic was independent, although; was linked to the opticians next door. Entrance to the clinic is via the opticians.
- The clinic was accessed by self-funding patients from the local area, however; the initial consultation was free-of-charge and no deposits were taken. This visit assessed suitability for the surgery.
- The clinic was open from 9am Monday to Friday and closed at 5.30pm and Saturdays when the clinic closed at 3pm. If treatments had taken place on a Saturday then the consultant reviewed the post-operative patients on a Sunday when the clinic was open only for these patients.
- The clinic was located in the town centre and opposite a public transport hub; there was also a short-stay public car park at the rear.
- The service ensured patients had an appointment with the refractive surgeon prior to the day of surgery as well as the optometrist.
- One of the surgeons was available to examine patients at the first post-operative appointment. The other surgeon delegated the first post-operative examination to one of the optometrists, although; was available if needed during that time.

Access and flow

- Patients were all self-referred by enquiring with the provider either face to face, by telephone, by email or contact form on the website.
- Treatments were planned according to patient requirements and consultant availability. These included evening and weekend (Saturday) treatments.
- Following an initial enquiry, patients were not called again to enquire if they wished to proceed with the treatment. A follow-up thank you letter, only, was sent two weeks later to anyone who had not made a decision about proceeding with a treatment.
- Between the initial consultation and treatment day, patients were advised that they could contact the clinic or consultant to discuss any queries.
- In the reporting period (May 2016 to April 2017), there were 344 Laser-Assisted in Situ Keratomileusis (LASIK) treatments and 31 Laser-Assisted Subepithelial Keratomileusis (LASEK) treatments that were all self-funded.
- The surgeons were available 24 hours a day post any treatment if required and patients would be seen at the clinic whenever necessary.
- There was a buddy system where the consultants covered each other during leave. In the event of unforeseen circumstances if key staff were unavailable, on a treatment day, the list would be cancelled and re-scheduled; there were no reports that this had occurred.

Meeting people's individual needs

- The clinic provided individualised care and treatment to all patients that attended. Staff told us that they only saw patients that had capacity to consent to treatment.
- Patient areas were all on the ground floor, with a ramp at the entrance, and was accessible for all including patients with reduced mobility, however; patients needed to be able to transfer independently from chair to theatre bed as no hoist was available.
- There was a portable hearing loop for patients with a hearing impairment, however; the clinic had not needed to use it. Staff provided an example of when strategies were used to communicate effectively with a patient who had lip-reading skills.
- Patients were greeted by staff on arrival, via the adjoining opticians. The reception area had seating for 10 people and also displayed large posters on the walls.
- Patients were advised, in information leaflets and verbally to be accompanied by a relative or someone close to them. They were encouraged to be supported in the recovery area but could also be accompanied in theatre during the treatment if requested.
- Patients and those accompanying them were offered free hot drinks. We were told that former patients often returned to visit staff if in the area.
- There was a choice of current magazines available in the reception area. There was also a television which we were told was used to show videos about the service.
- Patients were provided with an information booklet that was available only in English and there were no other version, such as easy read. There was no interpreter or translation services available for patients who did not speak English as a first language. Staff told us that

patients who did not speak English as a first language would usually use a family member to translate. Using a family member as a translator poses a risk that the patient will not be given accurate information about their treatment or fully understand the risks or complications of the treatment.
- Information was also available on the website, for the provider that included short videos from staff. Alternatively, patients were directed to a website that had been established by one of the surgeons that included additional guidance.
- The clinic was located on a main road in the town centre. The population of the town was multi – cultural and cosmopolitan.
- The service had an equal opportunities policy and all patients and visitors, we observed, were treated respectfully and equally as individuals irrespective of heritage or background.

Learning from complaints and concerns

- There were no complaints received by the service in the 12 months before inspection.
- The information provided to patients included the complaints procedure. This included signposting to an external body if they were not satisfied with the internal complaints process.
- All staff were aware of the complaints procedure. Any concerns, including any negative verbal feedback was dealt with straight away.

Are refractive eye surgery well-led?

Leadership and culture of service

- As there was a small team, there was very visible leadership daily in the clinic, by the registered manager. Staff told us that they were supported by their manager. The registered manager was responsible for the daily activities at the clinic with the owner of the clinic and adjoining opticians overseeing the management as well as in the role of optometrist.
- There was an open and transparent culture that encouraged staff to confidently speak up about concerns they had and report any incidents.
- There was a positive attitude and culture within the clinic where staff valued and supported each other. Staff were very proud of the clinic and worked well as a team to provide patient-centred care.
- All staff were involved with the care and treatment and many staff had worked at the clinic since it opened in 2001.The clinic did not use any bank or locum staff.
- The Royal College of Ophthalmologists (RCOphth) advertising and marketing standards guidance published in April 2017 includes that all advertisements for surgical procedures need to state that: “All eye surgical procedures carry a level of risk including not obtaining the desired outcome through to varying levels of visual loss. Your eye surgeon will discuss the risks and benefits including ones specific to your circumstances at the time of your preoperative consultation”, however; there was no evidence of this statement.
- The financial arrangements were discussed with patients and they received a receipt following transactions, however; there was no written terms and conditions between the provider and patients.

Vision and strategy

- There was no written vision or strategy at the clinic, although; future plans were verbally discussed that included extending services offered.

Governance, risk management and quality measurement

- The provider maintained a risk assessment log. These risk assessments were health and safety based. These were completed by the registered manager and clinical staff (consultant surgeons and registered nurse). They were reviewed in line with other policies. The level of detail varied with a lack of evidence of some policies or references to current guidance. There was no process in place to record and monitor organisational risks for the provider, such as sourcing all specialised medicines or retention of staff with the necessary skills.
- There was no audit programme in place to monitor practices at the clinic, such as environmental audits or records.
- All available policies were reviewed at least every three years. When updated, these were shared with staff that were required to complete a signing sheet for staff to demonstrate that they had read and understood the documents. It was found; however, the policies we reviewed did not always reference relevant guidance.

- There were no formal governance or minuted team meetings at the service. We were told that, as the service only had a small team, information would be informally shared between staff. Staff told us that one of the consultants had suggested starting quarterly meetings but at the time of the inspection this had not been implemented.
- Each staff file included records of an enhanced disclosure and barring check (DBS) criminal records check dated either 2014 or 2015. All staff with professional registration had a copy of a check. Following the inspection, the clinic manager told us that professional registration checks were carried out annually at their appraisal.
- There was no medical advisory committee (MAC) as there were only two consultants. We were told that if there was a concern about the surgeons then the registered manager would liaise with the consultant's responsible officers or the regulatory body. Staff files, for the surgeons, included details of their indemnity insurance. The provider had a practising privileges policy in place that reviewed the consultants' services every two years. This did not include a requirement to check current training records, such as life support training and safeguarding.
- Records were kept for traceability of medicines and instruments and the patient register was completed at the end of each procedure.

Public and staff engagement

- The clinic sought feedback from patients on an annual basis. Results were displayed on the website and brochure that included patients providing accounts of their personal experience. Feedback was consistently positive and examples were given when changes were made quickly in response to any aspects that could be changed to enhance patient experience further. One example that we were told about was a patient who was concerned about acquiring an infection if they touched the theatre bed. Staff responded immediately by placing extra sterile sheets on the area and the patient completed the treatment.
- The service did not complete a staff survey, due to the small size of the team. Staff were actively involved in all aspects of the planning and delivery of treatment and care and confidently aired their views. There were no formal minuted meetings, however; as a small team there were frequent face to face meetings.

Innovation improvement and sustainability

- The clinic was experiencing difficulties in sourcing a specialised item in the treatment of LASEK. There were concerns that they would need to explore an alternative approach.
- As well as the LASIK and LASEK that were currently offered, the ophthalmologists had also started offering Monovision (one eye has clear distance vision while the other has clear near vision) that included a contact lens trial prior to any decision to proceed with laser treatment.
- A clinical trial was in operation that involved cooling the eyes post treatment. Two patients had participated at time of inspection; the trial was ongoing so no results were available as yet.
- The clinic was also considering a new service of lens exchange; this was expected to include pre and post-operative care only with the surgery at an alternative location due to the different theatre requirements.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that all staff have received training in life support at the appropriate level.
- The provider must ensure that all staff have received training in safeguarding adults level two and there is a robust policy in place.
- The provider must ensure that processes are in place to ensure adequate supplies of medicines are available and in date.
- The provider must ensure that a system is in place to identify and manage anaphylaxis including training for all staff and availability of anaphylaxis kits.
- The provider must have a process and risk assessment in place for the management of cytotoxic medicines, including consent process, preparation and disposal.
- The provider must ensure staff have access to an infection prevention and control policy that reflects relevant guidance such as the Health and Social Care Act 2008 guidance Code of Practice including hand hygiene and audit.
- The provider must ensure that a process is in place to check the correct site of surgery prior to any treatment as recommended in World Health Organisation (WHO) checklists.
- The provider must have a system to monitor organisational risks with mitigations and actions in place.
- The provider must ensure that all necessary policies are in place and follow current national guidance.
- The provider must ensure that patients are fully informed of the risks associated with Mitomycin used in LASEK surgery.
- The provider must ensure that staff have received the necessary training and competency checks to carry out their duties.
- The provider must ensure there is a system in place to audit and monitor practices on a regular basis.
- The provider must include that “All eye surgical procedures carry a level of risk including not obtaining the desired outcome through to varying levels of visual loss. Your eye surgeon will discuss the risks and benefits including ones specific to your circumstances at the time of your preoperative consultation” in any advertising as per the RCOphth advertising and marketing standards guidance published in April 2017.

Action the provider SHOULD take to improve

- The provider should assess the need for patient monitoring equipment.
- The provider should ensure that records are patient identifiable to avoid them becoming separated
- The provider should have a process to monitor patients in the post-operative period following a treatment, before they leave.
- The provider should consider staff training for Mental Capacity Act 2005 (MCA) to enable assessment of patients.
- The provider should ensure patient needs can be met through access to an interpreter system for any non-English speaking patients and consider information in languages other than English.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for patients. There was no emergency equipment or emergency medicines available; most staff had not received life support training, were not following infection control guidance or preoperative checks which meant they may not have the skills or resources to carry out care safely; Regulation 12(1),(2)(a)(b)(c)(f)(g)(h

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Not all staff had received safeguarding training and there was no robust policy which meant staff may not recognise risks and actions to take if a concern. Regulation 13(1) (2) (3)

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance There was no process for organisational risks and policies and risk assessments were either missing or not robust which meant staff may not have the guidance to carry out care of patients Regulation 17 (1) (2) (a) (b) (f):