Optimax Laser Eye Clinics - Leicester

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

Ratings

Overall rating for this location

Are services safe?	Not sufficient evidence to rate
Are services effective?	Not sufficient evidence to rate
Are services caring?	Not sufficient evidence to rate
Are services responsive?	Not sufficient evidence to rate
Are services well-led?	Not sufficient evidence to rate

Overall summary

Optimax Laser Eye Clinics Leicester is operated by Optimax Clinics Limited. Facilities are available on one level, accessible by a flight of stairs. There is a stair lift for patients with reduced mobility. Facilities include a spacious waiting area, two consultation rooms, a topography room, a preparation room, one treatment room, where surgery takes place, and a recovery room.

Optimax laser Eye Clinics Leicester provides laser vision correction treatment and intra ocular surgery for the treatment of cataracts under topical anaesthetic to adults only.

Summary of findings

Patients are self-referring and self-funded and have visual problems caused by cataract or visual acuity deteriorating over time (failing eyesight). Visual acuity deterioration is not classed as a medical condition so is not treated by the NHS.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 7 September 2017. An unannounced visit took place on 15 September 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 service understood and complied with the Mental Capacity Act 2005.

Services we do not rate

We regulate refractive eye surgery, but we do not currently have a legal duty to ratethem 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:

- Staff understood their responsibilities to report incidents.
- Staff received adequate induction and refresher training.
- Laser safety measures were in place and were monitored.
- The clinic was visibly clean and staff followed procedures to prevent and control infection.
- Medicines were managed safely and staff were competent to administer and dispense medicines.
- Policies, procedures and treatments were based on recognised national standards and guidance.
- Patients receiving care at the service were screened for suitability to ensure correct laser surgery was provided.
- The patient pathway was undertaken in line with national standards and guidance.
- Advertising and marketing was appropriate and responsible.
- Staff were competent to carry out the duties allocated to them.
- Laser staff had additional training to carry out their duties safely.
- Procedures for obtaining consent were robust and in line with national standards and guidance.
- Without exception, care was delivered in a compassionate manner.
- Patients were involved in discussions about their treatment options.
- Staff recognised when patients were anxious and offered reassurance.
- Privacy and dignity was preserved at all times.
- The service was accessible and appointments were easy to book.
- Interpreter services were available if patients did not speak English as their first language.
- Complaints were managed in line with the provider's policy by the clinic.
- There was a clear leadership structure from service level to senior management level.
- Staff were aware of the corporate management structure and were clear about lines of reporting.
- Patient feedback was encouraged and was used to improve the service.
- When informed of concerns throughout our inspection the service took timely action to mitigate risks.

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

- The service did not have an incident reporting policy to guide staff in relation to incident reporting.
- The service did not have a duty of candour policy and the duty of candour requirements were not embedded within the service. At the time of our inspection, staff had limited understanding about the duty of candour requirements. Only the registered manager had undertaken this training at the time of our inspection.
- The service did not contribute to the National Ophthalmic Database Audit (NODA).
- Patient outcomes were not benchmarked with other services.
- Patient information leaflets were not available in different languages or formats.
- There was no clear vision or strategy within the service.

Summary of findings

- There was a lack of oversight in relation to some risks within the service and risk assessments had not been undertaken in relation to some risks.
- Staff engagement surveys were not undertaken within the service.
- The service was not following its human resources policy in relation to staff who had worked within the service for a long period of time and the frequency of which disclosure and barring service (DBS) checks should be undertaken.

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 one requirement notice for regulations breached. Details are at the end of the report.

Heidi Smoult

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery	**Not sufficient evidence to rate** 	We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

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Optimax Laser Eye Clinics - Leicester

Services we looked at

Refractive eye surgery;

Summary of this inspection

Background to Optimax Laser Eye Clinics - Leicester

Optimax Laser Eye Clinics Leicester is operated by Optimax Clinics Limited. The service opened in 2004. It is a private clinic situated in the centre of Leicester. The service primarily serves the communities of Leicester and Leicestershire. It also accepts patient referrals from outside this area.

The service has had a registered manager in post since 2011. At the time of our inspection, a new manager had recently been appointed and had registered with the CQC in April 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Carolyn Jenkinson, Head of Hospital Inspection.

Information about Optimax Laser Eye Clinics - Leicester

Optimax Laser Eye Clinics Leicester is registered to provide the following regulated activities:

- Diagnostic and screening procedures
- Surgical procedures
- Treatment of disease, disorder or injury

Patients are self-referring and self-funded; they attend an initial consultation with an optometrist followed by a consent appointment with the ophthalmic surgeon. Treatment takes place on a day case basis.

The team involved in the delivery of care includes ophthalmologists, a nurse, an optometrist and laser technicians.

On the day of our announced inspection, a laser vision correction clinic was taking place. On the day of our unannounced inspection, patients were attending for follow up appointments.

During our inspection, we spoke with nine members of staff, including registered nurses, laser assistants, the registered manager, optometrists and an ophthalmic surgeon. We also spoke with five patients. During our inspection, we reviewed 13 sets of paper records and three sets of electronic records. We placed comment boxes at the hospital prior to our inspection, which enabled staff and patients to provide us with their views. We received one 'tell us about your care' comment cards, which a patient had completed prior to our inspection.

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

Activity

- In the reporting period June 2016 to May 2017, there were 288 procedures carried out at the clinic.

Track record on safety

In the reporting period June 2016 to May 2017 there were:

- No never events
- No clinical incidents
- No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA) or healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No incidences of healthcare acquired Clostridium difficile (c.difficile)

Summary of this inspection

- No incidences of healthcare acquired Escherichia coli (E-Coli)
- Five written complaints and 23 written compliments

Services provided to the clinic under a service level agreement:

- Clinical waste removal including sharps and cytotoxic waste
- Interpreting services
- Laser protection service
- Maintenance of medical equipment

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?

Not sufficient evidence to rate

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:

- Staff received an adequate induction and refresher training.
- Laser safety measures were in place and were monitored.
- The clinic was visibly clean and staff followed procedures for the prevention and control of infection.
- Medicines were managed safely and staff were competent to administer and dispense medicines.

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

- The service did not have an incident reporting policy to guide staff in relation to incident reporting.
- The service did not have a duty of candour policy. Duty of candour requirements were not embedded and staff had limited understanding about the duty of candour requirements. At the time of our inspection, the registered manager had undertaken duty of candour training, but there was a plan to ensure all staff received this training.

Are services effective?

Not sufficient evidence to rate

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:

- Policies, procedures and treatments were based on recognised national standards and guidance.
- Patients receiving care at the service were screened for suitability to ensure correct laser surgery was provided.
- The patient pathway was undertaken in line with national standards and guidance.
- Advertising and marketing was appropriate and responsible.
- Staff were competent to carry out the duties allocated to them.
- Laser staff had additional training to carry out their duties safely.
- Procedures for obtaining consent were robust and in line with national standards and guidance.

Summary of this inspection

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

- The service did not contribute to the National Ophthalmic Database Audit (NODA).
- Patient outcomes were not benchmarked with other services.

Are services caring?

Not sufficient evidence to rate

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:

- Without exception, care was delivered in a compassionate manner.
- Patients were involved in discussions about their treatment options.
- Staff recognised when patients were anxious and offered reassurance.
- Privacy and dignity was maintained at all times.

Are services responsive?

Not sufficient evidence to rate

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:

- The service was accessible and appointments were easy to book.
- Interpreter services were available if patients did not speak English as their first language.
- Complaints were managed in line with the provider's policy by the clinic.

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

Patient information leaflets were not available in different languages or formats.

Are services well-led?

Not sufficient evidence to rate

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:

- There was a clear leadership structure from service level to senior management level.

Summary of this inspection

- Staff were aware of the corporate management structure and were clear about lines of reporting.
- Patient feedback was encouraged and was used to improve the service.
- When informed of concerns throughout our inspection the service took timely action to mitigate risks.

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

- There was no clear vision or strategy within the service.
- There was a lack of oversight in relation to some risks within the service and risk assessments had not been undertaken in relation to some risks.
- Staff engagement surveys were not undertaken within the service.
- There had been a failure of the service to follow its human resources policy in relation to the frequency of which disclosure and barring service (DBS) checks should be undertaken.

Not sufficient evidence to rate

Refractive eye surgery

Safe	Not sufficient evidence to rate
Effective	Not sufficient evidence to rate
Caring	Not sufficient evidence to rate
Responsive	Not sufficient evidence to rate
Well-led	Not sufficient evidence to rate

Are refractive eye surgery safe?

Not sufficient evidence to rate

Incidents and safety monitoring

- Incidents were reported on paper based incident report forms for adverse events and near misses. However, the service did not have an incident reporting policy or procedure in place to guide staff in the process of reporting and managing incidents. Without this guidance there was a risk that some incidents may go unrecognised or may not be appropriately investigated or resolved. Opportunities for learning from incidents may also be missed.
- Staff we spoke with told us if they felt they needed to raise an incident, they would speak with their manager.
- The service had reported no 'never events' in the 12 months prior to our inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- In the 12 months prior to our inspection, there had been no serious incidents requiring investigation. Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.
- The service manager undertook six monthly audits of incidents. Between January 2017 and June 2017, there had been 11 incidents reported, five of which were classified as near misses. There were no particular themes identified. A near miss is an unplanned event that did not result in injury, illness or damage; but had the potential to do so.
- The registered manager reviewed all reported incidents and undertook and documented any actions taken.
- We did not see and were not provided with any evidence of learning from incidents.

Duty of candour

- 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 other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person.
- There had been no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months prior to our inspection.
- The service did not have a duty of candour policy. This meant there was no guidance for staff to follow should they be required to invoke duty of candour within the service.
- The registered manager and three other members of staff had recently undertaken duty of candour training and although the registered manager had an understanding of the requirements of duty of candour, staff we spoke with had less of an understanding. The service had just started to roll out duty of candour training to its entire staff.

Mandatory training

- The service did not have a mandatory training policy but details relating to mandatory training were available in the service's staff handbook.

- Annual mandatory training courses were delivered as part of refresher training and development and included 'face to face' training and 'e-learning' modules. These included topics such as data protection, fire safety, violence and aggression, equality and diversity, introduction to safeguarding, disability and discrimination awareness, infection control, medicines training, manual handling, first aid, automated external defibrillation and basic life support and legionella and water safety.
- Staff we spoke with confirmed they received mandatory training annually, and we saw evidence of this in staff records.
- The registered manager maintained a training matrix, which demonstrated staff training was monitored to ensure staff were up to date with their training requirements.
- All relevant staff were trained in basic life support (BLS) and two members of staff were due to undertake immediate life support (ILS). The service had no incidents that required life support since it opened in 2004. The service did not provide surgery under sedation, which meant the staff were not required to undertake advanced life support training.

Safeguarding

- The service did not treat patients under the age of 18 years.
- The registered manager was the local adult and children's safeguarding lead and had undertaken an electronic 'leading on child protection' course. The registered manager was however unable to tell us what level of safeguarding training they had received.
- The registered manager was unable to tell us whether there was a national safeguarding lead trained to level four throughout the organisation.
- The service had a vulnerable adult's protection policy, which had been updated in August 2017. The policy defined what constituted a vulnerable adult, what constituted abuse and detailed the local authority contact should a safeguarding referral need to be made. The vulnerable adults protection policy also explained that staff should complete annual awareness training to enable them to understand how to respond to a potential safeguarding risk. Records demonstrated staff were up-to-date with this training; however, staff were unaware of the level of training they had undertaken.
- Local Authority safeguarding numbers were available in the staff changing area and all staff we spoke with were aware of how to make a safeguarding referral if they were required to do so.
- Although the service did not treat patients under the age of 18 years, it had a child protection policy, which had been reviewed in August 2017. The policy was in place to provide guidance for staff around children visiting the premises with an adult.
- The service had not had cause to report any safeguarding concerns since opening in 2004.

Cleanliness, infection control and hygiene

- All surgical procedures were undertaken within a standard ophthalmic operating theatre environment.
- There were reliable systems to prevent and protect patients from a healthcare-associated infection.
- The service had an infection prevention and control (IPC) policy in place, which provided staff with guidance on appropriate IPC practice, such as hand washing, the use of personal protective equipment (PPE), specimen handling, storage and transportation, management of waste and dealing with spillages.
- The service had a cleaning policy, which set out procedures to ensure clinic staff followed the same cleaning regimes within their treatment rooms.
- All areas we inspected were visibly clean.
- The service used single use (disposable) surgical instruments and a policy was available to provide guidance for staff on the safe use and disposal of these instruments. We saw that single use surgical instruments were appropriately disposed of following their use.
- Personal protective equipment such as gloves and aprons were readily available for staff to use and we observed staff using them appropriately.
- Throughout our inspection, staff were observed to be compliant with best practice regarding being bare below the elbows and staff providing treatments in the surgical theatre were observed to be wearing theatre clothing such as scrubs and hats.
- Throughout our inspection, staff working in the clinical areas were observed to be compliant with best practice regarding hand hygiene. However, we noticed there was no hand washbasin in the topography (scanning) room. We spoke about this with staff and with the registered manager who told us they used hand sanitising liquid between patient contact and there was a hand

washbasin in the optometrist room which was next door should they need to wash their hands. Although risks had been mitigated as staff had access to hand sanitising liquid, we noted this had not been formally risk assessed and had not been noted on the service's risk register.

- An infection control audit had been undertaken in September 2016. The audit identified that staff required new theatre clogs, as these had not been replaced for a number of years. At our announced inspection, we noted the theatre clogs were worn and were not visibly clean. We raised this as a concern with the registered manager who told us the theatre clogs were being used as spares. At our unannounced inspection, we saw the registered manager had taken action to replace the theatre clogs with new ones.
- A further infection control audit had been undertaken in July 2017 which showed the service was 100% compliant in the areas of clinical practices, use of protective clothing, decontamination, care of equipment and waste disposal. However the audit showed 77% compliance for the environment, 67% compliant for the use of personal protective equipment and the handling of sharps and 92% compliant for hand hygiene. Actions required to improve these results was included in the audit.
- A hand hygiene audit had been undertaken in August 2017and this demonstrated that all staff followed the correct technique for washing their hands and that staff did not wear long sleeves when undertaking sterile procedures.
- There had been no reported healthcare associated infections for this service in the 12 months prior to our inspection.
- At our announced inspection, we identified a large clinical waste bin was being stored in the staff changing area. This contained clinical waste and it was not appropriate that it was being stored in an area where staff were getting changed into clean theatre scrubs to enter the theatre area. We raised this as a concern with the registered manager. At our unannounced inspection, we saw the registered manager has taken action to remove the clinical waste bin to a more suitable area.
- Throughout the service, we saw that sharps bins complied with the UN 3291 clinical waste standards. These bins were used for the safe disposal of items such as needles. The service had a contract with an external company for the removal, disposal and replacement of sharps boxes.
- The service had a service level agreement with an external waste management company who collected clinical waste once a week.
- We saw completed and up to date cleaning schedules for all areas.
- There had been no incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA) or healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- There had been no incidences of healthcare acquired Clostridium difficile (c.difficile) or healthcare acquired Escherichia coli E-Coli.
- The clinic did not perform bilateral intra ocular surgery, which is operating on both eyes on the same day.
- Staff received training on infection prevention and control at induction and a refresher every year.

Environment and equipment

- The service had a theatre management procedure that was used on the day of each theatre list to ensure it was safe to use. This included undertaking equipment checks as well as preparing any necessary equipment and undertaking cleanliness checks.
- The service had a maintenance policy, as well as a clinic service schedule, which gave guidance to the clinic manager and relevant staff about the frequency of maintenance procedures required within the organisation.
- The service had an optical radiation safety policy and local rules were available for staff to follow.
- Local rules were stored in a folder in the registered manager's office. There was a list of authorised users and staff had signed to state they had read and understood them.
- The local rules also contained contact information for the Laser Protection Advisor. The LPA was external to the service and based in London. Staff could contact the LPA for personal queries such as safety precautions for pregnant members of staff.
- Laser assistants were trained by senior and experienced staff on how to calibrate and assist with the laser machine. They had also attended a core of knowledge' laser safety course

Not sufficient evidence to rate

Refractive eye surgery

- At our announced inspection, we saw that staff were wearing protective eye wear as stated in the local rules. However, staff told us this was the first time they had worn the protective eye wear. We raised this as a concern with the registered manager who told us staff should always wear the protective eye wear and would take action to communicate the importance of this with staff.
- We inspected the operating room where intra ocular lens (IOL) and refractive eye surgery took place. In line with best practice, the air-handling unit in the operating room delivered 20 air changes per minute and there was a procedure in place informing staff what to do if the unit failed.
- The controlled area was clearly defined and we noted a warning sign stating the laser was in used do not enter that could be seen from the waiting area. However, at our announced inspection, we noted there was no warning sign in the pre-operative room or the post-operative recovery area. The door to the operating room was unlocked and staff confirmed there were times when patients would be left alone in these areas. There was therefore a risk that patients could accidentally walk into the operating room when the laser was in use. We raised this as a concern with the registered manager. At our unannounced inspection, we saw that a risk assessment had been completed and action had been taken to ensure the doors were locked. A no entry sign had been placed on the operating room doors and staff were instructed that they should chaperone patients in the pre-operative recovery room and the post-operative recovery area at all times.
- All electrical cables were safely positioned and did not show any signs of wear and tear. These were checked on a weekly basis and a record was maintained of all checks undertaken.
- Control of substances hazardous to health (COSHH) regulation 2002 risk assessments were in place for a range of chemicals including gases, and cleaning fluids. At our announced inspection, we noticed there was not a COSHH risk assessment for the use of mitomycin C. Mitomycin C is a cytotoxic medicine, which improves the result of refractive eye surgery. COSHH regulations state that employers should have risk assessments and control measures in place to reduce exposure to workers. We raised this as a concern with the registered manager. At our unannounced inspection, we saw evidence that a COSHH risk assessment had been undertaken for the use of mitomycin C.
- At our announced inspection, we noted an oxygen cylinder was stored in the post-operative room but there was no warning sign on the door. We raised this with the registered manager. At our unannounced inspection, we noted a compressed gas warning sign was visible on the door to the room.
- An emergency trolley was available in the post-operative recovery room. Staff checked this on a weekly basis. All equipment was in date and in working order. We saw the checklist record had been signed and dated.
- The laser technician checked the calibration and the safety of the laser machine before each laser treatment session. Calibration and checks took place according to local rules.
- The service maintained a log of temperature and humidity conditions within the operating theatre. These were consistently maintained and demonstrated where the conditions were not in range an alert was sent to the service desk to initiate corrective action.
- We saw the maintenance record for the laser machine. The machine was serviced at least twice a year. Any problems with the machine in between servicing would be referred to the manufacturer who sent an engineer within 24 hours. We saw evidence where further support was required and where this had been actioned.
- There was an asset register for all equipment and all equipment we checked had an asset number.
- Other electrical equipment displayed labels to state they had been safety checked. We checked the labels on eight pieces of equipment and all were within their servicing schedule. The safety check labels demonstrated the equipment had been routinely checked for safety and detailed the date when the equipment was next due for routine servicing.
- There was one operating room where both IOL surgery and refractive eye surgery was performed. The room was spacious, fit for purpose and clutter free.
- The extraction of plume was automatic through a small suction machine attached to the laser machine. Plume is the vapour produced during laser treatments, which can be irritating to the eyes and could cause patients to feel nauseated.
- The laser assistants were responsible for the laser keys, which were kept in a locked key cupboard.

Not sufficient evidence to rate

Refractive eye surgery

Medicines

- The service had a medicines policy, which described the processes for prescribing, ordering, receiving, storing, administering, dispensing and disposal of medicines. The policy also covered medication errors, stocktaking and medication key safety. There was a separate policy and procedure for the safe use of cytotoxic medication.
- We checked the medicines fridge temperature log and saw that it was up to date and temperatures were within the recommended range. We also saw that ambient room temperatures were being monitored.
- Medicines were stored safely, within lockable cupboards. There was a medication key policy and the most senior member of staff working in the treatment room was responsible for the medication keys, which were signed out and signed back in again. Access was limited to the key holder and there was one set of keys available in order to ensure maximum security and ensure medicines were accessed appropriately. The most senior member of staff was responsible for the medicine keys and were required to sign them out at the beginning of the day and sign them back in at the end of the day.
- Patient records detailed current medications, allergies and a medical history to ensure consultants prescribed medications appropriately.
- Only staff with the required competencies were administering and dispensing medicines. Eye drops were prescribed by the surgeon and checked by an appropriately qualified member of staff.
- Local anaesthetic eye drops were administered by the surgeon prior to surgery taking place.
- The service did not use medicines for sedation for procedures performed at this clinic.
- The service had an emergency medicines box containing non-controlled drugs for use in an emergency. There was a list on the outside of the box to alert staff to expiry dates. Restocking of drugs was through the service drugs ordering systems.
- At the time of our inspection, the service had just introduced a more detailed policy covering the dispensing of medication for patients to take home following their surgery. Ultimately, the ophthalmic surgeon was responsible for dispensing medication to each patient and we saw this happen throughout our inspection.
- The registered manager undertook a monthly stocktake of all medicines within the service.

Records

- Patient records were held electronically and in paper format. The electronic system contained all the patients' details including assessments, surgery and medicines given. We looked at this system for three patients. These included pre-operative, intra-operative and post-operative information, which detailed information such as full details of the patient's medical history, previous medications, consultation notes, treatment plans and follow-up notes in order to keep the patient safe and determine the suitability of surgery.
- We reviewed 10 sets of paper based patient records and saw that consent for procedure was completed, consent to contact GP was completed and a 'cooling off' period was given. A 'cooling off' period is recommended best practice and allows patients time to think about whether they wish to proceed with treatment or not.
- All records containing patient information were stored securely and electronic records were password protected.
- Records were internally audited every three months. We looked at the audit information relating to June 2017 and September 2017. The service randomly selected 10 sets of patient records and used prompts to audit them. The audits showed that records were generally completed well but there were recommendations made to ensure information such as occupation, employer details and home telephone numbers should be obtained at consultation.
- Each time the laser machine was used it was recorded in a log and in the patient's record, we observed this taking place.

Assessing and responding to patient risk

- Patients were self-referring and attended a series of appointments prior to treatment during which they completed a health questionnaire. The health questionnaire was completed electronically with the help of a member of staff if necessary.
- At each appointment the risks, benefits and limitations of refractive eye surgery were explained to the patient. We observed this as part of the inspection and witnessed the patient signing to declare they understood the information they had been given.

Not sufficient evidence to rate

Refractive eye surgery

- Patients were only considered for treatment if they fulfilled the provider's suitability guidelines. We reviewed the criteria which not only assessed optical suitability, such as age related macular degeneration, but considered other health conditions. For example patients with epilepsy were considered suitable if they had been seizure free for two years.
- The surgeon performing the procedure always performed a pre-operative assessment with the patient and a minimum of one week was given for the patient to change their mind – the cooling off period. We reviewed 10 sets of patient records and found this to be the case in all the records we reviewed.
- The suitability criteria also included psychological disorders and patients who presented with psychological problems such as depression were required to have an assessment of their mental status.
- Patients who were taking warfarin were required to have a blood test to check their clotting levels through their GP. Warfarin is a medicine that reduces the risk of blood clots forming.
- Patients with high blood pressure were referred to their GP for further treatment before surgery was agreed.
- On the day of surgery, pre-operative assessments such as a general health check, blood pressure and heart rate and a prescription check were undertaken to ensure patients were still suited to the surgery previously selected.
- The surgical patient pathway included the completion of a surgical safety checklist for cataract surgery that had been adapted from the World Health Organisation (WHO) surgical safety checklist. This was not used for patients undergoing laser vision correction, but a modified checklist was used for this group of patients. We observed this checklist being used at our announced inspection and we saw completed WHO surgical safety checklists for intra ocular surgery in four sets of patient records.
- The surgical safety checklist for cataract surgery included a section for signing in, time out and signing out and a safety huddle took place prior to surgery and a debrief took place following surgery. The form included a checking requirement to ensure the planned refractive outcome was checked, as well as the lens model and power to be used and that the correct lens implant was present.
- We asked the service to provide evidence of any audits undertaken in relation to the WHO surgical safety checklist for intra ocular surgery. The registered manager confirmed that the WHO surgical checklist was not audited separately but patients notes were audited quarterly to ensure paperwork was completed and WHO checklists were filed in each patient's medical records. We looked at the audits for quarter two and quarter three. These audits did not refer to the WHO surgical safety checklist for intra ocular surgery. This meant there was no oversight to ensure the WHO surgical safety checklist for intra ocular surgery was being completed for all patients.
- The team had a safety huddle at the start of each treatment day. This allowed the sharing of information to enable a safe and smooth running of the surgical list.
- Post-surgery, patients remained in the service until they felt well enough to go home. As the surgery did not involve general anaesthesia or sedation, patients did not require any observations post operatively. Staff told us the most common issue immediately post-surgery was fainting and staff explained the steps they would take to address this. Staff explained that if necessary, they would call an ambulance for the patient.
- Post-surgery, patients were supplied with an out of hours telephone number which was answered by a member of the customer services team. The customer services team would then contact the patient's surgeon and arrange for the surgeon to contact the patient. In addition, each patient was provided with their treating surgeon's emergency contact number who would be on call between the hours of 6pm and 8am. Patients were advised to contact the clinic directly during clinic opening times.
- Post-surgery patients were also given detailed written instructions on aftercare and the time and date of their next appointment.
- The registered manager told us the service did not have a service level agreement with a local hospital in the event of complications. However, the contact details of a local hospital was documented in the medical protocols document dated March 2016. This stated the service was awaiting confirmation of a service level agreement. There had never been a need to transfer a patient to another healthcare provider, but staff told us for medical emergencies such as collapse, they would telephone the 999 emergency services.

Nursing and medical staffing

Not sufficient evidence to rate

Refractive eye surgery

- There were adequate numbers of suitably trained staff on duty on treatment days. Staffing numbers and skill mix complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres.
- The service employed two full time equivalent ophthalmologists and one optometrist under practising privileges. It also directly employed one full time equivalent registered nurse who had recently been appointed and two full time equivalent laser technicians/customer advisors. In addition, there was also a full time equivalent registered manager.
- Surgery observations and discussions with staff reflected that a qualified nurse and a laser assistant supported the surgeon.
- Monitoring of staffing levels was based upon the numbers of patients requiring refractive surgery and aftercare in the service. Clinics and surgery was scheduled dependant on the amount of patients and staff available in order that patients' safety was maintained.
- The clinic had a named Laser Protection Supervisor (LPS). The LPS had overall responsibility for the safety and security of the lasers including calibration of the lasers, safety checks, securing the area, making sure the lasers were shut down at the end of the treatment session, reporting incidents, reporting any technical problems with the lasers and ensuring other staff follow local rules on a day to day basis.
- The laser technicians undertook the role of deputy LPS when they were assisting the surgeon in the laser treatment room or if the registered manager was not on site. This meant there was always a designated LPS present when treatments were taking place and all staff knew who was the designated LPS for the treatment session. The laser technicians had attended core knowledge training.
- There was a minimum of four members of staff scheduled to work on laser treatment day and when patients attended for aftercare, and a minimum of five members of staff working on lens treatment days. There was a minimum of two staff members working on clinic days for patients attending for aftercare and consultations. This was in line with national guidance.
- During periods when the clinic was not busy, staff were requested to work at other clinics around the region. In addition, there was an effective system for engaging staff at short notice from other Optimax clinics to cover sickness and annual leave. Protocols were standardised throughout the organisation and staff felt at ease travelling to other sites to assist with surgery in their role. Staff were familiar with the teams at other sites and identified no concerns with this pattern of work.

Major incident awareness and training

- The service had a major incidents policy and procedure, which covered potential risks such as dealing with a bomb alert, fires, and gas leaks, floods due to freak weather conditions and internal flooding.
- Staff had received fire safety training as part of the mandatory training and were well equipped to keep patients safe in the event of a fire.
- Staff undertook resuscitation drills on a quarterly basis. Documentation provided following our inspection confirmed these drills took place in February 2017, April 2017 and July 2017.
- In the event of clinic closures or the whole business closing, there was a corporate closure strategy, which ensured that patients continued to receive aftercare as required.
- The service had emergency backup generators that would be initiated if there was a power failure. This ensured that treatment would not be compromised should there be a power failure.

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

Not sufficient evidence to rate

Evidence-based care and treatment

- Patients had their needs assessed and their care planned and delivered in line with evidence based guidance and standards. Optimax had a Medical Advisory Board (MAB), which set standards for all surgeons and optometrists across the service to work to. Standards were set according to National Institute for Health and Care Excellence (NICE) guidelines and recommendations from the Royal College of Ophthalmologists as well as guidelines by other relevant regulatory bodies. Minutes of these meetings showed that clinical protocols were discussed and amendments to current practices made to be in line with evidence-based practice.

Not sufficient evidence to rate

Refractive eye surgery

- Doctors meetings were held twice a year at provider level. These were attended by the doctors, the optometrists, the chief executive, chair of the board and the medical compliance manager. At this forum, information from the medical advisory board was shared such as changes to protocols or the introduction of new treatments.
- Policies and procedures we reviewed were aligned with recognised national standards and guidance. Pre and post-operative care followed the Royal College of Ophthalmologists Professionals Standards for Refractive Surgery April 2017.
- The service had a policy, which indicated that patients start their laser surgery following a clinical assessment, which involved a review by an optometrist prior to their consultation with the ophthalmologist. Where a patient was assessed as being unsuitable for laser surgery an explanation in writing was provided to them. This was undertaken in line with best practice guidelines in order to maintain patient safety.
- Pre-operative assessment included screening against a defined set of suitability criteria to ensure patients were suitable for their chosen treatment. The surgeon discussed with the patient any potential limitations of the treatment as well as the potential benefits. We observed these discussions taking place on the day of our inspection. Patients were given a minimum of one week for them to reflect on their decision to go ahead with the procedure. We saw this evidenced in all of the patient records we looked at.
- Laser treatment sessions took place in the morning or in the afternoon and a maximum number of eight patients were treated at each session. Lens surgery sessions tended to take place in the mornings and there was a maximum of 12 treatment slots per day. This was in line with best practice guidance.

Pain relief

- Patients undergoing ophthalmic surgery were treated under local anaesthesia. Anaesthetic eye drops were administered prior to treatment to ensure patients did not experience pain or discomfort. This enabled patients to remain fully conscious and responsive. Although there was no formal pain screening process, staff were able to monitor their pain throughout the procedure. We observed patients being asked if they were comfortable during treatment. Staff clearly informed patients about the expected level of pain during and after the surgical procedure.
- Patients told us they did not feel pain during their procedure and they felt informed regarding the best way to manage any post-operative pain.

Patient outcomes

- The service did not contribute to the National Ophthalmic Database Audit (NODA).
- Treatment outcomes were measured in terms of the surgeon's success rate and the patient satisfaction with their treatment journey. The treatment outcomes for all surgeons working for Optimax were monitored. This data was used to conduct a yearly audit of the individual surgeon's outcomes, which was discussed with the ophthalmologist at their appraisal.
- Information sent to us prior to our inspection indicated that in the 12 months prior to our inspection, there had been 12 incidence of unplanned re-treatment or treatment enhancement following refractive eye surgery.
  - We asked the service to provide us with evidence relating to the benchmarking of patient outcomes with other locations. The location did not provide this information. Following our inspection, the service told us they did benchmark data and that key performance indicators were discussed at senior management level and communicated to all clinics so they could see how they perform and where improvements could be made. However, the provider did not provide evidence of benchmarking or where improvements had been made. We were therefore not fully assured that outcomes were benchmarked or that action was taken as a result of benchmarking.

Competent staff

- Staff we spoke with had the correct level of skills and competencies to carry out their role. All new staff attended a comprehensive induction programme which included familiarisation with policies and procedures. Staff working with lasers worked alongside staff that were more senior until they had completed their core knowledge training.

Not sufficient evidence to rate

Refractive eye surgery

- The service had recently recruited a registered general nurse and they confirmed they had not been allowed to undertake roles and tasks until they had been signed off as competent to do so.
- The service did not use agency staff, but mobilised staff from other clinics when required. These staff were familiar with Optimax policies and procedures.
- The manager was the services' Laser Protection Supervisor (LPS), with overall responsibility for the safety and security of the lasers. The training for this role was renewed every two years. An external Laser Protection Advisor (LPA) was available for training and advice and supported as needed.
- All staff received an annual appraisal and monthly one to one meetings took place. Staff told us they found the one to one and appraisal process useful and beneficial.
- All of the surgeons who performed refractive eye surgery at the service held the Royal College of Ophthalmology certificate in laser refractive eye surgery.
- The laser technicians were trained to assist with laser treatment and had undertaken the core of knowledge training.
- There were systems to enable the revalidation of surgeons and there was an accountable person responsible for ensuring revalidation was valid.
- Staff had not received training in the handling or administration of cytotoxic medications such as mitomycin C. The registered manager told us this medicine was very rarely used and that staff did not prepare this medication. This medication came pre-prepared and was administered by the surgeon.
- Staff did not receive training relating to sepsis. This meant that staff may not consider sepsis as a complication of treatment or may not recognise sepsis in a patient presenting with symptoms.

Multidisciplinary working

- We saw good team working between ophthalmology surgeons, nurses and laser technicians in the operating theatre.
- We observed optometrists and ophthalmology surgeons liaising in the delivery of patient care.
- Staff understood the role of the LPA and knew how to contact the LPA if required.

Seven day services

- The service offered clinic appointments and treatments between the hours of 8am and 6pm, Monday to Saturday and ad hoc clinics were provided when required on Sundays, but staff told us this was rarely needed.

Access to information

- Patient records were held electronically, with some elements such as consent forms being held in paper format.
- All relevant staff could access patients' electronic notes from any clinic if required.
- Patients were given clear verbal and written instructions regarding necessary precautions before and after surgery. Doctors gave clear predictions of what vision the patient would be likely to achieve following their surgery and explained how long they would need to wait before this vision was available to them.
- Following surgery, all patients were given a letter detailing the procedure they had undergone and post-operative medication regime to take to their GP. Permission was also obtained from patients at the consultation stage, to enable the service to contact their GP if required.
- GPs could access optometrists and ophthalmic surgeons for advice if this was required.

Consent and Mental Capacity Act

- The service had a policy for consent to examination and treatment, which set out the standards and procedures for obtaining consent from patients for them to be examined or treated.
- According to the training data provided by the service, staff had not received any training on obtaining consent or the Mental Capacity Act. The registered manager told us that Mental Capacity Act was covered as part of equality and diversity training. We were unable to evidence this.
- Consent was obtained by the surgeon performing the treatment. Written and verbal information was given to the patient in order to ensure consent was as informed as it could be.
- We saw that consent was ongoing throughout the patient's journey. For example, laser technicians explained the imaging procedure and asked for consent to undertake the procedure.
- Between seeing the optometrist and the surgeon for the consent appointment, the patient was given a minimum

of one week to reflect on their decision to proceed with the treatment, the cooling off period. We reviewed 10 sets of patient records, all of which demonstrated that patients were given this time frame to reflect on the decision.

- Patient's capacity to consent to treatment was taken into account. It was the responsibility of the surgeon to assess whether the patient had capacity to consent. If there were any concerns, the surgeon would contact the patient's GP.
- Patients were always asked for consent to communicate with their GP we observed this during a patient consultation and saw evidence of this in the patient records we reviewed.

Equality and human rights

- The service had an equality and diversity policy. In addition, staff received equality and diversity training as part of their induction and as part of their on-going mandatory training.

Are refractive eye surgery caring?

Not sufficient evidence to rate

Compassionate care

- Without exception, we observed all staff treating patients with kindness, compassion, courtesy and respect. Staff interactions were positive and there was a familiarity with patients who had attended the service for a significant amount of time.
- Staff took time to interact with patients in a respectful and considerate manner. We observed a surgeon maintained a reassuring dialogue with a patient during surgery, talking to the patient and explaining when they were likely to experience sensations such as pressure in the eye, a burning smell or fluid running over the eye. This complied with the Royal College of Ophthalmology professional standards for refractive surgery.
- All staff at every stage of the treatment journey introduced themselves to the patient. Staff supported patients to understand relevant treatment options including benefits, risks and potential consequences. Patient advisors gave patients information about what to expect from laser surgery. This information was shared during one to one face-to-face consultations when patients were allocated ample time to ask questions. During this initial consultation, patients were given transparent and accurate information about all costs of potential treatment.
- Patient privacy and dignity was maintained at all times. Consultations took place in private rooms with doors closed to maintain the dignity and privacy of all patients.
- Some patients returned frequently to the service for aftercare appointments and the familiarity of staff with individual patients was warm and welcoming.

Understanding and involvement of patients and those close to them

- Throughout our inspection we observed staff interacting with patients before, during and following treatment. At each stage staff checked the patients understanding of the information they were given. Patients told us they were given enough information at a level they could understand and were encouraged to ask any questions at any time.
- We saw that patients brought those close to them into the clinic and they were involved in discussions where this had been the patients wish.
- We reviewed the providers advertisements on the Optimax Limited website and those displayed in the waiting areas in the clinic. The costs were clearly outlined.

Emotional support

- Throughout our inspection, we observed staff recognising when patients were anxious and reassuring patients, especially where patients were apprehensive about their treatment.
- Following treatment we observed staff instructing patients about post-operative care and how to instil eye drops and take their medication.
- Staff supported patients emotionally. For instance, one patient told us they felt a bit anxious and a member of staff had asked them if they would like someone to hold their hand.
- Staff got to know patients during the appointments prior to surgery and this relationship helped to put patients at ease. Where possible, the same patient advisor saw patients at all stages of their journey. All patients we spoke with agreed that staff made them feel comfortable and safe.

Not sufficient evidence to rate

Refractive eye surgery

Are refractive eye surgery responsive to people's needs?
(for example, to feedback?)

Not sufficient evidence to rate

Service planning and delivery to meet the needs of local people

- The service did not provide an emergency eye surgery service. They provided pre-planned procedures only.
- Optimax planned and delivered services for any person who wished to attend their clinics, with the exception of patients who had medical conditions, which meant they could not receive the treatments offered. In addition, Optimax did not treat patients under the age of 18, or those who were pregnant or breast feeding.
- The service provided pre-planned elective services only, which meant they were able to control the numbers of patients they could accommodate each day.
- All of the appointments for the service were managed at a central location where the diary was maintained. This team took calls from prospective patients who wanted an appointment to assess if they were suitable and for all consecutive appointments.
- The services were delivered in pleasant premises, with appropriate facilities for patients and staff. All patients we spoke with told us, they felt comfortable in the waiting areas at the service, where drinks facilities, magazines and information leaflets were available.
- All areas we inspected were well equipped. Patient waiting areas were suitable with the provision of magazines and hot and cold drinks.

Access and flow

- Patients self-referred to the service through a variety of methods, for example, on-line, through the corporate call centre or by visiting the clinic.
- In the 12 months prior to our inspection, the service had cancelled refractive eye surgery procedures for non-clinical reasons on four occasions.
- At the time of our inspection, there was no waiting list for refractive eye surgery. This meant patients did not have to wait for their treatment.
- The service did not monitor waiting times both prior to an appointment being arranged or when patients arrived for their appointment.
- The team took action to minimise the time that patients spent in clinic on their day of treatment. Patient arrival times were staggered to coincide with their allotted surgery time. This meant there was less time spent waiting in the clinic.
- There were no incidences of unplanned transfer of a patient to another health care provider in the 12 months preceding our inspection. This meant the service was able to recognise and address any potential complications to maintain quality of care to patients.

Meeting people's individual needs

- Each patient received an initial courtesy call to confirm their appointment to establish an initial rapport with them and to ascertain any special requirements whilst attending the service.
- The service made reasonable adjustments for wheelchair users and people with restricted mobility. For example, there was a separate entrance for patients who had conditions that affected their mobility and a stair lift was available for patients who required it. Doors and corridors were wide enough to accommodate a wheelchair and there was an accessible toilet for patients who required this facility.
- The service did not treat patients with complex health and social needs or learning disabilities.
- Interpreting services were available for patients who required this service. Staff we spoke with told us they were not aware of the interpreting service. This information had, however, been communicated with staff through an email.
- The service had a range of patient information leaflets available, explaining the various conditions and laser surgeries it offered, including pre and post care instructions. However, all patient leaflets and documents, including consent forms, were only available in English and at the time of our inspection could not be obtained in different languages.
- The service screened patients suitability for treatment at an initial consultation, if a patient had complex health and social care needs, this would be taken into account at this stage.
- The service did not comply with accessible information standard because they did not provide information in other formats such as braille or large print format.

Not sufficient evidence to rate

Refractive eye surgery

Learning from complaints and concerns

- The service had a complaints policy, which had been reviewed in September 2017. The policy detailed that complaints would be dealt with within 20 days of receipt. The policy gave the same level of importance to verbal complaints as it did to written complaints.
- Information regarding how to make a complaint was available within the clinic but this information was not made available to patients in the printed patient information guide or as part of the printed aftercare advice guide that was given to patients on discharge.
- Staff asked all patients to complete surveys at each visit in order to gauge their satisfaction with the service they received. The latest annual survey was displayed in the clinic patient's guidebook, for all visitors to see.
- Between June 2016 and May 2017, the service had received 23 written compliments and six complaints. Three of the complaints related to patients being unhappy with the results of their treatment, whilst the other three complaints related to patients being charged for missed appointments. All six complaints were managed under the formal complaints procedure and all six complaints were upheld.
- Where possible, complaints and concerns were dealt with at source and could be raised with the clinic manager where necessary. If it was not possible to resolve the complaint, patients were advised to make a formal complaint at corporate level.
- We did not see any evidence that learning from complaints was shared within the wider organisation.

Are refractive eye surgery well-led?

Not sufficient evidence to rate

Leadership and culture of service

- At location level, the service was led by the registered manager who was responsible for a team of three Optimax employees. Ophthalmologists and optometrists worked under the direction of the registered manager whilst working in the clinic but they were self-employed working under practising privileges. It was company policy for staff from other clinic locations to fill staffing gaps during the treatment days. The registered manager was responsible for these staff whilst they were on site at the Leicester clinic.
- The registered manager had the skills, knowledge, experience and integrity to lead the service with support from the central governance team. The registered manager was relatively new in post but had previously worked at the clinic as a laser technician. This meant the registered manager, although new in post had a good understanding of the service.
- There was a clear leadership structure from service level to senior management level.
- Staff told us that one individual following establishment in 1991 owned Optimax clinics Ltd. They explained the founder was well respected, accessible and approachable.
- Staff were aware of the corporate management structure and were clear about lines of reporting. Staff told us that senior managers were visible and approachable and the registered manager was readily available and often worked clinically alongside them. At our unannounced inspection, we observed the registered manager had been counted in the staffing numbers and was working on reception alongside a registered nurse. This meant there might be times when the registered manager may not have sufficient capacity to lead effectively.
- Staff told us they felt able to raise concerns with the registered manager. The team was small and there was a good sense of teamwork. Some staff were new to the service and told us they felt well supported in their role.
- Staff performance was audited and we saw evidence of this in personnel files. If poor performance was identified, this was addressed through one to one meetings and the appraisal process.
- All marketing campaigns were directed by the central corporate team. We observed information available was honest, responsible and complied with guidance from the Committee of Advertising Practice. Patients received a statement that included, terms and conditions of the service, the cost, and method of payment for their treatment.

Vision and strategy

- The strategic vision and forward vision of the service was determined at a corporate level. The service did not have a clear vision and strategy; however, there was a corporate core business plan for 2017, which set out the

company's purpose, vision and values. The vision was to be the UK's first choice for laser and lens surgery procedures and to provide high quality state of the art clinics and working conditions.
- Staff we spoke with had not been involved with the development of the vision and values and were not aware of them. The vision and values were not displayed within the service.

Governance, risk management and quality measurement

- The service had a clinical governance and risk management policy. This policy detailed the types and frequency of meetings that should take place, and the topics that should be discussed within the meetings. The policy indicated that complaints, incidents and near miss reports, clinic key performance indicators (KPIs), conference call actions, emails from head office and training and development should be discussed at these meetings.
- The monthly compliance teleconference was attended by the compliance manager, the director of operations, the diary team, the lens surgery lead and registered managers of clinics across the country.
- Monthly senior management team (SMT) meetings supported clinical governance and risk management. We reviewed the minutes of the March 2017, April 2017, May 2017 SMT meetings and saw that KPIs and training and development were discussed but there was no evidence that complaints, incidents and near miss reports were discussed. This meant there could be a risk that the SMT may not be fully aware of themes and trends relating to complaints, incidents and near misses at location level.
- The service had a risk register that contained a list of 30 generic risk assessment titles but did not include any specific risks related to the service. The risk register did not include a date the risk was entered onto it, the date it needed to be reviewed, details of mitigating actions or persons responsible for ensuring action plans for mitigation were completed. Risk registers are a management tool used to fulfil any regulatory responsibility and acting as a repository for all risks identified, Risk registers include information about each risk such as; the nature of the risk, who has responsible to monitor the risk and any measures in place to reduce the risks.
- The registered manager had gone through the risk register to identify potential and actual risks but the risk register had not been reviewed to ensure risks were being monitored and addressed.
- Concerns we identified during our inspection had not been included on the service's risk register. For example, we raised a concern that there was no hand washbasin in the topography room; this could increase the risk of cross contamination. Although this was a risk known to the registered manager, it had not been formally risk assessed nor had it been entered onto the service's risk register. We also raised a concern that patients who were left alone in the pre-operative and recovery room could accidentally walk into the operating theatre whilst the laser was in use because there was no signage to indicate the patient should not enter. Again, this had not been identified as a possible risk within the service.
- Risks we identified and raised with the registered manager at our announced inspection had all been actioned in a timely manner and we saw that steps had been taken to mitigate risks when we undertook our unannounced inspection. This demonstrated a service that acted on mitigating risks once the risk had been identified.
- We looked at the minutes of team meetings, compliance conference calls and senior leadership team meetings and found there was no discussion relating to the risk register. We were therefore not assured that governance processes were robust in relation to risk within the service.
- Medical professionals such as the optometrist and surgeons were employed under practising privileges. Practising privileges are where medical staff are not directly employed by the service but who have permission to practise there.
- All staff working under practising privileges were checked for suitability and were monitored on an annual basis by the Medical Advisory Board (MAB) to make sure they maintained the correct skills to undertake their role.
- Staff working under practising privileges were reviewed on an annual basis. However, there was a lack of governance around disclosure and barring (DBS) checks for staff working under practising privileges. All staff had a DBS check undertaken at the beginning of their employment. However, some staff had worked under these terms for a long time and when we reviewed their files there was not an up-to-date DBS check. In one staff

file, we found no evidence to suggest the surgeon had been checked since the year 2000. We raised this as a concern with the registered manager who spoke with human resources and confirmed the DBS check should be updated every three to five years. When the registered manager investigated this further, they found the surgeon had undertaken a DBS check in 2011. This meant the service was not following the HR policy for ensuring DBS checks were undertaken every three to five years.

- Each medical practitioner working under practising privileges received an annual appraisal.
- All medical practitioners working under practising privileges had professional indemnity insurance and this was evidenced in their personal file.

Public and staff engagement

- The service had a website where information could be obtained about the types of treatment available for patients. This included information about costs and finance. It also outlined the suitability criteria, and explained the laser eye surgery. The website also included information regarding a free consultation and lifetime after care as needed.
- Patient feedback was obtained from patients following their treatments. The feedback viewed was positive with patients recommending the service and describing positive results.
- The registered manager told us the service did not undertake staff surveys. As a small team, staff told us they had ongoing communication and felt well engaged within their team.

Innovation improvement and sustainability

- Although we found no evidence of innovation at this service, the location had just undergone a renovation to enable the implementation of cataract surgery.

Outstanding practice and areas for improvement

Outstanding practice

Start here...

Areas for improvement

Action the provider MUST take to improve

- The provider must review its policies in relation to incident reporting and duty of candour in order to support staff to deliver a safe service.
- The provider must review its governance processes to ensure a robust oversight of risk management within the service.
- The provider must ensure identified risks are properly assessed, consistently monitored and reflected in the service's risk register.
- The provider must ensure it is aware of the level of safeguarding training staff have received to provide assurance staff are trained at the correct level for their role.
- The provider must ensure the World Health Organisation (WHO) surgical safety checklist for intra ocular surgery is audited in order that it can assure itself that the risk of error during surgical procedures is minimised as far as possible.

Action the provider SHOULD take to improve

- The provider should consider contributing to the National Ophthalmic Database Audit (NODA).
- The provider should consider obtaining leaflets in different languages and formats.
- The provider should consider monitoring waiting times both prior to an appointment being arranged and when patients arrived for their appointment.
- The provider should consider developing a clear clinical vision and strategy within the service.
- The provider should consider undertaking an annual staff engagement survey.
- The provider should consider formal pain screening processes to establish whether pain relief for patients was adequate.
- Should ensure staff receive adequate Mental Capacity Act training.
- The provider should consider formalising a service level agreement with a local hospital so that in the event of a complication, patients can be transferred without delay.

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 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively, such systems or processes must enable the registered person to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity. How the regulation was not being met because: · Arrangements for identifying, recording and monitoring the ongoing management of risk were not effective. · Risk assessments had not always been undertaken for known risks within the service. · The risk register was not tailored to risks identified within the service. · The provider did not have a policy in place for the management of incidents or duty of candour. · Not all staff understood the requirements of the duty of candour regulation. · There was a lack of awareness around the level of safeguarding training staff had undertaken. · The service had not followed its human resources policy for the frequency at which disclosure and barring (DBS) checks should be undertaken. · The World Health Organisation (WHO) surgical safety checklist for intra ocular surgery was not being audited. Regulation 17(1) (2) (a) (b)

This section is primarily information for the provider

Enforcement actions

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.