Optimax Laser Eye Clinics - Birmingham

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Services we do not rate

We regulate refractive eye surgery, 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:

- 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.
- Staff using lasers had additional training to carry out their duties safely.
- Procedures for obtaining consent were robust and in line with national standards and guidance.
- Staff were very caring and patients were treated with privacy dignity and respect.
- Patients were involved in discussions about their treatment options.
- Staff recognised when patients were anxious and offered reassurance.
- 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.

However

- Staff had received training in emergency first aid and would follow the emergency procedure in place in the event of patients suddenly becoming ill. There was no service level agreement at the time of inspection to refer patients to the local acute hospital in the event of a complication.
- Following this inspection, we told the provider that it should take some actions to improve the above, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Summary of findings

Heidi Smoult

Deputy Chief Inspector of Hospitals

Overall summary

Optimax Laser Eye Clinics Birmingham is operated by Optimax Clinics Limited. Facilities were available on one level. Facilities included a reception/waiting room, a topography room where the service also prepared patients for treatment, three consultation rooms that the service used as recovery rooms on treatment days, the doctors' room where some treatments were also carried out and the treatment/operating room with the dirty utility room to the rear of this.

Patients were self-referring and self-funded and had 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 inspection on 25 May 2018.

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.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		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 Birmingham

Services we looked at
Refractive eye surgery.

Summary of this inspection

Background to Optimax Laser Eye Clinics - Birmingham

Optimax Laser Eye Clinics Birmingham is operated by Optimax Clinics Limited.

The service opened in 1995 and is part of the Optimax Clinics Limited Company which was established in 1991.

It is a private clinic located just outside of Birmingham city centre on Bristol Road.

The service primarily serves the communities of the Birmingham area. It also accepts patient referrals from outside this area.

The service provides assessment for laser refractive surgery, cataract and lens replacement surgery assessment, laser surgery and after treatment follow-up appointments.

The service provides treatment to people aged 18 years and over.

The service has had a registered manager in post for two years.

There have been no changes in usage or to the services provided since the clinic opened

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector.

Information about Optimax Laser Eye Clinics - Birmingham

Optimax Laser Eye Clinics Birmingham 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 included surgeons (ophthalmologists), registered nurses, optometrists and laser technicians.

On the day of our inspection, a laser vision treatment clinic was taking place together with an aftercare clinic. There was a total of 15 patients receiving treatment throughout the day.

We visited all the clinic areas and observed surgical procedures in the treatment room. We spoke with nine staff including; two registered nurses, one reception staff, one surgeon, one optometrist, two patient advisors/laser technicians, the registered manager and the compliance manager. We spoke with seven patients during the inspection; we reviewed four sets of patient records and five sets of staff files.

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 most recent inspection of the service took place on 08 January 2014 and found that the service was meeting all standards of quality and safety it was inspected against.

Four surgeons and three optometrists worked for the service under practising privileges. The service employed two registered nurses and seven patient advisors/laser treatment technicians.

Activity

- The service had carried out treatment on 558 eyes in the reporting period May 2017 to May 2018.

Track record on safety

In the reporting period May 2017 to May 2018 there were:

- No never events

Summary of this inspection

- No clinical incidents
- No incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA) or healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- No incidences of healthcare acquired Clostridium Difficile (C-Difficile)
- No incidences of healthcare acquired Escherichia Coli (E-Coli)
- 12 complaints one of which was upheld and 6 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
- The service had a company service level agreement for the control of infection and microbiological services with a Consultant Microbiologist.
- The service had a local service level agreement with Sandwell and West Midlands Hospitals for Pathology Referral Testing.

What people who use the service say

People who used the service told us that they were happy with the information, care and treatment provided to them.

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 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** the provider did not have a service level agreement in place with a local hospital so that in the event of a complication, patients could be transferred without delay.

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:

- 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.
- 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.

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.

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.

Summary of this inspection

We found the following areas of good practice:

- 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?

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.

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 areas of good practice:

- There was a clear leadership structure from service level to senior management level.
- Optimax Birmingham manager and team were supported by the 'Eye Hospitals Group limited' team structure.
- Staff were aware of the corporate management structure and were clear about lines of reporting.
- Staff felt part of the overall vision of the service.
- Patient feedback was encouraged and was used to improve the service.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Refractive eye surgery	N/A	N/A	N/A	N/A	N/A	N/A

Notes

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

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We visited all the clinic areas and observed surgical procedures in the treatment room. We spoke with nine staff including; two registered nurses, one reception staff, one surgeon, one optometrist, two patient advisors/laser technicians, the registered manager and the compliance manager. We spoke with seven patients during the inspection; we reviewed four sets of patient records and five sets of staff files.

There were no special reviews or investigations of the service on-going by the CQC at any time during the 12 months before this inspection. The most recent inspection of the service took place on 08 January 2014 and found that the service was meeting all standards of quality and safety it was inspected against.

Four surgeons and three optometrists worked for the service under practising privileges. The service employed two registered nurses and seven patient advisors/laser treatment technicians.

Refractive eye surgery

Summary of findings

Activity

- The service had carried out treatment on 558 eyes in the reporting period May 2017 to May 2018.

Track record on safety

In the reporting period May 2017 to May 2018 there were:

- No never events
- No clinical incidents
- No incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA) or healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- No incidences of healthcare acquired Clostridium Difficile (C-Difficile)
- No incidences of healthcare acquired Escherichia Coli (E-Coli)
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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

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The service had an incident reporting policy (Adverse Event and Near Miss Reporting Investigation Analysing and Learning policy) in place to guide staff in the process of reporting and managing incidents.
- Staff we spoke with told us if they felt they needed to raise an incident, they would speak with their manager and that they always had discussions and feedback from incidents they had raised.
- 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.
- The service manager undertook monthly audits of incidents. Between May 2017 and May 2018, there had been 12 incidents reported, of which two 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 saw evidence of incidents being raised. For example staff noticed a burning smell and saw that the amplifier temperature was out of range. The surgery for that day was cancelled and the patients were re-booked. An engineer was called and rectified the problem.

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 had a duty of candour policy for guidance for staff to follow should they be required to invoke duty of candour within the service. Staff knew and understood the duty of candour requirements and the service had rolled out duty of candour training to all staff.

Mandatory training

- 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.
- The provider's record of staff training showed that all staff (100%) were up to date with mandatory training.
- Staff we spoke with confirmed they received mandatory training annually, and we saw evidence of this in staff records.
- All relevant staff were trained in basic life support (BLS) and two members of staff (nurses) were trained to immediate life support (ILS). The service had no incidents that required life support since it opened in 1994. 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 which was up to date.
- The service had a vulnerable up to date adult's protection policy. 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 adult's 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.
- Local Authority safeguarding numbers were available 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, there was an up to date child protection policy in place. The policy was in place to provide guidance for staff around children visiting the premises with an adult. All staff had completed basic child protection safeguarding training.
- The service had not had cause to report any safeguarding concerns since opening.
- The registered manager was responsible for organising post-operative care and follow up of patients.

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 had access to an Infection Control Nurse employed by the company for their area who visited the service giving advice and training.

Refractive eye surgery

- 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 clinical areas were observed to be complaint with best practice regarding hand hygiene.
- The last hand hygiene audit was carried out between 29 March 2018 and 4 April 2018. The overall result was that staff were compliant with hand hygiene protocols.
- An infection control audit was undertaken on 7 February 2018 with an overall score of 95% compliance against an overall target of 100%. There were two training points which needed to be covered with some newer staff members and this was addressed in a clinic meeting and followed up with an email.
- There had been no reported healthcare associated infections for this service in the 12 months prior to our inspection.
- 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 Methicillin-Resistant Staphylococcus Aureus (MRSA) or healthcare acquired Methicillin-Sensitive Staphylococcus Aureus (MSSA).
- The service used only single use surgical instruments.
- There had been no incidences of healthcare acquired Clostridium Difficile (C Difficile) or healthcare acquired Escherichia Coli (E-Coli).
- All staff received training on infection prevention and control at induction and a refresher every year.
- The service employed two infection control nurse specialists who worked with staff at clinics to ensure that systems, processes and practice reflected relevant elements of NICE guidance regarding surgical site Infections.

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.
- Laser local rules were in place. These are developed for each area where lasers in excess of Class two are in use. The laser local rules concentrate on the local arrangements for managing laser safety, taking into account the requirements of the Laser Safety Standard.
- 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.

Refractive eye surgery

- 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.
- We saw that staff were wearing protective eye wear as stated in the local rules.
- There was one operating room where refractive eye surgery was performed. The room was spacious, fit for purpose and clutter free. In line with best practice, the air-handling unit in this room delivered six air changes per hour.
- The daily laser checks policy also stated that information was recorded on Optic, room temperature and humidity readings. If these were out because of the air-conditioning failure, this would automatically raise an alert to the service desk.
- The controlled area was clearly defined and we noted a warning sign stating the laser was in use do not enter.
- 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. There was 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. The compliance manager explained in detail how Mitomycin C was managed safely and the measures in place.
- An emergency trolley was available in the clinic reception. 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 also had an incident reporting policy and staff understood they would report to the service desk/property department if there was a system failure.
- 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 service desk 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.
- The laser assistants were responsible for the laser keys, which were kept locked away securely.

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. 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.
- Only surgeons (ophthalmologists) prescribed medication for patients.
- 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.
- The service had 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.
- Sign-off processes included the use of cytotoxic medicines, for example Mitomycin C to reduce post-operative haze.

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 four 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 four 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 wished to proceed with treatment or not. We saw this was in place and every patient had a cooling off period of at least seven days.
- The service ensured that appropriate pre-operative assessments were recorded both electronically and on paper. Assessments were undertaken at least a week before surgery and were comprehensive and detailed. These highlighted any risks which in turn were assessed by the operating surgeon who may telephone the patient's GP (with consent) to ensure that the patient was safe to undergo surgery.
- The service ensured that consultant operating records and the patient clinical records were communicated to the GP where necessary. We saw where the surgeon had communicated via a letter and written to a patient's GP with their consent.
- With consent care summaries were sent to the patient's GP/optometrist on discharge to ensure continuity of care within the community.
- Records were internally audited every three months. The most recent audit showed an improvement on recording the patients' blood pressure in the correct place.
- All records containing patient information were stored securely and electronic records were password protected.
- 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.

Refractive eye surgery

- 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.
- 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 co-morbidities or who were unable to consent and understand treatment were considered unsuitable for surgery.
- 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. This was referred to as the 'cooling off period'. We reviewed four 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. We observed this checklist being used at our inspection and we saw completed WHO surgical safety checklists in four sets of patient records.
- The surgical safety checklist (WHO) for laser 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.
- The service carried out a surgical safety checklist audit; this included observation of staff and records. The audit was done quarterly and was also checked by the compliance manager when the compliance audit was undertaken twice a year. Audits confirmed that safety checklists were being followed. We observed the WHO checklist being carried out for each patient.
- 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 and discuss potential patient risks .
- Post-surgery, patients remained in the service until they felt well enough to go home. All patients received a 15 minute check with the optometrist post operatively.
- Post-surgery, the patients were supplied with an out of hour's telephone number for their treating surgeon who would be on call for the first 24 hours between 6pm and 8am. In addition, each patient was provided with the customer services telephone number.
- 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 service did not have a service level agreement with a local hospital in the event of complications. However, the service had a Service Level Agreement for Pathology referral Testing with a local hospital and the contact details of this hospital was documented in the medical protocols.
- 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

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.
- Four surgeons and three optometrists worked for the service under practising privileges. The service employed two registered nurses and seven patient advisors/treatment technicians. The service also employed a full-time manager who was also the accountable officer for controlled drugs (CDs).
- 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 in the diary dependant on the amount of patients and staff available in order that patients' safety was maintained.
- The registered manager was the 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 diary was arranged so that a refractive optometrist was available on treatment days and was present for the next day for the first post-operative check-ups. The surgeon was available immediately post operatively. Staff in the clinic were aware that advice could be obtained from the clinic nurses in other clinics, head optometrist or other optometrists or doctors in other areas if the need arose. This meant that staff provision was in line with national guidance.
- 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 received annual practices in cardiac arrest procedures and this was documented.
- 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 services effective?

Evidence-based care and treatment

- The patient journey was effective in preparing patients and staff for treatments, all the relevant information was available to enable the team to deliver effective care and treatment to the patients. The company had a full online system, allowing access to information to relevant staff members at key stages of the patient journey.
- Communication within teams and between professionals was effective. Staff undertook a 'treatment day huddle' where patients' needs were communicated and discussed for that day and patient handovers between staff contained all relevant information about each patient.
- Patients had their needs assessed and their care planned and delivered in line with evidence based guidance and standards.

Refractive eye surgery

- Optimax had a Medical Advisory Board (MAB) in place, 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.
- 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 started 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. 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 20 patients were treated each treatment 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. We observed a patient was a little distressed and a nurse attending him asked if he required more pain relief. He said he did and the nurse administered this and the patient was less distressed.

Patient outcomes

- 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 assessed by the lead surgeon and used to conduct a yearly audit of the individual surgeon's outcomes, which was discussed at their appraisal. Surgeons' audits were benchmarked against each other and the RCO guidelines. We saw treatment outcomes were in line with RCO guidelines for all outcomes.
- Between May 2017 and May 2018, out of the 558 eyes treated by the surgeons the service had 40 retreatments, out of which 19 were laser top ups after lens surgery, 10 were laser enhancements after laser surgery and 11 were for patients who had their original treatment with another provider prior to it joining with Optimax.

- The service benchmarked data and key performance indicators. These were discussed at senior management level and communicated to all clinics so they could see how they performed and where improvements could be made.
- The Infection control nurse specialists made recommendations where necessary for example introducing care bundles to improve patient outcomes regarding surgical site infections.
- The service ensured that audits were undertaken in order to identify areas for improved outcomes,

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 (laser technicians) worked alongside more senior staff until they had completed their core knowledge training and were competent to use the lasers. Staff competencies were checked initially and then at regular intervals.
- 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 lead surgeon oversaw the recruitment, supervision and training of all the surgeons. Consultant surgeons only carried out surgery that they were trained, skilled, competent and experienced to perform. Comprehensive recruitment checks were undertaken before surgeons were employed to ensure that the surgeons had the skills and expertise required.
- The provider ensured that surgeons undertook a minimum of 50 hours of continuing professional development activity (CPD) per year across their whole practice, or 250 hours across the 5-year revalidation cycle. These activities were relevant to their refractive surgery practice and supported their current skills, knowledge and career development.
- In each surgeon's revalidation cycle there was at least one patient feedback exercise from their refractive surgery practice and presentation of the results for discussion at appraisal, demonstrating the actions taken and the learning achieved.
- 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 received training in the handling or administration of cytotoxic medications such as Mitomycin C. This medication came pre-prepared and was administered by the surgeon.
- All of the staff who provided follow up aftercare were trained to recognise signs of infection in patients.
- All staff received mandatory training which was up to date and recorded in the staff training matrix. Staff also received training pertinent to their job role for example equality and diversity, managing personal stress, disability and discrimination, slips and trips and violence and aggression.

Multidisciplinary working

- We saw good team working between ophthalmology surgeons, nurses and laser technicians in the operating theatre. Staff at all levels communicated effectively with each other.
- 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.
- Surgeons contacted patient's GPs with their consent when required or if there was any concerns about a patient's condition/suitability for treatment.

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.
- Surgeons would visit patients if required out of hours or arrange an extra clinic for them if they had any worries or concerns relating to their aftercare.
- Staff communicated with patient's GPs where required in the best interests of patients and to ensure safe and best possible results from treatment.

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.
- Mental Capacity Act (2005) training was included as part of staff induction and mandatory training updates.
- Consent was obtained by the surgeon performing the treatment. Written and verbal information was given to the patients ensure consent was as informed as it could be.
- We saw that consent was on going 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. This is in line with the Royal College of Ophthalmologist recommendations.
- 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.

Equality and human rights

- The service had a suitable 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.
- Equality and diversity underpinned all of the service's policies.

Are refractive eye surgery services caring?

Compassionate care

Refractive eye surgery

- 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 patients during surgery, talking to the patients and explaining when they were likely to experience sensations such as pressure in 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 and patients told us they understood the costs of their treatment.
- Staff told us they had accessed a sign language interpreter for a patient who was hard of hearing. The patient was then able to understand the treatment options available to them.

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 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

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

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.

Refractive eye surgery

- All of the appointments for the service were managed at a central location by a diary team.This team worked closely with customer service who took the majority of 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 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 not cancelled any refractive eye surgery procedures for non-clinical reasons.
- The service had improved waiting times by keeping patients informed and asking them to come in later than their appointment time if the service knew that the surgeon was running late.
- At the time of our inspection, there was no waiting list for refractive eye surgery. These meant patients did not have to wait for their treatment.
- 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.
- The service managed the provision of un-planned surgery, such as unexpected return to theatre, particularly at night, weekends and public holidays.
- All Lasik patients were seen within 24 hours of surgery and all Lasik/Tesa patients were seen within 36 Hours of surgery in follow-up clinics.
- Patients also had the telephone number of the surgeon on call that they could ring at any time if they were worried. A surgeon told us “on more than one occasion we have had to open the clinic at night or during the weekend to treat patients with post-operative complications”.

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 provision 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 doors and corridors were wide enough to accommodate a wheelchair and there was an accessible toilet for patients who required this facility.
- Interpreting services were available for patients who required this service. Staff we spoke with told us they were aware of the interpreting service and this information had, been communicated with staff through an email.
- The service had a range of patient information leaflets available in different language formats, explaining the various conditions and laser surgeries it offered, including pre and post care instructions.
- 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 and the surgeon and staff would liaise with the patient’s GP.
- The service offered a translation and interpretation service and could offer all patients, the information on a computer in clinic where they could increase the font size. Staff we spoke with told us they were aware of the interpreting service and this information had, been communicated with staff through an email.
- The manager explained how the service had enlisted a sign language interpreter to communicate with a person who could not hear.

Learning from complaints and concerns

- The service had a complaints policy which 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 and the complaints process was contained in the patient guide.
- Staff asked all patients to complete surveys at each visit in order to ascertain their satisfaction with the service they received. The latest annual survey was displayed in the clinic patient's guidebook, for all visitors to see. This contained questions for example about how patients would describe their treatment, how helpful and useful was the information they received, how helpful were the clinic staff during their treatment and how would they describe their aftercare service. Patients thought their treatment had been a positive experience overall.
- The service had received 12 complaints in the last 12 months one of which was upheld. Complaints included a patient unhappy about a cancellation, a patient not wanting to pay for class four laser treatment, and a payment plan issue. All complaints were resolved, all received apologies, and some were resolved locally at clinic.
- 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.

Are refractive eye surgery services well-led?

Leadership and culture of service

- Birmingham manager and team were supported by the 'Eye Hospitals Group Limited' team structure. This included a chairman of the board, a chief executive, a senior management team, an operations team, a finance team, a marketing manager and team, an administration team, a human resources team, a new business facilitator, a compliance manager, lens surgery/ultralase managers, Optimax clinic Birmingham ground force manager and staff.
- At location level, the service was led by the registered manager who was responsible for a team of nine 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.
- The registered manager had the skills, knowledge, experience and integrity to lead the service with support from the central governance team.
- 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. Staff told us that senior managers were visible and approachable and the registered manager was readily available. 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. Staff felt really 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.
- The provider met the requirements related to Duty of Candour (DOC). All staff had received training for this and said they understood DOC and that this was about being "open and honest" with patients when something went wrong. There was a policy in place for staff to follow and the manager would be auditing and monitoring DOC.

Vision and strategy

- The strategic vision and forward vision of the service was determined at a corporate level. There was a

corporate core business plan for 2018, 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.

- The surgeon, registered manager and compliance manager were aware of the company vision and other staff had some knowledge of this and how their job role fitted into the company's vision.

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.

  The service had a risk register that contained a list of generic risk assessments. Risks subjects included treatment of the wrong eye or prescription (mitigated by having patient safety checks and the WHO checklist), misuse of confidential information (mitigated by information governance and training and password protected 'Optic' and equipment user safety (mitigated by local laser rules, service and maintenance and having staff fire officers and first aiders).
- The registered manager had reviewed the risk register to identify potential and actual risks and the risk register was reviewed three monthly or more often to ensure risks were being monitored and addressed.
- 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 and all staff had a DBS check undertaken at the beginning of their employment . The policy on DBS checks was under review and the service was looking to implement checks at three and five year intervals for key staff members.
- 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 aftercare 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 Birmingham clinic overall patient satisfaction for laser surgery results for January 2017 to December 2017 showed 54% of patients thought their treatment was excellent and 42% of patients thought their care was good.
- Staff felt engaged with regular staff meetings and social events held.
- Corporate incentives were held and staff benefits such as employee of the month.

Innovation improvement and sustainability

Refractive eye surgery

- An occasional side effect after cataract surgery is Posterior Capsular Opacification (PCO) which causes blurry or cloudy vision. This is easily treatable using a class four laser. The service had obtained the laser, so patients did not have to travel long distances for this treatment.
- New and improved policies had been introduced.
- An adaptable service had been developed to fit the patients and to meet their specific needs.
- Reorganisation of the payment plan systems had made it easier for patients to pay for their treatment.
- The introduction of text messages to confirm appointments (consultants, surgeon assessments, treatments and aftercare).

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.