Optical Express - Cambridge Clinic

Quality Report

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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Summary of findings

Letter from the Chief Inspector of Hospitals

Optical Express Cambridge is operated by Optical Express Limited. Optical Express is a nationwide company offering general optometric services. The clinic provides laser vision correction procedures for adults aged 18 and over.

The clinic has pre-screening amenities, consultation rooms, and a laser treatment suite, which consists of a laser treatment room and surgeon's treatment room.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 18 December 2017, along with an unannounced visit to the clinic on 3 January 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 provider 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 rate them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- Patient safety was monitored and reviewed and incidents were reported and investigated and learning shared.
- Staffing numbers and staff skill mix were appropriate to deliver safe care and to assess and respond to patient risk.
- Patient records were complete and contained information about assessment, consent and treatment.
- Medicines were stored safely and administered to patients appropriately.
- All staff were up date with mandatory training and all had completed annual appraisals. Care was delivered by a suitably trained, multidisciplinary team that worked well together.
- Audits were regularly carried out to monitor the delivery of safe, effective care and treatment.
- The surgery team and the optometry team showed compassion towards patients. Staff listened to patients and showed respect for patients' dignity.
- There was a clear leadership structure and a positive working culture.

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

- The consent policy did not reflect Royal College of Ophthalmologists guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- There was no formal interpreter service available and patients were advised to bring family or friends to act as translators.
- All patient documentation was only available in English
- The service did not carry out a staff survey to engage with staff and gain feedback.

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

Summary of this inspection

Background to Optical Express Cambridge

Optical Express Cambridge is operated by Optical Express Limited. The clinic opened in 2007. The clinic primarily serves the communities of East Anglia. It also accepts patient referrals from outside this area.

The service has had a registered manager in post since October 2013. At the time of the inspection, a new manager had recently been appointed and was registered with the CQC in October 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 Fiona Allinson Head of Hospital Inspection.

Information about Optical Express Cambridge

Optical Express Cambridge is a high street optical practice, located in Cambridge city centre. Optical Express offers patients laser eye surgery and has been opened since 2007.

The treatment suite and regulated activities are delivered from the first floor of the high street clinic. Treatments took place at the Cambridge clinic two or three times a month dependant on demand. Pre-screening equipment and rooms are shared with the high street Optical Express shop on the ground floor. The first floor can be reached by stairs and there is a lift located at the back of the store.

Patients are self-referring and self-funded. The clinic provides laser vision correction procedures under topical anaesthetic using Class 4 and Class 3b lasers. There are four classifications for visible beam lasers with 3b and 4 being considered the highest levels. Ophthalmologists carried out the treatment.

Patients can make enquires via the clinics website, in person or by telephone via the Optical Express central customer services. The clinic provides laser surgery treatments approximately two days each month.

The service is registered to provide the following regulated activities:

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

During the inspection, we visited the laser treatment room, the consultation room, the discharge room and dirty utilities. We spoke with five members of staff including; a registered nurse, surgery manager, laser technician, a surgeon and a senior manager. We spoke with two patients. During our inspection, we reviewed 21 sets of patient records.

There were no special reviews or investigations of the service by the CQC at any time during the 12 months before this inspection. The service has been inspected once before and took place in January 2014, which found that the service was meeting all standards of quality and safety it was inspected against.

In the reporting period September 2016 to October 2017 there were 455 episodes of care recorded at the clinic. Of these 396 were laser- assisted in situ keratomileusis procedures. This is the most commonly performed laser eye surgery to treat myopia (near- sightedness) and hyperopia (far –sightedness and astigmatism). There were 59 laser- assisted sub-epithelium keratomileusis) refractive eye treatments. This changes the shape of the cornea using an excimer laser.

The service reported the following track record on safety:

- No Never events
- No Clinical incidents
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),

Summary of this inspection

- No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- 21 complaints

Services provided at the clinic under service level agreement:

- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- 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?

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

We found the following areas of good practice:

- There had been no instances of healthcare associated infection during the 12 months preceding our inspection. We saw that staff washed their hands and cleaned equipment thoroughly.
- There were systems in place to ensure that lasers were used safely. Staff were appropriately trained to operate lasers and laser equipment was maintained.
- Equipment was serviced regularly and all electrical tests had been completed and were in date.
- Medicines were stored securely and medicines stock was managed safely.
- Staff were up to date with mandatory training.

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

- Flooring in patient waiting areas appeared worn with visible black marks.

Are services effective?

We found the following areas of good practice:

- Patients received care in line with national guidelines and standards
- There were systems in place which ensured surgeons outcomes were monitored annually.
- There was an audit programme in place which monitored the service and ensured actions were taken to make improvements.
- Clinicians were supported to maintain up to date clinical skills and competencies.

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

- The consent policy did not reflect Royal College of Ophthalmologists guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Summary of this inspection

Are services caring?

We found that :

- Staff were caring and treated patients with dignity and respect. Patients told us they felt comfortable and safe with staff.
- Patients were involved in the planning and delivery of their care.
- Staff were able to recognise when a patient was anxious and support them during their treatment.

Are services responsive?

We found that :

- Services were planned to meet the needs of patients based on preference and choice.
- Patients were offered follow up appointments to ensure they received the right level of care.
- Complaints about the clinic were dealt with in a timely manner and information relating to the outcome of complaints were shared with staff.

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

- Patient information leaflets, documentation and consent forms were only available in English
- There were no formal interpreting services available and patients were asked to bring a family member or friend to translate.

Are services well-led?

We found that:

- There was effective leadership and good teamwork. Staff felt valued and there was a positive culture.
- There was a clear organisation structure and roles and responsibilities were clearly defined.
- There was a good system in place to obtain patient feedback which enabled the clinic to benchmark against other clinic across the organisation.

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

- Staff survey did not take place to enable the service to monitor and enhance staff engagement.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- There were clear processes in place to record incidents and monitor safety. The clinic had an up to date clinical incident reporting policy for staff to follow. This was due for review in January 2020. The policy set out the accountability, responsibility and reporting arrangements for all staff in relation to incidents.
- There was an electronic incident reporting system that was used to report clinical and non-clinical incidents.
- 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 surgery manager was responsible for recording incidents on the electronic reporting system. They told us that they would complete the incident form and interview staff members to obtain details of incident. This was then recorded on the electronic reporting system. When incidents were reported, investigations were carried out and lessons were learned and shared within the surgery team. All handling of incidents and complaints were completed at corporate level.
- The clinic did not report any incidents at this clinic during the 12 months prior to inspection. Therefore we were not assured that incidents were reported. However all staff understood their responsibilities to raise concerns and knew how to record safety incidents. A member of staff told us that incidents that occurred at other clinic locations were communicated to staff via email and a memo. Staff were required to sign to confirm that they had read the document. Another member of staff described an incident that had occurred at another Optical Express clinic location and the learning outcome from this incident.
- Complications following surgery were reported and monitored centrally. Evidence provided showed that eight patients experienced complications following surgery.
- Staff we spoke with demonstrated a good understanding of their responsibilities relating to duty of candour. There was a duty of candour policy in place since March 2017. 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.

Mandatory training

- Mandatory training was completed through a combination of face to face and e- learning. Staff could access e-learning modules at work or at home. The surgery services manager set training completion dates for staff and sent a weekly report on staff training to the medical director.
- Mandatory training consisted of 14 modules including; fire training, moving and handling, safeguarding, duty of candour, infection prevention and control and consent.
- Local training included the completion of competency assessments and laser training which was provided by laser application specialists who visited the clinic to deliver the training.
- Managers had clear oversight of mandatory training and compliance. The training records spreadsheet showed that nine out of eleven staff had completed their

mandatory training and their training records were up to date. Two members of staff that had not completed their mandatory training were new to the organisation and had yet to complete their induction training.

- All clinical staff received training in basic life support (BLS). The service did not provide laser corrective surgery under sedation, which meant the staff did not require advanced life support training. However, nurses at the clinic were trained to the level of immediate life support because they also worked in Optical Express clinics where intraocular lens surgery took place.

Safeguarding

- There was an up to date safeguarding policy in place that was in line with intercollegiate guidance. The policy included information about different types of abuse including physical abuse, financial abuse, modern slavery and radicalisation.
- Staff in the regional surgery team were trained in introduction to safeguarding vulnerable adults and safeguarding children level one and two. The surgery manager was the safeguarding lead and was trained in safeguarding children level three.
- All staff we spoke with understood their responsibility to recognise and report safeguarding concerns. Local authority contact details for adults and children's service were available in the front of the safeguarding folder in the staff office. There had been no safeguarding incidents reported during the twelve months before our inspection.
- The service did not treat patients under the age of 18 years and staff advised patients not to bring children to the clinic.

Cleanliness, infection control and hygiene

- Systems were in place to prevent and protect patients from infection. There was an infection prevention and control policy in place which was in date and due for review in January 2020. There had been no instances of healthcare acquired infection in the twelve months prior to our inspection.
- There were systems to ensure that the patient treatment areas and equipment used in patient care were clean. Optical Express did not employ an external company to clean the clinic and staff confirmed that they completed all cleaning tasks. Staff were provided with training in cleaning as part of the infection prevention and control mandatory training.
- Cleaning schedules were in place that reflected the standards and guidance from the Royal College of Ophthalmology. Staff told us that daily cleanliness checks were completed on each day of surgery. The treatment areas were cleaned at the end of each day of surgery and deep cleaned once per month. We saw completed checklists for three months prior to our inspection which showed cleaning was completed in line with policy.
- Treatment areas were visibly clean and tidy. We observed three patient procedures and saw that staff followed infection control protocols and cleaned diagnostic equipment between patient use.
- Staff used effective hand hygiene techniques. We saw that all staff were 'arms bare below the elbows'. Staff washed their hands thoroughly in accordance with National Institute for Health and Care Excellence quality standard QS61 Infection Prevention and Control. Staff wore personal protection equipment (PPE), including gloves, masks, hats and aprons.
- Observational hand hygiene audits were completed every surgery day. Five results from the previous six hand hygiene audits showed 100% compliance with effective hand hygiene measures. However the results from the audit completed on 21 November 2017 showed 75% compliance. The manager told us that where there was less than 100% compliance the manager gave feedback to the individual member of staff. A follow up audit on the same day showed 100% compliance.
- Clinical waste bins were foot operated and appeared clean. All surgical instruments used for laser refractive surgery were single use disposable. Waste was segregated and stored in containers in a locked room whilst awaiting collection. An external contracted company removed clinical waste from the clinic.

Environment and equipment

- The refractive eye clinic was situated on the first floor. There was a separately managed optometric practice on the ground floor.
- The laser treatment area consisted of a consultation room where patients were reviewed, a utility room, and

a surgery room, containing a treatment bed and large laser equipment. Access to these areas was via keypad entrance. There was a small discharge room located on the second floor.

- Areas were tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff. However although the flooring was made up of easy clean surfaces they appeared worn and there were several black marks. We saw that this had been noted in the most recent environment audit and had been escalated to head office.
- Equipment maintenance was carried out by technicians who visited the clinic to carry out the maintenance. Staff told us that technicians provided a good service and attended quickly if a fault developed.
- A contract was in place to service the treatment lasers every six months. We observed a maintenance folder listing the completed dates and due dates for maintenance for the laser equipment and machines. All maintenance was up to date.
- There were systems to ensure that laser surgery equipment was safe to operate on the day of surgery. Before surgery started, the laser technician calibrated the equipment according to the manufacturer's instructions. Staff told us that if equipment did not calibrate within range engineers were contacted and surgery did not proceed. Patients were offered surgery at an alternative clinic location or alternative surgery dates. This had not occurred during the 12 months prior to our inspection.
- Laser protection support was provider by an external supplier. The laser protection advisor (LPA) carried out a site visit and risk assessment every three years and re-issued or revalidated the protocols (local rules) that staff followed in the laser treatment room. Local rules were stored in a folder in the laser room. There was a list of authorised users and staff had signed to state they had read and understood them.
- The surgery manager was the designated laser protection supervisor (LPS).If they were not available the laser technician was responsible for the safe management of the laser control area.
- Emergency equipment was checked on surgery days. This consisted of oxygen tubing and mask, two airways and an oxygen cylinder which was full and within service date. The clinic did not have a defibrillator machine. Staff would ring 999 in an emergency.
- Controlled area signs were clearly visible and in working order. Hazard warning light boxes were switched on before use of the laser.
- A fire extinguisher was available which was within service date.

Medicines

- We reviewed the medicines management policy dated January 2017 which included the ordering, receipt, prescribing, administering, dispensing, storing and disposal of medicines and the training and competency of staff.
- The service had a policy regarding the use of cytotoxic medicines which was due for review in January 2020. Cytotoxic medicines are medicines that are toxic to cells, preventing their replication or growth. The provider had appropriate risk assessments, policies, and protocols in place regarding the handling of the cytotoxic medicines. Staff ordered cytotoxic medicines centrally and a spillage kit and appropriate waste disposal arrangements were available. The medicines management policy outlined the process for the administration of this drug due to the fact that it is not licenced for use in ophthalmic procedures. The policy highlights that the patient must give consent for this drug to be used. We saw that the consent form contained a specific section for patients to consent to the use of this drug.
- Medicines were stored at correct temperatures and within locked cabinets. Staff monitored fridge and room temperatures to ensure they were within normal ranges. We reviewed temperature logs for two months prior to our inspection and saw that regular checks were completed in line with the medicines policy.
- At the time of our inspection, no controlled drugs were stored or administered. Staff gave detailed verbal instructions to patients regarding their medicines to take home and this was confirmed on a written information sheet.

- Nurses or ophthalmologists administered medication such as eye drops and staff recorded this appropriately in patient notes with dose and strength of medicine given.
- We looked at four sets of patient treatment records. All detailed current medications, allergies, and patients' medical history. This ensured that medications prescribed by the ophthalmologist were safe to be given.

Records

- The provider held patient records electronically and in paper format. Records contained details including assessments, surgery, and medicines given.
- Staff stored all records containing patient information securely and electronic records were password protected.
- The registered manager carried out documentation audits every two month. We reviewed the data from audits completed in September and December 2017. Ten patient records were randomly selected and audited against specific prompts. The audits showed the records were mostly completed well with no required actions. We saw that in December the audit had found that a registered nurse had not signed a deletion in the notes. An action plan had been put in place to remind staff to sign any deletions made in the patient record.
- We reviewed four sets of patient records and found that they were complete. The records were clearly written and contained all the patients' details including assessments, surgery, laser details, medicines given and post-operative information.
- Where the patient consented, information relating to their treatment could be shared with their GP via the electronic system. Where necessary the GP could contact the surgeon via the contact details provided when the patient was discharged.

Assessing and responding to patient risk

- Patients were assessed for their suitability for treatment. Patients completed a health and lifestyle questionnaire prior to surgery. This enabled staff to identify any risk factors specific to the patient.
- An advanced trained optometrist conducted a pre-operative examination to identify risk factors such as the existence of diabetic retinopathy or high blood pressure.
- There were detailed protocols for clinicians to identify whether patients were suitable to undergo surgery and likely to obtain good results. The criteria considered the specific type of treatment offered, plus the existence of permanent conditions such as thin corneas, and temporary conditions such as breast feeding, and for medical conditions such as epilepsy, depression or diabetes.
- The service offered a telephone consultation and consent process where patients discussed their procedure with the operating surgeon instead of a face to face consultation. Data provided showed that 81% of patients had a telephone consultation and consent. There were 10 categories of patients where this was not available and the patient was required to have a face to face discussion. These included patients with a corneal dystrophy, patient with family history of keratoconus and patient with a visually significant corneal scar.
- Patients that had a telephone consultation were assessed by the surgeon on the day of surgery. The service told us that the operating surgeon would cancel the surgery if they had concerns during this pre-operative assessment. Data provided by the service showed that between January 2017 and the day of our inspection 12 patients had their surgery cancelled for clinical reasons following a face to face consultation with their surgeon on the day of surgery.
- We observed that the surgical team completed a modified World Health Organisation (WHO) five steps to safer surgery check list as recommended by the Royal College of Ophthalmology standards for refractive eye surgery. This was a process for ensuring staff completed a number of safety checks including patients' identity, completed consent, allergies and identifying and marking the operated eye for surgery prior to the procedure. We observed the verbal checks and these checks were recorded on the WHO surgery check list. However, this process was not audited so we did not have assurance that this was always completed.
- Staff knew what to do if a patient required emergency assistance. The Optical Express protocol stated that staff should telephone for an ambulance in the event of a collapse or cardiac arrest. All staff we asked confirmed

this. Staff told us that they completed collapse scenario training. The most recent training had been completed on 26 October 2017 and had simulated an anaphylactic reaction.

- Staff were trained in basic life support (BLS) and clinical staff were trained in immediate life support (ILS).
- The clinic did not have resuscitation equipment. However there was portable oxygen, airways and tubing available. The oxygen cylinder was full and within service check date.
- We observed two discharge consultations with patients. Information was clearly discussed and clear instructions were given about pain relief, administration of eye drops and infection risks.
- Staff informed us that they advised patients to call the clinic with general, non-urgent queries in working hours and the emergency number for out of hours. Calls to the emergency number were answered by the on-call optometrist who provided support to the patient and ensured that emergencies were managed appropriately. Staff said that the optometrist could call the operating surgeon out of hours for advice if the situation appeared urgent. The out of hours information was also available on the clinic website.

Nursing and medical staffing

- Surgery was only carried out at the clinic two or three days a month. There were no set days when the clinic was open. Nursing staff arrangements were dependent on when the clinic was open.
- There was one resident surgeon who was part of a regional team covering this location and other clinics nearby.
- The organisation's central scheduling team was responsible for managing staff rotas which meant that the clinic had sufficient, qualified staff to cover clinic days. Rosters were allocated six weeks in advance.
- There was a process to allocate staff at short notice from other clinics to cover sickness or annual leave. The surgery manager was responsible for requesting a team of staff to cover treatment days. If sickness occurred at short notice, this was escalated to the clinical services team who could access the staff database for the region. The clinic did not use agency staff.
- The clinic employed one full time resident surgery who undertook all the refractive eye surgery at the clinic over the previous 12 months. The surgeon was registered with the GMC and held the Royal College of Ophthalmology certificate in refractive eye surgery.
- An external company provided the laser protection adviser (LPA). Staff told us they were easy to access and the organisation had a long standing, professional working relationship with them.

Major incident awareness and training

- Laser treatment was not interrupted if electrical power failed mid-treatment. Laser equipment was fitted with an uninterruptible power supply sufficient to complete a surgical procedure. Those patients whose surgery had not started would be re-scheduled for another surgery date.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence based guidance. Policies and guidelines had been developed in line with the Royal College of Ophthalmology (RCO) Standards for laser refractive surgery and national guidance such as National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery. Policies and procedures were in date and staff were able to access these online and in paper form.
- Treatment criteria and suitability guidance were annually reviewed by the International Medical Advisory Board (IMAB). The board was made up of international refractive surgery experts who met to consider new research evidence, technologies and guidelines for best practice. Minutes from the annual IMAB meeting of 2016 showed that articles and documents relating to regulation, standards, and guidelines of the General Medical Council (GMC) and RCO in relation to refractive eye surgery were discussed.
- Changes to guidance were discussed and reviewed internally by the Medical Advisory Board (MAB). Any changes in guidance or protocols were shared with staff.

For example minutes from the MAB meeting dated 2016 members discussed the risks associated with treating patients with type one diabetes and agreed revisions to protocols to mitigate these risks.

- Pre- operative tests for elective surgery were in line with NICE guidelines NG45. Patient's medical history was discussed and tests and scans were completed to determine appropriate treatment for the patient.

Pain relief

- Patients undergoing laser refractive eye surgery received treatment under local anaesthesia. Staff administered topical eye drops into the eye prior to the procedure as a method of pain relief. This was in line with joint guidelines from the Royal College of Anaesthetists (RCA) and the Royal College of Ophthalmologists (RCOph, 2012). We saw that patients were asked if they were in any pain during surgery.
- Patients were prescribed anaesthetic eye drops post treatment. Staff provided patients with verbal and written instructions.
- Patient information leaflets were used to advise patients about what pain relief may be required when they returned home. This included the use of analgesic such as paracetamol to help cope with any pain.

Patient outcomes

- Optical Express used data to monitor the effectiveness and safety of treatment. Outcomes data was collected for every treatment undertaken including long term follow up data. The international medical advisory board and the medical advisory board reviewed this data.
- Specific data for the treatment outcomes obtained at the Cambridge clinic was not available because Optical Express monitored outcomes according to individual surgeons rather than locations. Treatment outcomes were measured in terms of the surgeon's success rate across all Optical Express locations. The outcomes data for the surgeon operating at the Cambridge clinic compared favourably to the outcomes data of other surgeons working for Optical Express.
- Each surgeon outcomes were assessed at the IMAB meeting where any necessary changes to effect and safety were reviewed and recommendations were made and discussed at the national Medical Advisory Board (MAB).
- Optical Express stated that they expected around 5% of treatments to require enhancement. Patients were made aware of the potential need for enhancement at the start of their treatment. The location completed one laser- assisted in situ keratomileusis and 11 laser-assisted sub, epithelium keratomileusis enhancement procedures between October 2016 and September 2017. Three enhancement procedures were undertaken where the primary treatment took place within the 12 month timescale. The reasons for enhancement were regression; quality of vision issues and desired outcome not achieved. The service reported that some of the enhancements undertaken at the location were for patients who did not have primary treatment within the last 12 months and therefore could not provide us with figure as a percentage of treatments at this location required enhancement. In the 12 months before our inspection eight patients experienced complications following refractive eye surgery. Seven of the complications related to abrasion, dry eye, and haze. One involved flap microstriae, which is an irregularity within the stroma of the corneal flap. There were no unplanned returns to theatre for refractive eye surgery
- Internal audit processes were in place to monitor staff compliance with safety protocols. The surgical services manager completed a monthly safety audit. This included infection control, incident and complaints management, patient satisfaction, record keeping, maintenance of equipment and personnel, emergency equipment, medicines management, laser safety, quality management and health and safety.

Competent staff

- Staff we spoke with had the correct level of skills and competencies to carry out their role. There was an induction programme in place, which lasted four to six weeks dependent on staff role. Staff completed competency assessments which were signed off by the staff member's line manager. Staff then spent a week observing each stage of the patient pathway from scanning to discharge.
- The competence of surgeons was checked before they were permitted to perform eye surgery independently. The medical director and clinical services director inducted surgeons. This included detailed information about the procedures; clinical suitability guidance; policies and procedures; diary and patient management

systems; protocols and pathways. Surgeons then shadowed the medical director or a senior surgeon and attended training with the laser manufacturer which included a period of supervised practice. The surgeon was required to undertake a number of procedures under the supervision of the medical director or senior surgeon following their training before they were entered onto the list of authorised users.
- The surgical services manager reviewed nursing staff competencies, such as medicines management, every three years.
- We saw all staff who worked at the clinic had received their annual appraisal. The medical director completed appraisals for surgeons and the surgery manager completed appraisals for resident staff such as registered nurses and technicians.
- All staff operating laser equipment were trained in this role. All staff completed the laser core of knowledge training day. The laser technician attended a one week course in the use of the lasers and associated equipment which was run by the laser manufacturer. Laser technician's competencies were reviewed every three years. Optical Express employed senior refractive trainers who carried out the laser competency assessments locally and supported technicians and the laser protection supervisor to ensure they remained skilled.
- The laser protection advisor (LPA) was a certified member of the association of laser safety professionals.

Multidisciplinary working

- We observed good multidisciplinary working between the team at the clinic. There was good communication and each member knew their role and carried it out effectively within the team.
- We saw the clinical team working well together in the treatment room. Each staff member was calm and professional and treated each other with respect.
- Staff worked across numerous sites in Optical Express which meant there was consistency within the service. Staff told us that the teams worked well together and they felt supported by their colleagues.
- Multidisciplinary working outside of the team was limited and dependent upon patient choice. Patients chose whether to give permission for the team to share relevant information with their GP. Where the patient consented a treatment summary was generated and sent to their GP. The patient was provided with a copy of this treatment summary.

Access to information

- Patient information was stored electronically and a hard copy file was available on the day of surgery. All information relating to the patient's treatment and care were available.
- All staff could access the computer system. This was password protected and provided staff with an access level dependent on their role. All staff involved in the treatment of patients had access to the patient records and were able to add information relating to the patients care and treatment.
- Policies and protocols were available for staff to access on the clinic intranet. Updates to protocols and guidelines were also available for staff to view.
- Patient information was available at all Optical Express locations. This meant that if a patient attended another location for their follow up appointment staff had immediate access to their treatment details.

Consent and Mental Capacity Act

- There was a consent policy dated September 2017 and this provided staff with guidelines on obtaining patient consent.
- All patients requesting laser refractive surgery had an initial consultation with an optometrist who provided the patient with an information folder which contained a copy of the treatment consent form, risks associated with the treatment and the benefits of the procedure. Part of this consultation involved the patient watching a video, which provided information on the treatment along with potential risks.
- Staff ensured that patients gave informed consent before they underwent treatment. Staff gave detailed verbal and written information about all risks, benefits, realistic outcomes and costs of treatments. Patient advisors, optometrists, surgeons and nursing staff all checked the patient's consent at every stage of the assessment and treatment process. Staff in the optometry team gave patients paper copies of the consent form to take away and read at home.
- Most patients were offered the option of having a telephone or video conference with the surgeon as opposed to a face to face consultation. Staff told us that

information was available on the intranet identifying some high risk categories of patients that were excluded from telephone consultations. We did not see this on the computer system but saw an email listing the categories of patients that should have a face to face consultation. During the twelve months preceding our inspection, 81% of consent consultations were carried out over the telephone.

- The surgeon reviewed patients who had a telephone consent consultation on the day of surgery. Patients were advised that the surgeon had the final decision as to whether the patient was suitable for surgery and that their operation could be cancelled. Data provided by the service showed that 12 patients were cancelled between January 2017 and December 2017 for clinical reasons.
- Optical Express protocol for patient decisions around treatment did not follow guidelines published by the Royal College of Ophthalmology. These guidelines had been discussed at the independent medical advisory board meeting and a decision was made to challenge the guideline rather than adapt current protocol. The Royal College of Ophthalmology recommends a minimum cooling off period of one week between the procedure recommendation and surgery. In exceptional circumstances, where a one-week cooling off period is impractical, the reasons for this should be agreed with the patient and documented in the medical record.
- The policy did state that for confirmation of timescales and the consent process staff must refer to the current relevant clinical directive on consent. The service had a professional standards directive dated July 2017 that stated that it was good practice for there to be a reflection period of seven calendar days between the discussion with the surgeon and the day of surgery. In instances where this is not appropriate, and with the agreement of the treating surgeon and the patient, there should be a time lapse of at least forty eight hours between the initial discussion with the surgeon who will carry out the procedure and the day of surgery to enable the patient fully to reflect on their decision and to seek further professional advice if they wish.
- Optical Express policy and directive did not require surgeons to document in patient's records the reason for the shortened cooling off period. During the twelve month preceding our inspection, 37% of surgeon consent appointments at the Cambridge clinic were carried out less than seven days prior to the day of treatment.
- It was the responsibility of the surgeon to assess capacity to consent. The consent policy included reference to the Mental Capacity Act 2005. Staff received training around capacity to consent as part of their consent mandatory training module. Concerns would be followed up with the patients GP with the patients consent.
- Mitomycin C is a cytotoxic medicine that is used in refractive eye surgery although it is not licensed for this purpose. The printed consent form explained that mitomycin C was an off licence medicine but did not highlight any risks of using this medicine in refractive eye surgery.

Are refractive eye surgery services caring?

Compassionate care

- Staff respected the identity and dignity of patients. All staff introduced themselves to the patient. We saw that staff communicated with patients in a respectful and considerate manner.
- We saw that staff were kind and patient. They gave reassurance to patients both before and during the procedure. The surgeon reassured the patient throughout the procedure, explaining to patients what sensations they were likely to experience during surgery. This complied with the Royal College of Ophthalmology professional standards for refractive surgery. One patient that we spoke with told us that they felt reassured after talking to their surgeon. They told us that they explained what their eye would be like after the procedure so they felt they knew what to expect.
- Patient feedback indicated that staff developed a positive environment for their patients. Outcomes from the patient feedback questionnaire for the 12 months prior to our inspection, showed an average score of 10 out of 10 for the question 'were you satisfied with the warmth and friendliness of your surgeon?' For the question 'did the surgery team make you feel comfortable and at ease?' the average score was 10 out of 10.

Refractive eye surgery

Understanding and involvement of patients and those close to them

- Staff told us that patients were asked to complete an on-line survey at various points during their care. The surgery experience survey was completed at the 24-hour post-operative visit, if patients were willing to participate.
- Patient feedback indicated they received clear information relating to their care. During the 12 months preceding our inspection, patient responses on the patient experience questionnaire indicated an average score of 9.9 out of 10 for the question 'was the post-operative eye drop regime and aftercare process explained to you clearly and effectively? For the question 'how satisfied were you that your surgeon answered all of your questions?' the average score was 9.6 out of 10. One patient we spoke with told us that they were given the opportunity to ask questions about their treatment and were given all the information they felt they needed.
- Staff helped patients to understand relevant treatment options including benefits, risks and potential consequences. Patients were given information about what to expect from laser surgery. Patients told us they understood this information. During the initial consultation, patients were given transparent and accurate information about all costs of potential treatment.
- We observed staff explaining instructions to patients and answering any questions patients had following surgery. Information included how to insert eye-drops at home, cleaning around the eye to prevent infection and activities following surgery. The staff member discharging the patients took time to ensure that the patient fully understood the information they were given.
- Staff provided patients with written information about aftercare and ensured that patients had the out of hours contact number if they had any questions or concerns following surgery.

Emotional support

- Staff told us that they understood that patients became anxious prior to and during their laser eye surgery. If appropriate for the patient, a staff member was allocated to sit with the patient during surgery to hold their hand.
- Patients could request a chaperone for any consultation as per the company policy. Two patients we spoke with told us that staff were very supportive and made them feel comfortable and reassured.
- We observed a staff member supporting a patient who was very nervous before and during their surgery. The staff member was very reassuring, continually checking that the patient was warm enough and felt ok to continue.

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

Service planning and delivery to meet the needs of local people

- The facilities and premises were designed and maintained for the service delivered. Waiting areas and treatment areas were spacious and well maintained. The clinic was easily accessible from the town centre. There was lift access to the patient areas.
- Patients could access the service either through self-referral, through an internet search or in response to marketing. The clinic did not do any NHS work and did not receive referrals from the NHS.
- The clinic's catchment area covered the immediate local population and patients from across East Anglia. Staff informed us that any person could attend any Optical Express clinic nationwide as the service could access electronic patient records from every clinic.
- The clinic generally undertook refractive eye surgery as and when demand dictated. Surgery days were carried out approximately two to three times a month depending on treatment needed. The clinic would increase the number of days of treatment in the month if required.

Access and flow

- Access to the service was timely. There was no waiting list for refractive eye surgery. Patients were offered an appointment on the next planned surgical list.
- As far as possible, the service offered appointments to patients to suit their needs. Refractive eye surgery was offered two or three days per calendar month. Patients could choose which month but the date was limited to the designated surgery day. Patients were able to attend another Optical Express clinic if the surgery dates at the Cambridge clinic were not convenient.

Refractive eye surgery

- The registered manager told us that the option of a telephone appointment with the surgeon for the consent process was popular with patients. They told us that patients were pleased to reduce their time spent travelling to appointments. There were 15 cancellations of surgery in the 12 months preceding our inspection. 13 of these cancellations had been for clinical reasons such as abnormal cornea shape or other ocular contraindications. One patient had converted to another optical solution and one patient was cancelled due to the service being unable to contact them.
- Patient arrival times were scheduled in line with their surgery time to avoid patients having a long wait in clinic. On the day of our inspection we saw that no patients were delayed for their surgery. The patient experience questionnaire completed during the 12 months preceding our inspection showed an average score of 4.3 for their satisfaction regarding the length of time they spent in the clinic on the day of treatment. The lower the score indicated the greater satisfaction with time waited. The company average was 5.6. The service did not monitor the time that patients spent waiting on the day of their surgery.

Meeting people's individual needs

- A hot drinks machine and cold water were available to patients. No food was provided by the clinic however food was available in the nearby shopping area.
- There was no formal interpreting service available for patients whose first language was not English. Patients were advised to bring a friend or relative to interpret for them. If a member of staff could speak their language, the team arranged for them to interpret where possible. Relatives and clinic staff members were not trained interpreters and this meant there was a risk that the patient and/or the treatment team would not fully understand the communication. The surgical services manager told us that there were plans to implement a telephone translation service. This service was not available at the time of our inspection.
- There was good access for wheelchair users. The clinic area was spacious and there was lift access. The manager told us that patients who used a wheelchair were invited to attend the clinic prior to their treatment day so their needs could be assessed. For example, patients were shown the treatment room and could see how they could manoeuvre their wheelchair before receiving treatment.
- Patient information leaflets were available, explaining the various conditions and treatments offered by the service, including pre and post care instructions. Pre-treatment written information included a clear explanation of what to expect during surgery as recommended in the Royal College of Ophthalmology standards for refractive eye surgery. However, all patient leaflets and documents, including consent forms were only available in English.
- The service did not treat patients with, learning disabilities or patients with complex health conditions. Screening procedures ensured that patients who required additional support were referred to alternative services with the support of their GP.
- There was not a hearing loop installed at the clinic to assist people who were hearing impaired. The registered manager told us that this was under review and hearing loops were to be rolled out across the network including this location.

Learning from complaints and concerns

- The service had a complaints policy, which provided guidance to staff on the processes they should follow in the event of a patient complaint. In the period October 2016 to September 2017, 21 complaints relating to the clinic were received and managed by the clinical services department team.
- We viewed the complaints summary and saw outcomes with actions taken were completed for each complaint. The complaints ranged from booking errors to quality of vision and patients expectation. Against each complaint, we saw a response had been made to each complaint and learning outcomes were actioned if required. The clinical services team managed these.
- Patient electronic files were updated so that the information regarding the complaint was accessible to the surgery manager who was then able to monitor progress.
- Staff informed us that if a verbal complaint was made on the day of treatment, the surgery manager would try to resolve any issues and address the complaint directly with those involved.
- Staff told us that if the nature of the complaint was not resolved locally, the central clinical services department took over the management of the process.
- Learning from complaints were shared at team meeting and via email. Staff confirmed this but were not able to give an example.

- The patients consent form and terms of condition document contained information about how to make a complaint. There was a notice at reception, which included a summary of the process. However, information on how to make a complaint was not provided in other languages for those patients who did not speak English.

Are refractive eye surgery services well-led?

Leadership and culture of service

- The company leadership arrangements were made up of the chief executive officer (CEO), optometry directors, operations director, and the clinical services team, which consisted of the refractive operations manager, surgical services manager and location surgery managers.
- Staff we spoke with told us that they felt supported locally by the surgery manager. They said they were a good manager and was approachable and managed their concerns. There was clear leadership. Staff knew their reporting responsibilities and the role they played within the service.
- Staff who worked at the service told us they enjoyed working at the clinic, and everyone got on well with each other. We observed a positive working environment during our inspection.
- The medical director who reported to the CEO managed the surgeons.
- Staff were happy with the working arrangements of rotating to other clinics. The surgery manager was responsible for another clinic in the region where staff also worked. This meant staff had consistency in their leadership.
- Marketing complied with guidance from Committee of Advertising. Patients received a statement, which included terms and conditions, which provided information on payment fees and details of the service provided. One patient we spoke with told us that costings were clearly explained and there were no hidden costs.

Vision and strategy

- The strategic direction of the service was determined at a corporate level. The corporate surgery services manager told us there were no formal plans or vision specific to the Cambridge clinic. Senior staff told us that plans for the future included opening new locations, maintaining and increasing the organisations profile and continuing to invest in electronic medical records system.
- The company had set up an International Medical Advisory Board (IMAB). The board was made up of world renowned refractive eye experts with no link to Optical Express. Optical Express finance the board and they met annually to review the organisations data and clinical protocols.

Governance, risk management and quality measurement

- Policies were in place which supported the governance structure. These policies gave staff clear guidance and outlined processes to follow. Policies included incident reporting, risk management and information governance.
- The service held monthly clinical committee meetings at which governance issues were discussed and addressed. Attendees included the clinical services director, the surgical services manager, medical director and surgical services manager. We saw minutes from the clinical meeting held in April 2017 and July 2017 and saw that governance issues were discussed such as Royal College of Ophthalmologist guidelines and mandatory training compliance.
- The location participated in quality monitoring of incidents, complaints and local audit. Quality monitoring data fed into the monthly clinical governance committee meeting which the medical advisory board (MAB) in turn oversaw. The MAB oversaw clinical changes in practice around treatment, surgery and the introduction of new technology. The chief executive chaired the MAB and all surgeons and heads of department were members of the board.
- The regional team held monthly meetings and local topics were discussed including incidents and any changes to practice. The meeting gave an opportunity for staff to raise any concerns.
- The was a local risk register in place. . The risks were colour rated according to levels of severity, red meaning highest risk level, amber meaning medium risk and green indicating low risk (RAG). We reviewed the laser

risk assessment which were within review date. Risks to patients and staff were low as only refractive eye surgery was carried out at this location and staff were trained and skilled to manage risks at the location.
- Relevant alerts received from the Medical Device Agency (MDA) or Health and Safety Executive (HSE) were communicated to the teams via a clinical directive which all staff were required to sign.
- We saw the personnel file of the surgeon who was primarily based at the clinic. The file contained evidence of general medical council (GMC) registration, an up to date appraisal with clinical outcomes data and current indemnity insurance.
- Local audits were completed which meant that the surgery manager was able to monitor the quality of the service. The surgery services manager oversaw the local audit programme.

Public and staff engagement

- The organisation did not conduct staff surveys. We were told by the surgery services manager the company was in the process of appointing a Freedom to Speak up Guardian who would start staff surveys through the organisation.
- Regular team meetings were held where staff were able to give feedback and raise concerns. Staff we spoke with said that they felt able to raise concerns and told us that the surgery manager was very approachable if they wanted to raise any issues.
- Patients were asked to complete a patient experience questionnaire following treatment. Results for January 2017 to December 2017 showed the clinic scored between 8.9 and 10 out of 10 for all questions answered.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The consent policy should reflect Royal College of Ophthalmologists guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider should carry out an audit to ensure WHO check compliance.
- The provider should provide a formal interpretation service for patients.
- The provider should ensure that patient information is available in other languages apart from English.
- The provider should consider conducting staff surveys to engage further with staff.