Optical Express - Southampton (The Avenue) 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?	

Overall summary

Optical Express Southampton is operated by Optical Express Limited. It is a nationwide company offering general optometric services which are outside the scope of registration and refractive eye surgery and laser vision correction procedures using Class 4 and Class 3b lasers for adults aged 18 years and above. We inspected refractive eye surgery only at this service.

The clinic is based on the ground and first floors of a multipurpose building in Southampton which was accessible by stairs.

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.

Summary of findings

The clinic was not operational every day, therefore there was only one staff member based there, which was the surgery manager. The surgery manager was on an extended absence of leave for one year from the clinic and another surgery manager was covering. Treatment lists were staffed by a regional surgery team that travelled and covered the Southampton, Reading and London areas who visited the clinic on surgery days.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 16 November 2017, along with an announced visit to the clinic on 6 December 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

Services we do not rate

We regulate refractive eye surgery services but we do not currently have a legal duty to rate them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- The service had systems for the reporting, monitoring and learning from incidents.
- Staff were aware of how to report incidents. Patient safety was monitored and incidents were investigated to assist learning and improve care.
- Staff received level two training for both safeguarding children and adults. A policy was in place and staff were aware of the responsibilities in reporting any safeguarding concerns.
- Patients received care in visibly clean and suitably maintained premises
- The staffing levels and skills mix was sufficient to meet patients' needs and staff assessed and responded to patient risks.
- Patient records were detailed with clear plans of the patient's pathway of care.
- Medicines were prescribed and administered to patients appropriately ensuring that they understood how to administer them.
- All staff their mandatory training and annual appraisals. Care and treatment was provided by suitably trained, competent staff that worked well as part of a multidisciplinary team.
- There was appropriate management of quality and governance and managers were aware of the risks and challenges they needed to address.
- Systems and processes were in place to keep staff and patient safe. There were good infection prevention and control procedures in place.
- Patients received a thorough assessment prior to treatment, were monitored during treatment and were given emergency contact numbers following their discharge.
- Policies, procedures and treatments were based on nationally recognised best practice guidance. Regular audits were carried out on a range of topics. Patient outcomes were measured and benchmarked.
- There was a comprehensive staff training programme in place including laser safety.
- Care was delivered in a compassionate way and patients were treated with dignity and respect. Patient were kept informed throughout their care and encouraged to ask questions. Staff recognised when patients may need additional support.
- There was a process for the reporting, monitoring and learning from complaints.
- There was clear visible leadership within the services. Staff were positive about the culture within the service and the level of support they received.

Summary of findings

- Managers were visible and respected by staff. Staff felt valued. There was a culture of honesty and openness. Patient feedback was encouraged. Effective recruitment processes were in place.
- The organisation recognised and rewarded staff through their weekly staff reward scheme.

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 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The clinic did not have access to any interpreting services and patients were asked to bring their own interpreter. This meant that staff might not be clear if patients had fully understood the risks and benefits of the surgery.
- Patient information leaflets, documents, and consent forms were only provided in English.
- Staff feedback, in the form of engagement surveys had not taken place.

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Amanda Stanford

Interim 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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Services we looked at
Refractive eye surgery

Summary of this inspection

Background to Optical Express - Southampton (The Avenue) Clinic

Optical Express Southampton (The Avenue) Clinic is operated by Optical Express. The clinic has been operational since 2014. The clinic primarily serves the communities of Hampshire. It also accepts patient referrals from outside this area.

The clinic has had a registered manager in post since 2014.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector and for the unannounced inspection a CQC specialist advisor. The inspection team was overseen by Mary Cridge, Head of Hospital Inspection.

Information about Optical Express - Southampton (The Avenue) Clinic

Optical Express, Southampton is registered to provide the following regulated activities:

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

The clinic is based on two floors of a multi-occupied building. Optometrist rooms are on the ground floor, with a consulting room, recovery room and operating theatre on the first floor. Patients are self-referring and self-funded. The clinic provides laser vision correction procedures using Excimer class 4 and class 3b lasers. Ophthalmic surgeons carried out the treatment. The clinic provides the service two days a month. Following an initial consultation appointment with an optometrist, the patient then has a follow up consent appointment with the surgeon. Treatment is offered on a day care basis.

The team involved in the delivery of care included ophthalmologist, nurse, operating department assistant, health care assistant, surgical associate, optometrist and laser technician. The team worked regionally across southern England. Scheduling of the team was managed by a dedicated scheduler based at the Optical Express head office.

On both our announced and unannounced inspection day, a laser vision correction clinic was taking place.

We inspected the laser treatment room (where the surgery took place), anaesthetic room, pre and post-operative rooms, discharge room, dirty utility room and examination rooms. We spoke with 10 members of staff including; an ophthalmologist, a nurse, an operating department practitioner, a health care assistant, an optometrist, a laser technician and senior managers. We spoke with 10 patients and two relatives. During our inspection, we reviewed five sets of patient records and three sets of staff personnel files.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The clinic has not received any previous inspection since registration in 2014.

Activity

- In the reporting period 1 September 2016 to 31 August 2017, there were 630 day case episodes of care recorded at clinic. The clinic offered two different types of refractive eye surgery all which required topical anaesthesia.

Track record on safety over the last 12 months

- No Never events

Summary of this inspection

- No clinical incidents
- No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA), or healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No incidences of healthcare acquired Clostridium difficile (c.diff)
- No incidences of healthcare acquired E-Coli
- Eight complaints.

Services provided to the clinic under service level agreement:

- Clinical waste removal including sharps and cytotoxic waste.
- Cytotoxic drugs service.
- Laser protection service
- Decontamination of sterile equipment.
- Maintainence 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:

- Staff were aware of how to report incidents. Patients' safety was monitored and incidents were investigated to assist learning and improve care.
- Staff received level two training for both safeguarding children and adults. A policy was in place and staff were aware of the responsibilities in reporting any safeguarding concerns.
- Patient received care in visibly clean and suitably maintained premises and their care was supported with the right equipment. Laser safety was well managed and records were appropriately maintained. Equipment was serviced regularly and all electrical tests had been completed.
- Medicines were prescribed and administered to patients appropriately ensuring that they understood how to administer them.
- Records were appropriately written and contained all the relevant consultations, health questionnaires and consent forms.
- A team brief session took place at the beginning of each surgery day to discuss patients and any issues. Prior to the patient's surgery an adaptive 'five steps to safer surgery' World Health Organisation (WHO) checklist was completed. WHO audits were completed to ensure that practice was embedded.
- Scenario based training sessions were completed on specific surgery days to support staff in managing and dealing with untoward situations.
- Staffing was managed by a central scheduler who ensured that the appropriate number of staff were present on surgery days.

Are services effective?

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:

- Care and treatment reflected current legislation and national guidance.

Summary of this inspection

- Patients received adequate pain relief and were advised how to manage their pain on discharge.
- The surgeon's statistics were reviewed to identify their establishment rate and safety score and compared against the organisation.
- Staff had received an appraisal that reviewed their performance.
- We saw evidence of good multidisciplinary working and staff reviewed patients at the beginning of the surgery day.
- Patient information could be accessed across all the Optical Express locations; this allowed information to be viewed at any clinic.
- Patients consented to the treatment several times prior to their surgery. We looked at 10 records and found them all to have consented more than seven days before their surgery.

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

- The consent policy did not reflect Royal college of Ophthalmologists Guidance 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Are services caring?

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:

- Staff treated patients with dignity and respect. Feedback from patients was consistently positive.
- Patient satisfaction surveys identified that patients were satisfied with the treatment and care they received.
- Patients were reassured at all times during their treatments and we saw that staff were compassionate.
- Patients told us they felt involved in the decision making process and were encouraged to ask questions. We saw that the consultant drew pictures to ensure the patient understood the process.

Are services responsive?

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:

Summary of this inspection

- Services were planned to meet the needs of patients, based on their own choice and preference. They could attend any Optical Express clinic for their post-surgery aftercare.
- Extra surgical lists were created to support the demand for surgery. There had been no cancellations for non-clinical reasons.
- There was a process for the reporting, monitoring and learning from complaints.

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

- The clinic did not have access to any interpreting services and patients were asked to bring their own interpreter. This meant that staff might not be clear if patients have fully understood the risks and benefits to the surgery.

Are services well-led?

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:

- The clinic had a clear leadership structure in place from the chief executive office to local leadership. Staff had an oversight of the location. A generic risk register was in place.
- There was a clear vision and mission statement that staff were aware of. They were displayed around the clinic for patients' information and to remind staff.
- The clinic had a lead for governance and quality monitoring. Staff attended meetings and were provided with minutes that they actioned to identify they had read.
- Appropriate checks had been completed for staff, these contained references and Disclosure and Barring Service (DBS) record.
- The organisation recognised and rewarded staff through their weekly staff reward scheme.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

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.

Incidents and safety monitoring

- There were no never events and no serious incidents in the reporting period 1 September 2016 to 31 August 2017. 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.
- The clinic had an incidents and near miss events policy in place from January 2017 which was due to be reviewed in three years. The policy stated the surgery manager was responsible for identifying and reporting any incidents and managing the process. Part of the process was to ensure that other staff were able to understand and report incidents in the absence of the surgery manager.
- There had been no incidents reported during the reporting period. Staff used their online incident recording process to record and report incidents. The staff we spoke with were aware how to report an incident and could describe the process. They had a good understanding of what an incident was and the different types of classifications.
- We saw in staff notifications and team meeting minutes where learning from incidents had been shared for example legionella checks had been increased following the discovery of mild levels of bacterium in the water. Legionella is a waterborne bacterium, which causes legionnaires disease. Staff described the incident management process to us and gave examples of incidents they had reported.
- The duty of candour (DoC) 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.
- We saw a DoC directive dated 2015 and this had been reviewed on January 2017. This explained the principles of DoC and staff had signed the directive once read. Those staff we spoke with were able to tell us elements of the process, in that it meant being truthful and open and transparent with the patient when things went wrong. We did not see evidence of the DoC having been put into use as the clinic had not needed to use the process.
- We were told the surgery manager investigated incidents of a low level. Incidents that were more serious were overseen and investigated by the corporate surgical services manager and clinical services director. They were able to review all incidents and emailed staff with all relevant feedback from any incident. At the time of our inspection there had been no serious incidents reported for the past twelve months, so we were not able to see any examples of the investigatory processes and lessons learnt.

Mandatory training

- We saw that all staff who worked at the clinic had completed all mandatory training topics. This safety related training was renewed every three years and included core topics such as: information governance, conflict resolution, infection control prevention, fire

safety, safeguarding children young people and adults, medicines management, health and safety, duty of care, consent, equality and diversity, and moving and handling. Consent training included the Mental Capacity Act 2005.

- Staff were given protected time to complete training at work or were paid time if they completed at home. The surgery services manager set training dates and a weekly report showing compliance rates was sent to the medical director.
- All staff completed an on line training package annually which included Mental Capacity Act and consent.
- All staff attending laser vision correction procedures had basic life support skills; the operating department practitioner and nurse attending intra ocular lens surgery procedures had intermediate life support skills. The organisations policy was to provide basic life support until the emergency services arrived.
- Staff who worked directly with the laser machines attended core knowledge training every three years and we saw evidence of this in personnel files, this included the surgical assistants and laser technicians.
- In the event the laser machine was upgraded or in light of new improved ways of working the machine manufacturer had a dedicated team of trainers who delivered training to staff.

Safeguarding

- The clinic did not provide treatment to young people under the age of 18; however children attended the clinic with patients and relatives. Safeguarding training was required for both adults and children.
- The safeguarding policy (January 2017) clearly described types of abuse and included guidelines of actions staff should take if they had any safeguarding concerns. It also informed staff where to find contact details for local safeguarding authorities. We saw the contact details displayed in the policy folder and staff told us they knew what to do if they became aware of a safeguarding event.
- All staff were trained to level two safeguarding procedures and the registered nurse who was the lead was trained to level three. Staff compliance rate for training was 100%. If staff needed advice from a level four children's safeguarding lead they would access this through the local safeguarding board. Staff attended safeguarding refresher training every three years.
- The clinic had not reported any safeguarding events in the reporting period.

Cleanliness, infection control and hygiene

- The clinic and treatment areas were visibly clean, well maintained with flooring that was easily cleaned and non-slip, and free from clutter.
- The clinic had an Infection Prevention and Control (IPC) policy, which provided staff with guidance and IPC procedures they should follow to minimise risk. Staff completed IPC mandatory training, which they refreshed every three years. All staff had completed this training. The surgery manager was the IPC lead for the clinic and the resident registered nurse assisted the manager with IPC issues and audits. A regional IPC link nurse was based in another clinic nearby.
- There had been no incidents of a healthcare acquired infection at the clinic from 1 September 2016 to 31 August 2017.
- During the reporting period, there were no incidents of Meticillin-resistant Staphylococcus aureus (MRSA) or Meticillin-sensitive staphylococcus aureus (MSSA) and there were no cases of Clostridium.difficile (C. diff) or E.coli infections.
- The clinic was visibly clean, monthly cleaning logs were in place; we reviewed the records from June 2017 to November 2017 and found them to be completed correctly. We saw that the treatment room had been deep cleaned on a regular basis. In addition, all areas of the clinic were cleaned regularly, including the pump dispensers, clocks and other equipment.
- Staff we spoke with were able to explain the policy and the role they played in meeting the expected standards. For example, staff knew the IPC checklists they had to complete each morning.
- The hand hygiene policy was based on the five moments for hand hygiene. The five moments for hand hygiene focuses on five moments when hand hygiene should take place, these are, before patient

contact, before undertaking a clean or aseptic procedure, following an exposure risk, after patient contact and after contact with a patient's surroundings.

- We saw the hand hygiene audits for August 2017 and September 2017. Over a 20 minutes period, staff were observed on a one to one basis. The results showed there was 100% compliance. Feedback was given on a one to one basis and action plans were implemented if staff did not meet compliance. Additional training was part of the action plan.
- We observed staff adhered to IPC policy during our inspection. Staff wore clean disposable scrub uniforms, closed toe shoes and their hair was tied back. During patient treatment, staff wore theatre caps, masks, and non-latex gloves and were bare below the elbows. This enabled During treatment, patients were provided with a cap to cover their hair.
- The sluice room was spacious clean and emergency eyewash was available for staff. We saw wall mounted handwashing gel was available.
- Morning IPC checks were conducted for the reception area, toilets, pre-screening areas, and there were checks on staff uniform. We saw the last three months checklists had been completed and signed by staff. The surgery manager was responsible for the monitoring of all IPC checklists.
- Staff conducted a monthly deep clean of the treatment room and we viewed the previous month's checklist, which had been completed and signed by staff.
- Clinical waste was kept separate to non-clinical waste and stored appropriately in a dirty utility room. Sharps bins were in place, dated, signed and off the floor in all areas, we visited. This reflected best practice guidance outlined in the Health and Safety Executive (HSE) The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Sharps bins were used by clinical staff to safely dispose of used instruments such as syringes, needles, and glass ampoules.
- Preparation of the operation/treatment site was described in the preparation of operation site procedure which was based on Royal College of Ophthalmology cataract surgery guidelines. We observed patients being told what to look out for after treatment such as signs of inflammation or infection.
- Most of the equipment used for surgery was disposable. The small amount of equipment that was multi use was decontaminated and sterilised by an authorised local company.
- Legionella testing took place every seven to ten days along with water temperature checks, we saw an up to date record of the checks. Legionella samples were sent for analysis every three to six months. Legionella is a waterborne bacterium which causes legionnaires disease.

Environment and equipment

- The service was positioned on the ground and first floor within a multi-purpose building. There was free on-site parking available and the building was easily accessible from the car park.
- All areas we inspected were well equipped. Patient waiting areas appeared comfortable with the provision of TV, magazines and hot and cold beverages.
- There was a named Laser Protection Advisor (LPA). The LPA reviewed the Local Rules every three years or more if required in response to any concerns with the lasers. Local Rules contain general guidance and instructions necessary to comply with legislation, standards and guidance for the safe use of lasers and/or other Light Therapy machine systems. If any changes were made to the Local Rules, the changes were disseminated to staff via a directive and discussed verbally with staff. We saw the document in which staff had signed to say they had read and understood the rules.
- A Laser Protection Supervisor was allocated by the central scheduling team for each laser treatment session; this was usually the laser technician. We saw the annual risk assessments of the laser treatment rooms were last completed in January 2017.
- We saw the list of authorised laser users and the signature list of staff declaring they had read, understood and would follow the local rules.

- The local rules also contained contact information for the Laser Protection Advisor. Staff could contact the LPA for personal queries such as safety precautions for pregnant members of staff.
- The clinic had a range of safety checks in place for equipment; all the check lists we reviewed showed that checks had taken place as scheduled and at the beginning of every treatment session.
- We inspected the intra ocular lens (IOL) operating room. The air handling unit in the operating room delivered 25 air changes per minute and there was a procedure in place informing staff what to do if the unit failed.
- We also inspected the laser treatment room and, with the patient's consent, observed a procedure taking place. All rooms where laser equipment was used were clearly signed with illuminated 'in use; do not enter' signs and were controlled by keypad entry. The room had controlled temperature and humidity this was checked prior to each procedure and recorded in the patient's notes and a separate log, we observed this being completed. There were no reflective surfaces in the line of the laser machine.
- The laser technician checked the calibration and the safety of the laser machine before each laser treatment session. The machine was also calibrated after every sixth eye procedure and we observed this taking place. Calibration and checks took place according to local rules.
- 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 were referred to the manufacturer who sent an engineer within 24hrs.
- The clinic was not required to have a resuscitation trolley and in the event that a patients condition deteriorated or they collapsed the team contacted the emergency services. The clinic did have access to an anaphylaxis box which contained all the relevant equipment that was needed. Other equipment was available such as spillage packs and eye wash packs. Staff at the clinic checked the contents and expiry dates.
- Control of substances hazardous to health (COSHH) regulation 2002 risk assessments were in place for a range of chemicals including gases, mytomicin C and cleaning fluids. Mitomycin C is a cytotoxic drug 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.
- Electrical sockets supported by an uninterrupted power supply (UPS) were coloured blue to distinguish them from others. The UPS was tested before each treatment session. If the power supply was lost the UPS provided enough power to complete the laser eye treatment or IOL procedure. The UPS system was also serviced annually and we saw a record of the last service.
- Compressed gas warning signs were visible on the doors of all rooms containing gas cylinders.
- The extraction of plume was automatic via a small suction machine attached to the laser machine. Plume is the vapour produced during laser treatments which can be irritating to the eyes and can create an unpleasant smell.
- The laser technicians were responsible for the laser keys which were kept in a locked key cupboard. We saw the laser technicians remove and return keys to the cupboard.

Medicines

- The clinic had a medicines management policy in place dated January 2017, which described the handling, storage, prescribing, recording, safe administration and disposal of medicines.
- No controlled drugs were stored or administered at the clinic and the surgeon prescribed all medicines.
- The resident registered nurse was responsible for ordering, receiving, recording and storing of medicines and there was pharmacist support available by telephone. One pharmacy supplied all medicines for the clinic.
- We reviewed the clinic's drug order stock book and the medicines we checked were in date and reconciled with the records.

Refractive eye surgery

- We found medicines were stored securely and appropriately. Medicines were ordered on an average every four weeks from an external supplier. Medicines requiring cold storage were stored in locked fridges and the temperature was monitored daily.
- Staff completed competency assessments for managing medicines. We noted from staff records, staff had been assessed for competencies for ordering, receiving, recording, storing, disposal, and dispensing of medicines.
- Mitomycin C eye drops were administered following refractive eye surgery. Mitomycin is used to decrease haze after surface abrasion procedures. We observed staff explain clearly the use of the drug and we saw consent was confirmed before use. Mitomycin is a cytotoxic drug, which means they contain chemicals, which are toxic to cells. We saw cytotoxic waste bins were used and observed the registered nurse dispose of the waste correctly. Staff told us the bins were disposed of after each surgery session.
- Medicines used during surgical procedures and given to patients to take home, were prescribed by the surgeon that had carried out the surgical procedure. There were prescription labels attached to each medicine package, with the patients name, date and instructions for dosage.
- We observed a patients discharge with a technician. The patient was provided with clear, concise instructions on how to use and store the medicines. The patient was provided with opportunities to ask questions and the patient was not discharged until they confirmed they understood all the instructions.
- The clinic held some emergency medicines (such as adrenaline for anaphylaxis) which were checked regularly and in date. These medicines were stored securely in a container in the laser treatment room.
- The gas cylinders, which contained various gases to re-fill the main laser machines, were kept in a storage room in an upright position and stored securely. Staff had been trained to transport the cylinders safely using the provided trolley.
- We checked all the oxygen cylinders and found they contained safe levels of oxygen and were all within their expiry date. All oxygen cylinders were stored safely. Topical anaesthesia eye drops that numb the surface of the eye and local anaesthesia injections given around the eye to stop the eye moving were administered by the surgeon.
- We checked the medicines fridge temperature log and saw that it was up to date and temperatures were within the recommended range.
- Only staff with the required competencies were administering and dispensing drugs. Eye drops were prescribed by the surgeon and checked by the registered nurse. Instillation of eye drops in the immediate post op/treatment period was delegated to a competent person. We saw in staff records that staff had been assessed as competent to give patients eye drops to take home and we observed during our inspection staff checking labels and verifying patient details.
- Medicines were managed according to the medicines management policy and staff attended medicines management training every three years.

Records

- The clinic had an information and records management policy in place from January 2017, for review in three years. This described the processes when completing notes, storage of notes and destruction of records.
- Each patient had both electronic and a paper set of records. Paper records were stored securely at the clinic until the patient was discharged and then archived off site by a dedicated archivist. The records could be retrieved by request if necessary, usually within three working days.
- Each patient completed a health questionnaire at their initial consultation which identified any risks associated with the laser surgery. At the initial consultation the patient was required to indicate on their health questionnaire whether they consented to information being shared with, or requested from their GP. If the patient had consented the electronic system automatically sent a discharge letter to the GP after the procedure had been completed.

Refractive eye surgery

- We reviewed five sets of patient records and saw that consent for procedure was completed, consent to contact GP was completed and allergies were recorded.
- All records containing patient information were stored securely, 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. We noted instrument traceability sheets were kept in an ordered fashion. These showed information on single use items used within the treatment.
- We reviewed records of the World Health Organisation WHO five steps to safer surgery checklist which included, sign in, sign out and time out. The three members of staff present in the treatment room had signed all checklists.
- An audit of records was completed on a quarterly basis and overseen by the manager. The clinic checked 10 sets of records and three on the electronic system. The checks were made to ensure the WHO safety checklist, consent and consultant input had been correctly completed and to check for trends. We reviewed the audits for March and July 2017. Audits achieved 90% and above. Actions taken for improving the quality of records was in evidence. This included considering using the date of surgery labels on consent forms as it was noted these were missing. The records we reviewed showed this was happening.

Assessing and responding to patient risk

- Patients were assessed for their suitability for treatment at the clinic prior to treatment; checks included health questionnaires, psychological suitability and prepared-ness, and eye examinations
- The risks of treatment were explained to patients and we observed four consultations where health checks and eye tests were undertaken. Lifestyle questions were asked so the clinic could make an informed decision about the different laser treatments. For example, patients who engaged in contact sports were better suited to a certain laser treatment as, although a longer recovery, the treatment was more robust and less liable to cause issues for those patients who played contact sport.
- After the eye examination was conducted the patient was provided with information on likely outcomes, but it was explained they would need to see the surgeon who would make the final decision and discuss everything again and review examination results. We viewed five patient records, which showed there was sufficient time between the initial consultation and surgeon consent to allow patients a time for reflection and to decide whether they wished to proceed with treatment.
- 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.
- Suitability guidelines also included other heath associated issues. For example, patients with epilepsy had to confirm they had been seizure free for three months and had to have a letter from their GP to confirm this.
- Staff conducted a team briefing at the start of the day. We reviewed the notes recorded for 6 December 2017. They showed discussion took place on the patient's treatment list for that day, any concerns regarding any patient and checks to ensure everyone knew the role they played. The briefing was attended by all staff.
- Staff used an adapted 'five steps to safer surgery' World Health Organisation (WHO) checklist to minimise errors in treatment, by carrying out a number of safety checks before, during, and after each procedure. During our inspection, we observed two patients' procedures, where the WHO checklist was followed and saw other patients' notes, which showed the WHO check had been completed.
- As part of the medical audit, the WHO checklist was measured and we reviewed the audits for March 2017 and July 2017, which showed 100% compliance.
- We observed staff following the procedure dated January 2017, for surgical site marking and verification which was based on National Patient Safety Agency guidance.
- The clinic used an operating theatre register. These registers are used to provide an ongoing record of patients that have undergone treatment at the clinic

and included the following information: patient name, age, address, diagnosis, names of attending doctors and assistants, date and time of procedure and anaesthetic used.

- A laser protection supervisor was always present throughout the patient's treatment.
- Patients were given an out of hours telephone number to use if they had any concerns following treatment. They were also given detailed written instructions on aftercare and the time and date of their next appointment. The out of hours telephone was answered by an optometrist who had additional training in post-operative care complications. The optometrist had access to an on call ophthalmology surgeon.
- The surgeon was available in the 24 hour period following the procedure. Managers told us that there were back up surgeons available in the event that the operating surgeon was not available, for example to cover illness or annual leave.
- The surgeon remained on site until the last patient left the clinic on the day of treatment.
- The clinic conducted quarterly collapse simulations and was attended by all staff who worked at the clinic.
- The clinic did not provide treatment which required local or general anaesthetic.
- There had been no patient transfers out of the clinic with the last 12 months. For medical emergencies, the clinic contacted emergency 999 services.
- Traceability forms were completed which provided a tracking and tracing system of equipment and treatments used in case of any concerns arising post procedure.

Nursing and medical staffing

- Surgical and laser treatment teams were allocated by a central scheduling team. This meant that the correct number of staff with the correct skills were allocated to each treatment session. A core team of staff worked across the Southampton clinic and other Optical Express clinics in their southern region. Managers told us the clinics were organised in exactly the same way so staff were familiar with equipment and where to find it. Staff we spoke with confirmed this.
- The laser team consisted of a surgeon, laser technician, nurse or scrub assistant, surgery assistant and coordinator. The IOL surgery team consisted of a surgeon, an anaesthetist, operating department practitioner, two scrub nurses and two health care assistants. These staffing levels complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres and were in line with MHRA guidance on laser safety.
- Nursing staff arrangements were dependant on when the clinic opened and this was dependant on patient demand. Therefore, there were no set days that the clinic opened.
- Staff with the appropriate skills were available to administer medications such as local anaesthetics, and monitor the patients until they were fit for discharge.
- An external company provided the Laser Protection Adviser (LPA). Staff told us they were easy to access and the organisation had a good professional working relationship with them. We reviewed evidence of their input into training for core skills knowledge. The LPA was a member of the board of the European Society of cataract and refractive Surgeons.
- The clinic had a named Laser Protection Supervisor (LPS). The LPS had overall responsibility for the safety and security of the lasers including calibration of the lasers, safety checks, securing the area, making sure the lasers were shut down at the end of the treatment session, reporting incidents, reporting any technical problems with the lasers and ensuring other staff followed local rules on a day to day basis.
- In addition all the certified laser technicians undertook the role of deputy LPS when they were assisting the surgeon in the laser treatment room. This meant there was always a designated LPS present when treatments were taking place and all staff knew who was the designated LPS for the treatment session. Laser technicians had all attended core knowledge training.
- Patients were seen by the optometrist post operatively and care pathways were in place for referral of the patient to specialist advice if required. The care pathways ranged from contacting the ophthalmic

surgeon for advice to liaising with other consultants or laboratory services if required. The surgeon retained overall responsibility for the patient following their treatment.

Major incident awareness and training

- Regular fire alarm tests were completed and staff were aware of the evacuation process. Fire escapes were marked throughout and clearly identifiable. Information was on the wall that identified where the meeting point was after evacuating the building. We saw that fire extinguishers were around the clinic in areas such as the laser treatment room.
- An effective uninterrupted power supply system was installed in the treatment rooms. It provided enough power for staff to complete a procedure and was checked prior to each treatment session. We saw the annual maintenance report.
- The team undertook scenario based training sessions on surgery days. These involved role play and had involved situations where patients had fainted, collapsed, received a head injury or had an anaphylactic reaction.

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 eye surgery and the National Institute for Health and Care Excellence (NICE) guidelines in relation to refractive eye surgery.
- The service followed NICE IPG64 guidelines on photorefractive eye surgery. Pre-operative tests for elective surgery were in line with NICE guidelines NG45. Patient's medical history was discussed and appropriate tests and scans were taken to help determine treatment.
- Policies and procedures were in date and staff were able to access these online and in paper form. 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 clinic had a laser safety policy dated January 2017 based on guidance from the MHRA which described staff responsibilities, health and safety and risk assessments. This was in line with the Laser Protection Advisor's latest report and was reflected in the local rulesThe service used suitability guidelines for refractive surgery to ensure that patients were appropriate for surgery. The document identified the various types of refractive eye surgery and whether individual patients were suitable for the surgery.
- The suitability guidance and treatment criteria were subject to review each year by the International Medical Advisory Board (IMAB). We saw that the document in use had been revised in August 2017.
- We reviewed the providers advertisements on the Optical Express website and those displayed in the waiting areas in the clinic. The costs were clearly outlined including the cost of medicines and follow up appointments.Patients we spoke with told us they were fully informed of the costs of the treatment and that there were no hidden extras.
- The provider had representatives on several national groups such as the Refractive Surgery Standards Working Group and the Optical Confederation. This meant that new and emerging best practice was shared within the organisation in a timely manner.
- Treatment sessions took place throughout the day, between 15 to 20 patients were treated at each session. This was in line with best practice guidance.
- The surgeon working on the day of our inspection was employed by Optical Express.
- The provider employed a biostatistician to carry out an annual audit of all surgeon outcomes. These were presented during the surgeon's annual appraisal meeting and benchmarked against the Royal College of Ophthalmologists and the European Society of Cataract and Refractive Surgeons.
- Regular monthly audits were completed for infection control, decontamination, air handling, incidents, complaints, patient satisfaction, record keeping,

maintenance of equipment, personnel files, emergency equipment, medicines management, laser and laser room practices, quality management and health and safety. We reviewed the audit reports for May 2017 and June 2017. Areas of concern had been identified and action plans put in place with dates for completion. Information was shared with staff through staff notifications and re audit showed practice had improved.

- Individual care pathways were in place and we reviewed samples, which included the management of a patient with dry eye. The pathways were in accordance with best practice guidance and provided information from the patient's start of their journey to discharge.
- Patients were seen post-operatively by an optometrist at a location of their own choice. There were also a number of pathways that staff could use for medical advice and support. The optometrist was able to call or email the operating surgeon directly in the event of any queries.

Pain relief

- During consultations, patients were advised that there may be some discomfort before they had surgery. This ensured that patients were prepared and understood what to expect.
- Local anaesthetic eye drops and local anaesthetic injections were prescribed and administered prior to treatment. Patients were asked if they were in any discomfort during surgery. Patients were prescribed anaesthetic eye drops post treatment. We saw staff made sure patients were provided with verbal and written instructions.
- Patients were given a follow up appointment three days after their treatment and their pain was monitored.
- Patients told us they did not feel pain during their procedure and were informed prior to surgery that they may feel some discomfort. We observed three patients being discharged who felt that the staff member had clearly discussed how to manage their pain, once they were at home.

Patient outcomes

- Each surgeon's individual outcomes were collected on an annual basis and were used as part of their appraisal. A full time biostatistician collected data from the patient's electronic files.
- Each surgeon outcomes were assessed at the IAMB meeting, where any necessary changes to effect and safety were reviewed and recommendations were made and discussed at the national Medical Advisory Board (MAB).
- The service expected to enhance approximately 5% of treatments. This meant that patients may have needed to return to the clinic to correct vision issues or to achieve an outcome in which the patient was satisfied. Patients were aware of the potential need for enhancement at the start of their treatment so they were not unexpected. Some of the enhancements that were completed at the clinic had not had primary treatment within the last 12 months. The clinic completed 66 enhancement procedures over the past year; this included primary surgeries that were completed more than one year ago. Out of the 66 enhancements, 20 were completed following surgery that had taken place between September 2016 and August 2017.
- In the past 12 months 141 patients experienced complications following refractive eye surgery. The majority of complications related to abrasion, dry eye, and haze. Most of the complications, for example abrasion required follow up appointments to increase lubrication. However, some required referral back to the surgeon for direct care and some cases just required more frequent follow up appointments by the optometrist. For dry eye complications there was a treatment pathway for staff to follow
- The clinic followed the Complex Case Directive dated August 2017, which provided staff with directions and actions to take for escalation and handling complex cases. The directive gave categories for each complex case, ranging from category A (Emergency) category B (Urgent) and category C (non-emergency). Under each category, a list of complications was provided and the pathway staff were required to follow.
- In the past twelve months, there were no unplanned returns to theatre for refractive eye surgery.

Competent staff

- Staff we spoke with said they had the skills and competencies to carry out the duties required of them. All new staff attended a comprehensive induction programme including familiarisation of policies and procedures. Staff working with lasers worked alongside more senior staff until they had completed the core knowledge training.
- Managers told us some staff were multi skilled and could perform a variety of roles within the laser and intra ocular lens teams. As some of the roles were task orientated and repetitive this enabled staff to maintain interest and staff told us this improved job satisfaction. For example the surgery associates could perform diagnostic procedures, discharge patients and act as scrub assistants.
- Medical staff also completed an induction programme and the core knowledge training. They shadowed the medical director and senior ophthalmologist during a period of supervised practice. If satisfactory, they were approved by the medical director and entered onto the list of authorised users.
- Information we received from the provider stated that the Ophthalmologist must undertake a number of procedures under the supervision of the Medical Director or senior Ophthalmologist following their training before they gained certification. The surgeons once approved by the Medical Director were entered onto the list of authorised users.
- Staff told us they attended an annual appraisal meeting with their manager and we saw evidence of this in the staff records we reviewed. All staff had attended an appraisal meeting within the last 12 months.
- Staff attended core knowledge training for laser machines. This was completed on a three-year basis. We viewed two staff members' personal records, which showed the completion of this competency. This meant they had received suitable laser equipment training and appropriate safety instructions. We saw the list of authorised laser users and staff had signed a declaration that they had read, understood and would follow the local rules.
- We viewed one registered nurses record and saw an appraisal had been completed; certificates of registration with the Nursing and Midwifery Council (NMC) and training competencies were complete. Competency checks included assessments for the scrub role. Revalidation checks of due dates were kept by the service.
- Every quarter the clinic carried out a simulated patient collapse to refresh staff on how to deal with such an emergency, we saw the report for the latest simulated event which indicated that staff had responded in a satisfactory way.
- The Laser Protection Adviser (LPA) support was provided by a recognised company. The LPA was a certificated member of the association of laser safety professionals. We saw a copy of the certificate which was due for renewal in 2020, along with a copy of their curriculum vitae. This showed they were knowledgeable in the evaluation of laser hazards and had the right skills and experience to perform the role.
- Optometrists had received additional training in pre and post-operative care. Training packages had been developed by the providers training department based at headquarters. We saw a copy of the training programme for post-operative care laser vision correction complications. The optometrist on duty told us they had attended the specialist training and we saw evidence of this in their personnel file.
- The laser technicians had attended additional competency based training in order to carry out the role of Laser Protection Supervisor. The competencies were reviewed every three years.

Multidisciplinary working

- We saw good multidisciplinary working between the team at the clinic. There was good communication and each staff member knew their role within the service.
- At the beginning of each surgery day, the team completed a team brief which discussed all staff's roles and responsibilities. The team brief also included information relevant to patients receiving surgery and an update on any specific issues or incidents.
- We observed the medical team working well together in the treatment room. The nurse anticipated

instruments to pass to the surgeon and the technician read out laser recordings to assist them with the procedure. Each staff member was calm, professional and treated each other with respect.

- Monthly team meetings were held and we reviewed copies of meeting minutes which showed there was good attendance from all staff. Time was allocated within the meetings to allow staff to raise any concerns or areas they wished to raise.
- Staff worked as part of a regional team and attended the clinic periodically when scheduled to work. All the staff we spoke with had been to the clinic many times and were aware of how the clinic was set up and managed.
- With patient consent, the service communicated with GP's for relevant information and patients GP's were able to contact the service through the out of hour's telephone line.

Access to information

- Medical records were mostly stored electronically except for a paper record of the care and treatment carried out on the day of surgery. Electronic patient records were password protected. The details from the paper record were entered in to the electronic record following treatment. The electronic record was accessible in every Optical Express clinic which meant if a patient presented at a different clinic to where they received initial treatment their record could be accessed.
- With the patient's consent, information on their treatment could be sent to their GP, via the clinics electronic system. The GP could access the patient's surgeon via the contact details provided on discharge.
- Organisation policies were accessible on the clinic's intranet and these included polices such as safeguarding and incident reporting. Updated guidelines were also available for staff to access.
- Throughout the clinic there was information displayed, such as fire regulation guidelines and infection control procedures such as 'the five moments of handwashing'.

Consent and Mental Capacity Act

- The clinic had a consent to treatment policy in place from January 2017. The consent appointment was made at least three days before any treatment took place. The service did not consent patients on the same day as treatment.
- The consent policy did not reflect Royal college of Ophthalmologists Guidance 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Patients attended an initial consultation with an optometrist where they watched a video and were provided with an information pack which contained consent forms, information regarding the procedure and expectations after the treatment. The patient signed a consent form to confirm that they had watched the video which described the risks and benefits of the surgery.
- If patients wanted to proceed with treatment they then had a consultation with the surgeon who would perform the treatment. The surgeon offered the same information on the benefits and risks associated with the procedure. Further diagnostic tests were also taken. The surgeon retained the responsibility for obtaining consent from the patient to proceed with treatment.
- From the five patients' records we viewed, we saw consent was legible and risks associated with procedures had been explained to patients.
- Staff told us that for those patients who did not speak English, they would be asked to bring somebody with them who could translate. Usually this was a family member or friend. For consent procedures, it is best practice for an independent interpreter to explain treatment options and to assist with consent. This would minimise the risk of coercion and to ensure medical and treatment information is translated accurately.
- All staff at the clinic had completed consent training, which included information on the Mental Capacity Act 2005.
- It was the responsibility of the surgeon to assess capacity to consent. Any concerns would be raised

with the patients' GP, with the patients consent. However, the surgeon had the final decision as to whether the patient was suitable to proceed with treatment.

- If patients were required to have Mitomycin C administered during surgery then this was consented for by the patient within the relevant section. This was due to the medicine being used off license and patients were required to be aware of this before it was used. Staff were aware of this and showed us within the consent document where this needed to be completed.

Are refractive eye surgery services caring?

Compassionate care

- We observed care being given in a compassionate way. Dignity and privacy were respected, patients were seen in private rooms, patient information was treated with confidentiality. This was in line with the dignity, privacy, respect and human rights policy January 2017.
- Staff treated patients with kindness, dignity, and respect. We observed staff interacted with patients in a positive, professional, and informative manner
- We observed seven procedures taking place. During all procedures the surgeon was talking to the patient, informing them what would happen, how they would feel and checking that the patient was comfortable.
- Patients told us staff helped them to feel relaxed and reassured.
- Patients were asked to complete an on line survey at the various consultation appointments they attended. The survey results were benchmarked against other clinics within the organisation. Southampton clinic scored about the same as the organisation average for other clinics, scoring ten out of ten for the question 'did the surgery team make you comfortable and at ease?'

Understanding and involvement of patients and those close to them

- All patients that we spoke with felt involved in the decision making, some patients told us that the risks and benefits of the surgery were discussed several times from the initial consultation up to the point of the surgery. None of the patients felt pressurised into having the surgery and felt they had made an informed decision.
- We observed staff interacting with patients before, during and after 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.
- There were leaflets available, which provided details of all the options available and the costs of treatment. The organisations website was clear and easy to use and gave an informative description of each procedure as well as other patient stories.
- We observed three patients that were discharged following their surgery, each patient was involved in the discharge process and staff ensured that the patient had understood the information given.
- There was clear information in patient leaflets and on the Optical Express website about the costs of treatment, aftercare and alternative treatment choices.
- With the patient's consent, chaperones, friends and relatives were involved in the discussions about treatment and treatment outcomes. Information about chaperones was displayed in the waiting room.

Emotional support

- We observed seven procedures in the laser treatment room and saw that the nurse who was present reassured the patients throughout the procedure. They provided support to an anxious patient and were able to allay their fears and concerns regarding treatment. They were kind, non-persuasive and made the patient feel relaxed.
- Following treatment patients were instructed in post-operative care and how to instil eye drops. Relatives and carers were also involved at this point if the patient required their support with the aftercare.

Refractive eye surgery

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

Service planning and delivery to meet the needs of local people

- Services were planned to meet the needs of the patients, for example patients could attend various other clinics for their consultations and then attend the Southampton clinic for their surgery. This allowed patients flexibility and choices to patients.
- Patients could access the service either through self-referral. They found out about the service through word of mouth, or through searching the internet or in response to marketing. The clinic did not treat any NHS work and did not receive referrals from the NHS.
- The provider generally undertook refractive eye surgery as and when patient demand dictated. Staff rosters were determined on a two monthly basis. Additional days could be fitted into the roster if the surgeon requested and staff were available.
- Pre-operative appointments were flexible beginning with an initial consultation with an optometrist and followed by a preoperative consent appointment with the surgeon. If necessary additional pre-operative consultations could be arranged if the patient needed more information prior to the procedure.
  Post-operative review appointments were delegated to an optometrist trained to manage post-operative complications. The optometrist had access to the surgeon for advice in the event of any concerns with the patient's treatment.
- Patients we spoke with told us they were given full explanations of the treatment, expectations and post-operative care. This was backed up by patient information leaflets, contact phone numbers and an informative website. We observed patients being encouraged to ask questions.

Access and flow

- The clinic did not have a waiting list for refractive eye surgery; patients would choose an appointment that was suitable for them.
- Patients were seen at the clinic at their own convenience, usually within four weeks of first enquiring about treatment. Appointments were also available at weekends.
- Patients had telephone consultations with the surgeon which were documented within the patient's file. These were then followed up with a face to face consultation with the surgeon prior to surgery. There were no unexpected returns for treatment. Returns to treatment were expected and normal in some cases to make minor enhancements to the outcome.
- Within the last 12 months, there had been no cancelled refractive eye procedures due to non-clinical reasons.

Meeting people's individual needs

- The clinic made reasonable adjustments for wheelchair users/people with restricted mobility, however the laser treatment room was upstairs on the first floor with no lift access. Therefore, due to building restrictions, some patients were not able to be treated at the Southampton clinic.
- The service did not treat patients with, learning disabilities or patients with complex health conditions. Screening procedures at the start of the patient's journey ensured those patients who required additional support were referred to alternative services with the support of their GP.
- Patients did not have access to interpreters or translation services. The website did not hold information in different languages.
- All patient information leaflets had the crystal mark. The crystal mark is a seal of approval for information written in clear, simple English.
- There was a range of information leaflets available throughout the clinic. They provided information on treatments and various conditions; however, they were only available in English.
- An equality and diversity policy dated January 2017 was in place and staff attended training every three years.
- There were hot drinks and biscuits available in the reception area along with a cold-water dispenser.

- Patients were provided with information on aftercare and emergency contact numbers if they felt the need to contact the service with any concerns.

Learning from complaints and concerns

- The clinic had a managing complaints and concerns policy in place from August 2016. The policy described the process and timescales required to respond to a complaint. Staff told us they knew how to manage a complaint and that information about complaints was shared during team meetings.
- Managers told us they would attempt to resolve verbal complaints on the day, more serious complaints were escalated to the clinical services director. Complaints could also be submitted via the website.
- From September 2016 to August 2017, the clinic had received eight written complaints which had been managed according to the clinic's complaints procedure. We reviewed the complaints which had been managed according to the complaints policy. We saw evidence that learning had been identified from the complaints and shared with staff through directives.
- 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.
- Written complaints were responded to by the clinical services team. The patient's electronic file was updated so the surgery manager could monitor the information regarding the complaint.
- We saw notices in the clinic and information in patient leaflets describing how to make a complaint. Information about how to make a complaint was also available on the website. Patient information on how to make a complaint did not include information about the Optical Complaints Consumer Service.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was a clear leadership structure in place. Staff identified that the chief executive officer was open, approachable and honest. Optical Express had held a conference call in May 2017 updating staff on the company and minutes were circulated for all to read.
- The surgeon was accountable to the medical director who reported to the chief executive.
- The clinic had a manager who was responsible for the day to day management of the service. Staff said they felt well supported and there was good teamwork. .
- Clinic managers were visible, part of the team and took part in the day to day running of the services as well as managing the staff. Managers were supportive and encouraging to staff.
- On the day of our inspection we saw managers coordinating the refractive eye surgery team effectively.
- Most of the staff we spoke with had worked at the clinic for several years, they told us it was a good place to work and Optical Express a good organisation to work for.
- Staff were complimentary about their workplace and colleagues; we did not see and were not told of any conflict within the workplace, however staff told us they were confident that managers could help to resolve conflict should it occur.
- Staff performance was regularly audited and we saw evidence of this in personnel files. If poor performance was identified managers told us this would be addressed through the appraisal process.
- A whistle blowing policy was in place, staff told us they were familiar with the policy and would be able to raise any concerns freely.
- Throughout our inspection by the things we observed, documents we reviewed and comments from staff and patients we spoke with, we determined the provider

was transparent in its approach to the treatment it provided. Patients told us there was no 'hard sell' and we did not see any evidence of irresponsible incentives.

- Staff were happy with the working arrangements of rotating to other clinics nearby. The surgery manager was responsible for another clinic nearby and staff therefore had consistency in their leadership.
- We observed marketing to be clear and 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. Patients told us they did not feel pressurised to go ahead with treatment from staff working at the clinic.

Vision and strategy

- The chief executive officer for the company had a vision of expanding the business to provide international services.
- The stated vision was to grow the business and be the best provider of eye care. On all computers there was a vision and mission statement which stated the vision was to lead in global elective and healthcare industry through using the most advanced technologies and by working with leaders in the healthcare industry.
- Annual International Medical Advisory Boards (IMAB) were set up with worldwide refractive eye experts with no link to Optical Express. The IMAB was financed through the company and met annually to review the data and clinical protocols. We saw minutes of the meetings which recorded medical advisors challenging or agreeing on the procedures completed by Optical Express.

Governance, risk management and quality measurement

- We saw that policies were in place for key governance topics such as information governance, incident management, risk management, management of complaints and staff recruitment. A theme throughout the policies was the importance the clinic placed on putting patients first in particular respecting equality and diversity and maintaining privacy and dignity. We saw the signature sheet where staff had signed to say they had read, understood and would follow the policies.
- The majority of policies and procedures had been reviewed in January 2017. This was prior to the publication of the Royal College of Ophthalmologists Professional Standards for Refractive Surgery in April 2017. The majority of policies were not due for review until 2020. However, where applicable relevant policies had been reviewed and revised earlier. For example, these included Duty of Candour (May 2017), Sepsis Awareness (September 2017), Consent (September 2017).
- Clinical committee meetings were held monthly by telephone conference. We reviewed recent minutes of the meetings, topics were relevant to the service and the minutes indicated where information should be shared across the organisation.
- The welfare and management of patients and management of risk policy dated January 2017, described risk assessment and action planning to mitigate against risk with reference to serious incidents and their management. The policy referred to staff training and the maintenance of local risk registers and described a safety culture.
- There was a system for assessing risks and identified risks were colour rated, red, amber or green (RAG), which meant the staff were able to assess each risk's severity. Action plans were developed to mitigate the risks as appropriate. . We reviewed the laser treatment risk register which identified potential risks, their severity and mitigating actions, risks identified were relevant to the environment and activity taking place. We also reviewed the LPA visit report January 2016 which had identified three actions which were all complete.
- The provider had a medical advisory board who was responsible for reviewing the performance of the surgeons working for the organisation.
- Local managers were involved in monitoring performance and audit and took action when required to make changes for improvement. The quality

management and clinical governance policy described how local managers contributed to the organisations objective of delivering safe and effective treatment to service users.

- The fit and proper person's checks were adopted for the company's director, nominated individual and registered managers.
- The organisation held meetings through which governance issues were addressed. These meetings included the clinical committee meeting which was held on a monthly basis. These meetings were attended by the clinical services director, medical director, surgical services manager, in house solicitor, and the responsible officer.
- We reviewed the meeting minutes of April 2017 and June 2017. Governance topics such as the opening of new clinics, Royal College of Ophthalmologists guidelines, appraisals, mandatory training and other relevant topics related to the service. The minutes supplied actions taken and information sharing.
- The location had quality indicators, which covered, incidents, complaints and local audits. This local quality information was fed into the clinical governance committee, which met once a month, and in turn fed into the Medical Advisory Board (MAB). The CEO headed the MAB and all surgeons and heads of departments were members of the board. The MAB managed changing practices, either to treatment, surgery techniques or the introduction of new technology.
- Local monthly team meetings took place at the clinic and local topics were discussed including incidents and any changes to practice (which had been fed from the MAB). The meeting allowed time for staff to raise any concerns.
- The clinic did not have a risk register because Optical Express holds a corporate risk register. However, there were risk assessments, which applied specifically to that location. These risks were colour rated, red, amber or green (RAG), which meant the clinic were able to assess each risk's severity. A red rating indicated a high risk, amber moderate and green low. We viewed the risks for laser risks and fire assessments. These were up to date, re-assessed, and kept for one year. As a single specialty service, the risks to patients were low and staff were trained and skilled to manage risks at the location.
- We were told by the surgery manager the top three risks of the clinic were needle stick injury, inflammatory response to treatment and an error of omission in the computer system. Staff we spoke with were aware of the risks and the steps they needed to take to reduce these risks.
- We saw evidence that checks for the surgeon's personnel file were completed and indemnity insurance was in place, an appraisal had been completed and clinical outcomes had been collected.
- The local surgery manager was able to manage performance and quality of the service through local auditing and was able to contribute feedback through their local meetings with the surgery services manager.

Public and staff engagement

- The corporate external website contained which provide the public with clinical and non- clinical information specific to the location.
- The organisation did not conduct staff surveys. We were told by the surgery services manager the company would appoint a Freedom to Speak Up Guardian who would start staff surveys through the organisation.
- Staff were encouraged to provide feedback at staff meetings. Staff told us that they would feel confident to discuss any issues at meetings or generally to the co-ordinator or surgery manager. We reviewed the minutes of the most recent team meetings which included information about incidents, complaints, patient feedback and policy updates.
- Patients completed an on line survey at the clinic after the initial consultation, following the day of surgery, one week post operation and four weeks post operation.
- Information from patient surveys was collated across the organisation and trends identified. For example, patients were expressing anxiety on the day of treatment about the length of time they were in the

clinic. In response the provider has improved its information for patients about what to expect on the day of treatment. Patients told us they understood that although the actual treatment took approximately 10 – 20 minutes other tests and checks needed to be carried out on the day and that they would be at the clinic between 2 – 3 hours.

- At the initial consultation with the optometrist the patient was given an information folder which included a copy of the terms and conditions, fees and information about methods of payment. We observed this information being discussed with a patient to check they understood it thoroughly.

Innovation improvement and sustainability

- Optical Express had a staff recognition and reward scheme called 'wonderful Wednesday'. The scheme took place every week to recognise valued members of staff. Staff could be nominated for the award by colleagues and successful staff members were rewarded by a gift such as a spa day.
- The company developed the International Medical Advisory Board. The board was made up of specialists independent of Optical Express. They met annually to discuss outcome data and gave recommendations about any changes required.
- The managing director was one of the eleven members of the refractive surgery standards working group (Royal College of Ophthalmologists) who have recently published the latest guidance from RCO 'Professional Standards in refractive Surgery' April 2017. The surgical services manager was an expert panel advisor with the Optical Confederation who were currently drafting new refractive surgery standards for providers.

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 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider should offer patients access to interpreting services instead of relying on individuals that attend with the patient.
- The provider should offer patient information in the form of leaflets and documents in other languages apart from English.
- The provider should develop staff engagement surveys.