Optical Express - Exeter 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

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Optical Express – Exeter Clinic provided laser eye surgery for adults who pay privately for their care and treatment. No NHS funded work was completed at this clinic.Optical Express Exeter (hereafter known as 'the clinic') was operated by Optical Express Limited (hereafter known as 'Optical Express'). The regulated activities at this location were diagnostic and screening procedures; and treatment of disease, disorder or injury and surgical procedures.

The clinic was situated on the first floor of a multi-occupied office building in Exeter city centre. The entrance to the clinic was on the first floor of this shared building. The first floor was accessed by stairs or a lift. At the time of our inspection, the service provided refractive eye surgery for day case adult patients. Part of the practice provided a general optometry service which falls outside the scope of registration.There were no inpatient facilities.

All surgery was carried out using topical anaesthesia. Refractive eye surgery was undertaken on approximately one day per month. On the day of surgery the patients were treated by a regional surgery team who moved between all locations within the South West dependent on demand at the various locations. This team consisted of the registered manager who was based in Exeter, plus staff who were based in other clinics but covered the Exeter clinic on surgery days. A separate team of optometrists and patient advisors in the general optometry service saw surgery patients prior to surgery. This team completed the patient's initial measurements and topography scans. Topography scanning is a non-invasive medical imaging technique for mapping the surface curvature of the cornea, the outer structure of the eye. Optometrists completed a consultation regarding suitability for surgery that included a discussion of fees terms and conditions. This same team saw patients after their surgery for follow up aftercare appointments. The surgical team and the optometry team worked under separate line management and clinical governance structures.

Patients referred themselves to the clinic for initial consultation. Patients were accepted for surgery if they met admissions criteria and if the optometrist and surgeon agreed that surgery was a viable treatment option.

During August 2016 to July 2017, there were a total of 1950 patient activities including 752 pre-surgery consultations, 268 eye treatments/surgical procedures and 930 aftercare appointments. We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 20 and 21 September 2017 along with an unannounced visit to the clinic on 28 September 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

We regulate refractive eye surgery services, but we do not currently have a legal duty to rate them. 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:

- 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 to ensure that lasers were used safely. The environment was designed and maintained for the use of lasers. Staff were trained to operate lasers and laser equipment was maintained.
- Patients were assessed for their suitability for surgery using current treatment criteria. There was a clear procedure for obtaining patient consent. There were adequate systems for follow up of post-surgery patients.
- Optical Express had an independent medical advisory board that reviewed treatment protocols to ensure these were based on current evidence. Clinicians were supported to maintain up to date clinical skills and competencies.
- Optical Express presented analyses of their clinical outcomes data to conferences hosted by the European Society of Cataract and Refractive Surgeons and the American Society of Cataract and Refractive Surgeons.

Summary of findings

- Staff built effective relationships with patients. Surgeons talked to patients during surgery to help patients to feel at ease. Patients told us they felt comfortable and safe with staff.
- The surgery team and the optometry team showed compassion towards patients. Staff listened to patients and showed respect for patients' dignity.
- The service offered flexibility around appointment times and dates and locations. There was no waiting list for surgery. Surgery was rarely cancelled.
- Optical Express encouraged feedback from patients. Staff told us they felt supported, and valued by their peers and their managers. Staff enjoyed their work. Leaders were well respected.

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

- There was a system for sharing learning from incidents at other locations, but this did not include discussion at team meetings.
- Staff did not always date the administration record for individual patient medicines.
- In the 12 months preceding our inspection, 14% of surgeon consent appointments were carried out less than seven days prior to the day of treatment. This did not comply with the Royal College of Ophthalmologists professional standards for refractive surgery.
- Not all reasonable adjustments were made so that disabled people could use the service on an equal basis to others. People with a hearing impairment were required to provide their own sign language interpreter and patients with mobility impairment were required to provide their own moving and handling equipment and a carer for surgery day. Staff did not always plan to meet individual needs effectively on the day of surgery.
- At a local level, the registered manager did not have a continual oversight of the entire patient journey.The optometry team and the surgery team were separated and there were no clear processes for the integration of quality information at a local level.
- Minutes of meetings did not provide a complete record of governance processes at a local or corporate level. The risk register was a collection of risk assessments rather than a live tool to monitor current risks to patient care or service delivery. The mitigation of risks such as non-compliance with guidance issued by the Royal College of Ophthalmologists was not clearly identified, mitigated and monitored.
- There were no staff surveys. There were no team meetings for the optometry team. There were no joint team meetings for the optometry and surgery staff who looked after patients on the surgery pathway.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with two requirement notice(s) that affected the refractive eye service. Details are at the end of the report.

Amanda Stanford
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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Optical Express – Exeter Clinic

Services we looked at
Refractive eye surgery;

Summary of this inspection

Background to Optical Express - Exeter Clinic

Optical Express – Exeter Clinic (hereafter known as 'the clinic') is operated by Optical Express Limited. The service opened in 2014 as a private clinic in Exeter, Devon. The clinic primarily served the communities of the South West. It also accepted patient referrals from outside this area.

The service provided refractive eye surgery for adult patients who paid privately for their care and treatment. No NHS funded work was completed at the clinic. No children were treated at the clinic. There were no overnight facilities.

The clinic had previously provided cataract intraocular lens implant surgery. In in January 2016 the service suspended provision of this type of surgery due to low demand. There had been an increase in the number of requests for this type of surgery and plans were in place to re-introduce intra-ocular lens surgery in the six months following our inspection.

At the time of our inspection, all surgery was carried out using topical anaesthesia. Refractive lens surgery was undertaken on one day per month. All patient activity was carried out at the clinic premises. When intraocular lens surgery is resumed, treatment will be provided using local anaesthetic and conscious sedation.

The registered manager was in post since July 2015. The service had not been inspected previously.

Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Catherine Campbell, inspection manager and Mary Cridge, Head of Hospital Inspection.

Information about Optical Express - Exeter Clinic

Optical Express – Exeter is situated in a shopping street in the city centre. The clinic is part of a nationwide chain Optical Express Limited that specialises in private laser eye and lens replacement surgery. The clinic was on the first floor of a multi-occupied building. The clinic was refurbished and opened in 2014.

There were 268 surgical procedures carried out during the period August 2016 to July 2017. No patients stayed overnight at the facility. During August 2016 to July 2017 there were 1682 outpatient total attendances; of these 752 were pre-operative consultations and 930 were follow-up care.

During the inspection, we visited the clinic and spoke with eight staff. This included registered nurses, laser technicians, ophthalmologist, optometrist, store manager, patient advisors, surgical services manager, registered manager, surgery support manager, operating department practitioner and the clinical governance manager.

We spoke with six patients and two relatives. During our inspection, we reviewed five sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service had not previously been inspected.

There had been no never events or serious incident reported in the preceding 12 months. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers.

Summary of this inspection

There were no incidences of hospital acquired infection such as methicillin-resistant Staphylococcus aureus (MRSA), methicillin-sensitive Staphylococcus aureus (MSSA), Escherichia coli (E-Coli) or Clostridium difficile (c.diff) in the last 12 months.

In the preceding 12 months, there were 22 complaints, all of which had been investigated at the time of inspection.

There was one permanent member of staff, the registered manager, employed in the surgery team at the Optical Express Exeter clinic. There was one member of staff, the store manager, employed in the optometry team at the Optical Express Exeter clinic. All other staff including the surgeon, registered nurses, operating department practitioners, optometrists and patient advisors were part of a regional team. The accountable officer for controlled drugs (CDs) was the surgical services manager.

None of the services provided were accredited by a national body

Services provided at the clinic under service level agreement:

- Clinical and or non-clinical waste removal
- Laser protection service

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 found that:

- 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 to ensure that lasers were used safely. The environment was designed and maintained for the use of lasers. Staff were trained to operate lasers and laser equipment was maintained.
- Medicines were stored securely and medicines stock was managed safely.
- Patients were assessed for their suitability for surgery using current treatment criteria. There was a clear procedure for obtaining patient consent. There were adequate systems for follow up of post-surgery patients.

However:

- There was a system for sharing learning from incidents at other locations, but this did not include discussion at team meetings.
- Medicines documentation was not always completed. Staff did not always date the administration record for individual patient medicines.

Are services effective?

We found that:

- Optical Express had an independent medical advisory board that reviewed treatment protocols to ensure these were based on current evidence.
- Clinicians were supported to maintain up to date clinical skills and competencies.
- Optical Express presented analyses of their clinical outcomes data to conferences hosted by the European Society of Cataract and Refractive Surgeons and the American Society of Cataract and Refractive Surgeons. Optical Express compared their outcomes data with the data in the National Ophthalmic Database. This provided a means of benchmarking the treatment outcomes of individual surgeons.

However:

Summary of this inspection

- Surgeon consent appointments were sometimes completed over the telephone and 14% were carried out less than seven days prior to the day of treatment. This did not comply with the Royal College of Ophthalmology standards for refractive eye surgery.

Are services caring?

We found that:

- Surgeons talked to patients throughout their surgery as recommended in the Royal College of Ophthalmology professional standards for refractive surgery.
- Staff built effective relationships with patients. Patients told us they felt comfortable and safe with staff.
- The surgery team and the optometry team showed compassion towards patients. Staff listened to patients and showed respect for patients' dignity.

Are services responsive?

We found that:

- The service offered flexibility around appointment times and dates and locations. There was no waiting list for surgery. Surgery was rarely cancelled.

However:

- Not all reasonable adjustments were made so that disabled people could use the service on an equal basis to others. People with a hearing impairment were required to provide their own sign language interpreter and patients with mobility impairment were required to provide their own moving and handling equipment and a carer for surgery day. Staff did not always plan to meet individual needs effectively on the day of surgery.

Are services well-led?

We found that:

- At a local level, the registered manager did not have a continual oversight of the entire patient journey.
- Minutes of meetings did not provide a comprehensive record of governance processes at a local or corporate level. The risk register was a collection of risk assessments rather than a live tool to monitor current risks to patient care or service delivery.Mitigation of risks such as non-compliance with guidance issued by the Royal College of Ophthalmologists was not clearly identified, mitigated and monitored.

Summary of this inspection

- There were no staff surveys. There were no team meetings for the optometry team. There were no joint team meetings for the optometry and surgery staff who looked after patients on the surgery pathway.

However:

- There was a clear vision for increasing the range of surgery carried out at the clinic
- There was a strong mechanism for patient engagement
- Staff told us they felt supported and valued in their work. Leaders were well respected.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

Incidents and safety monitoring

- The service monitored safety performance in terms of the competency of its staff, the incident reporting system, adherence to infection control policies, rates of infection post –surgery, and daily monitoring of equipment and facilities on treatment days. The teams used the incident reporting system and regular audits to highlight risks to safety in the service.
- Our inspection looked at the surgery team and the optometry team and these teams had diverging approaches to incident reporting.
- Staff in the surgery team and the optometry team understood their responsibilities to raise concerns and knew how to record safety incidents. However, there was a low reporting rate during January 2016 to December 2016, when the surgery team had only reported one incident. The surgical services manager explained that the absence of intraocular surgery at the Exeter clinic reduced the level of risk and led to a low incident reporting rate.
- 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 one incident that had been reported, involved a patient who had been given eye drops to take home that were one week past their expiry date. The surgical services manager investigated the incident thoroughly to understand failures in the process. The clinical services team also investigated the incident to understand how patient care might have been impacted. Immediate action was taken to rectify the situation. The registered manager for the clinic personally delivered a new bottle of eye drops to the patient's home and apologised for the mistake.
- Following the investigation of the incident, learning was identified and shared with the regional surgery team. Protocols for stock taking of medicines were revised to include further checks with a requirement for staff signature on completion. The change to the protocol was communicated to surgery staff at team meetings and via a directive that staff were required to sign.
- There was a system for sharing learning from incidents. Learning from the incident reported at the Exeter clinic was discussed at the team meeting and shared amongst the optometry and surgery teams. The surgical services manager informed us that few incidents occurred at the Exeter clinic, but more incidents were reported at locations where intra-ocular lens surgery was carried out. The learning from these incidents was communicated to staff by a surgical service directive that all staff signed. There had been 15 surgical services directives issued during the 12 months preceding our inspection. However the minutes of regional team meetings during the 12 months preceding our inspection recorded only one other incident from another location that was raised but not discussed in detail.
- Incidents reported by the optometry team were investigated. Two types of optometry incidents were reported: changes to treatment decisions, where the surgeon recommended a treatment option that was not the option recommended by the optometrist; and patient complications post-surgery. There had been four incidents of changes to treatment decisions reported by the optometry team during the twelve months preceding our inspection. Individual learning for the optometrist involved in the patients care was fed back to the optometrist by email. Every six months, optometrists and surgeons participated in a peer discussion group. This forum enabled the team to reflect on complex case scenarios derived from incidents that had been reported.

- When patients had post-surgery complications, these were investigated. There had been six incidences of patient complications following their surgery. Optometrists used a grading system to classify these complications. Optometrists reported patient complications to the clinical services team who provided advice and guidance regarding the most effective way to treat these patients. Part of this clinical review also involved an audit of the patient pathway by the clinical services team in conjunction with the medical director and the clinical services director.
- If an optometrist identified that a further surgical procedure might be needed to rectify an unresolved complication, the clinical services director, medical director and operating surgeon reviewed the optometrist recommendation. Learning from the review of these complex cases was generally not shared further than the clinicians involved.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. There had been no incidents that met the threshold for the duty of candour in either the surgery team or the optometry team. There was a duty of candour policy in place since March 2017 but Optical Express had not provided training regarding the duty of candour.

Mandatory Training

- In the 12 months before our inspection, all staff employed in the regional surgery team had completed mandatory training in systems and practices designed to keep patients safe. This training included an appropriate range of topics including conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety, information governance, infection prevention and control, moving and handling, safeguarding vulnerable adults, safeguarding children levels one and two. Some staff such as the duty manager had also completed safeguarding children level three.
- Staff at the Exeter clinic were trained in basic life support only. 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.
- Optometrists participated in mandatory refresher training for clinical competencies. However, this mandatory training did not cover the range of topics completed by the surgery team and did not cover all safety systems and processes. None of the optometrists had completed training in conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety, basic life support, infection prevention and control, moving and handling. Optometrists' knowledge of safe systems was dependent upon reading Optical Express clinical directives such as the professional standards directive and following guidance issued by the College of Optometrists such as for infection prevention and control.

Safeguarding

- The clinic employed systems to protect vulnerable adults. All staff we spoke with understood their responsibility to recognise and report safeguarding concerns. There was a safeguarding policy and this policy conformed to intercollegiate guidance. The registered manager was the safeguarding lead. All staff knew where to go for further advice if a safeguarding concern arose. There had been no safeguarding incidents during the twelve months preceding our inspection. No children were treated at the clinic and staff advised patients not to bring children to the clinic.
- All staff in the regional surgery team and the resident optometrist were trained in introduction to safeguarding vulnerable adults and safeguarding children level one and two. The surgeon and the registered manager were trained in safeguarding children level three.

Cleanliness, infection control and hygiene

- Reliable systems were in place to prevent and protect patients from a healthcare-associated infection. There had been no instances of infection during the twelve months preceding our inspection.
- There were systems to ensure that the patient treatment areas and equipment used in patient care were clean. Cleaning schedules were in place that reflected the standards and guidance from the Royal College of Ophthalmologists. The treatment areas were thoroughly cleaned at the end of each day of surgery and then deep cleaned once per week. Cleaning was undertaken by the staff employed at the clinic. Checklists were completed which showed cleaning was completed regularly and

consistently. We observed that staff followed infection control protocols regarding the cleaning of diagnostic equipment between patient uses. Treatment areas were visibly clean and tidy.

- There were systems to ensure that staff were following protocols for infection control. Clinic cleaning audits were completed every two months and action was taken to address any defects, for example removal of used mop heads, laminated sharps, injury posters obtained for the operating theatre.
- Staff used effective hand hygiene techniques. We observed laser refractive surgery and saw that the staff washed their hands thoroughly in accordance with National Institute for Health and Care Excellence quality standard QS61 Infection Prevention and Control. Staff wore disposable clothing including gloves, masks, hats and aprons. Hand hygiene audits in the surgery team were completed regularly every surgery day (once per month) and these showed that effective hand hygiene measures were used by staff. All staff were involved in the audit process by auditing each other. Where there was less than 100% compliance the registered manager gave feedback to the individual member of staff.
- Waste was managed according to best practice, segregated and stored in containers in a locked room whilst awaiting collection. All surgical instruments used for laser refractive surgery were disposable. There was a current service level agreement with a private company for the collection of clinical waste.
- Laser refractive surgery was performed in an operating theatre with an airflow system that minimised the spread of airborne infection. Humidity conditions in the operating theatre were maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used. Staff recorded a log of humidity conditions and this was checked as part of the infection control audit.

Environment and equipment

- There were recording systems that allowed details of specific implants and equipment to be provided rapidly to the Medicines and Healthcare Products Regulatory Agency when needed. Theatre staff attached the packaging with unique identification label to the patient's paper record.
- There were systems to ensure that laser equipment functioned safely during surgery. There was central equipment services team that arranged for the maintenance and testing of all equipment. All surgical equipment had been serviced and checked for electrical safety within the twelve months preceding our inspection. Fire extinguishers had been serviced within the twelve months preceding our inspection.
- There were systems to ensure that laser surgery equipment was safe to operate on the day of surgery. Before surgery started, the laser technician set up and calibrated the equipment according to the manufacturer's instructions and then repeated this process regularly throughout the day of surgery. This process produced data which was checked by the laser technician against expected ranges to monitor for any discrepancies. The laser technician emailed the manufacturers engineer at the end of every treatment day with this data.
- There were systems to ensure that surgery did not proceed if laser equipment was not functioning. Laser machines cut off automatically if the data inputted by the laser technician was out of the expected range. Laser technicians could contact experts in the clinical services team for immediate advice over the telephone and also had the option of contacting the manufacturer if a problem could not be resolved. If equipment did not calibrate satisfactorily, engineers were informed and surgery did not proceed. Patients were offered surgery at alternative clinic locations or alternative surgery dates. This had not occurred during the 12 months preceding our inspection.
- The laser protection advisor carried out a site visit and risk assessment every three years and re-issued or revalidated the protocols that staff followed in the laser treatment environment (local rules). All staff knew where to find the local rules and had signed to say they had read the latest version. In the event of any changes to the equipment (other than routine software upgrades) or any safety incidents, the laser protection advisor was notified and conducted a visit as necessary. Following the most recent laser protection advisor visit there had been no issues to address at this location.
- The treatment area was set up to mitigate the safety risks associated with laser treatment and complied with guidance issued by the Medicines and Healthcare Products Regulatory Agency. The laser controlled area was clearly defined. Illuminated warning notices were clearly visible. There was a key pad securing entrance to the operating theatre. Laser safety of the clinic

environment was assessed as part of the regular audit completed every three months. No issues were identified regarding laser safety in the twelve months preceding our inspection.

- There were systems to ensure that laser safety protocols were followed during surgical procedures. The registered manager was the laser protection supervisor with overall responsibility for the safety and security of the lasers. The registered manager was not a clinician and was not in the operating theatre during surgery. During surgical procedures, the role of the laser protection supervisor was delegated to the certified laser technician who was .responsible for ensuring the lasers were calibrated, safety checks completed, the area secure, lasers closed down at the end of the day, all incidents reported, laser performance issues communicated to the engineer, manager and the head office and safe custody of the keys.

Medicines

- There were effective systems for the management of medicines. The corporate policy for the management of medicines included the ordering, receipt, prescribing, administering, dispensing storing and disposal of medicines, emergency medicines, reporting of drug errors and adverse reactions plus the training and competency of staff. This policy served as a guideline for staff to follow. Medicines management was audited as part of the general clinic audit completed by the registered manager every one to two months. The most recent audit showed good compliance with the policy.
- Medicines were stored at correct temperatures and securely within locked cabinets. At the time of our inspection, no controlled drugs were stored or administered as part of the service provided. Staff gave detailed verbal instructions to patients regarding their medicines to take home and this was supplemented with a written information sheet.
- The use of cytotoxic medicines was well managed. The printed consent form clearly explained the risks of using cytotoxic medicines in refractive eye surgery. At this location, risks associated with the use of this medicine were managed with a risk assessment and policy to guide staff. For example, the cytotoxic medicine was ordered as a pre-prepared solution specifically for each patient as it was required. These medicines were stored in secure, rigid containers in a fridge. These medicines were collected in sealed cytotoxic waste bins by the waste contractors.
- However, nurses did not always complete an accurate record of medicines administered to patients. We reviewed five sets of patient records and in four of these staff had omitted to write the date against individual prescription items when these were administered. We highlighted this to the surgical services manager who discussed it with the team during the briefing on the day of our inspection.

Records

- There were safe systems for storing records. Electronic records were password protected and paper records were stored in locked filing cabinets in a locked filing room. No paper records were left unattended at the time of our inspection. On the day of treatment, the information from the paper record was entered onto the electronic file. Instrument traceability records and signed consent forms were scanned onto the electronic record and the paper record was archived off site.
- There were systems to ensure that staff followed best practice with regards to record keeping. Patient documentation was audited every one to two months by the registered manager for the surgery team. We saw that these audits frequently highlighted non-compliance. Where patterns of poor practice emerged these were addressed promptly. For example, when information was omitted on the patients file at the time of their optometry scans, the registered manager liaised with the store manager for the optometry team. The clinical services team audited documentation as part of the review of complex cases. We saw that staff in the clinical services team emailed optometrists individually to provide feedback on specific records which did not meet the required standard.
- Patient records were complete. We reviewed five sets of patient records. These records were legible and all aspects of the patient journey were recorded. Appropriate records were maintained each time a laser was operated. We saw that staff inputted a contemporaneous record of laser operations for every patient. This aspect of laser safety was audited as part

of the general clinic audit completed by the registered manager every one to two months. Results of this audit showed good compliance with documentation of laser activities.

Assessing and responding to patient risk

- There were systems to ensure that patients were assessed for their suitability for treatment. Prior to the day of surgery, patients completed a health and lifestyle questionnaire. This enabled staff to identify any risk factors specific to the patient. The optometry team undertook a thorough examination of the patient's individuals visual and lifestyle needs and assessed the patients understanding of the limitations and benefits of treatment. The patient's capacity to consent was included in this examination process.
- The optometrist pre-operative examination identified risk factors such as the existence of diabetic retinopathy or high blood pressure. Some risk factors resulted in the patient being excluded for surgery, for example, pregnancy. However, it was the responsibility of the patient to declare any potential for pregnancy as the service did not provide pregnancy tests.
- Clinicians made decisions to treat patients based on best practice and research evidence. Clinicians followed a detailed protocols to identify whether patients were well enough 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 systemic conditions such as epilepsy, depression, cancer or diabetes. In certain situations, a letter from the patients GP giving their opinion regarding the suitability of surgery was required prior to surgery taking place. For example, if a patient had a history of epilepsy. We checked the records of five patients and saw that the advice of the GP was sought for the management of a patient with diabetes.
- There were systems for completing verbal checks during surgery as recommended by the Royal College of Ophthalmology standards for refractive eye surgery. These processes had been introduced three months prior to our inspection. Managers did not have processes in place to be assured that the team completed the checks every time. For refractive eye surgery, we observed that the surgical team completed the verbal checks and these checks were recorded on a safer surgery checklist. However, this process was not audited.
- Staff did not use a recognised system for monitoring the deteriorating patient. Staff knew what to do if a patient required emergency assistance. The Optical Express protocol stipulated that staff were to telephone for an ambulance in the event of a cardiac arrest. All staff in the surgery team were trained in basic life support and all clinical staff were trained in immediate life support. There was no service level agreement in place to authorise transfer to an acute hospital in the event of a patient becoming seriously unwell during eye surgery.
- The clinic did not have resuscitation equipment. However there was an emergency stock of medicines available containing treatment for anaphylactic shock, diabetic coma, adrenaline, aspirin, and antihistamine, a spare inhaler for asthmatic patients and portable oxygen for patients feeling faint. These medicines were within their expiry dates.
- There was a follow up system to care for patients after their surgery. The surgeon was responsible for the post-operative and follow up care of all patients. A trained nurse or operating department practitioner monitored the patient in recovery and the surgeon examined the patient immediately post-surgery. The team gave patients an aftercare advice leaflet that included telephone numbers to call if they had concerns or queries post-surgery. This advised patients to call the clinic during working hours and an emergency number for out of hour's advice. An on-call optometrist answered the emergency number and called the operating surgeon for advice if the situation was potentially urgent. The out of hour's information was also available on the Optical Express website. If necessary, patients returned to the clinic for review with either the optometrist or treating surgeon. There was an emergency support system for urgent cases where the clinical services team co-ordinated care between the surgeon and optometrist in the event of for example, infection, and also co-ordinated external referrals to another consultant or laboratory services when required
- Staff took precautions to mitigate the risk of complications following eye surgery. Patients were carefully monitored to check for any sign of inflammation, irritation or infection post-surgery. The

optometrist reviewed patients the day after their surgery and then again at regular intervals until discharge. The optometrists told us they felt comfortable to contact the surgery team with any concerns identified post operatively. Optometrists could also contact the clinical services team for advice. Post-operative follow up appointments were scheduled for the morning to allow time for staff to arrange suitable urgent medical follow up for patients if the need arose. Optometrists could also directly refer patients to the surgeon for non-urgent follow up.

- Clinical staff we spoke with understood the importance of identifying sepsis and taking prompt action when required. Sepsis is a life threatening illness caused by the body's response to an infection. During the month of our inspection, the service had instigated a sepsis awareness protocol for staff in line with guideline NG51 Sepsis Recognition Diagnosis and Early Management published by National Institute for Health and Care Excellence (NICE). This protocol included identification of risk factors and symptoms and referred staff to use the NICE algorithm if a situation arose where they suspected a patient had sepsis.

Nursing and medical staffing

- There were sufficient staff to meet patients' needs. Staffing numbers and skill mix complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres. We checked the staff rosters for the three months preceding our inspection and saw that numbers of staff working on surgery days corresponded to the amount assessed as adequate by the provider.
- There were no staff working under practising privileges at the clinic. Bank staff were only used for intraocular lens surgery and so were not required at the Exeter location at the time of our inspection.
- In the surgery team, there was one member of staff permanently employed based at the Exeter location, this was the registered manager. All other staff present in the surgery team on treatment days were permanent members of staff based at different locations across the South of England.
- There was an effective system for engaging staff at short notice from other clinics to cover sickness or annual leave. The surgery team registered manager and the optometry team store manager were 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.
- There were systems to ensure that staff travelling between different bases were familiar with safety processes. All protocols were standardised throughout the company and staff felt at ease travelling to other sites to assist with surgery in their role. Staff were familiar with the teams in other sites and identified no concerns with this pattern of work. The same laser protection advisor was available to all staff via telephone if required.

Major incident awareness and training

- Laser treatment was not compromised if 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 effective?
(for example, treatment is effective)

Evidence-based care and treatment

- The refractive eye service followed evidence based protocols for treatment. Optical Express financed an international medical advisory board (IMAB) for refractive eye surgery. This board was headed by the chief medical officer for Optical Express and was attended by all the managing directors globally. The board was made up of international refractive surgery experts who met annually over several days to consider new research evidence, technologies and guidelines for best practice such as the Royal College of Ophthalmology Standards for refractive surgery. The IMAB used this evidence together with the Optical Express outcomes data to review the clinical protocols of the company, for example the suitability guidance and treatment criteria that clinicians used to make decisions to treat patients.
- All surgeons and heads of department plus the medical director and the clinical services director were members of the medical advisory board (MAB). This was an open meeting for discussion of the IMAB recommendations during which changes were agreed to treatment criteria

or protocols or decisions made to introduce new technology. For example, the corporate team issued a policy directive outlining how surgical teams should ensure compliance with the professional standards of the General Medical Council for doctors and the General Optical Council for optometrists

- Patients had their needs assessed and their care planned and delivered in line with evidence based guidance and standards. The medical advisory board set standards for all surgeons and optometrists. These standards were in line with national guidance such as National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery, Royal College of Ophthalmology Standards for Laser Refractive Surgery and Royal College of Surgeons' Professional Standards for Cosmetic Surgery.
- Minutes of the medical advisory board meetings showed that clinical protocols were discussed and amendments to current practices were made in line with evidence-based practice. For example, members agreed that it was necessary to see patients for laser surgery aftercare one day post-surgery. Members discussed the risks associated with treating patients with type one diabetes and agreed revisions to protocols to mitigate these risks.
- The service complied with NICE Interventional Procedures Guidance IPG164 Photorefractive (laser) surgery for the correction of refractive errors. For example, patients understood the potential benefits and risks of their surgical procedure by watching an information video. This was then followed up during consent discussions with the optometrist and surgeon.

Patient outcomes

- Optical Express used data to monitor the efficacy and safety of treatment. Outcomes data was collected for every treatment undertaken including long term follow up data. This data was reviewed by the independent medical advisory board and the medical advisory board. Twice a year Optical Express compared their outcomes data with the data in the National Ophthalmic Database.This provided a means of benchmarking the treatment outcomes of individual surgeons. Data for individual surgeons could be analysed for various specific outcomes. For example, distance vision one month post treatment, attempted versus achieved results. This data was used to conduct a yearly audit of the individual surgeon's outcomes which was made available to the registered manager.
- Specific data for the treatment outcomes obtained at the Exeter 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 and the patient satisfaction with their treatment journey. The outcomes data for the surgeon operating at the Exeter clinic compared favourably to the outcomes data of other surgeons working for Optical Express.
- Optical Express presented analyses of their clinical outcomes data to conferences hosted by the European Society of Cataract and Refractive Surgeons and the American Society of Cataract and Refractive Surgeons. However, they did not submit data to the National Opthalmic database or to the Private Healthcare Information Network (PHIN).
- Internal audit processes monitored 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. The most recent audit identified and addressed minor issues such as expired hand gel which required replacement.

Competent staff

- Staff had the right qualifications, skills, knowledge and experience to do their job. We checked two staff files and saw that all relevant documents were available such as evidence of identification, professional registration and qualifications. The surgeon was on the General Medical Council Specialist Register in Ophthalmology and held current indemnity insurance.
- There was a system for ensuring that staff files contained the relevant documentation, for example evidence of disclosure and barring checks, photographic identification. The registered manager had audited the personnel files of permanent staff

based at the clinic in February 2017. Minor omissions had been identified and actions taken to resolve these as arranging for out of date staff competencies to be reviewed.

- The competence of surgeons was assured before they were permitted to perform eye surgery independently. As part of the induction process of Optical Express, surgeons were inducted by the medical director and clinical services director. 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. This list was kept under review by the surgical services manager.
- Nursing staff competencies, such as medicines management, were reviewed every three years by the surgical services manager. All staff in the regional surgery team had completed an appraisal in the twelve months preceding our inspection.
- All staff operating laser equipment were trained in this role. All staff completed the laser core of knowledge training day. The laser technician was certified by the laser manufacturer following a one week course in the use of the lasers and associated equipment. Laser technicians participated in a review of their competencies every three years. Optical Express employed senior refractive trainers who carried out the laser competency assessments locally and supported technicians and laser protection supervisors to ensure they remained skilled.
- The clinical competencies of optometrists were up to date. Regional optometry development managers were responsible for inducting, training, developing, supporting and completing the appraisals of optometrists. This included training and developing optometrists to manage the post-operative side-effects and complications of refractive eye surgery. Staff competencies of the optometry team were reviewed annually during the appraisal process. All optometrists working at the Exeter location had received an appraisal in the twelve months preceding our inspection.
- Optometrists who treated eye surgery patients were trained to complete the additional clinical tasks of the surgery pathway. These optometrists participated in a two week training course that included an introduction to clinical governance processes, the electronic record system, and the patient pathway, the interpretation of diagnostic instruments plus practical observations of clinical practice.
- Optometrist's on-going training did not include refreshers of all essential safety systems and processes. Optometrists did not complete the mandatory training updates in topics such as basic life support, information governance. However the annual refresher training day for optometrists did include topics such as record keeping and communication skills. Following on from our inspection, 100% of the optometrists based at the clinic participated in level two safeguarding training for children and for adults.
- There were systems for the induction on non-qualified staff. Patient advisors participated in induction training and completed competency training and assessments during their probationary period.
- There were adequate arrangements for supporting staff employed by the clinic. More experienced members of staff acted as mentors for new staff and clinical staff met with their peers for support with the nursing revalidation process. Managers used a range of strategies to support staff returning to work following a period of absence

Pain relief

- The team used local anaesthesia to ensure that patients did not experience pain during surgery. The team were able to monitor their pain throughout the procedure because patients were fully conscious and responsive. Staff informed patients about the expected level of pain during and after the surgical procedure and patients told us their pain levels were as expected following their procedure. However, no audits of pain were undertaken.

Nutrition and hydration

- Patients had adequate nutrition and hydration whilst they were attending the clinic on surgery days. Patients had access to hot and cold drinks and biscuits in the waiting room of the clinic. Patients were not required to fast prior to their surgery.

Multidisciplinary working

- Multidisciplinary working outside of the team was limited and dependent upon patient choice. Patients chose whether to give permission for the team to share information with their GP. At their initial consultation, patients were encouraged to give consent to sharing of information with their GP. For those patients who consented, a treatment summary was automatically generated by the electronic records system and sent to the GP when the final appointment was recorded by the clinician. Patients were given a copy of their treatment summary on discharge.
- Staff within the team worked together for the benefit of the patient. Surgeons and other team members worked together as a team in the operating theatre and provided reassurance to the patients throughout the surgical procedures. Staff told us that the surgery team and the optometry team communicated well and could raise concerns when they needed to. However there was no structured forum for doing this such as a joint team meeting.

Access to Information

- Staff had the information they needed to provide care and treatment to patients. Systems were in place to ensure that all information was accessible to the surgery team. Prior to the surgery date, the clinical services team checked the electronic files of all patients scheduled to attend the clinic. This was to ensure that all necessary documentation and pre-surgery actions had been completed, for example, GP letter received if necessary.
- The system for storing individual patient records was accessible to staff who needed this information. The clinic used a password protected electronic patient record system. Different grades of staff could view, access and add records which were appropriate to their role at any of the Optical Express locations. The electronic record included details of any unexpected events occurring during surgery. The optometrist could access both the paper copy and the electronic record during their initial aftercare appointment.

Consent and Mental Capacity Act

- All patients accepted for laser surgery were able to give informed consent for the procedure. Patients who were requesting laser refractive surgery received a pre-operative assessment and thorough discussion of their needs with both the optometrist and the surgeon. This complied with guidance from the General Medical Council and the Royal College of Ophthalmology professional standards.
- 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 patients consent at every stage of the assessment and treatment process. Staff showed patients a video that explained the recommended surgery and provided written information about treatment options. Patients were offered a range of options for treatment as alternatives to refractive eye surgery. Staff in the optometry team gave patients paper copies of the consent form to read at home. There were no time limited deals offered. Surgeons made the final decision as to whether a patient had the mental capacity to consent to treatment. This assessment was recorded in the patient's electronic record.
- The Optical Express protocol for the consent process contradicted guidelines within the standards for refractive eye surgery published by the Royal College of Ophthalmologists which state that this consultation should be conducted face to face. Most patients were offered the option of having a telephone or videoconference with the surgeon as opposed to a face to face consultation. Some action had been taken to mitigate this risk. Optical Express had sent an email to staff identifying some high risk categories of patients that were excluded from telephone consultations. However, these guidelines were not yet incorporated into the clinical directive. During the twelve months preceding our inspection, 55% of consent consultations were carried out over the telephone.
- Optical Express protocol for patient decisions around treatment did not follow guidelines published by the Royal College of Ophthalmologists. 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. Potential patients were given a minimum of three days 'cooling off' period between agreeing to go ahead with the procedure and surgery being performed. The Royal College of Ophthalmologists 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. Optical Express policy 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, 14% of surgeon consent appointments were carried out less than seven days prior to the day of treatment. The average time between surgeon consent appointment and day of treatment was 27 days at the Exeter clinic.

- 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 clearly explained the risks of using this medicine in refractive eye surgery.

Are refractive eye surgery caring?

Compassionate Care

- Staff respected the identity and dignity of patients. Most staff used eye contact when speaking to patients. All staff at every stage of the treatment journey introduced themselves to the patient. Staff encouraged patients to maintain a sense of their identity by permitting patients to wear their own clothes throughout their treatment.
- Staff communicated with patients in a respectful and considerate manner. During initial consultations, staff explained the reasons for asking for personal information. When patients experienced difficulty adjusting to the treatment environment or became anxious during testing procedures, staff in the optometry team were kind and patient, and gave verbal reassurance. Surgeons maintained a reassuring dialogue with patients during surgery, 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.
- Patient feedback indicated that surgeons fostered a good relationship with their patients. During the 12 months preceding our inspection, patient responses on the patient experience questionnaire indicated 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 9.9 out of 10.
- Staff supported patients to understand relevant treatment options including benefits, risks and potential consequences. Staff in the optometry team gave patients information about what to expect from laser surgery. This information was shared during one to one face-to-face consultations when patients were allocated ample time to ask questions. Patients told us they understood this information. During this initial consultation, patients were given transparent and accurate information about all costs of potential treatment.

Understanding and involvement of patients and those close to them

- Patients were seen as partners in the treatment plan. We observed consultations and saw that staff involved patients in all aspects of the consultation process. We observed that staff encouraged patients to complete their own online health questionnaire but recognised that not all patients would feel comfortable using the computer and offered assistance with this task when appropriate.
- Clinicians used humour to quickly develop a relationship with the patient and put the patient at ease. Staff gave thorough explanations and encouraged patients to ask questions. Patients told us they felt comfortable asking questions
- 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 10 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 9.7 out of 10.
- Patients were encouraged to be actively involved in all aspects of their treatment journey, from completing of the initial health questionnaire to complying with aftercare advice.

Emotional Support

- Staff understood that patients became anxious prior to and during their laser eye surgery. The surgery manager had had eye surgery at the clinic, and spent time sharing the benefit of her experience with patients. We were told that surgery could be slowed down if this helped the

patient to remain calm. 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. The patients we spoke with agreed that staff made them feel comfortable and reassured.

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

Service planning and delivery to meet the needs of local people

- The 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.
- The team tried, wherever possible to provide continuity of care. For example, a patient would be seen by the same surgeon and the same optometrist throughout their patient journey. The need for continuity was identified in a clinical directive.
- Where people's needs were not being met, the company identified and used this to plan and develop new services. At the time of our inspection, patients were required to travel to Bristol to have intraocular lens replacement surgery. There were plans to reinstate the option of intra-ocular lens surgery at the Exeter clinic as there had been a rise in demand for this type of surgery.

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 on one day per calendar month. Patients could choose which month but the date was limited to the designated surgery day. If the surgery dates at the Exeter clinic were not convenient, dates at other clinics nationwide could be offered if the patient was prepared to travel. For patients who travelled long distances to attend the clinic, appointments were made for later in the day. The option of telephone appointment with the surgeon for the consent process was popular with patients who told us they were very pleased to reduce their time spent travelling to appointments.
- The service was rarely disrupted for avoidable reasons. The registered manager ensured that all necessary processing of patient information had been completed prior to the patient's arrival on their surgery day. This ensured that surgery was not disrupted for administrative reasons such as the non-return of a GP letter.
- There were very few cancellations of surgery. In the 12 months preceding our inspection, surgery had been cancelled on the planned day of surgery on four occasions. The cancellations had all occurred for clinical reasons, such as: persistent symptoms of 'dry eye'; patient's vision affected by wearing of contact lenses; patient misunderstanding of risks and alternatives to surgery; and variation between the pre-operative assessment and the assessment on the day of surgery. In addition, two patients had failed to attend their appointment on the day of surgery.
- The team took action to minimise the time that patients spent in clinic on their day of treatment. Patient arrival times were staggered to coincide with their allotted surgery time. Patients were encouraged to go for a walk in the city centre if their surgery start time was delayed. Patients we spoke with told us they were impressed how quickly they were seen in the clinic. Results of the patient experience questionnaire completed during the 12 months preceding our inspection indicated that patients were in the clinic for no longer than the anticipated time.The service did not monitor the time that patients spent waiting on the day of their surgery.

Meeting peoples individual needs

- Optometry staff considered the needs of patients with additional needs. We observed a patient advisor and optometrist consultation with a patient and saw that the staff considered the physical and emotional needs of patients they examined. This information was communicated to the surgery manager via a free text section on the patient's electronic medical record.
- Not all reasonable adjustments were made so that disabled people could use the service on an equal basis to others. We saw that the needs of patients with hearing impairment were not well met. Patients who used sign language as a means of communication were

not given equal access to care and treatment because trained interpreters were not provided free of charge. These patients were required to bear the cost of an interpreter themselves or bring along a friend or relative to interpret for them. There was no hearing loop available.

- We observed the surgery of a patient with hearing impairment. The team knew in advance that the patient relied on lip reading but this was not mentioned in the morning safety briefing. We saw that two members of the team took care to speak with their faces in view of the patient, but three members of the team did not attempt to do this. No alternative method of communication during surgery was agreed in advance which meant that the patient did not know when they were receiving instructions and the patient told us this increased their levels of anxiety during the procedure. Staff did not thoroughly check that the patient understood the information given during the final consent process before surgery and the medicines information talk given after surgery.
- Some limited adjustments were made to ensure that people with impaired mobility were given equal access to care and treatment. The main entrance to the optometry clinic and surgery suite was accessed via a lift or stairs and when the lift was out of order. Staff escorted patients to use a fire exit to access the surgery suite at ground level. Patients who required the use of a wheelchair for mobility were invited to come into the clinic in advance of their surgery to practise transferring in the theatre environment. However, patients with impaired mobility had to bring their own assistant and equipment for moving and handling on the day of surgery.
- Patients whose language was not English were not given equal access to care and treatment because trained interpreters were not provided free of charge. These patients paid for the cost of an interpreter themselves or brought along 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.
- Pre-treatment written information included a clear explanation of what to expect during surgery with instructions about how the patient can help the procedure, as recommended in the Royal College of Ophthalmology standards for refractive eye surgery. Written information to reinforce all verbal information was provided for all patients at various stages throughout the surgery pathway, including information prior to consent, during the consultation process, and during the medicines talk. Following their pre-operative optometrist assessment, patients were given a comprehensive eye health care and diagnostic report that included details of the health, prescription and diagnostics, the recommended treatment and surgeon details and cost of treatment.

Learning from complaints and concerns

- Complaints were handled promptly and were investigated. Patients were kept informed regarding the outcome of these investigations. Teams learned from complaints and shared this learning with other teams. For example, patients had complained regarding the parking facilities at the clinic. The initial letter to patients was amended to include direction to the nearest public car park.
- At a corporate level, Optical Express took action as a result of trends identified from complaints received from all clinics. For example, the investigation of several complaints revealed that patients had not clearly understood the information given to them at their initial consultation. In response, Optical Express had increased the font size used in the patient information pack and this had been accredited with a crystal mark from the Plain English Campaign for clarity in written documents.

Are refractive eye surgery well-led?

Leadership and culture of service

- There were systems to provide operational management of staff when working at the Exeter clinic. The optometry store manager was responsible for the routine operational management of the optometry team when they were working at the Exeter clinic and the smooth running of the optometry clinic on that day The registered manager was responsible for routine operational management of the surgery staff when they were working at the Exeter clinic and the smooth running of the clinic on that day.

- There were systems to provide clinical leadership to the surgery team and the optometry team. Staff from both teams told us they had confidence in the leadership structure and they felt supported in their roles. Members of staff told us they could access advice and guidance when they needed to.
- Clinical leadership of the surgery pathway was divided between two separate clinical governance structures and centrally supported by the clinical services team. Clinical leadership of the optometrists was provided by a regional optometry development manager who had oversight of the training and development and completed optometrist appraisals. The optometry development manager was supported in this role by the clinical services team and the medical director.
- Clinical leadership of the surgery team was provided by the surgical services manager who was responsible for all the surgery teams nationwide. The surgery services manager was supported in this role by the clinical services team and the medical director and clinical services director.
- Clinical leadership of the surgeons was the responsibility of the medical director and the clinical services director. They were supported in this role by the medical advisory board who were guided by the international medical advisory board.
- The culture of the service was focused on providing the best possible care for patients. At the Exeter location, optometrists and surgeons gave honest advice to patients regarding their best course of treatment, including the option of no treatment. At the initial consultation, patients were provided with written statements detailing the terms and conditions of the service being provided and amount and method of payment of fees.

Vision and strategy

- There was a clear vision for the expansion of surgical services at the clinic. The strategic direction of the service was determined at a corporate level. The vision for the Exeter clinic was the re-introduction of intra-ocular lens surgery. To enable this to happen, one of the clinic rooms required some refurbishment. Staff were already equipped with the competencies and the protocols to do this work because the regional surgery team carried out intra-ocular lens surgery at the other locations in the south west. The theatre was already equipped with air handling capacity and the laser equipment had been purchased.

Governance, risk management and quality measurement

- At a local level, the registered manager did not have a continual oversight of the entire patient journey. The optometry team and the surgery team were separated and there were no clear processes for the integration of quality information at a local level.
- At a corporate level, the safety and quality of the patient journey was monitored effectively. There was a central clinical services team responsible for the monitoring of various aspects of clinical governance across the entire patient pathway. This included specific members of staff who looked at complaints management, cancellations, the governance of optometrists, changes in policies and processes. All policies and procedures for the laser surgery service were reviewed during the 12 months preceding our inspection.
- At a corporate level, there were systems to ensure that clinicians made safe and effective decisions around patient care. Quality and compliance officers completed checks of every patient record two days prior to surgery. All action points raised from these checks emailed to the registered manager to action. If a patient presented for surgery and on examination, the surgeon disagreed with the clinical recommendation of the optometrist, this resulted in the surgeon completing a 'non-treatment form'. This triggered a review by the clinical services director who examined the clinical reasoning of both the optometrist and surgeon. Any learning from this review was shared with the relevant clinician. If an optometrist graded a patient with a complication post-surgery, this triggered a review of the patient journey by the clinical services team in conjunction with the medical director and the clinical services director.
- At a local level, the service took action to manage surgery risks. Managers identified risks as a result of incidents reported or audits completed. The registered manager in the surgery team was responsible for completing site specific audits such as documentation audits and infection control audits. They reported these to the surgical services manager, who monitored compliance and checked results to identify trends

across locations. The surgical services manager raised any trends or concerns at the clinical governance committee and informed the registered manager. . Audit action plans identified members of staff responsible for completing actions within a defined time period. Registered managers sent audit results to the surgical services manager for review. The registered manager had some autonomy to make improvements at a local level. For example, the surgery manager at Exeter had introduced an end of day cleaning checklist to encourage thoroughness in completion of these tasks.

- Where a risk was identified, the surgical services manager completed a risk assessment and staff signed to say that they had read the risk assessment. Alerts received from the Medical Device Agency (MDA) or Health and Safety Executive (HSE) were screened as relevant by the clinical services team and communicated to the teams via a clinical directive which all staff were required to sign.
- The local risk registers were a collection of risk assessments rather than a live tool to monitor current risks to patient care or service delivery. The risk assessments covered risks to health and safety of staff and patients such as needle stick injury or power failure during treatment. Risks were colour coded according to severity and were allocated a date for review. The surgical services manager stated there were no live risks at the Exeter location that needed monitoring. However, this assessment did not take account of the risks arising from corporate policy in relation to the surgeon consent process, which did not comply with the standards for refractive surgery issued by the Royal College of Ophthalmologists. The service did not clearly identify, mitigate or monitor this risk. The division of the patient surgical journey between two separately managed teams was not proactively risk assessed.
- The record of governance processes at a local level was not always clear or comprehensive. The regional surgery team participated in a monthly face to face meeting. Some items of discussion were standard agenda items such as health and safety, operational issues, complaints. Other aspects of safety performance were not regularly discussed. For example, there was no evidence of feedback from the investigation of incidents at other locations. The team did not discuss audit results as a standard agenda item. Not all actions were allocated a responsible person or time frame to complete the action. For example, training for the duty of candour was raised but no details of the discussion were recorded, no actions identified and no timescale confirmed. In the minutes we checked, there was no follow-up/monitoring of the actions from previous meetings.
- At a corporate level, there was a forum for discussion of clinical governance that spanned both the surgery and optometry teams. The surgical services manager participated in a monthly clinical governance committee teleconference. This forum consisted of the medical director, the responsible officer, the refractive operations manager, the clinical director and the surgical services manager. This forum provided a feedback mechanism to raise location specific issues and trends identified across locations.
- However, the records of the clinical governance committee teleconference did not provide assurance that all aspects of patient safety were monitored effectively. Examples of concerns identified during this call included surgeon recruitment, mandatory training, outcomes from recent inspections. These meetings did not have a standard agenda that covered the key risks pertinent to the service. The minutes did not identify specific actions to be completed within identified timeframes, or the named persons responsible for taking actions forward. Actions from previous meetings were not carried forward for review at subsequent meetings.

Public and staff engagement

- The service proactively sought and acted upon the views and experiences of patients. Patients completed a patient experience questionnaire at their initial consultation, one day after surgery and one month after surgery. Results of this survey were consistently positive. Patients were pleased with the outcome of their surgery. One patient described his new vision: 'everything is in high definition now'. These levels of satisfaction were reflected in the patient experience questionnaire which was completed at various stages throughout the surgical pathway including after the initial consultation, 24 hours following their surgery and three months following surgery. Scores indicated that 99.8% of patients were satisfied with the results of the surgeon working at the Exeter clinic. During the 12 months preceding our inspection, patients' responses indicated

an average score of 9.9 out of 10 for the question 'would you recommend vision correction surgery to your friends and relatives'. This was better than the average score companywide of 9.6 out of 10.

- Staff engagement included team meetings for the regional surgery team. We saw in these minutes that members of staff were encouraged to raise concerns and contribute ideas for improvement. The registered manager identified actions and allocated key persons responsible for completing these actions. Subsequent learning was shared between locations. For example, in the meeting staff had raised that the team were incorrectly using clinical waste facilities. Following discussion, it was agreed that one member of staff would design and carry out a clinical waste audit at the Bristol clinic and another member of staff would produce a list of what constituted clinical waste in the refractive eye surgery environment. This list was then shared across locations including Exeter. Subsequent meetings identified that a reduction in clinical waste had occurred as a result of these actions.
- However, the forums for staff engagement did not include all staff. There were no regular team meetings for the optometry team staff. No staff surveys had been undertaken during the 12 months preceding our inspection.

Innovation, improvement and sustainability

- Patient advisors scanned all patients who were assessed for refractive eye surgery using a diagnostic technology that produced a three dimensional map of each eye. The laser followed this personalised 'map' to allow treatment to be custom-fitted to the exact specification of each eye with microscopic accuracy.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure that the registered manager has clear oversight of the entire patent journey with clear processes for the integration of quality information at a local level.
- Ensure that reasonable adjustments are made to accommodate the needs of patients with a disability such as hearing impairment or mobility impairment.

Action the provider SHOULD take to improve

- Review the mandatory training provision to ensure optometrists have knowledge of all safety systems and processes
- Ensure that medicines administration records clearly document the date when individual medicines are administered to patients.
- Ensure that patients whose first language is not English are able to freely access interpreters
- Consider mechanisms for staff engagement that include the optometry team
- Consider protocols for recording of discussions within meetings to ensure that a comprehensive record is maintained with clarity around action points.
- Review the consent policy in line with the Professional Standards for Refractive Surgery published by the Royal College of Opthalmologists.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Assess monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity Minutes of meetings did not adequately record governance processes. Risk management processes were not comprehensive. At a local level, the registered manager did not have a continual oversight of the entire patient journey. The optometry team and the surgery team were separated and there were no clear processes for the integration of quality information at a local level.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care The care and treatment of service users must be appropriate, meet their needs and reflect their preferences. Patients with a hearing impairment were required to provide their own sign language interpreters. Patients with mobility impairment were required to provide their own moving and handling equipment and carer to operate this equipment. There were no hearing loops available for patients with hearing impairment. Staff did not plan effectively to meet the needs of people with hearing impairment.