

Optical Express - Manchester (Deansgate) 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

Overall summary

Optical Express - Manchester Clinic is operated by Optical Express. The service provides vision correction by intraocular lens surgery and laser treatment. Facilities include pre-screening facilities, consulting rooms, one operating theatre and a laser treatment suite.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 5 December 2017, along with an unannounced visit to the hospital on 19 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.

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:

- Staff understood and fulfilled their responsibilities to raise concerns and report incidents and near misses; they were fully supported when they did so. Lessons learned were communicated through clinical directives issued by the corporate team, by email to staff members, at team meetings and at pre-surgery safety briefs.
- There were clearly defined systems and processes to keep people safe and safeguarded from abuse and staff were aware of these.
- The clinic was visibly clean and we saw that clinic staff undertook daily cleaning duties.
- We saw that mandatory training records demonstrated that training records were up-to-date.

Summary of findings

- Staffing levels and skill mix were planned, implemented and reviewed to keep people safe at all times.
 - Clinical procedures and treatment aligned with recognised national standards and guidance. Policies were accessible to staff and up-to-date.
 - Staff had the skills they needed to carry out their roles effectively and in line with best practice. The learning needs of staff were identified and training was in place to meet those learning needs.
 - Staff received supervision as required and timely appraisal. Relevant staff were supported through the process of revalidation.
 - Staff could access the information they needed to assess, plan and deliver care to people in a timely way. Electronic records were accessible to staff throughout the organisation.
 - Consent was managed as a two-stage process and patients were given a cooling off period prior to the day of surgery.
 - People were treated with dignity, respect and kindness during all interactions with staff and relationships with staff were positive. People felt supported and said staff looked after them.
 - Patients we spoke to described being “really pleased with the service” and being very happy with the outcome of the surgery.
 - We saw staff members giving clear explanations to patients before giving care during the each examination and treatment to ensure they understood what to expect and why it was being done.
 - Facilities and premises were appropriate for the services being delivered. Reasonable adjustments to improve access to the service were accommodated where possible.
 - Patient information was comprehensive and the consent forms were detailed and easy to read.
 - People could access the right care at the right time and at a location convenient to them.
 - Complaints and concerns were taken seriously and staff were informed of any learning from complaints.
 - The local leadership promoted a positive, safe and efficient experience for patients and strong teamwork amongst staff.
 - There was a positive open culture; staff spoke about feeling happy working as a team and being confident to raise concerns with management.
 - The governance structure included corporate and consultant meetings to monitor and discuss clinical standards, patient safety and patient experience.
 - There was robust performance monitoring for consultants supported by an annual clinical audit report produced for each consultant.
 - The company had initiated a reward programme in 2017 for staff called ‘Wonderful Wednesday’ to recognise good performance.
- However, we also found the following issues that the service provider needs to improve:
- Checking procedures between individual members of the surgical team took place at various stages prior to surgery; however, we did not see the surgical team formally participate together in the ‘sign in’ and ‘time-out’ stage of the surgery safety checklist.
 - A consent policy (September 2017) was in place, but did not reflect The Royal College of Ophthalmologists (RCO) guidance (April 2017) for a recommended seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
 - There was no hazard sign outside the room storing gas cylinders or evidence of ventilation to the room.
 - Where the patient had surgery on both eyes during two separate procedures, it was difficult to identify which five steps to safer surgery checklist linked to each surgery due to gaps in documentation of the date the procedure took place.
 - On review of an incident report recording a near miss, the supporting investigation notes viewed during inspection did not demonstrate clear root cause analysis methodology.
 - Staff were unable to access patient information in other languages.

Summary of findings

- Management did not undertake a staff engagement survey or 'pulse check' to monitor job satisfaction and identify and address any 'hot spots' or issues that might be causing low morale or stress.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even

though a regulation had not been breached, to help the service improve. We also issued the provider with one requirement notice that affected refractive eye surgery. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating

Summary of each main service

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 - Manchester (Deansgate) Clinic

Services we looked at:

Refractive eye surgery

Summary of this inspection

Background to Optical Express - Manchester (Deansgate) Clinic

Optical Express - Manchester Clinic is operated by Optical Express and provides laser vision correction and intraocular surgical procedures. The clinic became operational in 2013 and primarily serves the communities of North West England. It also accepts patient referrals

from outside this area. Patients are self-referring and self-funded; the service provides treatment for patients over the age of 18 and does not provide treatment for children.

The clinic has had a registered manager in post since 2013.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor with experience in ophthalmology. The inspection team was overseen by Nicolas Smith, Head of Hospital Inspection.

Information about Optical Express - Manchester (Deansgate) Clinic

Optical Express, Manchester (Deansgate) Clinic is housed over three floors and has sole use of the building. The ground floor provides a general optometric service which falls outside the scope of registration and was not inspected. The first floor contains a patient waiting area, screening room, two consulting rooms, a pre-op assessment room, staff room and office, a store room and dirty utility room and the laser vision correction facility. The second floor contains a patient waiting area, consultation room, the ophthalmic theatre with anaesthetic room and recovery areas and a dirty utility room.

The clinic provides laser vision correction procedures under topical anaesthetic using Class 4 and Class 3b lasers and intraocular surgery (cataract surgery and refractive lens exchange procedures) to adults under local anaesthetic and conscious sedation. The treatments are carried out by ophthalmologists. The clinic provides the laser vision correction service approximately four days a month. The refractive lens surgery service takes place approximately 10 days a month.

Patients may enquire about treatment via the website, telephone or may already be existing optical practice patients. Following an initial consultation appointment with an optical practice optometrist, the patient must book an appointment with the surgeon.

The service is not operational every day; eight staff members are based at the clinic and are part of a larger regional team covering clinics in Liverpool, Leeds and Sheffield. There are three surgeons and one anaesthetist, directly employed by Optical Express who work at the clinic.

The clinic is registered to provide the following regulated activities:

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

Activity

In the reporting period, September 2016 to August 2017, there was 3,388 day case episodes of care recorded at this service. Of these:

Summary of this inspection

- 1,784 were natural lens replacement procedures (cataract surgery); the lens inside the eye that has become cloudy is removed and replaced with an artificial lens (called an intraocular lens) to restore clear vision.
- 1,120 were laser-assisted in-situ keratomileusis procedures. This is the most commonly performed laser eye surgery to treat myopia (near-sightedness), hyperopia (far-sightedness) and astigmatism.
- 262 were laser-assisted sub-epithelium keratomileusis refractive eye treatments; this procedure changes the shape of the cornea using an excimer laser.
- 222 were specialised laser treatments to improve vision after cataract surgery using an yttrium-aluminium-garnet laser.

During the inspection, we visited the operating theatre, anaesthetic room, clean and dirty utility areas, pre and post-surgery care areas, consulting and examination rooms, staff room and office and the laser treatment room. We spoke with ten staff including a registered nurse, health care assistants, reception staff, medical staff, operating department practitioners and managers. We spoke with seven patients. We reviewed 20 sets of patient records and six personnel files.

There were no special reviews or investigations ongoing by CQC at any time during the 12 months before this inspection. This was the first inspection at this location since registration with CQC.

Track record on safety

- No never events
- Clinical incidents – the clinic reported six incidents and one near miss August 2016 to September 2017.
- No serious injuries

No incidences of hospital acquired MRSA

No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)

No incidences of hospital acquired Clostridium difficile

No incidences of hospital acquired E-Coli

There were 31 complaints

Services provided at the clinic under service level agreement:

- Laser protection service
- Maintenance of medical equipment
- Clinical or non-clinical waste removal
- Lift maintenance
- Sterile services

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 understood and fulfilled their responsibilities to raise concerns and report incidents and near misses; they were fully supported when they did so. Lessons learned were communicated through clinical directives issued by the corporate team, by email to staff members, at team meetings and at pre-surgery safety briefs.
- There were clearly defined systems and processes to keep people safe and safeguarded from abuse and staff were aware of these.
- The clinic was visibly clean and we saw that clinic staff undertook daily cleaning duties and completed specific hygiene checklists for each clinical area. Infection and complication rates were seen to be similar to or better than the average performance across the group for October 2016 to September 2017.
- We saw that mandatory training records demonstrated that training records were up-to-date.
- Staffing levels and skill mix were planned, implemented and reviewed to keep people safe at all times.
- Risks to people who use services were assessed using the clinical suitability guidelines. Staff used the five steps to safer surgery checklist for intraocular and laser refractive surgery, including the safety briefing to staff and safety checklist for each patient.
- There were robust arrangements in place to ensure staff operated equipment safely and that equipment was well-maintained. Plans were in place to respond to emergencies including power back-up facilities in the event of a power failure.

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

- Checking procedures between individual members of the surgical team took place prior to surgery; however, we did not

Summary of this inspection

see the team formally participate together in the 'sign in' and 'time-out' stage of the surgery safety checklist. For example, we did not see a staff member lead the process by stating out loud the required checks to the team.

- On review of an incident report recording a near miss, the supporting investigation notes viewed during inspection did not demonstrate clear root cause analysis methodology.
- There was no hazard sign outside the room storing gas cylinders or evidence of ventilation to the room.
- Where the patient had surgery on both eyes during two separate procedures, it was difficult to identify which five steps to safer surgery checklist linked to each surgery, due to the gaps in documentation of the surgery date.

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:

- Clinical procedures and treatment aligned with recognised national standards and guidance. Policies were accessible to staff and up-to-date.
- The service ensured surgeons only carried out procedures in which they were trained, skilled and experienced. Information about people's care and treatment and their outcomes, was routinely collected and monitored.
- Staff had the skills they needed to carry out their roles effectively and in line with best practice. The learning needs of staff were identified and training was in place to meet those learning needs.
- Staff received supervision as required and timely appraisal. Relevant staff were supported through the process of revalidation.
- We saw effective multi-disciplinary working between the consultants, optometrists, trained nursing staff and the clinical assistants.
- Staff could access the information they needed to assess, plan and deliver care to people in a timely way. Electronic records were accessible to staff throughout the organisation.

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

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- The consent policy (September 2017) did not reflect The Royal College of Ophthalmologists' guidance (April 2017) for a seven 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:

- People were treated with dignity, respect and kindness during all interactions with staff and relationships with staff were positive. People felt supported and said staff looked after them.
- Patients we spoke to described being "really pleased with the service" and being very happy with the outcome of the surgery.
- People and staff worked together to plan treatment and there was shared decision-making. People were given adequate time to consider their treatment options.
- We saw staff members giving clear explanations to patients before giving care during the each examination and treatment to ensure they understood what to expect and why it was being done.
- Patients told us that they felt well-supported by staff during their surgical procedure and we saw all grades of staff making patients feel at ease during each stage, particularly while receiving intravenous sedation, during the operation and after surgery.

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:

- Services were planned and delivered in a way that met the needs of the service users. Flexibility, choice and continuity of care were reflected in the services provided. For example, by offering patients treatment at another practice location if specific dates for treatment could not be accommodated locally.
- Facilities and premises were appropriate for the services being delivered. Reasonable adjustments to improve access to the service were accommodated where possible.
- Patient information was comprehensive and the consent forms were detailed and easy to read.

Summary of this inspection

- Complaints and concerns were taken seriously and staff were informed of any learning from complaints.
- Optical Express did not have a contract for translation services. At the time of the inspection, the company was in the process of arranging access to translation services through a national provider.

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

- Staff were unable to access patient information in other languages.

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 local leadership promoted a positive, safe and efficient experience for patients and strong teamwork amongst staff.
- The senior leadership was knowledgeable about quality issues and priorities, understood what the challenges were and took action to address them.
- There was a positive open culture; staff spoke about feeling happy working as a team and being confident to raise concerns with management.
- The governance structure included corporate and consultant meetings to monitor and discuss clinical standards, patient safety and patient experience.
- There was performance monitoring for consultants supported by an annual clinical audit report produced for each consultant.
- Optical Express offered in-house training and access to external training to ensure staff were competent to fulfil their role
- The company had initiated a reward programme in 2017 for staff called 'Wonderful Wednesday' to recognise good performance.

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

- Management did not undertake a staff engagement survey or 'pulse check' to monitor job satisfaction and identify and address any 'hot spots' or issues that might be causing low morale or stress.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- Staff recognised incidents and reported them appropriately, managers investigated incidents and shared lessons learned with the team and wider service. The service had reported no Never Events from September 2016 to August 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- We saw that there was an electronic incident reporting system in place and a policy to support the management of clinical and non-clinical incidents. Staff told us how they would report an incident and how they would learn of the outcome and any lessons or changes to practice. They told us they felt comfortable contacting the corporate surgical services team to discuss any concerns about incident reporting. Lessons learned were communicated through clinical directives issued by the corporate team, by email to staff members, at team meetings and at pre-surgery safety briefs.
- There were seven clinical incidents reported by the Manchester clinic from August 2016 to November 2017. One incident involved a near miss implantation of the wrong lens. Whilst this was avoided during the final safety check, the incident was investigated and lessons about improving the checking procedures were communicated to staff. On review of the incident

report, the supporting investigation notes did not clearly demonstrate root cause analysis methodology. Managers told us that the investigators had received training in root cause analysis.

- The duty of candour (DOC) is a regulatory duty that relates to openness and transparency. It 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. A corporate duty of candour policy was in place and staff we spoke with were familiar with the concepts of being open and honest with patients. The surgical services manager and director were responsible for identifying and implementing the process if required and this was reflected in the duty of candour policy. No instances of implementing the duty of candour occurred at the Manchester clinic from September 2016 to October 2017.
- The corporate team collated data on infection and complication rates for the ophthalmic surgical activity at each location. The performance at the Manchester clinic was seen to be similar to or better than the average performance across the group from October 2016 to September 2017. We saw evidence that there was a system operating to manage central public safety alerts about clinical equipment, medical supplies and medicines.

Mandatory training

- We saw up-to-date training records and certificates of attendance; all staff had completed the required training. The service provided staff with access to an e-learning programme of training modules. The service introduced the programme in 2017 and staff told us they found it easier to complete the modules at a time suitable to them. The surgical services

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manager monitored mandatory training compliance and reported training levels to head office weekly. Modules included consent, conflict resolution, equality and diversity, fire safety, safeguarding, infection prevention and control and information governance.

- All staff received training in basic life support and the operating department practitioners and theatre scrub nurses on the rotational surgical team received training in immediate life support.

Safeguarding

- Information provided by the service showed that all staff were trained in adult safeguarding level two and child safeguarding level two. A safeguarding policy was in place that covered child and adult safeguarding and referred staff to the safeguarding folder at each clinic for local instructions. Contact details for the local authority and safeguarding services were seen in the safeguarding folder in the office at the Manchester clinic. The policy included reference to the national PREVENT strategy to combat extremism and radicalisation.
- The service did not treat patients under the age of 18 and no visitors were allowed in the surgical department. Staff could not recollect ever making a safeguarding referral at the clinic but were confident about how to escalate concerns internally and to the local authority if needed.

Cleanliness, infection control and hygiene

- The clinic was visibly clean and tidy and the clinic employed a cleaner to provide general cleaning duties. We saw that clinic staff undertook daily cleaning duties in their assigned clinical areas such as the laser rooms and operating theatre and completed specific hygiene checklists for each area.
- We saw staff had access to dirty and clean utility rooms to manage the decontamination of instruments and clinical waste management. We saw staff wash ophthalmic instruments prior to sending these to an external service provider for decontamination and sterilisation. Staff could easily access written procedures to manage this process.
- If, during the initial consultation, the patient was identified as an MRSA risk due to occupation (such as

healthcare worker) or had a previous history of being MRSA positive, the patient received a five day course of antibiotic eye drops to be used prior to surgery. A written protocol was in place for this approach.

- We saw that all staff were compliant with training on infection prevention and control, hand hygiene and sepsis. We saw a guide to recognising symptoms, diagnosis and early management of sepsis displayed in the clinical areas to prompt staff.
- There were wall-mounted soap and gel dispensers available throughout the clinic. We saw sharps bins were used appropriately and that clinical and non-clinical waste was segregated. Staff used personal protection equipment appropriately and disposable theatre uniforms on surgery days to reduce the risk of infection. During surgery, we observed staff using aseptic technique and wearing sterile surgical gowns. Aseptic technique means using practices and procedures to prevent contamination from pathogens. It involves applying the strictest rules to minimise the risk of infection.
- Managers in the corporate surgical services team conducted monthly audits on areas such as decontamination, hand hygiene and infection control. We saw copies of these audits and the documented actions taken for improvement. We requested data on monthly compliance rates but the provider did not supply these. The clinic manager and surgical services team monitored outcomes.
- The service reported no cases of MRSA or MSSA from September 2016 to August 2017. There had been three cases of DLK Grade 3 or 4 (diffuse lamellar keratitis – a sterile non-infectious inflammation of the cornea which may occur after refractive surgery). The incidence rate was 0.2% compared to the corporate rate of 0.1%; comparative national data was not available.

Environment and equipment

- All areas were tidy and well-maintained. The floors had a wipeable covering and were visibly clean. Staff and patients accessed the first and second floor by a lift or by stairs. Maintenance records for the lift were up-to-date.

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- Resuscitation equipment was accessible on the first and second floor and checked on the days that surgery was scheduled. The trolley was not locked or tamper-proof but only accessible to clinical staff. Staff would call 999 in the event of an emergency. Portable oxygen cylinders were in date and ready for use. The operating department practitioner checked the anaesthetic equipment prior to each use.
- Spare gas cylinders for the laser machines were stored upright in a small storeroom on the first floor. There was no hazard sign to indicate gas storage or evidence of ventilation to the room.
- Surgeons performed intraocular refractive surgery within a standard ophthalmic operating theatre environment and laser refractive surgery in a minimal access intervention operating environment with a keypad entry system. Hazard warning lights were in place outside the laser room for use when the laser was in operation. Emergency call bells were in place in the operating theatre and laser room. We saw appropriate monitoring equipment in use in the operating room during the operating procedure and period of conscious sedation.
- There was an operation register which contained the date and details of each procedure, the surgeon, supporting staff and patient. Staff recorded identification details using a manufacturer's sticker for each lens implant in the patient notes. They also recorded medical equipment serial numbers for all procedures to ensure traceability after surgery, if required.
- All rooms were identified with a sign but not all signs related to the current use. For example, one consulting room was used for storage and the pre-assessment room was labelled recovery room. The dirty utility room on the first floor was propped open and had no sign.
- We saw the maintenance folder with copies of recent service maintenance records for all relevant equipment. The manufacturers sent technicians to carry out maintenance checks and all records were up-to-date. Staff told us that the technicians were supportive and accessible at short notice. Optical Express employed an electrician who was responsible for electrical safety checks on portable appliances. We saw evidence of up-to-date testing on portable equipment.
- A laser safety policy was in place; the company did not have a formal optical radiation committee. If any concerns about operating the lasers needed addressing, a member of the senior team liaised with the laser protection adviser. We saw that staff recorded room temperature and humidity measurements prior to operating the lasers. If these were not within the expected parameters, surgery would not go ahead.
- 'Local rules' (or safe working procedures) reflect safe working practices and relate to the day-to-day safety management of lasers. We saw that the local rules at the clinic were current and accessible to staff in a folder in the laser room. Staff involved in the provision of laser treatment signed to confirm they had read and understood the rules. We saw evidence of certificates issued to surgeons as authorised users of the laser equipment and a list of authorised users in the local rules folder.
- Optical Express contracted an external laser protection advisor to provide expertise and advice on compliance with applicable health and safety legislation requirements. They carried out a site visit, a risk assessment and revalidated the local rules every three years. We saw the documentation and latest reports from August 2015 which raised no concerns.
- The designated laser protection supervisor was the clinic manager from another branch in the region. The supervisor and laser technicians received training from the laser manufacturers in the safe calibration and operation of the lasers. This included three days training from the manufacturer and two days from the in-house senior refraction technician. We saw evidence of calibration procedures carried out as required. If the laser protection supervisor was unavailable to attend on treatment days, a laser technician undertook the role of deputy supervisor.

Medicines

- A medicines management policy for the safe and secure management of medicines was in place, current and accessible to staff. Medicines were held

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securely in locked cabinets or refrigerators in the clinical areas and the nurse or operating department practitioner held the keys. When the clinic closed, staff placed the keys in a locked key press in an office.

- The medication for conscious sedation was held in a locked cabinet in the anaesthetic room. Staff witnessed and recorded administration and wastage of this medication in a register; we saw wastage was put in a large container with ground material to soak up the drug. This was to ensure the drug was not put in the water system by disposing it in the sink. There was a current policy for administering and managing the drug used for conscious sedation.
- Staff regularly checked medicines stock for quantity and expiry dates. Medicines we examined were all in date. Staff restocked medicines by using an in-house electronic ordering system. Patients received eye drops before and after surgery and these were administered by the nursing staff. Eye drops were supplied in pre-labelled containers for patients to take home.
- Medicines requiring refrigeration were held in drug fridges which monitored the temperature electronically. Staff kept a daily record of the temperatures to ensure that these were within the expected parameters to maintain the integrity of the medicines. We saw that medicines were stored at the correct temperature. We saw that oxygen cylinders were monitored for levels of oxygen and the 'use by' date. All cylinders were in date for use.
- We reviewed 20 sets of notes including the prescription sheet; the surgeon prescribed all medications. The prescription sheet contained pre-printed prescriptions and did not include a box for recording allergies. However allergy information was on the health questionnaire in all the patient records reviewed.

Records

- The clinic had an electronic medical record system to manage patient records as well as hard copy patient records used during the surgical treatment. Staff held hard copy records securely in locked filing cabinets and archive facilities were available.
- Hard copy records included a health questionnaire, pre-assessment documentation, eye screening results,

an extended informed consent document, terms and conditions for the surgery, medication sheet, operation details, five steps to safer surgery checklists and traceability details for the clinical supplies and instruments used. We saw that there was a comprehensive pre-assessment completed by the optometrist and reviewed by the surgeon.

- We reviewed 20 intraocular lens (IOL) refractive surgery and laser refractive surgery hard copy records (including pre and post-operative patients) and saw that most records were complete, legible and dated.
- However, eight surgical safety checklists had illegible signatures and no designated title for the person completing the form. Seven out of eight did not state the date of the procedure. Where the patient had surgery on both eyes during two separate procedures, it was difficult to identify which surgery checklist linked to each surgery due to the gaps in documentation. The national template for the surgical safety checklist includes the date and procedure. We informed staff of this at the time of inspection and action was planned.

Assessing and responding to patient risk

- Prior to treatment, patients received a full evaluation and screening by the optometrist to assess suitability for surgery. The optometrist discussed possible surgical options and level of suitability with the patient and had access to the surgeon by phone if there were any queries. The suitability guidelines for refractive surgery candidates primarily assessed the condition of the eye(s) to be treated but did include guidance on suitability for treatment in the case of a number of systemic conditions such as diabetes, cancer and heart related conditions. If there were any concerns, patients were required to obtain a letter from their GP to confirm their condition and medical treatment before surgery.
- The surgeon reviewed this information and discussed the treatment of choice with the patient prior to obtaining consent. Both the surgeon and the optometrist were clear that they only recommended surgery when enhanced vision was considered achievable despite the desire of the patient to have surgery. The risks associated with each procedure

Refractive eye surgery

were individually set out in the consent form and the template required the patient to initial each risk statement to indicate that they had read and understood each risk.

- There were two corporate policies for 'surgical site marking and verification for correct site surgery'; one for laser surgery patients and one for intraocular lens surgery patients.
- On the day of surgery, we saw that the optometrist marked the patient on the face to indicate which eye was to be operated on during their consultation. The nurse also put a patient identification sticker on the patient's gown, on the chest on the operative side. This was not required in the policy but was used as an additional indicator.
- Staff used the five steps to safer surgery checklist for intraocular and laser refractive surgery. Both patient checklist templates were based on the National Patient Safety Agency template with local amendments for the laser treatment checklist. The process requires a verbal briefing prior to the start of the surgery session for all theatre staff and verbal checking procedures stated out loud with the patient and team at 'sign-in' before sedation, 'time-out' before surgery started and 'sign-out' at the end of the procedure. A debriefing for the team should take place at the end of the session.
- A completed pre-operative team briefing checklist was present for the intraocular and laser surgery sessions we reviewed. The pre-operative theatre briefing stated the number of patients to be operated upon and how many of each lens type (multifocal or monofocal) would be inserted. The surgery manager named patients regarding allergies and any other relevant medical condition, ensured staff were clear about roles and that there were no issues with equipment.
- We saw that the surgeon and anaesthetist were not present for the team briefing at the start of the day but were briefed separately by the surgery coordinator, as they arrived later than clinic staff. Ideally the surgeon and anaesthetist should be present with the rest of the team for the team brief.
- We saw safety checks being made at all stages of the patient journey on the day of surgery including at biometric testing and during the optometrist,

pre-assessment nurse and consultant consultations. We saw safety checks between staff and patient prior to sedation in the anaesthetic room; between staff and patient and between individual staff members at handover in theatre prior to surgery. The surgeon was responsible for drawing the correct lenses from stock prior to surgery and confirmed the lens as correct with the scrub nurse immediately prior to implant. However, we did not see the surgical team formally participate together in the 'sign in' or 'time-out' stage of the surgery safety checklist. This would involve stating out loud and verbally confirming to the team present in the room the patient's name, the procedure and which eye, the planned refractive outcome, the lens model and power to be used and if the correct lens implant is present.

- The operating surgeon remained on-site and was available to manage any concerns until the last patient of the day was discharged. There were arrangements in place for patients to contact the clinic or an out of hours contact number to discuss concerns after discharge with an optometrist who would refer the patient to the operating surgeon if required. If an emergency arose and the operating surgeon was not available to assess the patient, the patient would be seen by another ophthalmic surgeon contracted by Optical Express. All patients were seen in the clinic the morning after surgery to check the condition of the eye and vision.
- The surgery services manager and support team completed risk assessments for a variety of potential scenarios or in response to an identified risk following staff reporting an incident. These were available for staff to access in hard copy and on the intranet.
- The laser manager told us that there was a patient collapse scenario practiced every three months for staff working in the Optical Express clinics in the north region. The scenario varied and might be based on cardiac arrest, choking or a drug allergy.
- If a post-operative complication required urgent intervention, the examining optometrist contacted the clinical services team on their dedicated 'pre and post-operative advice' telephone line. For example, if a

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patient attended with a post-operative infection, the examining optometrist called clinical services that then contacted the surgeon and liaised between the surgeon, optometrist and patient to organise treatment.

Nursing and medical staffing

- Staffing levels were based on the number of surgical procedures listed each week across the region. The clinic did not hold surgery or laser treatment sessions every day; there were eight staff members based at the clinic who were part of a larger regional team covering clinics in Liverpool, Leeds and Sheffield. The head office staff coordinator managed staffing centrally and moved the surgical team members around the region to staff intraocular lens and laser surgery sessions as required.
- At a local level, the surgery coordinator monitored the skill mix for each list and raised any concerns to head office. The regional surgery team included operating department technicians, scrub nurses and health care assistants. The clinic did not use agency staff.
- The clinic employed three resident ophthalmic surgeons each working part-time and engaged an anaesthetist from a medical staffing agency. The surgeons' qualifications included either the Royal College of Ophthalmologists certificate in laser and refractive surgery or being a member of the General Medical Council Specialist Register in Ophthalmology. We saw evidence of indemnity insurance in the consultants' personnel files.

Major incident awareness and training

- In the event of power failure during any surgical or laser procedure, there was an emergency battery pack that provided back-up power for a further 15-30 minutes to complete the procedure. There were emergency power sockets in theatre to which critical equipment was connected. It was part of the daily checks in theatre to ensure the equipment was plugged into the emergency sockets prior to the start of each surgery session.
- Staff told us there was a monthly fire drill in the clinic and we saw fire safety equipment such as alarms and extinguishers to manage an outbreak of fire.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Clinical procedures and treatment aligned with recognised national standards and guidance; for example, Royal College of Ophthalmology Standards for Laser Refractive Surgery. The executive team were in the process of considering the most recent Professional Standards for Refractive Surgery issued by the Royal College of Ophthalmologists in April 2017. Optical Express employed five of the ten expert panel advisors responsible for developing the 'Multi-Disciplinary Professional Standards for Refractive Surgery' (Optical Confederation June 2017), including the medical director, surgical services manager and clinical services director.
- A suite of corporate clinical policies were current and accessible to staff on the intranet. Each referred to relevant national professional guidance and had an issue and review date. We were told that the International Medical Advisory Board established by Optical Express approved all policies and guidelines.
- The Suitability Guidelines for Refractive Surgery Candidates document was a corporate document and approved in 2016 by the International Medical Advisory Board. The board met once a year and discussed new technologies, research publications and advances in refractive surgery.

Pain relief

- Patients received an anaesthetic block to the eye during refractive eye surgery and local anaesthetic eye drops before and after surgery. They were advised to take over the counter medications such as paracetamol for any discomfort after the procedure. Patients we spoke to stated they were kept comfortable throughout their surgery and had minimal discomfort afterwards.

Patient outcomes

- The National Ophthalmology Database Audit (NODA) collects, collates and analyse a standardised, nationally agreed cataract surgery dataset from all centres providing NHS cataract surgery in England &

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Wales. Optical Express surgeons did not contribute data to NODA as they did not operate on NHS funded patients. All patients self-funded and self-referred themselves for refractive surgery.

- The company had a full time biostatistician (based in the USA) who collated data for each surgeon's surgical outcomes. Common fields for audit were: total number of treatments, mean age and gender, pre-operative optometry measurements, treatment types, one month post treatment distance vision (myopia), one month post treatment distance vision (hyperopia), one month refractive predictability, attempted versus achieved results, surgeon safety and efficacy over time, estimated enhancement rate and complications. Each year, the surgeon received a report of their clinical outcomes and these contributed to the appraisal process. The biostatistician audited data from the electronic medical record completed for each patient.
- The clinic completed 16 secondary enhancement surgeries following intraocular lens surgery from September 2016 to August 2017. The surgeons did expect to undertake a second procedure on 5% of the primary vision correction treatments; this was not unplanned or unexpected. The reasons for enhancement procedures were regression, quality of vision issues and desired outcome not achieved.
- The clinic completed 65 secondary enhancements following laser refractive surgery from September 2016 to August 2017 where the primary treatment itself took place within the 12 month data period. The clinic expected to enhance approximately 5% of laser vision correction treatments. Patients were aware of the potential need for enhancement prior to surgery and we saw this was listed as a risk on the pre-printed consent form.
- Performance data was collated for management review and compared clinic performance with corporate-wide performance. We were unable to confirm that the clinic compared its performance with any available national data for internal reporting.

Competent staff

- The service ensured surgeons only carried out procedures in which they were trained, skilled and experienced. Both the surgeons we spoke to had

many years of experience in their specialty. We saw evidence of the surgeons' qualifications from the Royal College of Ophthalmologists to undertake laser refractive surgery and intraocular refractive surgery.

- The manufacturers supplied training to the ophthalmologists to operate the specialist laser equipment. Any ophthalmologist new to the service received an induction supervised by the medical director and clinical services director of Optical Express which introduced the surgeon to the company policies and procedures including clinical suitability guidelines, clinical activity management and patient care pathways.
- We saw two personnel files for surgeons and this included evidence of current General Medical Council registration, professional qualifications, attendance at relevant educational conferences for continuous professional development, clinical performance audit reports for their annual appraisal and professional references.
- The service ensured that all named laser personnel were competent. For example, the designated laser protection supervisor and laser technicians received training from the manufacturer for safe operation of the laser equipment and the 'core of knowledge' training. We saw the staff operating the laser equipment signed to confirm that they had read and understood the 'local rules' for operating the laser equipment safely.
- We saw evidence that all staff had received basic life support training and that the operating department technician had immediate life support training. As a stand-alone service, the protocol was to call 999 in the event of patient collapse and support the patient until emergency services arrived. No staff were trained at advance life support level. The service provided staff training and displayed guidance on how to recognise and treat sepsis.
- Staff at various levels of seniority described their induction period and the support received from more senior members of the team before they worked independently. The induction included in-house training and shadowing staff to observe practice. There were competencies in place for each staff role involved in the surgical and laser patient care pathway

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and evidence of an appraisal during 2017 in each of the personnel files we reviewed. An optometrist manager managed professional development for the optometrists and we were told their annual review process was currently changing to a more detailed appraisal process.

Multidisciplinary working

- We saw effective multidisciplinary working between the consultants, optometrists, trained nursing staff and the clinical assistants. Staff were flexible in their roles, for example the operating department practitioner was also trained to conduct biometric eye measurements.
- With the patient's permission, the optometrist contacted the GP for further information if required before surgery. Otherwise the clinic only informed GPs of the surgical procedure after discharge if the patient chose to inform them.
- Clinic staff attended the morning team brief which included safety information about the patients receiving treatment that day and any other safety update about procedures. We did not see evidence that the surgeon or anaesthetist attended this meeting but they did receive the key information on their arrival. The surgical services manager led regional team meetings on a monthly basis which included discussion of incidents, risks, complaints and compliments and the actions taken to ensure improvement.

Seven-day services

- The clinic was open six days per week and provided all patients with access to an out-of-hours telephone service to speak to an optometrist and be referred to the surgeon, if necessary, about post-operative concerns.

Access to information

- Staff received mandatory training in information governance and information and records management policy was in place. Access to electronic patient medical records was password-controlled and staff had to complete a competency assessment before being able to access, create or amend electronic records.

- The electronic record included information on past medical history, previous ophthalmic procedures, allergies, consent details, pre-assessment records and operation notes. Staff at other Optical Express clinics could access a patient's electronic record if the patient completed their treatment at a different clinic.
- Hard copy records were well-organised and used on the day of surgery. The electronic record was updated after surgery and certain hard copy records scanned onto the electronic record.
- The surgeon shared medical records with the patient's GP or other specialty consultant with the patient's consent.

Consent and Mental Capacity Act

- Refractive surgery is normally carried out on patients with the capacity to consent and staff we spoke to understood the principles of informed consent. Staff received a mandatory training module on consent; staff told us there had been no instances they could remember where consent was sought for a patient without capacity.
- The optometrist saw the patient for an initial consultation and assessment and told us that they would alert the surgeon to any concerns they had about a patient's capacity to make decisions about their treatment. The surgeon and optometrist described how they would not recommend surgery to a patient unless there was clear clinical evidence that improvement could be achieved and the patient had the capacity to consent.
- The optometrist assessed patients for treatment options at the initial consultation based on discussions with the patient, the outcome of their clinical examination and assessment of clinical suitability using the company guidelines. The patient viewed a video at the initial consultation about the recommended procedure, risks and benefits and took a detailed consent form home to read at their own pace.
- We saw that the clinical review form included a section titled "consented in store by" which was signed by the optometrist. If the treatment plan was unclear, the optometrist referred the patient to the surgeon for further discussion of options prior to the final

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consultation with the consultant to discuss consent. Staff told us some patients lived out of the area and chose to have a telephone consultation rather than travel to the clinic. The reason for the telephone consultation was not routinely documented in the patient records we reviewed. Out of 16 hard copy records, we saw that seven consultations were by phone, four records were unclear and five took place face-to-face.

- A consent policy (September 2017) and Professional Standards Directive (July 2017) relating to consent was in place at the time of inspection. The directive referred to Guidance for doctors who offer cosmetic interventions (General Medical Council 2016) and Multi-disciplinary professional standards for refractive surgery providers and clinical teams (Optical Federation 2017). The policy and directive did not reflect The Royal College of Ophthalmologists (RCO) guidance (2017) recommending a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon. The July 2017 directive stated that “It is good practice for there to be a reflection period of seven (7) calendar days between the discussion with the surgeon and the day of surgery” and referred to a minimum two day reflection period prior to surgery. Optical Express revised the directive in February 2018 to state: “A minimum reflection period of one week is recommended between the procedure recommendation and surgery. In exceptional circumstances, where a one-week reflection period is impractical, the reasons for this should be agreed with the patient and documented in the medical record.”
- We saw there had been an audit of the cooling-off period to assess consent practice in light of the new professional standards. From January to December 2017, at Optical Express Manchester, 80% of patients achieved consent seven or more days prior to surgery and 20% less than seven days prior to surgery. Of the 20% of patients who achieved consent less than seven days prior to surgery, 71% were consented six days prior to surgery and no patients were consented on the day of surgery without a reflection period.
- The consent form template was clearly laid out and easy to read. It ensured patients read and initialled each element of information to confirm their

understanding about the procedure and the risks and benefits. The patient signed a separate document which recorded the terms and conditions for the procedure including costs. The consultant signed the consent form on the day of face-to-face consultation or the day of surgery if a telephone consultation had taken place.

Are refractive eye surgery services caring?

Compassionate care

- We saw staff treat patients with kindness and respect and as individuals, taking into account their personal needs such as having a family member with them during consultations. Staff asked patients to complete the surgery experience survey at the 24 hour post-operative visit, if patients were willing to participate. The surgery manager reviewed the results of the survey each month. The patient scored each question and the surgery services manager monitored trends to identify areas to make improvements. The scores for each clinic were benchmarked against the company average of all clinics. The Manchester Clinic scored similarly or better than the company average for all categories in the care and welfare survey and slightly less than the company average for satisfaction with vision after surgery.
- Patients we spoke to described being “really pleased with the service on both days” and being very happy with the outcome of the surgery. One patient told us they felt unprepared for the waits between each stage of the process such as the pre-assessment final check and going into surgery. However we saw staff keep patients informed of progress and chat to patients to check on their needs and make them feel at ease while they waited.

Understanding and involvement of patients and those close to them

- Patients told us that they received sufficient information and were given adequate time to consider their treatment options. They felt involved in the decision-making process and supported by staff to understand the treatment options, including risks,

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benefits and potential consequences. Patients received documented terms and conditions including costs for their surgery which they read and signed prior to treatment starting.

- The optometrist invited the patient to discuss what they hoped could be achieved by having refractive surgery such as less dependence on glasses or contact lenses. A discussion about vision needs and lifestyle assisted the joint decision-making about the possible options.
- We saw staff members giving clear explanations to patients before giving care during the surgical procedure to ensure they understood what to expect and why it was being done. For example, oxygen was piped under the drape over the head during intraocular surgery and the scrub nurse explained to the patient why this was done.

Emotional support

- Patients told us that they felt well-supported by staff during their surgical procedure and we saw all grades of staff making patients feel at ease during each stage, particularly while receiving intravenous sedation, during the operation and after surgery.
- Patients could have a chaperone or family member with them during all consultations if that was what they wished. We saw staff check with patients throughout examinations and treatments to ensure that they felt comfortable and able to ask any questions.
- We saw staff check with patients during the post-operative recovery stage to ensure that their needs were met for refreshments and pain relief. Staff discussed information about what to be aware of during first post-operative night and how to access the service if the patient had any concerns during the night.

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

Service planning and delivery to meet the needs of local people

- The service offered choice and flexibility, for example, by referring patients to another practice location if

specific dates for treatment could not be accommodated locally. The clinic was open on Saturdays to meet the needs of patients who could not attend follow-up appointments during the week.

- The service ensured patients had a consultation with the surgeon prior to the day of surgery and a surgeon was available to examine the patient at the post-operative appointment. Further follow-up appointments were with the optometrist who could access the surgeon for any questions about the condition of the eyes post-operatively.

Meeting people's individual needs

- The main waiting areas were well-lit and furnished with seating with a wipeable surface. Patients could use a lift to access the first and second floors. There were magazines and a television to distract patients while they waited. Hot and cold drinks were available on site and patients could access local shops to buy snacks if needed. There were toilet facilities on each floor including disabled toilet facilities. The room on the top floor for pre-operative patients waiting to go into theatre had no magazines or television to distract the patient while they waited to have their procedure.
- At initial consultation, the patient was assessed to identify any specific individual needs. Following consultation, this information was communicated to the clinic manager to make reasonable adjustments on the day of surgery. Staff made reasonable adjustments for people with restricted mobility, such as using a wheelchair, providing the patient could transfer to the laser couch/theatre bed unaided and lie flat. There were circumstances where it would not be possible to provide the service to people with specific head and neck mobility restrictions if the patient was unable to position themselves to undergo the required diagnostic scans or lie flat.
- Staff used diagrams and posters to illustrate the anatomy of the eye and what happened during procedures to aid the patient's understanding. There were posters on the wall and leaflets available to inform patients of aspects of the treatment and care. Patients received verbal and written discharge

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instructions prior to leaving the clinic after surgical treatment. All written communication was in English; the service did not offer written communication in large print or translated into other languages.

- Optical Express did not have a contract for translation services; staff told us these were required infrequently. When translation was needed, patients brought their own translator who could be an English speaking friend or family member; this is not best practice. At the time of the inspection, the company was in the process of arranging access to translation services through a national provider.

Access and flow

- Patients could access treatment in a timely manner and at a location convenient to them. Patients referred themselves for treatment by accessing the Optical Express website, discussing surgical treatment during a routine eye test or attending the local clinic to make an enquiry. Waiting times for treatment were not audited as these were generally minimal.
- During the inspection, we saw that the operating lists ran on time and that patients were kept informed of the waiting periods between stages of the pre-operative period. Patients told us that they felt it was an efficient service.
- From August to October 2017, there were four intraocular surgeries and two laser refractive surgeries cancelled on the day of surgery for clinical reasons and none for non-clinical reasons. During the same period, 17 intraocular surgeries were postponed on the day of surgery of which 13 were rescheduled; two laser refractive surgeries were postponed of which one was rescheduled. All the postponements were for clinical reasons.
- There were no instances of unplanned transfer of a patient to another health care provider in the last twelve months.

Learning from complaints and concerns

- There was a complaints policy in place and staff were aware of how to manage complaints. Staff dealt with concerns raised by patients at a local level in the first instance and escalated complaints to the clinical services team if these could not be resolved quickly, for a more formal investigation and written response.

An in-house solicitor supported the clinical services team with complaints management and told us that they were working more closely with the Optical Consumer Complaints Service when resolving complaints.

- The complaints policy stated a complaint should be acknowledged within two working days and not later than seven working days; the acknowledgement could be by telephone or in writing (including by email). The provider sought to fully address each complaint within 10 days if possible or within 20 days where necessary. If this was not possible, the patient was to be kept up-to-date about when a response could be expected. The complaints data we received did not include timeline information and we were unable to confirm whether these timelines were met.
- From September 2016 to August 2017, there were seven complaints to the laser refractive surgery services and 24 complaints to the intraocular lens surgery services. Of these 31 complaints, 12 were about dissatisfaction with visual outcome, 11 about terms and conditions relating to costs, six about customer service and two about quality of vision. Staff had identified a common thread in feedback about waiting times between stages of the care pathway on surgery day and were looking at ways to improve this.
- Patients received phone calls to discuss their concerns and a full written response to answer formal complaints. Changes made following complaints included improving clarity of communication about the waiting period before an enhancement procedure could be carried out and maintaining contact with patients during the waiting period prior to the scheduled surgery.
- Information about how to make a complaint was displayed in the clinic, on the website and included in the terms and conditions. Options included complaining to the Optical Consumer Complaints Service for optical services or the General Medical Council for surgical services.

Are refractive eye surgery services well-led?

Leadership and culture of service

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- The local leadership promoted a positive, safe and efficient experience for patients and strong teamwork amongst staff. The clinic manager was actively involved in the daily activities of the clinic and took the role of surgery manager on days when surgery was scheduled. The staff spoke about feeling happy working as a team and being confident to raise concerns with their immediate manager or with the surgery services team.
- Regional managers and the surgery services team supported clinic managers in their management role. Staff described the surgery services manager and support managers as very supportive, responsive and easily accessible by phone to help resolve clinical issues. A staff member who had previously been a clinic manager described receiving support from management every surgery day during their first six months in post, as they did not have experience of managing surgery lists.
- We saw that staff worked well together and were positive about travelling to different clinics as part of a regional team. The staff talked about how the service encouraged them to be open, honest and transparent. This was reflected in their approach to reporting incidents and staff awareness of the no blame culture. Staff told us they enjoyed seeing the impact of refractive surgery which was considerable for many patients and this made the job rewarding.
- Optical Express offered in-house and access to external training to ensure staff were competent to fulfil their role; however there was no evidence of further development such as management training or support to access professional training.
- From the material that we saw, the marketing of services and management of terms and conditions complied with guidance from Committee of Advertising Practice and the Royal College of Ophthalmologists' standards published April 2017. Patients received a statement that included terms and conditions of the service being provided and the amount and method of payment of fees. Patients we spoke with had not felt pressurised to go ahead with treatment and there had been no 'hard sell'.

Vision and strategy

- Optical Express had a corporate mission statement that reflected their aim to be a leader in the "global elective and healthcare industry." Their core values and vision statements were displayed on the corporate website and communicated through posters in the clinic. Whilst staff were not aware of the detail of corporate strategy, they were aware of plans and changes to local and regional services such as the introduction of new technology and the opening of new locations.

Governance, risk management and quality measurement

- The governance structure included the executive board which comprised of the chair / chief executive, the chair of the International Advisory Board (IMAB), the finance director and the board secretary. The chair of the IMAB was a consultant ophthalmologist based in the United States. The medical director was a consultant ophthalmologist in current practice with Optical Express.
- Staff discussed governance issues at the regional team meetings, the clinical committee quarterly meetings, the Optical Express consultants' group meeting held six monthly and the IMAB which met annually.
- We saw the minutes of the clinical committee quarterly meetings which did not have a standard agenda but included clinical governance, operational and regulatory matters. We did not see discussion of safety incidents or complaints at this meeting but understood that the corporate surgical services and clinical services teams discussed performance in these areas. It was not clear how summary data for patient experience, patient safety and clinical effectiveness was presented at senior management and executive level.
- Anaesthetists were employed through an agency and they had access to an anaesthetist responsible officer to conduct appraisal and revalidation procedures. Consultant ophthalmologists were employed directly by Optical Express and did not require practising privileges.
- We saw that medical registration with the General Medical Council, evidence of qualifications and indemnity insurance records were up-to-date in personnel files. Optical Express was a designated body

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and provided consultants with an appraisal system and access to revalidation through the responsible officer, the medical director. There was a robust consultant appraisal system in place supported by an annual clinical audit report produced by the company biostatistician for each consultant. The medical director oversaw clinical performance and would address any concerns should these arise.

- Optical Express did not report clinical activity to the National Ophthalmic Database Audit as patients were self-funded and the database was for NHS activity. However staff told us that the company biostatistician analysed and reported clinical activity and outcomes to inform management of consultant performance, operational performance and quality of care.
- We saw monthly audits took place on a range of activities in the clinic including infection control, hand hygiene, documentation, personnel files, patient satisfaction, complaints, medicines, maintenance and laser safety. Records of the results were held electronically and in hard copy in the clinic.
- The surgeon told us that Optical Express consultants attended group meetings and discussed clinical governance issues such as review of clinical practise and amendments to policies and clinical assessment documents.
- The International Medical Advisory Board (IMAB) was a group of international ophthalmologists sponsored by Optical Express who met annually to discuss the latest trends and advances in refractive surgery. Members of the board discussed current clinical practice at Optical Express and made advisory decisions to maintain or amend practice based on clinical evidence. Advisory decisions made by Optical Express surgeons and the IMAB supported the development of clinical standards and policies at Optical Express.
- The surgical services team completed clinical and non-clinical risk assessments for risks identified through incidents and for potential risks. We saw that a risk assessment had been completed for a near miss wrong lens implant and that action had been taken to reiterate the checking procedures already in place to

prevent this happening again. Staff we spoke to knew how to escalate concerns about risks and ensure they were addressed through risk assessments and actions to reduce the risk.

- Management communicated changes to practise or lessons learned through surgical directives issued by email and discussions at team meetings. These outlined the problem and the action staff needed to take to avoid repetition. The regional team meeting minutes demonstrated the team discussed the outcome and learning from incidents and near misses, complaints, compliments and risk assessments.

Public and staff engagement

- The company engaged with the public via the web on their corporate site and on social media. They sought patient feedback through their website and encouraged patients to participate in satisfaction surveys while in the clinic. Management monitored the results and compared clinic performance with the average company performance. Staff told us that feedback was mostly positive at the clinic.
- We saw evidence of monthly staff meetings taking place. These meetings provided regional staff the opportunity to be updated by management and discuss clinical and operational matters. Staff told us that while they did not have formal one-to-one meetings, they could access supervision and advice whenever needed.
- Management did not undertake a staff survey or 'pulse check' to monitor job satisfaction and identify any 'hot spots' or issues that might be causing low morale or stress. However, the company had initiated a reward programme in 2017 for staff called 'Wonderful Wednesday' to recognise good performance. Staff were aware of this scheme and one of the clinic's staff members had been successful in receiving an award.

Innovation, improvement and sustainability

- The local leadership promoted a positive and efficient experience for patients and strong teamwork amongst staff.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Checking procedures between individual members of the surgical team took place prior to surgery; however the service must ensure the surgical teams formally participate together in all stages of the surgery safety checklist.

Action the provider **SHOULD** take to improve

- All patients should receive seven days cooling off period between the surgeon consultation and procedure in line with the service's Professional Standards Directive dated February 2018.

- The service should ensure investigation reports reflect clear root cause analysis methodology.
- The service should maintain a complete record in respect of dating surgical safety checklists.
- The service should ensure that staff can access patient information in other languages if required.
- The service should review the safe and secure storage arrangements for gas cylinders.
- The service should consider introducing a staff engagement survey to monitor job satisfaction and identify and address any issues that might be causing low morale or stress.

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
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Checking procedures between individual members of the surgical team took place prior to surgery; however we did not see the surgical team formally participate together in the 'sign in' or 'time-out' stage of the surgery safety checklist. For example, at the 'sign-in' stage, this would involve stating out loud and verbally confirming to the team present in the room the patient's name, the procedure and which eye, the planned refractive outcome, the lens model and power to be used and if the correct lens implant is present. Providers must do all that is reasonably practicable to mitigate risks. They should follow good practice guidance and must adopt control measures to make sure the risk is as low as is reasonably possible. Regulation 12(2)(b)