

Optical Express - London (Harley Street) 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 Harley Street is operated by Optical Express Limited. Optical Express is a nationwide company offering general optometric services. The clinic provides laser vision correction procedures for adults aged 18 years and above. The clinic is based on the ground floor of a multipurpose building in London.

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

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 13 September 2017, along with an announced visit to the clinic on 22 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? 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. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- Patient safety was monitored and incidents were investigated to assist learning and improve care.
- Patients received care in visibly clean and suitably maintained premises and their care was supported with the right equipment.
- The staffing levels and skills mix was sufficient to meet patients' needs and staff assessed and responded to patient risks.
- Patient records were detailed with clear plans of the patient's pathway of care.
- Medicines were stored safely and given to patients in a timely manner.

Summary of findings

- All staff had completed their mandatory training and annual appraisals. Care and treatment was provided by suitably trained, competent staff that worked well as part of a multidisciplinary team.
- There was clear visible leadership within the services. Staff were positive about the culture within the service and the level of support they received.
- There was appropriate management of quality and governance and managers were aware of the risks and challenges they needed to address.

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

- Patient information leaflets, documents, and consent forms were only provided in English.
- There were no formal interpreter services available for patients. Patients were advised to bring their own interpreter to the clinic, or use a family member.

- There was no organisation vision or strategy in place.
- Staff feedback, in the form of engagement surveys were not happening
- The consent policy stated a “cooling off” period of three days prior to surgery procedure. The new Professional Standards for Refractive surgery (April 2017) recommends a “cooling off” period of one week, less so in exceptional circumstances. While the clinic did provide patients with a terms and conditions document, which supplied information on the procedures available and the associated risks and benefits, which patients took away with them. The actual time frame between the confirmed consent with the surgeon and actual treatment was usually three days.

Amanda Stanford

Interim Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

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Summary of this inspection

Background to Optical Express - London (Harley Street) Clinic

Optical Express, Harley Street is operated by Optical Express Limited. The clinic opened in December 2008. The service primarily serves the communities of the London area. It also accepts patient referrals from outside this area.

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

Our inspection team

The team that inspected the service comprised a CQC lead inspector Jane Brown and another CQC inspector.

The responsible head of inspection: Hospitals is Nick Mulholland.

Information about Optical Express - London (Harley Street) Clinic

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

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

The clinic is based on the ground floor of a multi-occupied building. Patients are self-referring and self-funded. The clinic provides laser vision correction procedures using Excimer class 4, Femtosecond class 3b, and yttrium-aluminium-garnet (YAG) class 3b laser machines. Ophthalmologist surgeons carry out the treatment. The clinic provides the service 10 days a month. Following an initial consultation appointment with an optometrist, the patient then has a follow up consent appointment with the surgeon. Treatment is offered on a day care basis.

As the clinic is not operational every day, the clinic has four resident team members, which includes an ophthalmologist surgeon, a registered nurse and two technicians; and they form part of a regional team covering London and the southeast area.

During the inspection, we visited the laser treatment room, pre and post-operative rooms, discharge room, dirty utilities, and examination rooms. We spoke with nine members of staff including; registered nurses,

ophthalmologists, laser technicians and senior managers. We spoke with four patients and one relative. During our inspection, we reviewed five sets of patient records and five sets of staff personnel files.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The service had last been inspected in April 2014, where it was found that the service was meeting all standards of quality and safety it was inspected against.

Activity

In the reporting period June 2016 to June 2017, there were 5,073 inpatient and day case episodes of care recorded at the service. Of these 2,046 were laser-assisted in situ keratomileusis, (LASIK) procedures. This is the most commonly performed laser eye surgery to treat myopia (near-sightedness), hyperopia (far-sightedness), and astigmatism. There were 301 Laser Assisted Sub-Epithelium Keratomileusis (LASEK) refractive eye treatments. This changes the shape of the cornea using an excimer laser. They also performed 247 specialised laser treatments using an yttrium-aluminium-garnet (YAG) laser.

Track record on safety

- No Never events
- No clinical incidents

Summary of this inspection

- No incidences of healthcare acquired meticillin-resistant Staphylococcus Aureus (MRSA), or healthcare acquired meticillin-sensitive Staphylococcus Aureus (MSSA)
- No incidences of healthcare acquired Clostridium difficile (c.diff)
- No incidences of healthcare acquired Escherichia coli (E-Coli)
- 19 complaints

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- Laser protection service
- Maintenance of medical equipment
- Pharmacy
- Uninterrupted Power Supply
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate refractive eye surgery.

We found the following areas of good practice:

- There were policies and procedures to support the reporting of incidents and staff knew how to report incidents of all severities.
- The service actioned and acted upon Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts.
- There were robust measures in place to manage the safety of lasers.
- Medicines were stored safely and staff administered medicines to patients in accordance with the clinic's policy.
- All staff had completed mandatory safety training.
- Equipment was serviced regularly and all electrical tests had been completed and were in date.
- There were sufficient competent staff to deal with patient's care and treatment.
- Staff followed good infection control procedures and the clinic was visibly clean.
- Equipment was well maintained and available.

Are services effective?

We found the following areas of good practice:

- Patients received care according to national guidelines and standards.
- Advertising and marketing was appropriate at the location.
- There were systems, which ensured surgeons outcomes were measured and monitored on an annual basis.
- There was a regular audit and actions were taken to make improvements.
- Staff sought consent from patients prior to treatment.
- Suitably trained, competent staff that worked well as part of a multidisciplinary team provided care and treatment. All staff had completed their appraisals.
- Additional training was provided to staff using laser equipment, which ensured patient procedures were carried out safely.

However:

- The service did not follow the Professional Standards for Refractive surgery (April 2017) recommendations of a "cooling off" period of one week after obtaining consent from patients.

Summary of this inspection

However, patients told us they received sufficient information to make an informed decision and adequate time between consenting to and the day of treatment. Patient records showed this was happening.

Are services caring?

- Staff were caring and treated patients with dignity and respect.
- Patients were involved in the planning and delivery of their treatment and care.
- Feedback from patients was positive.
- Clear information was provided about the costs of treatment and procedures.
- Staff were able to recognise anxious patients and assist them during their treatment of care.

Are services responsive?

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

However:

- Patient information leaflets were not available in different languages.
- There were no formal interpreting services available and patients were asked to bring a family member, carer, or friend to their consultation to translate.

Are services well-led?

- There was effective teamwork and good leadership, which created a positive culture.
- There were clear organisational structures, roles, and responsibilities.
- There were good governance, risk and quality systems, and processes that staff understood.
- There was a good system in place for patient feedback. This enabled the service to benchmark against other clinics across the organisation.
- The organisation recognised staff through their weekly staff reward scheme.

However:

Summary of this inspection

- There was no organisation vision or strategy in place.
- Staff engagement in the form of surveys did not take place, which meant the organisation could not monitor staff motivation.

Refractive eye surgery

Safe

Effective

Caring

Responsive

Well-led

Are refractive eye surgery services safe?

Incidents and safety monitoring

- Optical Express Harley Street had not reported any never events in the last twelve months from September 2016 to August 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- The clinic had an Incidents and Near Miss policy dated January 2017. This provided staff with reporting, escalation, and investigation processes. Staff were expected to complete an incident report form and submit this to the surgery manager. The surgery manager submitted the incident electronically, so there was a system of tracking and tracing incidents corporately.
- There had been no incidents reported during the reporting period. The staff we spoke with were aware how to report an incident and could describe the process. They had a good understanding of what an incident was and the different types of classifications.
- We were told the surgery manager investigated incidents of a low level. Incidents that were more serious were overseen and investigated by the corporate surgical services manager and clinical services director. They were able to review all incidents and emailed staff with all relevant feedback from any incident. At the time of our inspection there had been no serious incidents reported for the past twelve months, so we were not able to see any examples of the investigatory processes and lessons learnt.
- We viewed an incident report, where a patient did not proceed with treatment due to anxiety. The incident report showed actions taken. The patient was advised to see their GP, and the report showed the information was fed back to the relevant staff member.
- There were four 'low level' reported incidents from April 2017 to August 2017. The incident report showed they covered areas such as: postponement of treatment due to equipment related matters, and postponement of treatment as a patient had not been issued a consent form prior to the day of surgery. We saw outcomes taken from these reported incidents. The patient who had not been consented was prioritised and re-booked at a time that suited their needs. An investigation showed the patient had been incorrectly given two copies of terms and conditions instead of one with the consent form. Staff were provided with feedback and asked to double check the information given to patients pre-treatment.
- We viewed team meeting minutes of 6 September 2017, which showed incidents, were discussed with staff. The information for incidents at this team meeting reaffirmed to staff how to report an incident. Ten members of staff from the clinic attended the meeting. The meeting declared there were no incidents reported and no feedback to give to staff.
- The surgery manager was able to describe a change made to staff working practices, which had occurred from a reported incident. An incident was logged, regarding a surgeon who kept leaving the keys to one of the laser machines on top of the machine. As a result, from the incident reported, staff now had to sign a form to say they had removed the keys and the surgery manager checked this.
- Surgical services directives were sent to each location. These were clinical directives, which were sent from the head office regarding important changes. Each staff member had to sign the directive to show they had read and understood the information. We saw a surgical

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service directive regarding incorrect discharge medication being recorded in the patient files at a different location. This had been highlighted through the quarterly medical audits. The fault was happening through a default button within the electronic system, which automatically listed a drug that was not provided to patients. Although staff were correctly recording the medication they had given, the default button included another drug, which had not been given. Therefore, staff were instructed not to use the default system, but to manually list the drugs given to patients. We saw the directive had been read and signed by all members of staff.

- The surgical services manager had received root cause analysis (RCA) training for serious incidents. RCA are investigations to identify why and how safety incidents happen.
- The duty of candour (DoC) is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- We saw a DoC directive dated 2015 and this had been reviewed on January 2017. This explained the principles of DoC and staff had signed the directive once read. Those staff we spoke with were able to tell us elements of the process, in that it meant being truthful and open and transparent with the patient when things went wrong. We did not see evidence of the DoC having been put into use as the clinic had not needed to use the process.

Mandatory training

- We saw that all staff who worked at the clinic had completed all mandatory training topics. This safety related training was renewed every three years and included core topics such as: information governance, conflict resolution, infection control prevention, fire safety, safeguarding children young people and adults, medicines management, health and safety, duty of care, consent, equality and diversity, and moving and handling. Consent training included the Mental Capacity Act 2005. Staff were given protected time to complete training at work or were paid time if they completed at home. The surgery services manager set training dates and a weekly report was sent to the medical director.

- All staff had completed annual basic life support training. Staff were not trained to an immediate or advanced level of life support, as the treatment provided at the clinic did not include the use of local or general anaesthetic. The clinic did not have the equipment required to intubate, and the organisations policy was to provide basic life support until the emergency services arrived.

Safeguarding

- Safeguarding was part of mandatory training. All staff were trained to level two for children's safeguarding procedures and level two for adults. The surgery manager was trained to level three safeguarding for children's and adults and was the safeguarding lead for the clinic.
- The clinic had a safeguarding policy, which described the types of abuse, and concerns staff should report. There were clear lines of escalation and contact details for the local authorities. We saw contact details displayed in a folder, which was easily accessible to all staff.
- The policy referenced the Care Act 2014, which included key changes to information relating to adult safeguarding. The safeguarding policy included information on the PREVENT strategy, which is a government directive. At the heart of PREVENT is safeguarding children and adults and providing early intervention to protect and divert people away from being drawn into terrorist activity. However, the policy did not refer to female genital mutilation (FGM) and the guidance staff should follow in the event of concerns raised.
- The clinic did not provide treatment to young people under the age of 18 years of age and young children were not allowed in the treatment area.
- Staff we spoke with had an understanding of safeguarding. Any safeguarding concerns were reported to the surgery manager, who escalated these to the necessary local borough safeguarding teams.
- Staff had access to the 'skills for health' website, which is a non-profit organisation committed to the development of an improved and sustainable healthcare workforce across the UK. Safeguarding training and guidance was available through this website.
- No safeguarding concerns were reported to the CQC during the year up to our visit.

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Cleanliness, infection control, and hygiene

- The clinic had an Infection Prevention and Control (IPC) policy, which provided staff with guidance and IPC procedures they should follow to minimise risk. Staff completed IPC mandatory training, which they refreshed every three years. All staff had completed this training. The surgery manager was the IPC lead for the clinic and the resident registered nurse assisted the manager with IPC issues and audits. A regional IPC link nurse was based in another clinic nearby.
- Staff we spoke with were able to explain the policy and the role they played in meeting the expected standards. For example, staff knew the IPC checklists they had to complete each morning.
- We saw the hand hygiene audits for August and September 2017. Over a 20 minute period, staff were observed on a one to one basis. The results showed there was 100% compliance. Feedback was given on a one to one basis and action plans were implemented if staff did not meet compliance. Additional training was part of the action plan.
- We observed staff adhere to IPC policy during our inspection. Staff wore clean disposable scrub uniforms, closed toe shoes and their hair was tied back. During patient treatment, staff wore theatre caps, masks, and non-latex gloves and were bare below the elbows. This enabled good hand washing techniques and reduced the risk of cross infection, as long sleeves can interfere with this process. During treatment, patients were provided with a cap to cover their hair.
- We observed three members of staff and saw they washed their hands in accordance with the World Health Organisation (WHO) 'five moments for hand hygiene'. Posters were displayed throughout the clinic, which provided information on the 'five moments for hand hygiene' in line with WHO guidance.
- We saw hand-sanitising gel was available at points of care in all clinic rooms. This was in line with Health Technical Memorandum (HTM) 'Infection control in the built environment'. The sinks had elbow operated taps, which was in accordance with the Health Building Note 00-09: 'Infection control in the built environment'.
- The sluice room was spacious clean and emergency eyewash was available for staff. We saw wall mounted hand washing gel was available.
- We viewed the IPC audit results of 4 September 2017. The audit covered areas of the environment, utilities, laundry, waste disposal, sharps, and cleanliness. The overall score was 81%. The surgery services manager told us partial compliance was between 76-84% and a preferred compliance was over 84%. We saw actions taken as a result, which included removing a hand-washing poster from the women's toilet, as this was seen to be too old. During our inspection, we saw a new poster was displayed. All action plans were dated and signed by the surgery manager.
- An external cleaning company cleaned the clinic at night. The cleaning staff were not allowed in the treatment rooms, to prevent damage to the sensitive laser equipment. Nursing staff at the clinic cleaned the treatment rooms and we viewed the cleaning schedule and checklist for the months of June, July, and August 2017. All checks had been completed and signed by the relevant members of staff. Checks were conducted at the start and end of the working day.
- Morning IPC checks were conducted for the reception area, toilets, pre-screening areas, and there were checks on staff uniform. We saw the last three months checklists had been completed and signed by staff. The surgery manager was responsible for the monitoring of all IPC checklists.
- Staff conducted a monthly deep clean of the treatment room and we viewed the previous month's checklist, which had been completed and signed by staff.
- Sharps bins were in place, dated, signed and off the floor in all areas, we visited. This reflected best practice guidance outlined in the Health and Safety Executive (HSE) The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Sharps bins are used by clinical staff to safely dispose of used instruments such as, syringes, needles, and glass ampoules.
- All instruments used for treatments were single use and could be disposed of after treatment.
- An annual legionnaire test was conducted and we saw the documentation; which showed the necessary checks had been made. Legionella is a water borne bacteria that can be harmful to people's health. The water tests for legionnaires disease complied with the Control of Substances Hazardous to Health Regulations 1989; Section 3(2) of the Health and Safety at Work Act 1974. Water temperature checks were completed on a daily basis and we saw records from 14 July 2017 to 11 September 2017 to show the checks had been made.
- During the reporting period, there were no incidents of MRSA or MSSA and there were no cases of C.diff or E.coli infections.

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Environment and equipment

- The clinic and treatment areas were visibly clean, well maintained, and free from clutter.
- The service was positioned on the ground floor within a multi-purpose building that housed other health services. The public entered the building through the main door which was security locked. Access was gained by speaking to the front of house staff member through an intercom.
- Patients were seen in a consultation and another room for diagnostic tests. Their treatment was undertaken in a laser treatment room. There was a further surgeon's treatment room and patients were taken to a separate room to recover. All rooms afforded patient privacy.
- The treatment room comprised of refractive eye lasers used for treatment and a treatment bed, sluice room and dirty and clean rooms.
- Three types of laser machine were used at the location. The first two were located in the dedicated laser room and were maintained under a contract, which provided for an annual service, a quarterly engineer's check and an emergency call out service. The YAG laser could be moved between treatment rooms as required. There was no service contract in place for the YAG laser, but it was repaired if found to be out of calibration during the routine calibration checks.
- The clinic met the standards recommended by the Royal College of Ophthalmologists (RCO) for a safe environment within the treatment room. There was minimal access for intervention, warning hazard signs were illuminated both internally, and externally to show treatment was underway.
- Within the treatment room, daily temperature and humidity checks were recorded, which is in line with recommended guidance.
- The dedicated laser treatment room was visibly clean and suitable precautions had been taken to meet the requirements of the laser local rules, health, and safety at work requirements. The controlled area was clearly defined with warning signs displayed so staff and patients knew not to enter. The room was accessed via keypad entry. Blackout blinds were fitted on the windows and other reflection hazards were minimised. We reviewed evidence of regular testing and servicing of the equipment and the availability of safety eyewear.
- The laser technician before each use performed safety and calibration checks. The machines also had safety warnings and failsafe cut outs built into the laser software. We observed the checklists for the months of July and August 2017 had been completed and signed by staff.
- The location had a contract with an external Laser Protection Advisor (LPA) who was responsible for undertaking risk assessments, providing advice, and training on laser safety training. They also drafted and issued suitable local rules and working practices and investigated adverse laser incidents. We noted the risk assessments and local rules were reviewed on a three yearly basis and the dates showed they were in order. We viewed the Local Rules for the three laser machines. The rules contained information on the control of hazards, responsibilities, risk assessments, laser hazards, and gas hazards. Staff had signed the rules to show they had read and understood all the information.
- Staff attended core knowledge of training every three years with the LPA. We viewed staff records, which showed all staff had completed their training.
- The surgery manager at the location was the Laser Protection Supervisor (LPS) and directly supervised all optical radiation protection at the location in line with the Local Rules. The laser technicians were LPS trained and would assume the role when the LPS was not available.
- We reviewed evidence demonstrating the air-handling unit in the operating room was checked on a daily operational basis and there was information, which told staff what to do in the event of unit failure.
- We observed electrical safety checking labels were attached to electrical items showing they had been tested and were safe to use.
- The stock room and dirty sluice room were well organised and tidy.
- All flooring was easily cleanable and in accordance with Health Building Note (HTM) 00-10 part A: Flooring. All work surfaces appeared to be clean and were clutter free.
- Ophthalmic diagnostic equipment that was not in use had appropriate covering to keep the machines clean and dust free.
- Emergency equipment was available and checked on operational days. All items were correctly stored and ready for use. The clinic did not have a defibrillator machine. Staff told us they would contact emergency services if they needed to.

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- All storage areas, including the dirty sluice room were visibly clean and tidy.
- All fire exits and doors were kept clear and unobstructed. Emergency exits were clearly signed and easy to access.
- There were risk assessments in accordance with control of substances hazardous to health (COSHH) regulation 2002 for a variety of chemicals, which included gases, chemicals, mitomycin and cleaning products. COSHH are regulations employers need to abide by to prevent or reduce their worker's exposure to substances that are hazardous to their health.
- Waste in all clinical areas was separated and in different coloured bags to identify the different categories of waste. This was in accordance with HTM 07-01, Control of Substances Hazardous to Health and the Health and Safety at work regulations. All waste was kept appropriately in bulk storage bins on the clinic premises, which was collected by a specialist waste company on a weekly basis.

Medicines

- The clinic had a medicines management policy, which described the handling, storage, prescribing, recording, and safe administration, and disposal of medicines.
 - The clinic had no controlled drugs and the surgeon prescribed all medicines.
 - The resident registered nurse was responsible for ordering, receiving, recording and storing of medicines and there was pharmacist support available by telephone. One pharmacy supplied all medicines for the clinic.
 - We reviewed the clinic's drug order stock book and the medicines we checked were in date and reconciled with the records.
 - We found medicines were stored securely and appropriately. Medicines were ordered on an average every four weeks from an external supplier. Medicines requiring cold storage were stored in locked fridges and the temperature was monitored daily. We observed the logbook with checks made from July 2017 to Sep 2017. All checks had been completed.
 - Staff completed competency assessments for managing medicines. We noted from staff records, staff had been assessed for competencies for ordering, receiving, recording, storing, disposal, and dispensing of medicines.
- Mitomycin C eye drops were administered following refractive eye surgery. Mitomycin is used to decrease haze after surface abrasion procedures. We observed staff explain clearly the use of the drug and we saw consent was confirmed before use. Mitomycin is a cytotoxic drug, which means they contain chemicals, which are toxic to cells. We saw cytotoxic waste bins were used and observed the registered nurse dispose of the waste correctly. The bins were disposed of after each surgery session.
 - Medicines used during surgical procedures and given to patients to take home, were prescribed by the surgeon that carried out the surgical procedure. There were prescription labels attached to each medicine package, with the patients name, date and instructions for dosage.
 - We observed a patients discharge with a technician. The patient was provided with clear, concise instructions on how to use and store the medicines. The patient was provided with opportunities to ask questions and the patient was not discharged until they confirmed they understood all the instructions.
 - The clinic held some emergency medicines (such as adrenaline for anaphylaxis) which were checked regularly and in date. These medicines were stored securely in a container, which was readily available with resuscitation equipment.
 - The gas cylinders, which contained various gases to re-fill the main laser machines, were kept in a storage room in an upright position and stored securely. Staff had been trained to transport the cylinders safely using the provided trolley.
 - We checked all the oxygen cylinders and found they contained safe levels of oxygen and were all within their expiry date. All oxygen cylinders were stored safely.

Records

- The clinic had an electronic medical system and a hard copy of surgical records. The hard copy record was archived off site and a full time archivist managed these records. On receipt of the hard copy, it was scanned and saved. On the day of treatment, the information from the hard copy was entered onto the electronic file. The electronic record was, therefore, integrated with the hard copy file with the exception of the instrument traceability records and signed patient consent form. This information could be retrieved through the archivist who was able to send the scanned record.

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- We reviewed five sets of patient records and saw consent forms were signed and legible. Consent forms provided patients with information relating to risks associated with the procedure. We saw prescription charts had been signed by the surgeon and registered nurse. Included in the records were the patients' medical history, eye tests, and scans taken. The examination included psychological testing and asking about the patient's motivation for having treatment. We saw informed discussions between the surgeon and patients were in-depth with discussed outcomes, expectations, risks, and recovery.
 - We noted instrument traceability sheets were kept in an ordered fashion. These showed information on single use items used within the treatment.
 - We reviewed records of the World Health Organisation WHO five steps to safer surgery checklist which included, sign in, sign out and time out. The three members of staff present in the treatment room had signed all checklists.
 - All files were of a standard format and were neat and clear for staff and patients to read.
 - At initial consultation, the patient was required to indicate on their health questionnaire whether they consented to the clinic contacting their GP and we noted patients who consented provided their GP's details. The electronic system automatically sent a 'discharge' letter to the GP if the examiner had completed the patient's last examination record.
 - An audit of records was completed on a quarterly basis and overseen by the manager. The clinic checked 10 sets of records and three on the electronic system. The checks were made to ensure the WHO safety checklist, consent and consultant input had been correctly completed and to check for trends. We reviewed the audits for March and July 2017. Audits achieved 90% and above. Actions taken for improving the quality of records was in evidence. This included considering using the date of surgery labels on consent forms as it was noted these were missing. The records we reviewed showed this was happening.
- Assessing and responding to patient risk**
- Patients were assessed for their suitability for treatment at the clinic prior to treatment. Checks included health questionnaires and eye examinations.
 - The risks of treatment were explained to patients and we observed two consultations where health checks and eye tests were undertaken. Lifestyle questions were asked so the clinic could make an informed decision about the different laser treatments. For example, patients who played rugby and martial arts were better suited to a certain laser treatment as, although a longer recovery, the treatment was more robust and less liable to cause issues for those patients who played contact sport.
 - After the eye examination was conducted the patient was provided with information on likely outcomes, but it was explained they would need to see the surgeon who would make the final decision and discuss everything again and review examination results. We viewed five patient records, which showed there was sufficient time between the initial consultation and surgeon consent to allow patients a time for reflection and to decide whether they wished to proceed with treatment.
 - Suitability guidelines also included other health associated issues. For example, patients with epilepsy had to confirm they had been seizure free for three months and had to have a letter from their GP to confirm this.
 - Psychological issues were part of the assessment criteria. Patients with disorders such as depression also required a supportive letter from their GP. Other checks included whether patients had rheumatoid arthritis, MRSA, whether patients had a pacemaker, and keratoconus, which is a non-inflammatory eye condition.
 - Patient suitability and treatment criteria were discussed at the annual International Medical Advisory Board (IMAB) meeting. This meeting comprised of refractive eye experts who were independent of Optical Express.
 - Staff conducted a team briefing at the start of the day. We reviewed the notes recorded for 22 September 2017. They showed discussion took place on the patient treatment list for that day, any concerns regarding any patient and checks to ensure everyone knew the role they played. The briefing was attended by all staff.
 - The laser treatment team consisted of a 'scanner'; a registered nurse, a laser technician, the surgeon and a discharger. The 'scanner' was responsible for checking the patient's identification, eye scans, and the results of other pre-assessment tests. The nurse would collect the patient and assist the surgeon during the operation. The nurse was also responsible for dispensing the medication for the patient to take home after the procedure. The technician was responsible for ensuring

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the laser was correctly calibrated and working within safe parameters. The surgeon performed the procedure and the discharger waited with the patient in the recovery area until they were able to leave.

- Staff used an adapted 'five steps to safer surgery' World Health Organisation (WHO) checklist to minimise errors in treatment, by carrying out a number of safety checks before, during, and after each procedure. During our inspection, we observed two patient procedures, where the WHO checklist was used correctly and saw other patient notes, which showed the WHO check had been completed fully.
- As part of the medical audit, the WHO checklist was measured and we reviewed the audits for March 2017 and July 2017, which showed 100% compliance.
- The clinic used an operating theatre register. These registers are used to provide an on-going record of patients that have undergone treatment at the clinic and included the following information: patient name, age, address, diagnosis, names of attending doctors and assistants, date and time of procedure and anaesthetic used.
- A laser protection supervisor was always present throughout the patient's treatment.
- Post-operative patients were assessed in the recovery room by either a registered nurse or technician. They were provided with written instructions for aftercare and follow up appointments. We observed a technician provide aftercare instruction to a patient. The discussions were informative, clear and provided useful information for after care instruction.
- There was an out of hour's telephone line available for patients to use if they had an emergency or concern. The line was managed by an optometrist who had access to a surgeon.
- The surgeon remained on site until the last patient left the clinic on the day of treatment.
- The clinic conducted quarterly collapse simulations and the last was completed on 6 September 2017 and attended by all staff who worked at the clinic.
- The clinic did not provide treatment, which required local or general anaesthetic.
- There had been no patient transfers out of the clinic with the last 12 months. For medical emergencies, the clinic contacted emergency 999 services.

- Traceability forms were completed which provided a tracking and tracing system of equipment and treatments used in case of any concerns arising post procedure.

Nursing and medical staffing

- Nursing staff arrangements were dependent on when the clinic opened and this was dependent on patient demand. Therefore, there were no set days that the clinic opened.
- There were two resident surgeons who formed part of a regional team covering other clinics nearby.
- The organisations central scheduling team managed staff rosters, which meant the clinic had sufficient, suitably qualified staff to cover clinic days. Rosters were allocated one to two months in advance. The surgeon was allocated first and other staff were rostered according to treatment at the clinic.
- The surgery manager reviewed rosters to ensure suitably trained staff and an appropriate skills mix covered all clinic days.
- There were no staff vacancies at the time of our inspection and the clinic did not use agency staff.
- An external company provided the Laser Protection Adviser (LPA). Staff told us they were easy to access and the organisation had a good professional working relationship with them. We reviewed evidence of their input into training for core skills knowledge.
- The surgery manager was the clinic's named Laser Protection Supervisor (LPS). A further two certified technicians were also trained to be deputy LPS when the manager was not present. The technicians worked within the treatment room, so this meant there was a LPS present during patient treatment.

Major incident awareness and training

- Fire escapes were clearly marked throughout the clinic and easy to access. There were fire extinguishers in every room of the clinic and these had been checked by an official external company.
- The clinic had an emergency lighting system and there was an uninterrupted power supply system, which was installed in the treatment room. This gave a supply of power up to 30 minutes, which meant patient treatment could be completed. The system was checked at the beginning of the working day and we saw the annual servicing maintenance report.

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Are refractive eye surgery services effective? (for example, treatment is effective)

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance. Policies and guidelines had been developed in line with the Royal College of Ophthalmology (RCO) Standards for laser refractive eye surgery and the National Institute for Health and Care Excellence (NICE) guidelines in relation to refractive eye surgery. Policies and procedures were in date and staff were able to access these online and in paper form.
- Suitability guidance and treatment criteria were subject to critical review annually by the International Medical Advisory Board (IMAB). The IMAB comprised of refractive eye experts who had no link to the company. Guidance and any recommended changes were discussed and reviewed internally via their Medical Advisory Board (MAB). Any changes in guidance or protocols were disseminated to staff. The MAB meeting minutes of 2016, included recommendations to follow the General Medical Council (GMC) guidance pertaining to cosmetic procedures, which went live on June 2016 and applied to refractive eye surgery.
- We noted from the annual IMAB meeting of 2016 that articles and documents related to regulation, standards, and guidelines of the GMC and RCO in relation to refractive eye surgery were discussed.
- Staff had access to clinical suitability guidelines through the organisations intranet.
- If a big change was made in relation to evidence based care and treatment guidelines, the organisation sent a directive from the clinical service director.
- The service followed NICE IPG64 guidelines on photorefractive eye surgery. The surgeon made the appropriate tests and checks pre-treatment and ensured robust consent was obtained. Patients were supplied with information on the potential risks of the treatment.
- Pre-operative tests for elective surgery were in line with NICE guidelines NG45. Patient's medical history was discussed and appropriate tests and scans were taken to help determine treatment.

- Care pathways were in place and we saw samples, which included the management of a patient with dry eye. The pathways were in accordance with best practice guidance and provided information from the patient's start of their journey to discharge.
- Regular monthly audits were conducted for infection control, incidents, complaints, record keeping, maintenance of equipment, medicines management and health and safety. We viewed a variety of audits, which showed actions were taken against any areas of concern. For example, the environment audit dated 4 September 2017, showed a compliance of 81% which was below the set standard of 85% and higher. The report showed areas of concerns such as a bin by a sink had spillage marks on the outside and the action plan showed the bin had been cleaned, reviewed and checked. The cleaning of bins was now part of the daily environment checklist and the surgery manager monitored this as part of their checks as well.

Pain relief

- Local anaesthetic eye drops were prescribed prior to treatment. Patients were asked if they were in any discomfort during surgery.
- Patients were prescribed anaesthetic eye drops post treatment. We saw staff made sure patients were provided with verbal and written instructions.
- Patients were given a follow up appointment three days after their treatment and their pain was monitored.
- Patients were told to purchase analgesic such as paracetamol to help cope with any pain.
- Patients were asked about the monitoring of their pain within the patient questionnaire. However, we did not see any results for this part of the questionnaire.

Patient outcomes

- Each surgeon's individual outcomes were collected on an annual basis and were used as part of their appraisal. A full time biostatistician collected data from the patient's electronic files.
- We viewed one surgeon's clinical outcome compiled data. The data collected included patient feedback of a positive and negative nature and a score of patient satisfaction with surgeon care was collated.
- The data collected enabled the service to monitor the demographics of their patients in terms of patient age, gender, treatment type, and procedure type and

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ablation profile. The surgeon's efficacy and safety data was rated. The surgeon scored 58 for efficacy and 53 for safety. A score of 50 represented outcomes that were on par with expected Optical Express levels.

- The surgeon's complication rate was monitored and we noted the surgeon scored 0.62% complication rate for the 3,878 consecutive procedures they had completed. This was in line with the organisations expected standards.
- The cancellation rate for the surgeon was collected along with enquiries to patient-derived regulated bodies such as the GMC and GOC to see if complaints and legal inquiries had been made. No complaints or inquiries had been made for this surgeon.
- Each surgeon outcomes were assessed at the IMAB meeting, where any necessary changes to effect and safety were reviewed and recommendations were made and discussed at the national Medical Advisory Board (MAB).
- The service expected to enhance approximately 5% of all treatments. Patients were made aware of the need for enhancement at the start of their journey so they were not unexpected. Some of the enhancements undertaken at the location were for patients who had treatment at another location and maybe several years into their primary treatment. The service completed 113 enhancement procedures during the past year and the primary treatment date ranged from 2004 (from other locations) to 2016. The reasons for enhancement were regression; quality of vision issues and desired outcome not achieved. For laser treatments, which corrected near sightness, farsightness, and astigmatism using two lasers, there were 71 enhancement procedures with the primary date ranging from three in 2012 to 12 in 2016. 19 patients had their primary treatment and enhancement within the last twelve months.
- For treatments that used one laser 42 enhancement treatments were completed with the primary date ranging from 11 in 2004 to eight in 2016. Three patients had their primary treatment and enhancement within the last twelve months. There were 15 abrasion complications, 10 dry eye visions unaffected six months after procedure and five dry eyes with reduced best corrected vision six months after treatment.
- In the past 12 months 86 patients experienced complications following refractive eye surgery. The majority of complications related to abrasion, dry eye, and haze. Most of the complications, for example

- abrasion required follow up appointments to increase lubrication. However, some required referral back to the surgeon for direct care and some cases just required more frequent follow up appointments by the optometrist. For dry eye complications there was a treatment pathway for staff to follow
- The clinic followed the Complex Case Directive dated August 2017, which provided staff with directions and actions to take for escalation and handling complex cases. The directive gave categories for each complex case, ranging from category A (Emergency) category B (Urgent) and category C (non-emergency). Under each category, a list of complications was provided and the pathway staff were required to follow.
- In the past twelve months, there were no unplanned returns to theatre for refractive eye surgery.

Competent staff

- We saw all staff who worked at the clinic had received their annual appraisal. The medical director completed appraisals for surgeons and the surgery manager completed appraisals for resident staff such as registered nurses and technicians.
- We viewed four staff records and noted the appraisal for each staff member. The appraisal looked at four areas, clinical competency, patient advocate, mentor/leader responsibilities, and whether they were a good team member. There was an area for planning and development opportunities. We saw for one technician staff member there was a plan in place for development to a senior refractive eye technician.
- All competencies had been completed such as the checking of calibration of lasers and this had been certified by the laser manufacturers. Other competencies such as the reporting of incidents had been assessed and completed. Checks had been completed for identity of passports, mandatory training certificates, appraisals, and competency assessments.
- Staff attended core knowledge training for laser machines. This was completed on a three-year basis. We viewed two staff members' personal records, which showed the completion of this competency.
- We viewed one registered nurses record and saw an appraisal had been completed; certificates of registration with the Nursing and Midwifery Council (NMC) and training competencies were complete. Competency checks included assessments for the scrub role.

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- Revalidation checks of due dates were kept by the service. Patient feedback was supplied as part of a support package to help with the process.
- Registered nurses had attended an optometrist meeting on dry eye to use as part of their revalidation portfolio.
- We viewed the surgery manager's record and identified the certificate obtained for the Laser Protection Supervisor role. All competencies and checks for this role were in place. They were subject to three yearly competency reviews to assess their skills and keep up to date with latest guidance.
- There were a number of technicians who were also trained to LPS level. The surgery manager was the clinic's main lead who had overall responsibility for the safety of lasers. As they were not based in the treatment room, the technicians were able to undertake the role of LPS to assist in the treatment room.
- We saw evidence that all staff who worked with lasers had completed core knowledge training as well as attending manufacturers training. This was refreshed every three years.
- The list of authorised laser users had been signed to state staff had read, understood, and followed local rules.
- The Laser Protection Advisor (LPA) was a certified member of the association of laser safety professionals. All staff knew who they were and had met them personally.
- Some staff were multiskilled and were able to perform a multitude of functions within the clinic, such as, discharging patients and act as a scrub assistant. Staff told us this meant their role was varied and made it more interesting.
- All staff completed three yearly competency assessments which included pre-screening, assisting in theatre, patient discharge and laser technical duties. We saw competencies completed for the three members of staff records we viewed.
- There was an induction programme, which lasted four to six weeks dependent on staff role. After competency assessments, (which were signed off by the staff member's line manager), staff had a week of observations from the patient journey to discharging and scanning.

Multidisciplinary working

- We saw good multidisciplinary working between the team at the clinic. There was good communication and each staff member knew their role within the service.
- We observed the medical team working well together in the treatment room. The nurse anticipated instruments to pass to the surgeon and the technician read out laser recordings to assist them with the procedure. Each staff member was calm, professional and treated each other with respect.
- There were monthly team meetings and we saw minutes of the meeting of August 2017 where there was good attendance from all staff. There was time allocated within the meeting for staff to raise any concerns or areas they wished to raise.
- Staff worked across multiple sites in Optical Express, which meant there was consistency within the service.
- With patient consent, the service communicated with GP's for relevant information and patients GP's were able to contact the service through the out of hour's telephone line.

Access to information

- Patient information was stored electronically and a hard copy file was kept for day surgery. The records kept all patient related information for the patient's pathway of care.
- With the patient's consent, information on their treatment could be sent to their GP, via the clinics electronic system. The GP could access the patient's surgeon via the contact details provided on discharge.
- The electronic system was password protected but available to all staff involved in patient care. Dependent on their role each staff member was able to add important patient information in relation to their procedure throughout the patient's treatment.
- Organisation policies were accessible on the clinic's intranet and these included polices such as safeguarding and incident reporting. Updated guidelines were also available for staff to access.
- Throughout the clinic there was information displayed, such as fire regulation guidelines and infection control procedures such as 'the five moments of handwashing'.

Consent and Mental Capacity Act

- There was a consent policy dated January 2017 and this provided staff with guidelines on obtaining patient consent.

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- At the initial patient consultation, the optometrist provided an information folder to the patient, which contained a copy of the treatment consent form, risks associated with the treatment and the benefits of the procedure.
- We observed an initial consultation, where the patient was provided with the relevant information on the treatment to allow them to make an informed decision. Part of the consultation involved the patient watching a video, which provided further information on the treatment, along with the potential risks associated to the treatment.
- If patients wanted to proceed with treatment they then had a consultation with the surgeon who would perform the treatment. The surgeon offered the same information on the benefits and risks associated with the procedure. Further diagnostic tests were also taken.
- The consent appointment was made at least three days before any treatment took place. The service did not consent patients on the same day as treatment. However, the new Professional Standards for Refractive surgery (April 2017) recommends a “cooling off” period of one week.
- From the five patient records we viewed, we saw consent was legible and risks associated with procedures had been explained to patients.
- We were told for those patients who did not speak English, they were asked to bring somebody with them who could translate information. This was usually a family member or friend. However, for consent procedures, it is best practice for an independent interpreter to explain treatment and assist with consent, to minimise the risk of coercion and to ensure medical information is translated correctly.
- All staff at the clinic had completed consent training, which included information on the Mental Capacity Act 2005.
- It was the responsibility of the surgeon to assess capacity to consent. Any concerns would be raised with the patients GP, with the patients consent. However, the surgeon had the final decision as to whether the patient was suitable to proceed with treatment.

Are refractive eye surgery services caring?

Compassionate care

- We observed staff were caring and compassionate in interactions with patients. Staff treated patients with kindness, dignity, and respect. Staff interacted with patients in a positive, professional, and informative manner.
- We observed two surgery procedures. The surgeon explained the treatment and asked the patient at every step of the procedure if they felt comfortable.
- We observed nursing staff collecting patients from the waiting room, shaking hands and introducing themselves prior to consultation.
- The four patients we spoke with said the staff were very friendly, kind, and considerate.
- Patients were asked to complete an on-line survey at various points during their care. The surgery experience survey was completed at the 24-hour post-operative visit.
- We reviewed patient feedback data for the months of July 2017 and August 2017. The feedback showed for July 2017, 35 patients responded and for scores out of 10 (10 being the highest), 100% were over nine. For August 2017, 31 patients responded and again 100% of feedback scored over nine. Questions asked included “Did the surgery team make you feel comfortable?” and “Was the post-operative eye drop regime explained clearly?”
- Compliments were printed off by the surgery manager and given to staff.
- We saw positive feedback cards from patients, one had written, “Support of nurses calmed me.”

Understanding and involvement of patients and those close to them

- Staff involved patients in their care, and gave time to discuss procedures.
- We spoke to two patients who described the initial consultation, investigation, and treatment options. The patients said, staff encouraged them to think before making a decision about treatment.
- We observed staff during a consultation, consent, scanning, surgery, and discharge. At each different

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stage, staff informed the patient of what they were doing and checked their understanding of the procedure. The procedures were not rushed and patients were given time to reflect and ask questions.

- One patient did inform us that when they made the initial contact through the organisations website they were then contacted every day by the 'call centre' to see if they wanted to proceed with treatment. They found this a nuisance, but could not fault the care and kindness they had received from staff at the clinic.
- There were leaflets available, which provided details of all the options available and the costs of treatment. The organisations website was clear and easy to use and gave an informative description of each procedure as well as other patient stories.
- Information on chaperones was displayed at the reception area. This meant patients were able to involve relatives, friends, and chaperones in their discussions about treatment and care. This was with the patients consent.

Emotional support

- We observed two procedures in the laser treatment room and saw that the nurse who was present reassured the patients throughout the procedure. They provided support to an anxious patient and were able to allay their fears and concerns regarding treatment. They were kind, non-persuasive and made the patient feel relaxed.
- We spoke with four patients who told us the staff made them feel comfortable and relaxed and eased their fears for any concerns they had with their treatment. We observed a technician speaking kindly and supporting the patient with aftercare treatment. They spoke calmly, answered all the patients' questions, and asked how the patient was feeling. They told the patient what to anticipate in terms of post treatment discomfort and how to minimise their concerns.

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

Service planning and delivery to meet the needs of local people

- Patients could access the service either through self-referral through word of mouth, or through an internet search or in response to marketing. The clinic did not do any NHS work and did not receive referrals from the NHS.
- The provider generally undertook refractive eye surgery as and when patient demand dictated. Rosters were conducted on a two monthly basis and extra days could be fitted into the roster if the surgeon wished to do so. The clinic sometimes opened on a Sunday to meet patient demand.
- Other nearby Optical Express clinics were available for patient access and allowed for flexibility when planning the service.
- Patient's appointments were flexible and they could be seen at different clinics to suit their needs.
- Comparisons were made against each location and operational meetings were conducted every Monday to discuss planning and delivery of the service.
- Four patients we spoke with told us they had received all the necessary information and clear explanations of what to expect, prior to their treatment.

Access and flow

- Patients were self-referring and appointments were made to suit patient requirements. The clinic could afford the benefit of utilising clinics nearby, which allowed for better patient choice of appointment times.
- Patient's initial consultation appointments lasted approximately 20-30 minutes but the full patient journey for treatment lasted two to three hours.
- The clinic had flexible opening times and would open on a Sunday to meet patient demand.
- Within the last 12 months, there had been no cancelled refractive eye procedures due to non-clinical reasons.

Meeting people's individual needs

- There was good access and spacious room for wheelchair users and patients with limited mobility. Patients with wheelchairs were invited to access the service before their treatment day so their needs could

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be assessed and accommodated for. For example, patients were shown the treatment room and how they could manoeuvre their wheelchair before receiving treatment.

- There were hot drinks and biscuits available in the reception area along with a cold-water dispenser.
- Magazines and a television were available in the reception area.
- There was a range of information leaflets available throughout the clinic. They provided information on treatments and various conditions; however, they were only available in English.
- The service did not treat patients with, learning disabilities or patients with complex health conditions. Screening procedures at the start of the patient's journey ensured those patients who required additional support were referred to alternative services with the support of their GP.
- There was no access to translation services or an interpreter. Patients were asked to bring a relative or friend to accommodate them.
- Patients were provided with information on aftercare and emergency contact numbers if they felt the need to contact the service with any concerns.

Learning from complaints and concerns

- The service had a complaints policy, which provided guidance to staff on the processes they should follow in the event of a patient complaint.
- From May 2016 to June 2017, 19 complaints were received at the location. We viewed the complaints summary and saw outcomes with actions taken were completed for each complaint. The complaints ranged from booking errors to quality of vision and patients expectation. Against each complaint, we saw a response had been made to each complaint and learning outcomes were actioned if required. These were managed by the clinical services team.
- The patients consent form and terms of condition document contained information about how to make a complaint. There was a notice at reception, which included a summary of the process. However, information on how to make a complaint was not provided in other languages for those patients who did not speak English.
- Verbal complaints were dealt with by the surgery manager in an attempt to resolve the issue as quickly as possible with a satisfactory outcome for both parties. If

the complaint escalated further, the clinical services department were then involved in the process. The organisation employed a solicitor assisted with the management of complaints.

- Written complaints were responded to by the clinical services team. The patient's electronic file was updated so the surgery manager could monitor the information regarding the complaint.

Are refractive eye surgery services well-led?

Leadership and culture of service

- The corporate leadership arrangements consisted of the chief executive officer (CEO), optometry directors, operations director, and the clinical services team, which consisted of the refractive operation manager, surgical services manager, and location surgery managers.
- Staff we spoke with talked positively about the surgery manager. They said they were supportive, approachable and managed their concerns. There was clear leadership. Staff knew their reporting responsibilities and the role they played within the service
- Staff who worked at the service told us they enjoyed working at the clinic, and everyone got on well with each other.
- Surgeons were managed by the medical director who reported to the CEO.
- The corporate surgery services manager visited the clinic every four to six weeks and there was a good working relationship between the surgery manager and the surgery services manager. The surgery manager felt supported in their role.
- Staff were happy with the working arrangements of rotating to other clinics nearby. The surgery manager was responsible for another clinic nearby and staff therefore had consistency in their leadership.
- We observed marketing to be honest and complied with guidance from Committee of Advertising. Patients received a statement, which included terms and conditions, which provided information on payment fees and details of the service provided. Patients told us they did not feel pressurised to go ahead with treatment

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from staff working at the clinic. However, one patient told us, when they had made an initial enquiry through the organisations website, they were contacted every day by the call centre and they found this annoying.

Vision and strategy

- The corporate surgery services manager told us there was no formal vision for the organisation. Staff were not aware of the organisations values. However, they were able to tell us the organisations strategic plans involved opening more clinics across the country and to invest in advancements for treatment.
- We were told by the surgical services manager that the service set up the first International Medical Advisory Board (IMAB). The board was made up world renowned refractive eye experts with no link to Optical Express. Optical Express finance the board and they met annually to review the organisations data and clinical protocols.

Governance, risk management, and quality measurement

- There were policies in place to support the governance of the organisation. These key policies provided staff with clear guidelines and processes to follow. Such key policies included risk management, incident reporting, information governance, medicine management and privacy, dignity, respect and human rights.
- The organisation held meetings through which governance issues were addressed. These meetings included the clinical committee meeting which was held on a monthly basis. These meetings were attended by the clinical services director, medical director, surgical services manager, in house solicitor, and the responsible officer.
- We saw the meeting minutes of April 2017 and June 2017. Governance topics such as the opening of new clinics, Royal College of Ophthalmologists guidelines, appraisals, mandatory training and other relevant topics related to the service. The minutes supplied actions taken and information sharing.
- The location had quality indicators, which covered, incidents, complaints and local audits. This local quality information was fed into the clinical governance committee, which met once a month, and in turn fed into the Medical Advisory Board (MAB). The CEO headed

the MAB and all surgeons and heads of departments were members of the board. The MAB managed changing practices, either to treatment, surgery techniques or the introduction of new technology.

- Local monthly team meetings took place at the clinic and local topics were discussed including incidents and any changes to practice (which had been fed from the MAB). The meeting allowed time for staff to raise any concerns.
- The clinic did not have a risk register. However, there were risk assessments, which applied to the location. These risks were colour rated, red, amber or green (RAG), which meant the clinic were able to assess each risk's severity. A red rating indicated a high risk, amber moderate and green low. We viewed the risks for laser risks and fire assessments. These were up to date, re-assessed, and kept for one year. As a single specialty service, the risks to patients were low and staff were trained and skilled to manage risks at the location.
- We were told by the surgery manager the top three risks of the clinic were needle stick injury, inflammatory response to treatment and an error of omission in the computer system. Staff we spoke with were aware of the risks and the steps they needed to take to reduce these risks.
- We saw evidence that checks for the surgeon's personnel file were completed and indemnity insurance was in place, an appraisal had been completed and clinical outcomes had been collected.
- The local surgery manager was able to manage performance and quality of the service through local auditing and was able to contribute feedback through their local meetings with the surgery services manager.
- The fit and proper person's checks were adopted for the company's director, nominated individual and registered managers.

Public and staff engagement

- The organisation did not conduct staff surveys. We were told by the surgery services manager the company would appoint a Freedom to Speak Up Guardian who would start staff surveys through the organisation.
- Patients were able to leave feedback online at the clinic or through the organisations website. We were told there was a good level of response. For the year 2016, the level of patient response was approximately 40%. The clinic regularly received scores of 100% above the rating of nine, (scores were given up to 10).

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- As part of the patient experience questionnaire, the clinic asked patients questions such as, “Was the post-operative eye drop regime explained clearly?” For July 2017 out of 35 patient questionnaires completed, the clinic scored 100% nine or above. (The scores were rated 0 to 10).
- We were told changes made from patient feedback included changing the patient flow during mixed treatment and consent appointment diaries. The patients attending for consent appointments with the surgeon were prioritised to reduce waiting time dissatisfaction as these patients often attended during lunch breaks.
- There were regular team meetings where staff were able to raise any concerns and staff we spoke with said they felt comfortable to do so. They told us they were happy to discuss issues with the surgery manager who had an open door policy.

Innovation improvement and sustainability

- Discussions were in place to make the locations surgery manager the overall manager for all London clinics. They would have another manager working with them,

but this would make the London region more consistent between each site and to share best practice. Having an overall manager would allow more focus on quality issues and staff interaction.

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

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should offer patient information in the form of leaflets and documents in other languages apart from English.
- The provider should offer formal interpretation services for patients.
- The provider should consider developing a corporate vision and strategy.
- The provider should start staff engagement surveys.
- The service should follow the Royal College of Ophthalmologists recommendations relating to consent processes and the “cooling off” period between confirmed consent with the surgeon and surgery.