Optical Express - London (Shaftesbury Avenue) Clinic

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optical Express – London (Shaftesbury Avenue) Clinic is operated by Optical Express Limited. Facilities at the location include one laser treatment room, one surgeon's examination room, one discharge room and one screening room.

The service provides laser correction procedures using class 4 and class 3b lasers carried out by ophthalmologists.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 11 December 2017, along with an unannounced visit to the clinic 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 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 issues that the service provider needs to improve:

- The consent policy did not reflect Royal College of Ophthalmologists 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- There was inconsistent management of the environment, which resulted in clinical areas not always being clean and free from dirt and dust.
- There was evidence of a lack of consistency in local leadership, which was also reflected in feedback from staff.

However, we found the following areas of good practice:

- Patients were involved in their care and had the opportunity to ask questions at all stages of their treatment.
- Staff treated people with kindness, care, respect and dignity.

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 three requirement notices that affected refractive eye surgery services. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (South East)

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Refractive eye surgery.

Summary of this inspection

Background to Optical Express - London (Shaftesbury Avenue) Clinic

Optical Express – London (Shaftesbury Avenue) Clinic is operated by Optical Express Limited. It is a private clinic in London. The clinic provides services to patients who refer and pay for treatment themselves.

The clinic has not had a registered manager since July 2017. At the time of the inspection, a new manager had recently been selected and was in the process of registering with Care Quality Commission (CQC). After our inspection they withdrew their application and the provider told us they were recruiting a new manager.

The clinic also offers general optometric services. We did not regulate or inspect these services.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and three specialist advisors with expertise in surgery. The inspection team was overseen by David Harris, Inspection Manager.

Information about Optical Express - London (Shaftesbury Avenue) Clinic

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

Activity (October 2016 to October 2017)

- In the reporting period October 2016 to October 2017 there were 2523 procedures.
- 100% of patients were self-funded.

Two surgeons, one registered nurse and one lab technician worked at the clinic. The surgeons worked substantively for NHS services and provided treatment here under contract.

Track record on safety:

- No never events.
- Six clinical incidents, none with harm.
- No serious injuries.
- 13 complaints.

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 issues that the service provider needs to improve:

- The environment was not consistently well maintained or cleaned and there was evidence of dust and dirt, including in the laser treatment room.
- Eye drops, including prescription-only steroid drops, were issued by a non-prescriber who was not always supervised. Patient group directions were not in place. The surgeon did not maintain oversight of the medicines.
- Internal safety memos indicated inconsistent practice in relation to patient records.

However, we also found the following areas of good practice:

- There was evidence of improved practice from hand hygiene audits.
- Incidents were investigated and lessons learned. Staff understood and adhered to the duty of candour.

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:

- A structured appraisal system was in place and the provider offered competency-based opportunities for development.
- The service planned clinical policies in line with the Royal College of Ophthalmologists Standards for Laser Refractive Surgery.
- An audit programme was in place and was used to establish quality and performance benchmarks for each surgeon and for the clinic.
- We found consistent practice in pain management.

However, we also found the following areas the provider needs to improve:

Summary of this inspection

- Although there was a well-defined laser supervision structure in place, clinical staff did not demonstrate good knowledge of this and did not always know who the laser supervisor was.
- The consent policy did not reflect Royal College of Ophthalmologists 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:

- Staff treated patients and their relatives with kindness and respect.
- Surgeons involved patients in decisions about their care and treatment and offered the chance to ask questions for the duration of their care.
- Results from the patient experience questionnaire were consistently good and were similar to or better than the provider's national average. This included for care from surgeons and overall experience.

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:

- There was no waiting list for treatment and surgery was offered based on demand.
- The facilities available enabled patients to be treated in a calm and welcoming atmosphere.
- The service was working to improve the information available to people in other languages.
- There was evidence of learning from complaints including sharing between teams and changes in practice.

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.

Summary of this inspection

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

- The local leadership structure was unclear to staff and there was a lack of consistent oversight.
- Staff described varying experience of the working culture and some said they only received support if they could find a manager to contact.
- Governance systems did not result in improvements to quality and safety. There was little learning from audits, complaints or incidents that staff could identify.

However we also found an area of good practice:

- A governance system was in place that the surgical services manager used to track the implementation of changes to policies or new protocols across each clinic and with each member of staff.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The service reported no never events in the 12 months leading to our inspection and no serious incidents. 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.
- Between November 2016 and November 2017, the service reported six incidents. Two incidents related to a breakdown of the laser during procedures. In both cases, staff followed organisational policy to maintain patient safety. Other incidents related to an unplanned return to theatre and unexpected reactions to surgery, including a patient who fainted.
- Staff said they would report an incident to the person in charge on the day. However, they said they did not usually get feedback. Staff worked across multiple sites and therefore would not find out if any changes or improvements had been made at this clinic. Not all staff knew if there was a formal incident-reporting system.
- Surgeons and the surgical services manager demonstrated awareness of the principles of the duty of candour, including the need to be open and honest when things went wrong. For example, when the laser had failed part way through a procedure the surgery manager had apologised, explained the situation and implemented the correct company policy to resolve the situation. The duty of candour related to national guidance that healthcare professionals be open and honest with patients when something goes wrong.
- There was evidence staff provided patients with a clear and truthful explanation when things went wrong, in line with the principles of the duty of candour. All of the staff we spoke with understood this and could give examples of when they had used it.
- We saw evidence improvements to practice as a result of incidents or monitoring from looking at safety memos. For example, in October 2017 a patient records audit identified a need for more accurate documentation in relation to procedures carried out. Twelve members of staff had signed this memo to indicate they had read and understood it. As staff from multiple areas worked in this clinic it was not possible to establish this figure as a percentage of the total staff who had or could work here. Surgery managers checked all of the staff in their area had signed memos and directives at monthly regional meetings.
- The provider disseminated patient safety alerts through clinic managers. As this clinic did not have a permanent manager, the person in charge on each day reviewed safety alerts in their briefing to staff available on the day.

Mandatory training

- Mandatory training included up to 12 subjects depending on each individual's role and these were updated annually or every two to three years. Modules included patient discharge, to take away medicines dispensing, laser procedure screening, infection control, basic life support and customer care.
- Nurses and surgery managers were up to date with mandatory training in discharge processes, to take away medicines, laser vision correction scrub procedures and infection control. Surgery associates, who provided a dual crole between theatre assistance and pre-procedure preparation, were 79% compliant

with mandatory training requirements. The provider monitored training within this group as staff worked on a mobile basis, which meant training compliance could not be linked to a single location.

- Of staff who were listed as working permanently at this clinic, 100% had up to date mandatory training.

Safeguarding

- In the London area team, 100% of staff had completed safeguarding adults level 2 and safeguarding children level 2 as part of the provider's mandatory training programme. However, one individual said they did not know what we meant by safeguarding and had not heard of the term before. A senior member of staff on duty said they did not know what sort of safeguarding training the organisation provided.
- Clinical staff were trained to recognise signs of coercion and would not provide treatment until this was investigated either through the local authority safeguarding team or the patient's GP.
- The surgery manager was the designated safeguarding lead. As surgery managers differed day to day, this was not always the same person. However, all surgery managers who could work in the clinic were trained to level 3. Where this individual was not usually based at this clinic, they could access local safeguarding hub information on site. However, staff did not always know who the designated safeguarding lead was.
- We found evidence staff acted on safeguarding concerns.
- An up to date safeguarding policy was in place and readily accessible on site. This included local escalation pathways for staff.

Cleanliness, infection control and hygiene

- The surgery lead in charge on each shift was the overall lead for infection control. This individual was named in the daily surgery briefing checklist. This individual was responsible for ensuring the standards of cleanliness in the treatment room complied with the Royal College of Ophthalmology professional standards and guidance.
- The provider's cleaning and infection control policy stated that cleaning should take place monthly and at the end of each day, on days the theatre was operational. In addition, daily hygiene checks were in place prior to the service opening. We were unable to confirm that staff always fully completed checks. For example, one checklist had been dated and not completed. The most recent monthly audit noted staff did not include clocks, emergency lights, air vents or pump dispensers when cleaning. Senior staff we asked said air filters and flow devices should be included in audits, and they did not know why this was not taking place.
- Infection control audits were not always being completed. There were gaps in audits, a failure to act on audit outcomes, and evidence in the environment that audits were improperly carried out. For example, we saw on one infection control audit, staff stated they had not cleaned the pump dispenser in the theatre after a procedure because it "looked clean". Two previous audits noted there were no hand towels in the toilets, which raised concerns that staff did not consistently implement learning from audits. In one audit, the manager had noted they had marked surgical staff as compliant with the personal protective equipment (PPE) policy, but had not witnessed this; instead, they based their judgement on previous observations. One audit noted the laser room humidifier was drained at the end of each day and another audit noted the humidifier had been decommissioned. However, the provider confirmed the first audit was correct and the humidifier was in use and was regularly serviced.
- Between August 2017 and December 2017, compliance with hand hygiene standards was 95% during 14 observations. This was an overall average figure and represented results ranging from 78% to 100%.
- We observed good infection control practices, including appropriate hand wash practices, use of antibacterial alcohol gel, and personal protective equipment (PPE) in relation to gloves and scrub suits. However, we also saw a laser technician did not use appropriate PPE or gel their hands when decontaminating the operating table after a

procedure. We observed theatre staff did not always change facemasks between procedures or patients. This meant risks associated with cross-contamination were not consistently managed.

- We observed staff set up a sterile procedure trolley and found they maintained the sterile field. However, the wheels on the stainless steel trolley were rusty, which presented an infection control risk.
- The provider included infection control risks on the clinic's risk matrix in relation to training. The matrix noted staff must maintain up to date training and knowledge of infection control policies.
- The provider followed the requirements of the Hazardous Waste (England and Wales) Regulations 2005 with regards to waste disposal. However, staff in theatres did not always adhere to the Association for Perioperative Practice best practice in regards to hazardous waste disposal. For example, we saw staff used the same hazardous waste bag for five consecutive patients on the first day of our inspection
- We found variable standards of cleanliness and environmental management during our inspection. On the first day of our inspection there was visible dust on the metal base of the operating table. An external company had carried out a deep clean in this area 48 hours beforehand and the theatre had not been used since then. The surgical services manager told us the build-up of dust was due to building works. On our unannounced inspection we saw that the theatre floor and equipment was clean and free from dust. However, the air vent in the theatre was dusty, and there was no evidence of a process in place to regularly check this and remove dust. This meant there was not an effective safety management process in place to ensure the theatre remained free from dust. This presented a risk to patients undergoing treatment that dust would interfere with their procedure.

Environment and equipment

- The provider told us the interim surgery manager was the laser protection supervisor and in their absence a designated laser technician or scrub assistant would be the laser protection supervisor. However, none of the nurses, technicians or surgery managers knew about this arrangement.
- The risk assessment for the laser room noted all appliances should be tested for electrical safety annually, but we did not see evidence of this in practice.After our inspection the provider told us they followed updated Health and Safety Executive guidance that meant lectrical equipment was tested for safety at intervals of between three and five years.
- The risk assessment for the laser room stated the laser treatment room must be secured by an illuminated warning sign and restricted access when in use. Although a sign was in situ, we saw staff enter and leave the room when it was switched on, and the door was unlocked and unmonitored. The sign remained illuminated even when the theatre was not in use. This meant staff did not always ensure laser treatment was carried out in a controlled area that was clearly defined.
- Laser equipment servicing records indicated three services between April 2016 and December 2017. The manufacturer's documentation noted this equipment should be serviced every three months. We asked the surgical services manager about this who said this had been changed to every six months by the provider, which had been approved by the manufacturer. The equipment records were in line with Medicines and Healthcare products Regulatory Agency Surgery (MHRA) guidance in relation to laser safety.
- The use and storage of sharps bins met the requirements of the European Council Directive 2010/32/EU in relation to labelling and location.
- Waste bins were fit for purspose in a clinical environment. For example, they had non-touch pedal operation and closed tops.
- Staff consistently documented temperature checks on the medicines fridge, water temperature and emergency medicines. We saw staff had documented these checks on each day the clinic was open for surgical procedures.
- Staff documented all disposable equipment used during each procedure as part of their traceability records.
- Housekeeping staff completed a weekly checklist that was used to ensure good practice in keeping fire exits

and escape routes clear from clutter. The building manager had documented monthly fire alarm tests and tests of emergency lighting every seven to 10 days.

- The last fire risk assessment had been completed in September 2017; this reflected the risk for staff who worked across different areas, as they may not be familiar with the policies and procedures at this clinic. The fire risk assessment noted all staff new to the building must have training in the fire safety action plan, which included the requirement to switch off laser equipment in the event of an emergency. Three members of staff we spoke with said they were aware of the overall fire policy, but had not received specific training for this clinic. Another member of staff said they had completed fire training online, but it had never been discussed, and they did not know where the different fire exits were in this building.
- There was a system in place to sign laser room keys in and out of the storage cupboard. Only authorised staff were permitted to access keys and individuals were named in the laser register.
- Staff used disposable surgical instruments for all procedures and documented traceable equipment in patient records.
- We saw evidence that all relevant staff had read and signed Local Rules procedures in line with the MHRA guidance on lasers, intense light source systems and light-emitting diodes (LEDs) – guidance for safe use in medical, surgical, dental and aesthetic practices (September 2015). This related specifically to staff on site during our inspection dates. Staff worked across multiple sites and there was no local system of assurance in place that indicated all staff who could work at this clinic always maintained knowledge of these. After our inspection the surgical services manager told us they maintained a register of each staff member's attendance at laser safety training and had assurance that all staff were up to date.

Medicines

- On the first day of our inspection, we saw a completed prescription chart without a name or signature of the person completing it. This meant we could not verify if the prescription had been completed by an appropriately qualified member of staff.
- Staff did not use a system to ensure the correct and safe labelling of eye drops. For example, we observed a nurse attach pre-printed labels on eye-drop boxes after the procedure, but they did not check the correct labels had been attached to the correct eye drops. This was not in line with the service's risk matrix, which stated drug label checks must take place prior to each administration.
- During our later unannounced inspection, the surgeon signed and dated a prescription for eye drops and the nurse checked this before dispensing the drops. In each case, the nurse explained how to use the drops to the patient and provided a printed information sheet. This process meant medicines were sometimes given without supervision from a clinician.
- We observed staff dispose of cytotoxic eye drops in appropriate hazardous waste bins, which complied with the Control of Substances Hazardous to Health Regulations (2002). Cytotoxic medicines are chemicals that are toxic and must be handled using specific safety processes. Medicines storage processes included safe, secure storage for cytotoxic eye drops and appropriate risk assessments were in place. Staff made people aware of the risks associated with these medicines, including that Mitomycin C was a medicine used off-label from it's licensed purpose. Consent forms included details of this.
- Staff checked and documented each patient's allergies in their clinical notes and reconfirmed these on the day of the procedure.

Records

- Staff used an electronic system to document pre-assessment and eye examination information. Surgical records were completed in hard copy and then added to the electronic record by an off-site archivist. The archivist scanned notes into each patient's electronic medical record and access was restricted to authorised staff only.
- A senior person from the head office carried out a quarterly records check. We looked at the two most recent audits, from June 2017 and November 2017, which included 20 patients overall. In June 2017, eight of the 10 records audited had missing or incorrect clinical outcome data, including information from pre-operative eye scans. In one patient record, a

member of staff had documented incorrect post-operative medicine. This audit also found there was insufficient use of patient identification stickers. In November 2017, the audit found broad improvement in these areas; however, it noted in two patient records that the dates on the treatment documents were incorrect. The manager identified staff had printed the documentation before the treatment date and then updated them by hand elsewhere in the record. In all cases, the manager e-mailed staff with the audit action plan to remind them of correct procedures and in one case spoke with a member of staff directly. In one instance the manager noted they did not know the member of staff responsible for an error and so had spoken with their manager instead. There was no consistent method of ensuring staff read, understand and implemented action plans. This meant we were not assured improvements or changes made were always understood and implemented by staff.

- We looked at a sample of eight patient's records and found them to be consistently completed with signed consent and clear documentation of the procedure undertaken. Staff also documented patient's medical history, allergies, medicines and any information specific to their follow-up information.
- We observed staff completed appropriate records each time a laser was operated as well as patient pre-operative assessments.
- From looking at safety directives issued internally, we were not assured records were always safely or consistently managed. For example, we found instances of incorrect documentation or incomplete documentation of a procedure. Although staff were required to read such memos, there was no structured system in place to ensure changes were always made.
- Clinicians provided a summary of each patient's care and treatment to their GP if they gave consent.

Assessing and responding to patient risk

- Staff used the Royal College of Ophthalmologists Standards for Laser Refractive Surgery, the National Institute for Health and Care Excellence (NICE) guidance and the General Medical Council guidance for doctors who use cosmetic interventions when assessing patients to be suitable for surgery.
- A modified World Health Organisation (WHO) surgical safety checklist had recently been implemented. We did not find staff consistently used this. For example, on the first day of our inspection, we saw staff had completed the WHO checklists on paper but had not verbalised it in the treatment room. This meant the checklist procedure did not enhance or ensure surgical safety because staff did not use it appropriately. During the second day of our inspection, we saw the surgical team fully verbalise the checklist for both procedures we observed. We spoke with three members of staff about this. Two individuals said they always used the WHO checklist. One individual said although the checklist had been introduced they felt it was only a paper-based exercise and said it was not embedded into standards.
- Systems were in place to identify risks to patients before procedures. Staff adhered to these although incidents and complaints indicated a need for more in-depth pre-treatment checks to more fully identify risks.
- An optometrist carried out a pre-operative assessment a minimum of one-week before a procedure took place in line with National Institute for Health and Care Excellence (NICE) best practice guidance IPG164 and the Interventional Procedures Advisory Committee. This included an eye test and retinal examination to ensure a surgical procedure was likely to be safe.
- The provider had a policy in place that meant procedures could take place without a registered nurse in the theatre room. Although this had never occurred in this clinic, a risk assessment was in place to ensure a suitably qualified scrub assistant could assist to ensure procedures could continue safely.
- Staff confirmed with patients if they had eaten prior to their procedure and that they had an escort to take them home afterwards.
- Emergency equipment was available on the premises, included stocks of emergency medicines, such as adrenaline, as well as oxygen, a biohazard spill kit and a first aid kit.
- The surgical services manager documented checks of medicine stocks against MHRA alerts. There had been no alerts that required action in 2017.

Refractive eye surgery

- The regional surgery team participated in a patient simulated collapse exercise on a quarterly basis to ensure clinical staff were prepared to manage medical emergencies.
- From observing procedures, there was not always a clearly defined laser safety supervisor in place. We spoke with a surgical team about this who said they all knew what to do, and so did not need to identify a laser safety supervisor. There was always a trained member of staff in the treatment room but the lack of structure presented a risk.
- Patients had access to a 24-hour medical hotline for advice and urgent assistance after their treatment.
- In the event of serious complications, clinical staff arranged for patients to be transferred to another of the provider's clinics or to an NHS emergency department.

Nursing and medical staffing

- Two ophthalmological surgeons and a registered nurse were based at the clinic. All other staff, including additional surgeons and nurses, were 'pooled' within a London-wide mobile team. Both surgeons held the Royal College of Ophthalmology certificate in laser refractive surgery.
- Staffing was planned in line with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres, and the skill mix in line with MHRA guidance on laser safety. Where there was a registered nurse present the service met these best practice standards. There was not always a laser protection advisor or supervisor on site,although telephone access was always available. The service's laser protection advisor worked for another organisation and was available by telephone. The laser protection supervisor was a surgery manager within the provider's London team who was not there whilst laser procedures took place during our inspection.
- The location had two members of permanent staff, which included one registered nurse and one laser technician. The London regional team staffed this clinic, which included two surgery managers, two registered nurses and eight surgery associates. Most staff worked according to a mobile working policy, which meant they were assigned to different locations depending on planned procedures.
- Surgeons worked for other healthcare providers as well as Optical Express Limited, and provided services here based on demand and according to individual contracts. If staff needed support or consultation with another medical consultant during treatment, they contacted another of the provider's clinics or the nearest NHS hospital.
- A team of five surgeons provided care and treatment in London and the national clinical lead was responsible for this team.

Major incident awareness and training

- A back-up power supply was in place in the event the laser failed during a procedure. We saw evidence this was tested frequently. This related solely to the power of the equipment and could not prevent the technical failures that had occurred.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- The service planned clinical policies in line with the Royal College of Ophthalmologists Standards for Laser Refractive Surgery and the National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery (IPG164). Policies were readily available to staff, although some individuals told us they rarely referred to them.
- The service was a member of a refractive eye surgery standards working group as a strategy to benchmark practice. In addition, the provider had selected some laser technicians to work with the laser manufacturer to become senior refractive trainers. These staff members carried out laser competency assessments and supported technicians in clinical practice.
- The surgeon verbally counted down from 40 seconds for each use of cytotoxic eye drops and from 20 seconds for the beginning of each laser procedure, which was in line with national guidance.

- Staff used national guidance from the Royal College of Ophthalmology to assess patients' needs and plan their care and treatment. The surgical services manager monitored compliance with this through patient records audits.
- The provider had introduced the World Health Organisation (WHO) surgical safety checklist for surgical procedures. This was a new initiative and had not yet been audited.
- The laser protection advisor carried out a site visit every three years and re-issued local rules or revalidated the existing rules.
- Each surgeon carried out a series of seven audits as part of their annual appraisal process to benchmark performance and patient outcomes against the rest of the provider. This included for attempted versus achieved outcomes for specific procedures and efficacy and safety scores. In addition the team carried out a monthly laser safety audit to maintain practices against national standards.
- In 2016 the provider carried out an audit of clinical outcomes nationally to benchmark practice with similar services in the NHS.

Pain relief

- Staff administered anaesthetic eye drops for pain relief prior to each procedure and asked patients to tell them if they felt any pain.
- Staff ensured each patient understood their post-operative instructions before they left the clinic, which included advice to take oral over-the-counter pain relief if needed.
- As part of the aftercare programme patients had access to a 24-hour clinical helpline, which included advice on pain management.

Patient outcomes

- As part of the appraisal process, surgeons compared their outcomes with refractive error norms in line with National Institute of Health and Care Excellent (NICE) guidance on photorefractive laser surgery. This was part of the provider's clinical analysis standards.
- Surgeons ensured patients understood post-operative care instructions such as restrictions on driving, how to use eye drops, and who to contact with further questions. We saw staff paid attention to detail, such as in asking patients if they cooked, and warning them that fumes, steam or smoke could affect their recovery and the success of the procedure.
- As part of the pre-operative assessment, surgeons discussed the improvement in vision patients could expect after their procedure. Staff told us they defined 'success' based on what the patient hoped surgery would achieve and whether they were happy with the results. During our observations, surgeons offered the chance of success as a percentage to each patient based on their pre-operative assessment.
- The provider had a full time biostatistician (based in the USA) who collected data from patient electronic files to correlate the surgeons' annual outcomes. Each year, the surgeon was presented with their clinical outcomes, which were discussed and evaluated as part of the surgeon's appraisal process.
- In the 12 months leading to our inspection, the service reported two instances of infection within five weeks of a procedure, and three cases of diffuse lamellar keratitis (DLK), which is an inflammation of the cornea. The risk of DLK was noted on the service risk matrix, which identified a clean environment and moderation of temperature as key control factors.
- The provider monitored how patient's felt about their clinical outcome after the procedure through the patient experience questionnaire (PEQ). In 2017 1859 patients completed this and results were similar to the national average for the provider. Patients scored the clinic 8.2 out of 10 for overall satisfsaction with their vision post-treatment.

Competent staff

- The service checked and recorded a continuing professional registration check of surgeons with the General Medical Council on a monthly basis.
- The medical director and clinical services director carried out the induction for each new surgeon, who completed three phases of training before they could work unsupervised. Clinical applications specialists from the laser manufacturer's training team carried out competency training with surgeons, which included supervised practice.

- The provider developed staff into dual or multiple roles where they were able to demonstrate appropriate skill, competency and ability. For example, laser technicians and nurses were able to train to cover roles for both laser correction services and intra-ocular lens services. Extended roles included responsibilities in up to eight areas, such as post-operative recovery and training roles.
- A clinical supervisor maintained oversight of surgeons, and an external surgeon or physician carried out appraisals.
- Every three years, the laser protection advisor carried out core of knowledge training with all staff who were trained to operate the laser.
- There was a system in place to ensure all staff received appropriate training and competency checks before they were able to practice. Although this was documented by the surgical services manager not all of the staff we spoke with understood the training process. For example, one member of staff said they had not had any formal training to assist in the treatment room, and instead had "learnt on the job."
- The medicines policy and risk matrix noted that only qualified, competency-assessed staff were able to administer or dispense drops. However, we spoke with one member of staff who said they had not undertaken competency training, and were able to dispense drops from watching colleagues do this.
- The surgical services manager told us new staff undertook two days of induction, which included mandatory training, followed by task-based competency training related to their individual role. In addition, they told us staff were supernumerary until they had successfully completed their training. Staff we spoke with said this was not adhered to consistently. However, a personnel file audit in November 2017 indicated all staff had completed an induction.
- Staff were required to undergo an annual appraisal. A personnel file audit in May 2017 found two surgeons had no appraisal on file. A repeat of this audit in November 2017 found one surgeon had undergone an appraisal in December 2016 and the other surgeon in December 2015. The surgical services manager explained this audit reflected local record-keeping rather than actual appraisal completion dates and that they held evidence each surgeon completed an appraisal in December annually.
- Staff told us they were not always offered regular supervision through the year following their annual appraisal. After our inspection the surgical services manager told us monthly team meetings provided a similar function to regular supervisions.
- A personnel file audit in November 2017 indicated one registered nurse did not have professional references on file. The audit indicated the human resources department were investigating this and the individual had a clear Disclosure and Barris Service (DBS) check in place.
- The laser technician or nurse carried out the World Health Organisation surgical safety checklist prior to each procedure. When the nurse was unavailable, the laser technicians were asked to cover this role in theatre. One individual we spoke with said they did not feel competent to do this.

Multidisciplinary working

- Optometrists carried out a pre-screening assessment for each patient that included a discussion of the procedure and potential complications.
- Where patients experienced complications after a procedure, staff referred them to the most appropriate specialist service. For example, when one patient developed an infection, the surgeon reviewed them and referred them to a specialist eye clinic. We saw evidence the service liaised with the specialist eye clinic and maintained contact with the patient as part of continuing aftercare.

Access to information

- Staff used an electronic clinical records system that could be accessed from any branch. This meant patients could move between clinics without the need to repeat tests or scans.
- Electronic tests and eye scans were held on the provider's centralised system. This meant records were available to all surgeons providing services.
- All staff had access to patient details such as allergies and medical history.

- Records generated by clinicians were available to staff or other providers if necessary, and care summaries or discharge information was communicated to GPs.

- Staff had access to all policies and standard operating procedures through the online system.

Consent and Mental Capacity Act

- Staff documented patient's consent in their clinical records in line with the provider's consent policy, which had been updated in September 2017. However, the consent policy did not reflect the GMC October 2016 update that patients must be offered a seven day cooling off period between the initial and final consent meetings. Two surgeons told us patients were sometimes given a cooling-off period of 48 hours if they requested it and the surgeon had no concerns. This did not meet the minimum of seven days recommended by the Royal College of Ophthalmologists.

- The refractive optometrist documented patient consent during the initial consultation, which was followed by a consent appointment with the operating surgeon prior to the day of the procedure. On the day of the procedure, the surgeon documented final consent on the electronic system in a 'day of surgery consent declaration' document. However, we found inconsistent practice in the documentation of this. For example, during the first day of our inspection, the consent confirmation process was verbal and this was not documented at the time; instead the surgeon noted this retrospectively. On the second day of our inspection, we saw staff documented confirmation of each patient's consent at the time this was given.

- Staff told us they did not receive training in the Mental Capacity Act (2005) (MCA) and relied on their understanding of each patient to decide if they had the mental capacity needed to make their own decisions. After our inspection the surgical services manager provided additional detail. They told us the provider requires that only the operating surgeon is responsible for assessing mental capacity and that surgeons follow GMC guidance on mental capacity and ethical practice. In addition all staff receive MCA training as part of the duty of care module. All staff who worked in this clinic had completed duty of care training. We were not able to establish why all staff could not demonstrate knowledge of the MCA.

Are refractive eye surgery services caring?

Compassionate care

- During all of our observations staff spoke to patients and their escorts with kindness and compassion. This included reassurance where patients experienced anxiety or nervousness.

- We observed four surgical procedures. We saw staff helped to keep patients calm and comfortable throughout and answered questions readily when asked.

- The service carried out a monthly patient experience questionnaire (PEQ) to measure how patients felt about their experience. In 2017 906 patients completed a survey in relation to their care and welfare. In all eight measures the clinic performed similarly to, or better than, the national average for the provider. For example, the clinic scored a maximum score of 10 for surgeons making patients feel comfortable and at ease. Patients scored the clinic 9.8 out of 10 for the warmth and friendliness of surgeons. The clinic's overall recommendation score was 9.4 out of 10, which was similar to the national provider average of 9.8.

- During the pre-surgical process staff took the time to ask patients about any specific personal, cultural or social needs they had in relation to their treatment.

Understanding and involvement of patients and those close to them

- In the 2017 PEQ results, patients rated the clinic 9.2 out of 10 regarding how surgeons answered their questions and 9.9 out of 10 for the explanation provided for their after-care regime. Both results demonstrated a high standard of practice and were in line with the provider's national results.

- We saw all patients were supported to understand treatment options, including risks, benefits and

potential consequences, as per NICE quality standard 15, statement 5 and Royal College of Ophthalmologists professional standards for refractive surgery. However, from looking at complaints it was not always evident patients fully understood this information before undergoing a procedure.

- During our observations, we saw staff involved patients in discussions about planned procedures, such as explaining how the laser worked. In each case, staff asked the patient and their escort if they had any questions; where people had doubt, they confidently gave as much information as they could to help people make an informed choice.
- There were separate procedures in place for consent for clinical procedures and discussions about treatment cost. This meant staff discussed consent and provided information within their professional knowledge and skills and meant there was no conflict of interest between clinical and finance information.

Emotional support

- Throughout all of the procedures, we observed staff reassured patients before, during and afterward their procedure. This included gentle encouragement during the laser procedure to remain calm and still, and reassurance while they were recovering in the darkened recovery room.
- During the preassessment process, staff explained that surgical procedures could only be carried out if the patient brought someone with them to escort them home afterwards. This was also a strategy to ensure the patient remained calm and had emotional support before and after the procedure.
- We saw staff facilitated a relaxed and friendly environment in the waiting area and recovery area and made themselves readily available to answer questions.

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

Service planning and delivery to meet the needs of local people

- Patients accessed the service by making an appointment on the provider's website or by telephone. The clinic did not provide NHS services.
- Other Optical Express clinics were able to carry out procedures, which increased the flexibility of the service.
- The service ensured patients had an appointment with the refractive surgeon prior to the day of surgery, and a refractive surgeon was available to examine the patient at the first post-operative appointment.
- We reviewed a sample of complaints and found that patients often found it difficult to obtain post-operative appointments due to the lack of substantive staff based at this clinic. Although the provider responded to these and provided follow-up appointments it was not evident access was improved as a result of the feedback.
- Surgical procedures took place in facilities specifically equipped for this purpose. However, there was a lack of environment oversight during our inspection. For example, some parts of the building that patients used for pre-assessments were so cold we saw they had to wear coats and scarves while being assessed. Access to the clinic was by two steep flights of stairs. Although a platform lift was available, this was not signposted and on the clinic floor was partially obstructed by furniture.
- All procedures were carried out in line with Royal College of Ophthalmology professional standards. This meant if another surgeon than the individual planned carried out a patient's procedure, they used the same standards.

Access and flow

- Most staff worked according to a mobile contract as part of a strategy to ensure smaller clinics remained viable. This meant the service could be responsive to demand and offer patients appointments that suited them.
- There was no waiting list for procedures at the time of our inspection, and the service demonstrated flexibility to meet patient's needs with regards to appointment times.

- The surgery manager on the day contacted patients who did not attend a booked appointment and helped them to reschedule.

Meeting people's individual needs

- The service was in the process of establishing a new contract with an interpreting service, which would enable patients to receive language support at all stages of their treatment.
- Posters advertising services and care information were provided in different languages. The provider had asked local managers to identify the most common languages spoken in the local population, and to provide posters based on this information. The posters advised patients that leaflets about treatment could be provided in languages other than English on request.
- The service had dedicated facilities for initial screening and counselling, pre-operative assessments, retinal scans, and for pre-discharge recovery.
- Staff demonstrated variable responsiveness to individual needs. For example, when one patient disclosed an allergy immediately prior to their procedure, staff conducted a thorough check of the environment and ensured appropriate medicines was kept next to the operating table before beginning the procedure. However, in another instance, a patient fainted and vomited during a procedure. Staff maintained checks on the patient, and a registered nurse supervised them but the surgeon continued with the procedure. There was no documented evidence of a risk assessment for this patient following their initial reaction.
- Patients received a statement that included the terms and conditions of service being provided and amount and method of payment of fees.
- The service did not treat patients with complex medical or mental health needs. Patients with such needs were identified during the pre-assessment procedure and staff referred them to their GP or an appropriate walk-in eye centre.

Learning from complaints and concerns

- There was a formal complaints policy in place. This was readily available in the clinic and on the provider's website. Patients also received this information in printed form with their aftercare pack. A dedicated customer services manager was in post at the provider's head office and supported local surgery managers in investigating and resolving complaints.
- Complaints were handled confidentially and a senior member of staff from the provider ensured patients were kept up to date following receipt.
- Between July 2016 and September 2017, the service received 13 formal complaints. Five of these related to patient outcomes, and two each related to pre-operative advice, quality of vision, customer service and terms and conditions. We saw evidence the service investigated complaints, and in some cases changed practice as a result. For example, as a result of a patient being declined for surgery on the scheduled day, the service increased the clinical checks completed during the consent process to ensure each patient was suitable.
- From July 2016 to September 2017, 38% of complaints related to patient dissatisfaction with their visual outcome. However, staff had noted in patient records the likelihood of success as well as risks; we observed staff offer detailed, realistic and accurate information to patients during pre-operative discussions. In addition, where patients were unhappy with the outcome of their procedure, the service offered an enhancement procedure if this was appropriate, as well as a contact lens trial.
- However, learning from complaints to improve processes was inconsistent. For example, in March 2017, one patient complained when they had been discharged from the clinic with expired eye drops. The surgical services manager found surgeons routinely kept eye drops on their desks and outside of the medicines control system. This also identified an ineffective stock control system, which we saw remained during our inspection. The outcome of the complaint recommended surgeons improve their handling of eye drops, but there was no formal check in place to ensure this had occurred.

Refractive eye surgery

Are refractive eye surgery services well-led?

Leadership and culture of service

- The location did not have a registered manager in post, but a manager from another location had submitted an application to CQC shortly before the inspection. After our inspection they withdrew this application, and the provider told us they were recruiting a new manager. We were unable to speak with the interim manager in post at the time of our inspection.
- All of the staff we spoke with said the national surgical services manager would be their first point of contact and referral for concerns or issues in the clinic. This manager worked nationally across the organisation's clinics and there was not a structured, well-defined process at the location.
- The general manager of the provider's retail store that shared the same building had overall responsibility for the premises and environment, although staff were not aware of how to contact them.
- Staff described the working culture variably, and some said they only received support if they could find a manager to contact. One member of staff said, "It can be a lonely place to work. You're often not sure who you'll be working with or who is in charge." Another member of staff did not know what the organisation's governance structure was or who to contact with problems in the senior team.
- Staff did not know who to contact in the organisation for help in relation to sickness or human resources-related matters. One member of staff said, "HR can only be contacted by e-mail not by phone. I've tried e-mailing them twice when I felt overwhelmed by work and I needed help but no-one contacted me"
- There was limited evidence the culture facilitated a strong safety ethos or environment of learning. For example, in July 2017, the surgical services manager identified staff entered incorrect information in a patient's discharge prescription records, accompanied by a note to explain another medicine had been given. In addition, the provider had introduced a sticker for staff to add to consent forms to make the date of a procedure clear. However, this was not included in the policy, and the surgical services manager told us individual staff were able to choose if they wanted to use this or not.

Vision and strategy

- The senior team told us their vision was to focus on innovative technology and stay up to date with the latest developments in laser technology. They said this was clearly defined by the organisation.
- Staff we spoke with did not know about the service vision and strategy and said they did not feel a part of a defined future plan.
- The provider had an international focus on developing new technologies and clinical processes for laser eye treatment and regularly presented their work and findings in global forums.

Governance, risk management and quality measurement

- The surgical services department provided a link between surgery managers and surgery teams to facilitate auditing and training.
- The international medical advisory board maintained oversight of the organisation, as well as trends and changes in demand and technology.
- Digital images taken as part of pre-assessment were encrypted onto an electronic storage device and then deleted following surgery. Patient scans were saved in the memory of the laser machine with restricted access. Although this meant digital information was secure, storage of paper records was not always appropriate. For example, on our unannounced inspection we saw a box of patient records on the floor of the office. The records were not secured and included details of consent, pre-operative checks and other medical information.
- The provider was a member of the British Safety Council, which meant they had access to guidance and training for risks associated with health and safety. A director was responsible for health and safety, and a group safety officer carried out quarterly safety audits.
- An up-to-date risk matrix was in place, which staff used to identify risks to the service according to

likelihood and severity. Although each risk had control measures in place, it was not always evident the clinic was compliant with these. For example, to mitigate the risk of diffuse lamellar keratitis, a type of infection, the risk matrix required the clinic to be clean and kept at a moderate temperature.

- There were a series of 19 risk assessments in place for the service. All were originally dated August 2013 with the requirement of an annual review. The risk assessments were very basic and reviews did not indicate how the service managed risks and clinical governance. For example, the same member of staff had signed annual updates from 2013 to 2017 and noted that there had been no injuries or accidents, and that control measures were "adequate." The risk assessments did not identify the tools staff used to assess and mitigate risk. In addition, there was a consistent lack of up to date information. For example, the medicines risk assessment noted that a daily stock control book was in place for medicines. It did not state who was responsible for this, and during our inspection we saw evidence of poor stock control. This reflected our findings during the inspection. Afterwards the surgical services manager told us there were 22 practice risk assessments, which had all been reviewed in July 2017. In addition they told us in the absence of evidence relating to safety issues or incidents, risk assessment processes or criteria would not normally be updated.
- The surgical services manager, clinical governance manager and medical director held a monthly conference call as part of the clinical governance system. There was a standing agenda to include incidents and complaints and other issues affecting quality assurance and performance.
- Surgeons were required to hold professional indemnity insurance, which the provider checked monthly.

Public and staff engagement

- The surgical services team shared learning with staff nationally to ensure evidence of good practice was made available to everyone.
- Surgeons met with the Independent Medical Advisory Board (IMAB) annually to discuss changes in practice and policies. Although members of the IMAB contributed, the nature of this group meant many members attended remotely through video conferencing.
- Staff had monthly team meetings and the chief executive provided a weekly newsletter. We saw that minutes included details of discussions regarding policy updates, quality measures such as audit outcomes and complaints and internal corporate changes. However, some staff we spoke with could not remember any recent discussions in staff meetings and said they did not think minutes were produced for these. Staff said it was more usual for the senior team to communicate through memos than for them to receive structured feedback.

Innovation improvement and sustainability

- There was limited evidence the service was sustainable with the staffing model in place. Three members of staff told us they were often exhausted and felt overstretched at work.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that surgical safety checklists are used for every procedure and used in line with World Health Organisation guidance.
- The provider must ensure the clinical environment is clean and free from dust.
- The provider must ensure all staff involved in care and treatment are appropriately trained and their competency checked and recorded.

Action the provider SHOULD take to improve

- The provider should ensure that risk assessments are thoroughly reviewed and action plans put in place to drive forward safety and service improvement.
- The provider should ensure all staff demonstrate a detailed understanding of their responsibilities in relation to safeguarding.
- The provider should review staff training requirements and completion.
- The consent policy should reflect Royal college of Ophthalmologists 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The use of the World Health Organisation surgical safety checklist was not consistently embedded in practice. Care and treatment must be provided in a safe way for service users. The registered person must ensure that the safety processes and safeguards used for treatment ensure each patient's safety.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Staff assisting in the treatment or laser room did not always have the necessary competency checks or training. Sufficient numbers of suitably qualified, competent skilled and experienced persons must be deployed.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment Clinical areas were not always in a suitable condition or clean. The provider must ensure cleaning and infection control procedures are fit for purpose and that clinical areas are free from dirt and dust.

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA 2008 (Regulated Activities) Regulations 2010 Respecting and involving people who use services **The provider must ensure governance systems and processes are robust, consistent and demonstrably lead to improvements in the service. Evidence must be available this information is accessed by staff before they carry out clinical duties.**