London Centre for Refractive Surgery (Ultralase Harley Street)

Quality Report

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

Ratings

Overall summary

London Centre for Refractive Surgery is operated by Ultralase Eye Clinics Limited. The service is for day cases only. Facilities include an operating treatment room, for treatment of refractive eye conditions, an assessment room, recovery room and patient preparation room.

The service provides lens surgery only, which includes refractive lens exchange and implantable contact lenses. The clinic is situated on the ground floor of a multi-occupied building in London Harley Street. No NHS funded treatment is completed at this clinic.

We inspected this service using our comprehensive inspection methodology. We carried out this announced inspection on 15 November and 29 November 2017.

Summary of findings

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 areas of good practice:

- Incidents were investigated to assist learning and improve care. Patients were treated in visibly clean and suitably maintained environment and their care was supported with the right equipment.
- The staffing levels and skills mixed were sufficient to meet patient demand and staff assessed and responded to patient risk.
- All staff had completed their mandatory training and had received an appraisal. Care and treatment was provided by competently trained staff that formed part of a multidisciplinary team.
- Patient records gave detailed information of the patient's pathway of care and were kept safe.
- Medicines were stored safely and given to patients in a timely manner.
- Staff kept patients well informed throughout the pathway, ensuring their understanding and consenting patients verbally and with written consent.
- Patients were positive about the care and treatment they had received. We observed staff treating patients with compassion and kindness. Staff always respected patient privacy and dignity.
- There was a positive culture where staff were comfortable in raising concerns and issues, staff felt the local leadership team were approachable and supportive.
- The service demonstrated they took immediate action to improve the quality of their service.
- 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.
- Staff feedback in the form of engagement surveys were not happening.

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

Amanda Stanford

Interim Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

Contents

Summary of this inspection

Background to London Centre for Refractive Surgery (Ultralase Harley Street)

London Centre for Refractive Surgery is operated by Ultralase Eye Clinic Limited. The clinic opened in 1991. It is a private service in London. The service provides refractive eye surgery for patients over the age of 18 years. The service primarily serves the communities of inner and outer London. It also accepts patient referrals from outside this area.

The current registered manager has been in post since November 2016.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,and an assistant CQC inspector. The inspection team was overseen by Nick Mulholland, Head of Hospital Inspection.

Information about London Centre for Refractive Surgery (Ultralase Harley Street)

The service is situated in central London and 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 two types of lens surgery, refractive lens exchange, this is where the natural lens is removed and replaced with an artificial lens and implantable contact lenses, where the lens in positioned in front of the natural lens. The clinic provides the service Monday to Saturday, dependant on patient demand.

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 include a registered nurse, two technicians, and senior managers; and they form part of regional team covering London and the southeast area. Optometrists and surgeons had practising privileges to work at the clinic.

During the inspection, we visited the treatment room, pre and post-operative rooms, discharge room, dirty utilities and the patient waiting area. We spoke with eight staff including; registered nurses, ophthalmologists and senior managers. We spoke with four patients. During our inspection, we reviewed four sets of patient records.

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 has been inspected once in July 2014, which found that the service was meeting all standards of quality and safety it was inspected against.

Activity (September 2016 to August 2017)

- In the reporting period, there were 623 inpatient and day case episodes of care recorded at the clinic. Of these, 556 were refractive lens exchange and 67 were implantable contact lens treatments.

Track record on safety

- There were no Never events
- There were no clinical incidents
- There were no incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

Summary of this inspection

- There were no incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- There were no incidences of hospital acquired Clostridium difficile (c.diff)
- There were no incidences of hospital acquired E-Coli
- The service had received five complaints

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Grounds Maintenance
- Laundry
- Interpreting services
- 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, where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Staff had a good understanding of the processes to follow in the reporting of incidents and the different types of incidents to report.
- The service acted upon Medicines and Healthcare products Regulatory Agency (MHRA) safety alerts.
- Staff had completed mandatory safety training.
- Good infection control procedures were followed by staff and the environment appeared clean and tidy.
- Equipment was plentiful and well maintained.
- Staff had received training on duty of candour and this was included as part of their mandatory training.

Are services effective?

We found the following areas of good practice

- Care and treatment was delivered in line with legislation, standards and evidence based guidance.
- Advertising and marketing was appropriate at the location.
- There was a regular audit and actions were taken to make improvements.
- There was suitable trained and competent staff that worked well as part of a multidisciplinary team.
- Staff consistently sought both verbal and written consent from patients.

Are services caring?

We found the following areas of good practice

- Feedback from patients was consistently positive about the care and treatment they had received.
- We observed staff always treating people with kindness, dignity, respect, and compassion.
- Staff kept patients informed about their care and treatment and ensured their understanding.
- Staff recognised when people needed additional support and provided reassurance to patients.

Summary of this inspection

Are services responsive?

We found the following areas of good practice

- 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 at the clinic were dealt with quickly and taken seriously.

However:

- Patient information leaflets were not available in different languages apart from English.

Are services well-led?

We found the following areas of good practice

- There was effective teamwork and good leadership, which created a positive culture.
- There were clear organisational structures, roles, and responsibilities.
- There were good governance and quality systems and processes that staff understood.
- There was a good system for collecting and listening to patient feedback. This enabled the service to benchmark against other clinics throughout the organisation.

However:

- A top risk of the clinic, identified by most staff, was not listed on the risk register. However, the risk had been identified by the organisation and plans were in place to tackle the risk.
- Staff engagement in the form of staff surveys did not take place, which meant the organisation could not monitor their services from the staffs perspective.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- Staff we spoke with understood the importance of reporting incidents and were able to describe the systems used within the organisation.
- Staff reported incidents using an electronic reporting and near miss form on the services intranet. This was sent to the compliance team who handled incidents from all locations. This meant they had oversight from across all clinics and could identify themes and trends. The compliance team reported to the clinic in the form of e-mail and a monthly report was sent to the registered manager.
- The service had not reported any never events or serious incidents in the twelve months prior to our inspection. 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 chief operating officer was responsible for the investigation and reporting of any serious incident.
- There were 11 minor incidents reported in the past twelve months. The incidents ranged from small technical faults to minor clinical incidents. We saw examples of incidents, the investigatory process followed and actions taken as a result. For example, one minor clinical incident related to a patient being referred to another healthcare provider as an extra precaution after a minor complication occurred during surgery. After the incident, the patient returned to the clinic to have their second eye treated and this resulted in the patient gaining positive clinical outcomes in both eyes. We saw from the investigatory processes that the patient's safety was not compromised and the whole journey of patient's treatment proved to be successful in terms of outcome.
- Feedback on incidents and actions taken were discussed in monthly staff meetings. Due to the small size of the service, most feedback was given on a face-to-face basis.
- The central compliance team had oversight of Medicines and Healthcare products Regulatory Agency (MHRA) alerts and these were forwarded to the services location when required. There had been several alerts in the past twelve months prior to our inspection and these were kept in a folder and communicated to staff throughout the clinic.
- The compliance team fed incident reports, trends and themes on a monthly spreadsheet to the senior management team and feedback and shared learning was discussed in the monthly compliance conference calls, which the registered manager attended.
- The registered manager told us if any urgent incident information needed to be communicated this was done in the pre-theatre briefing, which was used as another avenue to communicate to staff.
- 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 evidence staff had received DoC training as part of their mandatory training and staff was able to describe a good understanding of the process.
- Although there had been no serious incidents reported within the last twelve months, we were told of occasions the clinic would use the principles of DoC when things went wrong. For example, an incident occurred when patient treatment had to be abandoned because the

incorrect lens had been ordered. The patient was provided with a verbal apology and the clinic was open and honest to the patient on what went wrong. This was followed with a letter to the patient. This was recorded as an incident and actions taken as a result showed a more robust checking system was put in place to ensure the correct lens for patient treatments were routinely checked a few days prior to their appointment. This meant any problems could be rectified.

Mandatory training

- Mandatory safety training was renewed annually and included the following topics, data protection, health and safety, manual handling, infection control and prevention (IPC), safeguarding, duty of candour, fire safety awareness, medicines management and equality and diversity.
- Even though lasers were not used within the clinic, two staff members had completed laser core of knowledge training. All staff completed an online training package annually.
- We viewed records, which showed the manager had oversight of all staffs mandatory training, which included dates when courses were completed and a colour coded system to show outstanding training. Red indicated out of date training and orange showed training was due within one month.
- From the staff training matrix we saw there were two staff members who had orange codes against the health and safety topics. The manager was able to verify the booked date's staff were due to complete this training.
- Records reviewed reflected that all staff members were trained and up to date with Basic Life Support (BLS). One staff member had completed training to Intermediate Life Support (ILS) level. This meant the service was able to intervene and provide the necessary skills for those patients who required life support. The service did not provide surgery under sedation and anaesthesia, which would warrant Advance Life Support (ALS) training.

Safeguarding

- Safeguarding was part of mandatory training. All staff were trained to level two safeguarding procedures for both children and adults. The registered manager was trained to level three 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.
- The clinic did not treat patients under the age of 18 years old, and, therefore, staff had minimum contact with young people at the clinic. However, staff were trained in safeguarding for children's, as children could attend the waiting area with their relatives.
- Staff we spoke with had an understanding of safeguarding. Any safeguarding concerns would be reported to the registered manager, who escalated these to the necessary local borough safeguarding teams. There were contact numbers of the relevant external organisations to contact at the clinic.
- The manager confirmed that there had never been a safeguarding concern in the service and there had been no reported safeguarding issues logged with CQC.

Cleanliness, infection control, and hygiene

- The clinic had an Infection Prevention and Control (IPC) policy ratified in August 2017, which provided staff with the IPC processes they should follow to minimise the risk of infection. Staff completed IPC training as part of the organisation induction training package and completed IPC mandatory training on an annual basis. All staff at the clinic had completed IPC training. The registered manager was the IPC lead for the clinic.
- We reviewed the most recent infection control audit and an overall score of 96% was achieved. The audit covered areas such as, environment, waste disposal, personal protective equipment (PPE), care of equipment, decontamination, hand hygiene, clinical practice, and sharps handling.
- The audit identified areas the service needed to take action to reduce risk of infection. For example, the audit identified the wooden flooring throughout the clinic was dusty. As a result, the registered manager took action, escalated the concerns, and as a result the clinic, contracted a new external cleaning company. We saw there were robust arrangements in place to monitor the external company, through regular meetings and a feedback book where staff were able to make daily comments if they found concerns.
- An external company provided a 'deep clean' of the theatre twice a year. We saw the certificate to show this had taken place in July 2017.
- Staff completed a theatre checklist on treatment days. Checks were made at the start of the day to verify the scrub sink, patient trolley bins and mops were all in

place, clean and ready for use. We saw records were kept to ensure the necessary daily checks had been completed and these had been dated and signed by staff.

- We observed staff adhere to the IPC policy during our inspection. Staff wore a clean uniform of scrub suits, closed toe shoes and their hair was tied back. During patient treatment, staff wore theatre caps, masks, and overall aprons.
- Staff were bare below the elbow, which enabled good hand washing techniques and reduced the risk of cross infection, as long sleeves can interfere with this process.
- We observed members of staff wash their hands in accordance with the World Health Organisation (WHO), 'five moments of hand hygiene'. There was hand-sanitising gel 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'.
- There were posters above all sinks to remind and inform staff of information on hand washing techniques.
- All sinks had elbow operated taps, which was in line with the Health Building Note 00-09 'infection control in the built environment.' The sluice room was clean and emergency eye wash was available for staff throughout the clinic.
- 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 to dispose of used instruments such as syringes, needles, and glass ampules.
- The majority of instruments were single use and disposable. The small amount of equipment that was multi use was decontaminated and sterilised by a recognised local company.
- The clinic underwent an annual legionella water test and we saw the certificate to show the test had been completed by a specialist external company. Legionella is a water borne bacteria that can be harmful to people's health. The water tests for legionnaire's disease, complied with the Control of Substances Hazardous to Health Regulations 2002: Section 3(2) of the Health and Safety at Work Act 1974. Water temperature checks were completed on a weekly basis and we saw records to show these checks had been completed.
- During the last twelve months, there had been not been any incidents of Meticillin-resistant Staphylococcus aureus (MRSA) or Meticillin-sensitive Staphylococcus aureus (MSSA) and there were no Clostridium difficile (C.diff) or E.coli infections.

Environment and equipment

- The clinic and theatre areas were visibly clean and well maintained. The service was positioned on the ground floor of a multi-purpose building that housed another health service. The public entered the building through the front door which was security locked. Access was gained by speaking to the front of house staff member through an intercom system.
- The building was listed which meant limited adjustments could be made without thorough consultation beforehand. Space was limited in terms of the layout of the clinic. The clinic manager's office, staff room, stock room, and changing facilities for staff were contained within one large room and appeared cramped. However, the space had been divided into sections and managed to provide clear segregated areas for use. We were told there were plans in place to re-design the area within the clinic.
- Although the treatment room was small, the space was sufficient for staff to provide safe treatment for patients. The treatment room had been adapted and updated. For example, all flooring was easily cleanable and in accordance with Health Building Note (HTM) 00-10 part A: Flooring.
- The layout and environment of the service allowed for good patient access and flow and defined areas were zoned and clearly marked. For example, there were clean and dirty zones and separate clean and sluice/ dirty rooms. This meant clean and dirty equipment was kept separated.
- Patients were seen in a consultation room where diagnostic tests could be taken. Treatment was undertaken in the treatment room and patients were taken into a separate recovery room. All rooms allowed private conversations to take place.
- The treatment room consisted of a treatment bed and microscopic equipment used during procedures. There

was a separate clean room, which contained clean equipment and storage for medicines, and a separate sluice room. These rooms were well organised, and appeared clean, and tidy.
- Ophthalmic diagnostic equipment that was not in use, had appropriate coverings to keep the equipment clean and dust free.
- Emergency equipment was available. We saw evidence of regular checks to ensure all equipment was in date, and ready for use, such as, oxygen, defibrillator, epi-pens and first aid equipment.
- We saw evidence that appropriate safety checks had been completed and recorded by staff members on a variety of equipment, such as emergency call bells, room temperature checks within the theatre and within drug cupboards that contained medicines.
- The registered manager kept a robust system of equipment maintenance records, and we saw certificates of maintenance checks had been completed recently for electrical appliance testing, blood pressure monitors, ophthalmic equipment, air condition unit, and emergency lighting.
- Waste in all clinical areas was separated and in different coloured bags, to identify the different categories of waste. All waste was kept in bulk storage bins on the clinic premises and collected by a specialist waste company on a weekly basis.

Medicines

- The medicines policy clearly described obtaining; prescribing, recording, handling, storage and security, dispensing, safe administration and disposal of the medicines held at the clinic.
- The resident registered nurse was responsible for the management of medicines at the clinic. The clinic held no controlled drugs and the surgeon prescribed and dispensed all medicines.
- The registered nurse ordered the medicines for the clinic, according to patient activity. We reviewed the clinics drug order stock book and the medicines we checked were in date and reconciled with the records. Medicines were stored neatly in locked cupboards in the clean room within the treatment room. The registered nurse held the keys for the medicine cupboards.
- We found medicines were stored securely and those requiring cold storage were stored in a fridge and the temperature was monitored and recorded. We saw evidence of the log checks made for the previous three months.
- Used and expired medicines were disposed of in appropriate specialist sharps bins, and collected by a specialist company. We saw evidence of drug disposal forms that were in use. The form contained information on the name of the medicine disposed, the batch number, the signature of the staff member disposing of the medicines, and a witness signature.
- The surgeon prescribed all medicines to patients following treatment. We observed the surgeon hand the medicines to the patient and provide instructions on their use and storage. There were prescription labels attached to each medicines package.
- All patient records we reviewed, held information on the patients current medicines, any allergies and a medical history, to ensure medicines prescribed by the surgeon were safe to be given.
- We observed the registered nurse provide discharge information to a patient. The information given by the surgeon was reaffirmed by the nurse and the patient was provided with opportunities to ask questions.
- The clinic held some emergency medicines, such as adrenaline for anaphylaxis, which had been checked for expiry dates and were in date. These medicines were secured in a container, labelled clearly, and readily accessible with resuscitation equipment.
- We checked all the oxygen cylinders and found they contained safe levels of oxygen and were stored safely.
- There were quarterly drug stock audits completed at the clinic. We saw the audits for March, June, and September 2017. Checks were completed on medicine expiry dates, batch numbers, and stock levels. The audits showed high compliance and no concerns were highlighted.
- The clinic did not use cytotoxic drugs.

Records

- Records were both electronic and paper based. Paper based records were used by the surgeon and members of staff on the patient's treatment day. Paper notes were scanned into the electronic system and this held a comprehensive record of the patient's entire pathway of

care within the clinic. Patient information on the electronic system could be accessed by other clinics, which meant patient treatment appointments could be tailored to meet their needs.

- Records contained patient details, including assessments undertaken and medicines given. We found detailed information was recorded on the patients file. Signed consent forms were included in all records.
- We reviewed four patient records and found all the records to be complete and contained the relevant information, such as, eye prescriptions, health assessment questionnaires, diagnostic results, pre-treatment questionnaire, signed consent, pre-operative records, day care pathway records, World Health Organisation (WHO) Five steps to safer surgery checklist, and comprehensive notes from the surgeon and other medical practitioners. All patient records were clear, concise and of a standard format.
- After treatment, patients were provided with a letter detailing the treatment and medicines prescribed. The letter could be sent to the patients GP with their consent.
- At the time of inspection, we saw patient personal information and medical records were managed safely and securely. During clinics, all medical records were kept in a locked office and transferred to the consultant when the patient arrived.
- Quarterly record audits were completed and the recent audit showed a high compliance was met with no concerns. The registered manager told us if any audits highlighted concerns this would be fed back to the relevant staff member and discussed in the monthly team meetings.

Assessing and responding to patient risk

- Patients were assessed for the suitability for treatment at the clinic prior to treatment. The patient completed a detailed pre-treatment form on their first visit. Checks were completed on the patients' medical history and eye tests were performed to assess the patient's suitability.
- We observed two consultations where patients were assessed prior to proceeding with treatment. The risks of the treatment were explained clearly and health checks and eye diagnostic tests were completed.
- After the first consultation, the patient was provided with information on the treatment, the risks associated, and likely outcomes. This information allowed the patient to make an informed decision. Patients were told they would need to see the surgeon who would make the final decision and discuss everything again and review examination results.
- The patient was then booked to see the operating surgeon, who took further diagnostic tests and assessed the patients suitability and the consent form was signed. The operating surgeon took the final decision regarding whether the patient was able to have treatment.
- Records we reviewed confirmed all patients had been seen by the operating surgeon prior to the treatment day for assessment checks. We viewed four 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.
- On the day of treatment, a day case pathway record was completed. This pathway provided detailed information of the patient's medical history, and sections for each staff member, involved in the different stages of the patient's journey to complete their relevant sections. For example, there were sections the preparation nurse completed such as patient observations, which included blood pressure, pulse, and oxygen saturation levels. Other details included sections on warfarin, anti-coagulants, and diabetes.
- The pathway included a patient handover to theatre, where the patient's identity was checked and verified on the patient's wristband, allergies present, eye drops administered, and confirmation from the patient of treatment.
- During treatment, the patient's observations such as blood pressure and their oxygen saturation monitored during surgery and further observational checks were made post- treatment. The pathway included sections for checking a GP letter was printed for the patient and whether an escort was present and follow up appointments confirmed. Staff told us the pathway record was an excellent tool in reconfirming and prompting all the necessary steps to take through the patient's pathway of care.
- At the start of the day, staff conducted a pre-theatre briefing. We observed a meeting, where all staff from the

clinic were present including the operating surgeon. The patient list was discussed in terms of treatments, any concerns, allergies; reaffirmation that the patient's correct lenses were present and staff identified their role in the surgical pathway. The meeting gave the opportunity for all staff to raise any concerns and reaffirm their understanding of the treatment day.

- At the pre-operative review, the surgeon marked the patient's eye that was due to be treated and the patient was asked to confirm what eye was to be treated and to point to the eye as well.
- Staff used an adapted version of World Health Organisation (WHO) Surgery Safety Checklist and Five Steps to Safer Surgery, which is used to minimise errors during treatment, by carrying out a number of safety checks before during and after each patient procedure. We observed staff using the WHO safety checklist correctly. A white board was used during the treatment with the patients name, procedure, lens details, and any allergies. The day case pathway included sections staff were required to complete to show the WHO checklist had been completed. We reviewed previous patient records and were able to verify that the WHO checklist had been completed correctly.
- The service did not audit the WHO checklist to ensure staff were correctly completing the lists. However, on our return inspection, the registered manager had implemented an audit checklist and this was now used throughout the organisation. This showed the service had been proactive and took action to improve the quality of their service. We saw staff had checked 10 sets of patient's notes and found all WHO checklists had been completed correctly. We were told this audit would be conducted on a quarterly basis.
- Post-operative patients were assessed in the recovery room by a registered nurse. They were provided with written instructions for aftercare and follow up appointments. We observed a registered nurse provide aftercare instruction to a patient. The discussions were informative, clear and provided useful information for after care. The surgeon visited the patient post-operatively and prescribed medication for the patient to take home dependant on their treatment. They gave instructions for use and storage. The surgeon remained on site until the last patient left the clinic on the day of treatment.
- Patients were provided with an emergency card with contact details for their surgeon, so that they could contact them directly if they had any concerns. During clinic opening times patients were made aware they could contact the clinic directly for advice.

Nursing and medical staffing

- There were three ophthalmologists and four optometrists who had practising privileges at the clinic. The granting of practising privileges is a process within independent healthcare, where a medical practitioner is granted permission to work in an independent hospital or clinic. The surgeons had the appropriate qualifications and certification for their role, such as certificate in laser and refractive eye surgery. Medical staff were registered with the General Medical Council (GMC) and were fellows of the Royal College of Ophthalmologists (RCO).All of the optometrists were registered with the General Optical Council (GOC).
- There were two registered nurses and three patient advisors who worked within the organisation. Nursing staff arrangements were dependant on when the clinic opened and this was dependant on patient demand. They worked flexibly to meet the needs of the service. The clinic also used a bank nurse who had previously been employed by the service and was experienced in the surgical procedures.
- The registered manager reviewed rosters to ensure suitably trained staff with the appropriate skills mix covered all clinic days. Surgeons worked with the organisations diary team and were able to provide dates they were available, at least three months in advance. This enabled the clinic manager to provide rosters to staff in advance of their duties.
- Most staff were trained in various competencies, which meant they were able to perform different roles within the clinic and this provided flexibility for the service. For example, the registered nurse was trained in pre-assessment, post-operatively and was able to work in the treatment room.

Major incident awareness and training

- The clinic had an emergency lighting system and uninterrupted power supply, which was installed in the treatment room. This gave enough supply of power to

allow the surgeon to complete treatment. The system was checked at the start of the day and we saw an annual maintenance report to verify the system was serviced and in good working condition.
- Fire escapes were clearly marked and easy to access. There were plentiful fire extinguishers throughout the clinic and we saw records to verify they had been checked by an external company and were in good working order.
- A six monthly fire drill was conducted by staff and we saw evidence the last drill was successfully completed in July 2017.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance. Policies and guidelines we reviewed by the medical advisory board (MAB) and included relevant best practice guidance such as National Institute for Health and Care Excellence (NICE) and The Royal College of Ophthalmologist (2017 RcOph guidance) .
- We saw evidence that nationally recognised guidelines were discussed in the MAB meetings. The minutes of the meeting on May 2016 showed that there had been discussion about the Royal College of Ophthalmology guidelines - Professional Standards for Refractive Surgery 2017.
- 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. The surgeon discussed with the patient any potential limitations of the treatment as well as the potential benefits. We noted from records we reviewed the minimum of one week (usually two) was given for them to reflect on their decision to go ahead with the procedure. Patients we spoke with said they were given every opportunity to change their mind if they wished and did not feel they had been coerced into proceeding with treatment.
- Regular audits took place for topics such as, infection control, incidents, complaints, 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 annual IPC audit raised concerns with the standard of cleaning undertaken by an external company. As a result, a new external cleaning provider was contracted and a robust monitoring of their work is now completed.
- 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.

Pain relief

- Patients undergoing treatment at the clinic were treated under local anaesthesia. Patients were conscious during treatment and were able to tell us they had not felt any pain.
- Staff did not use a pain assessment tool but frequently asked patients if they were comfortable and in any pain throughout their treatment journey.
- Patients were prescribed anaesthetic eye drops post treatment. We saw staff made sure patients were provided with verbal and written instructions. The written instructions gave information on what to do for symptoms requiring immediate attention and they included severe, prolonged, unrelenting eye pain in and around the eye.
- The day case pathway record showed post operatively patients were asked if they were comfortable with an acceptable level of pain recorded on the record.

Patient outcomes

- The surgeon's outcomes were monitored every six months for effectiveness and used as part of their appraisal. Treatment outcomes were measured in terms of patient satisfaction and success rate. We reviewed one surgeon's clinical outcomes. Compiled data showed the total number of cases completed within the six months. The post op success rate for the surgeon was 94% against a national average of 84%. There had been no surgical complications as in posterior capsular rapture, no never events or medical – legal complaints.
- The data collected enabled the service to monitor the demographics of their patient in terms of patient age, gender, treatment type, and procedure type.
- 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. We saw the patient satisfaction for the surgeon gave results of 35% of patients thought it was good, 20% excellent, 35% worthwhile, and 10% not worthwhile.

- We were told each surgeon outcomes were assessed at corporate level, where any necessary changes to effect and safety were reviewed, and recommendations were made and discussed at the national Medical Advisory Board (MAB).

Competent staff

- Staff records we reviewed demonstrated staff had the correct skills and competencies to carry out the duties required of them. Surgeons held the Royal College of Ophthalmology (RCO) certificate and surgeons who worked within the clinic also worked for NHS acute hospitals.
- We reviewed the personal file of the surgeon working during our inspection. It contained the following: RCOG certificate, Disclosure and Barring Service (DBS) police checks, practising privileges letter, indemnity insurance, General Medical Council (GMC) registration, revalidation and appraisal history from the NHS hospital, references, curriculum vitae (CV) training certificates and evidence of continual professional development.
- We reviewed personal files of the registered nurse and bank nurse. We saw the files contained CV, DBS checks, references, contract of employment, Nursing and Midwifery Council (NMC) registration, immunisation history, induction programme and evidence of mandatory training certification and competency assessments such as pre-assessment and pre-operative training.
- We saw from staff records, annual appraisals had been completed and the development needs of the staff member were taken into account. Revalidation checks were included as part of the appraisal process. Staff told us of additional courses they had attended and other training they had received such as meeting another specialist surgeon from another healthcare provider who was able to provide specialist support and information on refractive eye surgery.
- A three day induction training session was held at the organisations training centre. This occurred one month after the new staff member had started, so they could become acclimatised with the organisations, before completing the comprehensive training. The three day course covered laser and lens treatments. Staff shadowed a senior member of the team as part of their induction and did not work independently until they had successfully passed core competency assessments.
- Staff told us there was always a member of staff who was immediate life support (ILS) trained on duty and all other staff had successfully completed basic life support (BLS) training. As a single specialty service that did not use sedation or anaesthesia, the risk to patients was low.

Multidisciplinary working

- We observed the medical team working well together in the treatment room. The nurse anticipated instruments to pass to the surgeon and another nurse observed the patient and co-ordinated the treatment plan. Each staff member was calm, professional and treated each other with respect.
- We saw records to show regular team meetings took place at the clinic, which demonstrated collaborative team working and shared learning.
- There was a pre-theatre team briefing at the start of the day. The meeting was led by the surgeon and information on each patient was discussed. Staff from across the clinic were actively involved in the meetings discussions.
- Due to the small size of the service, staff knew each other well, and we observed a friendly and professional atmosphere, where each staff member was open and honest with each other.
- Communication with the patient's GP was encouraged with the patients consent. GPs were able to access the service through the out of hour's telephone number.

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 patients, consent information on the patient's treatment could be sent to their GP, via the services electronic system. The GP could access the patient's surgeon via the contact details provided on discharge.

- Throughout the clinic there was information displayed, such as fire regulation guidelines and infection control procedures such as 'the five moments of handwashing'.
- Patient records could be accessed by other clinics, which meant a consistent flow of patient information for the patient's treatment pathway, if they were seen at another clinic.

Consent and Mental Capacity Act

- At the initial patient consultation, the patient was explained the risks and benefits associated with the treatment. We observed consultation appointments where the patient was provided with the essential information to allow them to make an informed decision. The patient completed a pre-treatment questionnaire, which gave a list of questions, which enabled the patient to state true or false as to whether they understood and was provided with the correct information in relation to their treatment.
- If the patient wanted to proceed with treatment, they then had an appointment with the consulting surgeon who would perform the treatment. The surgeon would reiterate the risks and benefits of the procedure and take further diagnostic tests. The consultant surgeon had the final responsibility to assess the patient's capacity to consent and whether the patient was suitable for treatment. A consent form was then signed by the patient.
- The organisations consent policy was ratified in July 2017 and gave clear guidelines for consent procedures. There were consent forms tailored for each different treatment. The consent policy stated a minimum 'cooling off' period of one week between the surgeon's assessment and treatment, which was in line with national recommendations. All records we reviewed showed patients were given a sufficient 'cooling off' period before they went ahead with treatment.
- We were told by the service and interpreter would be provided to those patients who did not speak English. Leaflets and information provided by the clinic were not provided in other languages apart from English.
- All staff we spoke with were able to demonstrate an understanding of the Mental Capacity Act 2005 (MCA) and Deprivation of Liberty Safeguards. Staff were able to describe and give examples when patients may lack capacity to make their own decisions and how this was managed. If a patient lacked the capacity to make an informed decision, they would not be treated at the clinic. Treatment was on an elective basis and therefore patients were required to be fully compliant during the procedure.

Are refractive eye surgery services caring?

Compassionate care

- Staff treated patients with kindness, dignity, and respect. Staff interacted with patients in a positive, professional, and informative manner. We observed medical staff collecting patients from the waiting room, shaking hands and introducing themselves prior to consultation.
- We spoke to three patients pre and post procedure who said, "The staff here are kind, professional, friendly and made them feel relaxed." They commented on feeling comfortable throughout the procedure and the nurse checked regularly they were not in pain. Both patients could not think of any way the service could be improved, as it had been a very positive experience.
- Patient consultations took place in private rooms, which allowed the patient to speak confidentially.
- Patient feedback was captured by the service. We saw for the results of a patient survey from January 2016 to December 2016, the clinic scored 96% for overall patient satisfaction. Patients were asked 20 questions designed to establish the level of satisfaction the patient experienced from first contact to the results of the treatment received. Questions such as, "How would you describe the results of the treatment?", "How well did the clinic staff help you through the consultation?", "How would you describe the aftercare?", and "How well did staff prepare you for any discomfort experienced during and/or after treatment." However, the survey did not indicate how many patients had supplied feedback. The results were benchmarked against other clinics to see if any reoccurring themes could be identified.

Understanding and involvement of patients and those close to them

- Staff introduced themselves by name to the patient and relatives.

- We spoke to a patient who described the initial consultation, investigation and was then told the treatment options. The patient was encouraged to go home and to think before making a decision about treatment. This was in line with best practice allowing the patient time to consider all options.
- We observed patient consultations, where the patient was provided detailed information on the treatment options, the benefits of the procedure and the risks associated with treatment. A pre-questionnaire form was completed by the patient. The form allowed the patient to acknowledge and ensure they understood the information supplied during the initial consultation.
- We observed different patients through the different stages of treatment. At all times staff explained the procedure and gave the patient time to ask questions and reaffirm their understanding of what was happening. Staff were clear, did not use technical words, and made the patients feel relaxed and comfortable.
- The patient was encouraged to bring someone with them on the pre-assessment and treatment day, to support them when they travelled home.

Emotional support

- Throughout our inspection, we saw staff built a rapport with patients, which made them feel comfortable and at ease. We saw a patient who was slightly nervous, being provided with support and kindness by the staff. They made the patient feel relaxed and the patient confirmed the support of the staff made them feel less anxious.
- After the procedure, staff asked the patients if they were in any discomfort. There was no rush to discharge patients. Patients did not leave until they were clinically fit, but also until they were comfortable to leave.

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

Service planning and delivery to meet the needs of local people

- Patients could access the service either through self-referral, word of mouth or through an internet search or in response to marketing.
- For those patients requiring laser surgery that could not be accommodated at the clinic, they were seen at another clinic within the organisation. Patients were provided options to choose where they would receive pre and post-surgery support.
- Information we reviewed before the inspection, showed the service opened Monday to Saturday from 8am to 6pm, dependant on patient demand. Ad-hoc Sundays were available, again dependant on patient demand.
- Appointments were made through the organisations central line and we were told there were short waiting times to be seen at the clinic. A central diary team worked with the surgeons and optometrists to plan diaries up to three months in advance which allowed the clinic manager to arrange staffing levels, plan rotas and arrange cover if required in advance.
- Three 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 without a GP or optician's reference. The service was able to utilise nearby clinics, which meant patients had more flexible appointment times to suit their needs.
- The service did not monitor waiting times, but had systems in place to ensure patients were not delayed. The clinic booked two patients per hour to ensure there was no overcrowding and to avoid patients being rushed. At the time of our inspection, there were no patients on a waiting list for treatment at the clinic.
- Patients were informed before treatment that the treatment could take up to two to three hours for the whole journey. Staff members told us they did not feel pressurised to take or accommodate extra patients.
- The registered manager told us cancellations would usually be made at least three weeks before, and the patient would be immediately informed and an alternative date would have already been made. There had been no cancelled procedures in the last twelve months due to non-clinical reasons.
- During our inspection, we saw patients were not kept long or faced lengthy delays. Follow up appointments could be arranged at other clinics at the patient's convenience.

- In the past 12 months, the clinic had two unplanned re-treatments or treatment enhancements. We saw details of the treatments and the outcomes for the patients, which were positive.
- In the last twelve months, there had been seven occasions of unplanned return of a patient to theatre following treatment. We reviewed the occasions and found they were due to lens repositioning and lens rotation. All occasions showed continued monitoring and improvements of the patient procedure.

Meeting people's individual needs

- The waiting area was spacious and hot and cold drinks were provided while patients waited for their appointments. Hot and cold drinks were available to patient relatives, carers or friends who escorted them
- The building was restricted and did not meet the Equality Act, as there was no wheelchair access. However, this information was made clearly available to patients at their initial contact with the service. Alternative clinics with wheelchair access were provided. The building was listed and, therefore, could not be adapted to accommodate wheelchair access.
- There was a range of patient information available throughout the clinic. However all patient leaflets and documents were not provided in other languages apart from English.
- Patients were provided with information on aftercare and emergency contact numbers if they felt the need to contact the service with any concerns.
- Surgical treatment parameters were bespoke for each patient according to their refractive error and the level of correction required. For example, some patients chose to have laser treatment and have mono vision to enable them to see both and near and far. Those patients booked into a neighbouring clinic for laser treatment and lens surgery patients had the choice to have multifocal lens implanted as opposed to a monofocal lens.
- Patients were given information about surgeons who worked for the clinic and were able to choose a surgeon of their choice, dependent on their availability.

Learning from complaints and concerns

- There was a complaints policy, which provided guidelines on how patient's complaints were handled. There was a designated complaints department within the organisation.
- If a patient complained in writing, this was handled by the complaints department and the clinic manager would receive a monthly report. The clinic manager would have to include any relevant comments if the complaint related to their clinic.
- We reviewed five complaints made at the clinic from September 2016 to September 2017. The nature of the complaints ranged from the type of treatments to costs. Each complaint had the outcome listed and actions taken to rectify concerns if they had been made.
- We saw the investigatory processed taken in dealing with a complaint and saw an interim letter was sent to the patient to informed them that their complaint was being dealt with and they would receive a full response to their complaint with 20 working days from the date of the letter. We saw an example of the full response to a complaint made and saw the patient was provided with an apology, an explanation, and resolution in an attempt to satisfy the patient. The letter showed an open, transparent, and honest approach to apologise to the patient when things went wrong.
- There were notices displayed throughout the clinic on how patients could raise a complaint.

Are refractive eye surgery services well-led?

Leadership and culture of service

- Locally the service was led by the registered manager. They received support from the compliance manager and the director of operations at corporate level.
- There were clear leadership and governance systems in place at the clinic. The registered manager had the skills and knowledge to lead the service in effectively and professionally. They had ensured staff were supported with good supportive governance and quality monitoring systems.
- Staff we spoke with talked positively about the registered manager. They said they were supportive, approachable and managed their concerns. Staff knew their reporting responsibilities and the role they played at the clinic. Staff said they felt valued.

- The compliance manager visited twice per year and the registered manager said they had a good working relationship and were able to raise and escalate concerns quickly.
- We found information available was honest, responsible, and complied with guidance from the Committee of Advertising. Patients received a statement that included terms, and conditions of the service being provided, the cost, and method of payment for the refractive eye surgery.

Vision and strategy

- We reviewed the services statement of purpose, which said the aims and objectives of the company were to provide eye surgery under the safest conditions possible.
- The strategic vision and direction was led at a corporate level. The registered manager felt they were able to input their ideas and suggestions via the monthly clinical teleconference call.

Governance, risk management and quality measurement

- There were systems in place both corporately and locally, that made sure effective, and safe decisions were made regarding patients care. Centrally there were specific teams who managed complaints, looked at changes in guidelines, policies and processes and governance of optometrists. Locally the policies and processes in place provided guidelines and a framework from which the staff could work.
- Most medical practitioners were working under practising privileges at the service. The Medical Advisory Board (MAB) had oversight and ensured staff maintained their skills before they started. We viewed meeting minutes from several MAB meetings and saw incidents, patient's expectations, clinical parameters, complaints were discussed, and actions set in place.
- A monthly compliance teleconference took place led by the director of operations and joined by the compliance manager, registered managers across the country, the lens surgery lead, and the diary team. Corporate and clinic level issues were discussed including risks, incidents, and complaints. We saw from the meeting in September 2017 a new verbal complaints log had been devised to help capture verbal complaints to identify trends.
- The service showed they acted upon concerns. We saw from the meeting in September 2017 that discussion took place around a new medicines dispensing policy the service was devising in reply to concerns raised at a previous inspection at another location.
- Risks were identified, monitored, and managed. The clinic had a risk register that was reviewed on a quarterly basis. We saw risks were rated in accordance to the severity, the mitigating actions taken, and the review date on the monitoring of the risk. There was a staff member allocated to owning and taking charge of the risk.
- As a single speciality service, the risk to patients was low. Staff were able to corroborate what risks were included on the risk register. The top risks to the clinic were personal injury to staff when cleaning, prevention of contamination in the treatment room and weekly water testing to prevent the risk of legionella. We saw mitigating actions and the monitoring and review date of each risk. For example, for the risk of personal injury when cleaning, staff were instructed to place a warning hazardous sign to show the area was being cleaned.
- When a risk was identified, the registered manager raised the risk and the compliance manager gave approval. However, during the inspection, the lack of space within the clinic was listed as an issue by most staff, yet this was not listed on the clinics risk register.

Public and staff engagement

- Ultralase operated a touch screen system completed by patients at each aftercare to the point of discharge. This enabled the company to evaluate individual clinic and overall company performance of patient satisfaction throughout the patient journey. The company was able to analyse satisfaction results on a day-by-day basis if required to ensure that if any untoward issues appeared they could be investigated and addressed promptly.
- From January 2016 to December 2016, 149 patients participated in the survey and the overall satisfaction result was 96%. Approximately 52% of patients though the service was excellent, 37% good. The clinic scored 0.4% for both very poor and not worthwhile.
- There had been no staff survey undertaken within the 12 months prior to our inspection. However, there were regular team meetings where staff were able to raise concerns and staff we spoke with said they felt comfortable to do so.

- There were staff forums and regular news letters were sent to staff which provided the latest information on the service.
- There was a nurse conference held annually, so all registered nurses across the organisation could met and share experiences.
- Staff told us they had regular appraisals and they felt they were useful with regard to raising concerns and personal development. Staff gave us examples of training courses they had been able to attend for their own development and of instances where they had been encouraged to apply for promotions within the organisation.

Innovation improvement and sustainability

- The clinic manager responded positively to learning and ensuring the quality of the service improved. For example during the inspection we asked the service if they audited the WHO checklist to make sure staff were correctly completing this, and they told us they did not. On our return inspection, the registered manager had devised a WHO audit programme and we were told this had been implemented across the organisation. We saw a WHO audit had already been completed they were able to present the results to us.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

Action the provider SHOULD take to improve

- The provider should make sure patient information leaflets are supplied in other languages apart from English.
- The provider should make sure all risks associated to the clinic are listed on their local risk register.
- The provider should consider the use of a formal staff engagement surveys.