

London Vision Clinic

Quality Report

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

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

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

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

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

Overall summary

London Vision Clinic is operated by London Vision Clinic Partners Limited. The clinic has no overnight beds as the service only offers day case procedures. The clinic is set up over four floors, with lift access to each floor. Facilities include two operating theatres (one for laser surgery and the other for cataract surgery), 10 consultation rooms, four testing rooms and one medication room. There were two relaxation rooms as well as two separate reception areas.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on the 12th December 2017, along with an unannounced visit to the clinic on the 18th 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.

The main service provided by this hospital was Refractive Eye Surgery. We regulate refractive eye surgery but we do

Summary of findings

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:

- A maintenance schedule was in place to ensure all equipment at the clinic was maintained and serviced.
- Theatre lists and clinics were planned in advance and there were enough staff with the right skills to ensure patients received safe care.
- Without exception, patients told us they were treated with kindness and compassion by all staff. Patients spoke positively about the customer service and the care they had received.
- The clinic had a dedicated research team, who monitored patient outcomes and we saw patients received good outcomes following refractive surgery at the clinic.
- The clinic had bespoke electronic medical record software which allowed staff to document all stages of the patient's journeys. Records we reviewed all contained the necessary assessments and documentation.
- All staff were aware of the process of reporting incidents and we saw that clinic managers investigated all incidents and provided feedback to staff.
- Staff followed safe systems for the management of medicines including the use of cytotoxic medicines.
- All staff we spoke with were very complimentary of the leadership of the service and told us that the management team were very visible and approachable; they felt 'like a family.'
- Surgeons at the clinic were highly skilled and had also been involved in developing laser equipment along manufacturers.

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

- The consent policy did not reflect the Royal College of Ophthalmologist's standards 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon
- The clinic did not have a safeguarding adult policy and at the time of the inspection. Staff had not received training on safeguarding adults, although training was booked for April 2018.
- Hot water temperature recording in both operating rooms were below the recommended temperature, which was not in line with HTM 04-01 Safe water in healthcare premises.
- Although the senior management team were aware of some the risks within their service, these risks were not formally recorded on a risk register.
- The clinic did not have a Medical Advisory Committee in place to provide oversight of the quality and safety at the clinic.
- We observed some staff did not follow best practice with regard to infection prevention and control, as their arms were not bare below the elbow.
- The clinic did not offer a translation service and patients were asked to bring their own interpreters, which meant that family members were often used to interpret.

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 a requirement notice that affected surgery. Details are at the end of the report.

Amanda Stanford

Interim Deputy Chief Inspector of Hospitals

Summary of findings

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London Vision Clinic

Services we looked at

Refractive eye surgery

Summary of this inspection

Background to London Vision Clinic

London Vision Clinic is operated by London Vision Clinic Partners Limited. The clinic opened in 2016. It is a private clinic in London providing refractive eye surgery and cataract surgery. The hospital primarily serves the communities of London and the surrounding areas and also accepts patient from outside this area and overseas

The hospital has had a registered manager in post since the opening of the clinic in 2016.

Our inspection team

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

Information about London Vision Clinic

The clinic is registered to provide the following regulated activities:

- diagnostic and screening
- surgical procedures
- treatment of disease, disorder and injury

The clinic undertakes refractive surgery (laser) on patients aged 18 and above. The clinic does not provide treatment and care for children and young people.

All patients are self-referring, through enquiries via the website or by phone and are self-funded.

During the inspection, we examined all areas of the clinic, including consultation areas and operating rooms. We spoke with 12 staff including; registered nurses, patient care co-ordinators, reception staff, medical staff, laser technician, and senior managers. We spoke with six patients. As part of our inspection, we also reviewed six sets of patient records.

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

Activity (December 2016 to November 2017)

- In the reporting period of December 2016 to November 2017, the clinic performed 3014 laser procedures and 32 cataract surgical procedures.
- All cases received topical anaesthesia. (The application of anaesthetic products to the area being operated on).
- No cases required anaesthetic blocks, intravenous sedation or general anaesthetic (GA).
- All patients were self-referred and self-funded.

Four surgeons were employed in substantive posts and one surgeon worked at the clinic under practising privileges. One ophthalmic nurse also worked under practicing privileges.

The clinic employed nine nurses, nine optometrists, two technicians, six administrators, eight clinic co-ordinators and eight patient care coordinators. There were also two members of staff employed in the research department. The accountable officer for controlled drugs (CDs) was one of the clinic managers.

Track record on safety during the reporting period of December 2016 to November 2017:

No Never events

No serious incidents

Summary of this inspection

No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

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

No incidences of hospital acquired Clostridium difficile (c.diff)

No incidences of hospital acquired E-Coli

23 complaints were received between January and November 2017, of which nine were formal written complaints.

Services accredited by a national body:

- ISO 9001:2015

Services provided at the hospital under service level agreement:

- Clinical and non-clinical waste removal
- Laser protection service
- Maintenance of medical equipment
- Surgical sterilisation service
- Cleaning services

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate refractive eye surgery, where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Patients underwent thorough assessments prior to surgery and were carefully monitored following their operation. There was access to expert advice outside of working hours.
- All staff were aware of the process of reporting incidents. We saw that clinic managers investigated all incidents and provided feedback to staff.
- Staff attended mandatory safety training and we saw completion of this was monitored by the clinic managers.
- Protocols for safe use of lasers were consistently followed by staff.
- Records were of high quality and all records we reviewed were complete.
- Staff followed safe systems for the management of medicines including the use of cytotoxic medicines.
- There was always enough staff available to meet the needs of the patients.
- We observed a good level of cleanliness and hygiene throughout the clinic.
- A maintenance schedule was in place to ensure all equipment at the clinic was maintained and serviced.

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

- We observed some staff did not follow best practice with regard to infection prevention and control, as their arms were not bare below the elbow.
- The clinic did not have a safeguarding adult policy and at the time of the inspection staff had not received training on safeguarding adults. We noted this was booked for April 2018.
- Hot water temperature recording in both operating rooms were below the recommended temperature, which was not in line with HTM 04-01 Safe water in healthcare premises.

Are services effective?

We found the following areas of good practice:

Summary of this inspection

- Patient care pathways were based on National Institute for Health and Care Excellence (NICE) and Royal College of Ophthalmologists guidelines.
- Staff received the appropriate training, and competencies were signed off prior to staff working independently.
- The clinic managers and other staff regularly undertook a wide range of audits to monitor compliance against policies and we saw actions were taken as a result of audit findings.
- Patients received good outcomes and we saw the clinic had a dedicated team to monitor outcomes data. All patient outcomes were published and patients were able to review these when choosing to have their surgery.
- However:
- Although staff were aware of Royal College standards (April 2017) for refractive eye surgery and the recommendation of a minimum cooling off period of one week, we saw evidence a large number of patients were asked to sign a waiver so their surgery could take place less than one week from gaining consent.

Are services caring?

We found the following areas of good practice:

- Staff interacting with patients in a caring, kind and compassionate way.
- Feedback from patients was very positive and patients told us staff were excellent and provided a good level of care.
- Patients told us staff kept them well-informed. They were given opportunities to ask questions about their care and relatives were encouraged to be involved.
- Information on pricing was included in the patient information leaflets and clearly explained to patients.

Are services responsive?

We found the following areas of good practice:

- Patients we spoke with told us the appointment system was easy to use and they had no problems arranging a suitable appointment.
- Theatre lists were finalised in advance and patients were asked to attend at staggered times on the day of their operation. These ensured patients were not waiting for a long period of time for their surgery.
- Patient knew how to complain, and we saw that all complaints were investigated fully within the agreed timescale.

However:

Summary of this inspection

- The clinic did not offer a translation service and patients were asked to bring their own interpreters, which meant that family members were often used to interpret.

Are services well-led?

We found the following areas of good practice:

- All staff we spoke with were very complimentary of the leadership of the service. We were told the management team were very visible and approachable; they felt 'like a family.'
- The senior management team met regularly to discuss quality and safety issues.
- The senior management team were clear of the vision and strategy, which was to continue to pioneer advancements in technology and research by sharing outcomes, and to develop the cataract surgery service.
- Risks were identified as a result of incidents reported or audits completed and were reviewed and investigated by the clinic managers.

However

- Although senior management team were aware of some the risks within their service, these risks were not formally recorded on a risk register.
- Some risk had been identified and discussed at leadership meetings but no remedial action had been taken for over a year.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- There was a system in place for reporting of incidents. Staff we spoke with during our inspection were aware of the types of situations where incident forms should be completed, including near-misses. Staff told us they would complete an incident report and forward to the clinic managers, who investigated all incidents at the clinic. The clinic managers transferred the incidents onto an electronic system during their investigation.
- Staff received individual feedback from the clinic managers, who also told us learning from incidents, were discussed at staff supervision and regular staff meetings. Staff we spoke with during the inspection confirmed this.
- Staff told us there was an excellent reporting culture and they were encouraged to highlight any potential incidents in line with the clinic's preventative action and risk assessment policy. We reviewed this policy and saw staff were encouraged to be proactive and take preventative actions through risk assessments, audits and feedback in order to avoid incidents from occurring.
- There were no never events reported during the reporting period. 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 December 2016 and November 2017, the clinic reported six clinical incidents and five non-clinical incidents. We reviewed all incidents and saw three of the clinical incidents were related to equipment issues and the other three were due to patients receiving incorrect glasses from the clinic's suppliers. We saw evidence the clinic managers had escalated the matter to the suppliers.

- We saw that one of the clinical incidents occurred when there was a fault with the laser machine and planned surgeries were not able to go ahead on the day. We reviewed the incident report and saw evidence the clinic managers and surgeon kept all patients affected fully informed throughout and rescheduled their surgery for the next day.
- Staff understood the need to be open and transparent when something goes wrong, in line with the duty of candour requirement. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- The senior nurse also told us they received National Patient Safety Alerts and alerts from the Medicines and Healthcare products Regulatory Authority. This meant they had accurate and up to date information confirming that best practice guidance was used to improve care and treatment.

Mandatory training

- The clinic managers kept a mandatory safety training matrix. They monitored this to ensure staff had completed the required training to maintain the safety of patients, visitors and themselves.
- Mandatory training modules were delivered by external contracted companies and were a mixture of face to face and online modules.
- We looked at the training matrix for each group of staff and saw evidence staff were provided with training relevant to their role. Staff received training on manual handling, basic life support, health and safety, laser safety, fire safety, infection prevention and control as well as customer service. These training were undertaken annually. We noted nursing staff were also booked to attend training on cataract surgery in

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January 2018. All staff we spoke with confirmed they attended these training sessions. We noted completion with mandatory training was 100% for the reporting period.

Safeguarding

- Staff we spoke with were aware of their responsibilities in relation to safeguarding vulnerable adults. Staff told us they did not have experience of raising a safeguarding alert but would always discuss with the clinic managers if they had any concerns. However at the time of the inspection, staff had not received training on safeguarding. The gap in training had been identified by the clinic managers and all staff had been booked to attend training in April 2018 with an external training provider.
- The clinic did not have a safeguarding adults policy in place. The clinic managers informed us the policy was due to be written following the training booked for April 2018. There was also no designated lead for safeguarding, although staff told us they would escalate to the clinic managers, if they had any concerns.
- Although the clinic did not offer services for children and young people, children were allowed to accompany adults during their consultations but not on the day of their surgery. The clinic had a child protection policy in place to guide staff on their responsibilities towards the children attending the clinic and how to escalate any concerns they may have. However staff did not receive training on child protection.

Cleanliness, infection control and hygiene

- We observed all surgical areas to be visibly clean and staff we spoke with were clear of the level of cleanliness and hygiene they expected at the clinic. The clinic had a contract with an external cleaning company and we saw evidence cleaning staff were in attendance daily, with cleaning logs fully completed.
- The cleaning contract included weekly cleaning and quarterly deep cleaning of the operating rooms. All clinical equipment was cleaned by nursing staff.
- The clinic also carried out antibacterial sampling tests of both operating rooms quarterly. We saw that recent results had showed some areas of non-conformity and the cleaning schedule had been amended to address these.

- We saw antimicrobial wipes were readily available in consultation rooms as well as operating rooms for staff to decontaminate equipment between patients.
- All ophthalmic packs used during laser procedures were single patient use and disposable. This minimised the risk of cross infection.
- Staff kept a log of temperature and humidity conditions demonstrating that these were being maintained consistently within the required range for the safe operation of laser equipment as specified by the manufacturer's guidelines. Temperature and humidity recording at the time of the procedure was also documented in the patient's electronic intra-operative records.
- There was easy access to personal protective equipment (PPE) and staff used this during their activities as required. Hand washing facilities were available throughout the clinic with hand washing posters on display.
- We observed staff decontaminating their hands prior to clinical intervention and between patients, in line with infection control policy. However, we saw some nursing staff were not bare below the elbow, and as a result could not be certain to wash their hands and wrists in accordance with best practice. Staff had wrist watches on and one nurse had a wrist watch under the gloves during a laser procedure. We highlighted this to the clinic managers on the day, who assured us this would be discussed with staff immediately.
- We observed correct segregation of waste, including clinical waste and sharp items. Sharps boxes were available in surgical areas, and the clinic had a contract with an external company for the collection and correct disposal of sharp boxes. All sharp boxes we saw had been correctly assembled, dated and not overfilled.
- Decontamination of surgical instruments used during cataract surgery was carried out by an external decontamination company through a service level agreement. Staff told us this arrangement worked well and there had been no issues since the clinic started performing cataract surgery.
- The clinic had a water maintenance and Legionellae's disease prevention policy in place. A contract was in place with an external company, which carried out six monthly performance checks and inspections of the water systems, including water temperature monitoring. We saw the hot water temperature recordings in both operating rooms were below the recommended

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temperature, which was not in line with HTM 04-01 Safe water in healthcare premises. This non-compliance was also noted in November 2016, when a Legionella risk assessment was carried out by an external contractor. No actions had been taken since the risk assessment to rectify this issue.

- The clinic carried out infection prevention and control (IPC) audits, which included hand hygiene, sharps disposal, disinfecting equipment, storage of equipment and cleaning schedules. These audits showed 100% compliance during the reporting period.
- Two of the nurses were the infection prevention leads at the clinic and attended annual external training. The nurses then cascaded the IPC training to all other staff annually. They also led on IPC audits.

Environment and equipment

- All surgical areas were observed to be tidy and well maintained; they were free from clutter and provided a visually clean environment for patients, visitors and staff to move around freely.
- Entry to the clinic was via an intercom system, which meant that access was controlled by reception staff. All visitors at the clinic were required to wear visitor badges to clearly identify them.
- We looked at clinical areas including, consultation rooms and the laser and cataract operating room. Clinical areas were observed to contain equipment that was required for examination and testing.
- There was controlled access to the laser room with adequate signage to indicate when the room was in use. This was in line with the local rules.
- We saw local rules were in place to cover the use of the laser located in the clinic. The lead laser technician, who is also the nominated laser protection supervisor at the clinic, ensured all staff read and understood the local rules as part of their induction. Staff we spoke with were aware of these local rules.
- The laser protection advisor (LPA) was an external consultant who carried out laser risk assessments and staff training on laser safety. The laser protection supervisor liaised with the LPA as required but generally the LPA only visited the clinic when new equipment are purchased. The contact details of the LPA were readily available to staff, should they require any advice.
- Records available indicated that the clinic had an ongoing maintenance schedule to check and service the equipment available, including laser and theatre

equipment. The management team told us any equipment or areas of the environment that needed to be repaired or replaced were actioned rapidly in order to maintain the safety of patients.

- A resuscitation trolley was available to staff and a security tab was present, which meant staff would be aware if the bag had been tampered with. We checked the resuscitation trolley and found all the equipment and anaphylaxis (severe allergic reaction) medication was in date. The trolley was checked every weekday and we saw signed checklists to evidence this.
- The resuscitation trolley also contained an automated external defibrillator (AED) and the Resuscitation Council (UK) poster on the use of an AED was available within the trolley. The battery of the AED was checked and replaced at regular intervals.
- We observed equipment stock in the storage areas was CE marked. This ensured that all equipment was approved and compliant with relevant safety standards.

Medicines

- The two senior nurses were the location leads for the safe and secure handling of medicines and one of the clinic managers was the Controlled Drug (CD) Accountable Officer.
- The clinic had an up to date management of medicines policy to ensure safe management and handling of medicines. We saw the policy outlined responsibilities for ordering, storing, prescribing and administration of medicines, including CD's.
- The electronic medical records contained a standard prescription of pre-operative and post-operative medication for all patients undergoing refractive eye surgery. This consisted of eye drops, non-steroidal anti-inflammatory tablets and one dose of sleeping tablets.
- The service did not use any patient group directions (PGD's) and none of the nurses were trained in non-medical prescribing. All medicines were prescribed by the surgeon and we saw evidence all prescriptions were signed by the surgeon in the records we reviewed.
- All pre-operative eye drops were administered by nurses and patients were given clear written and verbal advice to self-administer their post-operative drops. All medications patients took home were clearly labelled by the nurse.
- One of the senior nurses was responsible for maintaining medication stock and ordering as required.

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- All CD's were stored in a locked cupboard and the key to the CD cupboard was kept in a separate safe with combination lock. The nursing staff told us only surgeons and nurses had access to the CD stock. We saw evidence the nursing staff undertook CD stock checks daily.
- The service monitored fridge and room temperatures to ensure all within normal ranges, which meant that medicines were stored at the correct temperature. All temperature logs we reviewed showed that medicines were stored within the correct temperature ranges.
- The clinic did not use intravenous anaesthetics. They only used local and topical anaesthetic for surgical procedures. In some exceptional cases, the surgeon may prescribe mild sedation in the form of a sleeping tablet pre-operatively. This was usually in order to help exceptionally nervous patients to relax.
- The clinic had a small stock of Mytomycin, although staff told us this was not used on a regular basis. Mitomycin is an anti-cancer drug. Its main use is in cancer treatment as it interferes with the growth of cancer cells and slows their growth and spread in the body. Mitomycin may also be used for other purposes. Ophthalmology is not one of its licensed uses although it is used for clinical procedures including refractive eye surgery and glaucoma. We saw the mytomycin was stored in a wall mounted locked cabinet within the laser operating room. The cabinet included protective wear when handling mytomycin as well as spillage kits.
- Patients were advised of the risks associated with the use of Mytomycin during the consenting procedure with the consultant.
- There was an up to date policy as well as a risk assessment in place for the use of the cytotoxic drug, Mytomycin. Staff told us Mytomycin was prepared and administered solely by the surgeon, who also disposed of all swabs and syringes in the dedicated purple top yellow boxes.
- We looked at the records of six patients and noted all relevant stages of the patient pathway were documented clearly. We saw that staff inputted a record of laser operations for every patient, including laser machine settings, room humidity and temperature settings.
- All communication with patients was recorded on the EMR and we saw that staff were able to assign patients for review using the EMR. For example, if the patient care co-ordinator received a call from a patient, they would document the call and if the patient required a call back from a clinician, they could assign this to the clinician's to do list on the EMR. Similarly optometrist could assign specific patients they wanted the surgeons to review.
- The research manager could also pull specific data directly from the EMR, which was used for research and internal audits.
- The records held patient information indefinitely and was backed up by external servers, which meant patients could request their records any time after their treatment.
- We noted that the ophthalmologist who performed cataract surgery under practicing privileges reviewed patients post-operatively at a different clinic nearby. His clinic letter was then uploaded on the electronic records at London Vision Clinic to ensure staff at the clinic were kept fully informed.

Assessing and responding to patient risk

- Patients receiving care at the clinic were carefully screened and suitability accessed, during their pre-operative consultations, to ensure their needs could be met, and treatment was appropriate. This ensured that patient care needs were planned and delivered safely.
- We saw the electronic medical records included adapted versions of the World Health Organisation Surgical Safety Checklist for both refractive and cataract surgery. We observed staff were compliant with the overarching principles of the WHO surgical safety checklist and the National Patient Safety Agency (NPSA) 'five steps to safer surgery' guidance. All records we reviewed also included completed WHO checklist. The clinic carried out an audit of the use of the checklist. Following the audit in November 2017, the clinic took steps to remind staff of the importance of the 'team brief' and for discussions to take place with staff at clinical meetings.

Records

- The clinic had a bespoke electronic medical records (EMR) system. The EMR included templates for all stages of the patient pathway as well as medication prescription.
- Consent forms were in paper form to allow patients to sign them. Immediately after surgery, the consent forms were scanned and uploaded on the EMR.

Refractive eye surgery

- Following the surgery, patients were escorted to a recovery area by the surgeon or nurse, where they were able to lie down. Staff told us that patients did not require post-operative observations such as blood pressure monitoring. Once they felt ready and the aftercare had been discussed, patients were able to leave the clinic. Patients were not required to have an escort, unless they had been administered an oral sedative pre-operatively.
- All patients were booked a follow-up appointment with the surgeon the day after their surgery. This was booked prior to the surgery and patients were informed it was essential they attend this appointment. The clinic did not carry out surgery on Fridays.
- Patients were subsequently expected to attend follow-up appointments at three to four weeks, three months and 12 months. Patients were then discharged at the 12 months appointment, if they were satisfied with their outcomes.
- Contact numbers for the clinic, including out of hours arrangements, were on the aftercare and medication advice leaflets which staff gave to and discussed with patients. There was an ophthalmologist available at the clinic during working hours and out of hours; the clinic's phone was able to send a message to one of the ophthalmologists. They would be able to provide advice or arrange to see the patients urgently, if required. All post-operative patients were given their surgeon's mobile number as part of the discharge process.
- All patients received a follow-up phone call from a nurse the afternoon following their surgery, to ensure their recovery was going as planned.
- All staff at the clinic had received training on Basic Life Support (BLS) except for two surgeons who had undergone Immediate Life Support training. Staff informed us they would call the emergency services if a patient's condition suddenly deteriorated during their time at the clinic. There had been no incidence of unplanned transfer of care within the last 12 months.
- The clinic appointed two clinical fellows about a year ago. The fellows were directly employed by the clinic and were both ophthalmologists on the GMC specialist register. The fellows assisted the two surgeons in theatre as part of their training in refractive surgery.
- Cataract surgery, at the time of our inspection, was carried out by another ophthalmologist who held practicing privileges (where a medical practitioner is granted permission to practice) at the clinic. We reviewed the personnel file of this surgeon and saw the file contained a valid Disclosure and Barring Service (DBS) certificate, up to date appraisal and evidence of their GMC registration.
- Consultants provided cover for each other and patients were always able to get in touch with a consultant, if they had any queries or needed to see someone urgently due to post-operative complications.
- There were nine nurses directly employed by the clinic and all nurses we spoke with told us there was always enough staff available to meet the needs of the patients.
- The clinic did not use bank or agency staff and staffing was planned in advance according to clinic and surgery lists. There were no staff vacancies at the time of the inspection.
- The clinic also employed nine optometrists, who provided pre-operative and post-operative reviews for patients undergoing surgery. The clinic did not provide general optometry services.
- The clinic managers maintained a log of all each staff's professional registration and were able to remind staff when these were due for renewal.

Major incident awareness and training

- The clinic had an up to date disaster recovery policy outlining steps staff were to take in the events of normal business being interrupted, such as power cuts, interruption of phone services or IT issues. All staff we spoke with were aware of the policy, and hard copies were located in designated places in the clinic.
 - The laser machine had in-built back-up to ensure treatment was not compromised if power failed mid-treatment.
 - All staff had access to annual fire training and the team practiced the fire evacuation procedure annually.
- **Nursing and medical staffing**
 - The clinic had two full time ophthalmologists who carried out all refractive eye surgery at the clinic. One of the surgeons was the medical director and co-founder of the service. Both surgeons were on the GMC Specialist Register in Ophthalmology and were well published authors on research in refractive surgery.

Refractive eye surgery

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Patient care pathways were based on National Institute for Health and Care Excellence (NICE) and Royal College of Ophthalmologists guidelines.
- Staff were aware of the new RCO Professional Standards for Refractive Surgery guidance (April 2017) and ensured the clinic was compliant with the guideline. The medical director was involved in the development of these guidelines.
- The clinic employed a dedicated research team to assist the surgeons in continually reviewing their results and looking at ways to develop their practice to further enhance patient outcomes.
- The medical director at the clinic was heavily involved in research in refractive surgery and had published over 135 articles on refractive eye surgery in medical journals as well as being the editor of the Therapeutic Refractive Surgery section for the Journal of Refractive surgery. The surgeon also held several professorships internationally. This ensured staff at the clinic were always kept abreast of new development in refractive eye surgery.

Pain relief

- We observed local anaesthetic drops were applied pre-operatively to ensure the patient did not feel any discomfort. Patient feedback indicated they did not experience pain during their procedure and most did not require pain relief post-operatively.
- Patients were prescribed anti-inflammatory eye drops to take home; with clear instructions on its use should they feel any discomfort in their eyes.

Patient outcomes

- Staff counselled patients for the possibility of an enhancement procedure following surgery at initial consultation and evaluation as well as during the consenting process with the surgeon.
- There was no incidence of an unplanned return to theatre following refractive eye surgery in the previous 12 months.
- The percentage of patients that needed further surgery after their initial surgery was 6%, which was better than

the Royal College of Ophthalmologists standard. During the 12 months preceding our inspection, 172 patients out of a total of 2,796 patients returned for further treatment following their initial refractive eye surgery.

- The clinic did not submit data to the National Ophthalmology Database and Private Healthcare Information Network (PHIN). The research manager told us these databases did not record data for the type of refractive laser surgery the clinic performed. However the clinic was currently involved in development of a database specific to refractive eye surgery.
- The surgeons we spoke with during the inspection were proud of the outcomes they achieved at the clinic. Their aim for all procedures was to restore normal vision or better without the use of glasses or contact lenses.
- The clinic continually audited their outcomes data and published their results in peer-reviewed articles as well as on its website. Potential patients could review these when making their choice of where to have their surgery.
- We saw that following blended vision surgery, (used to correct both distant and near vision) 98% of patients were able to read normal newsprint.
- The clinic offered treatment for patients with high prescriptions and we saw that 93% of patients with myopia (short-sightedness) of -8.1 to -12.5 achieved 20/20 vision (normal) and 67% achieved better than normal vision. For prescriptions of -2.0 to -8.0, 98% achieved normal vision and over 71% achieved better than normal vision.
- All patients, irrespective of their initial prescription achieved 20/40 vision (This means the patient has to stand at 20 feet to see letters that a person with 20/20 vision could see at 40 feet), which is the UK minimum driving standard.

Competent staff

- The laser protection supervisor underwent training by the manufacturer to ensure they were knowledgeable and competent in the use of all laser machines within the clinic. They maintained a close link with the laser manufacturer and were able to contact them if there were any queries.
- The laser protection supervisor had attended the Core of Knowledge training as well as training to be

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accredited as a laser technical operator. The laser protection advisor was also approved to carry out preventative maintenance work on the laser machine, following training by the manufacturer.

- The clinic managers had recently introduced an induction checklist for all new starters. However all nurses we spoke with confirmed they had received a thorough induction at the start of their employment, despite this not being recorded on a checklist previously.
- All nurses underwent competency training prior to working independently. We saw evidence of completed competency documents during the inspection.
- New members of staff were given the opportunity to shadow various members of the multidisciplinary team (MDT) and increase their knowledge of the pre-operative testing, surgical procedure and aftercare.
- The clinic had recently started performing cataract surgery and we saw evidence the existing nurses have been undergoing training to increase their skills and knowledge in relation to cataracts. The training was being delivered by an experienced ophthalmic nurse, who was currently working at the clinic under practicing privileges, alongside the cataract surgeon. Nursing staff we spoke with told us the cataract training had been very good.
- Both surgeons perform refractive eye surgery on a daily basis and were involved in research in this field. The surgeons were on the General Medical Council specialist register and held Royal College of Ophthalmologists Certificate in Laser Eye Surgery.
- The medical director was also the lead medical consultant for a well-known laser manufacturer and had contributed to the development of new laser machines.
- All staff received yearly training on laser safety and we saw evidence the local rules for laser were read and signed by all members of staff.
- Staff received training on laser equipment via the manufacturer and the laser protection supervisor told us he was currently undergoing 'train the trainer' training so he could take up this role in the future.
- Each member of staff was allocated a personal training budget to enable them to attend any relevant courses identified during their appraisal.

- Appraisal rates were 100% for nurses and technicians and 80% for optometrists. Surgeons received appraisals from an independent medical practitioner organisation and we saw completed appraisals when we reviewed the personnel files.

Multidisciplinary working

- We saw an excellent proactive, multidisciplinary approach to co-ordinating patients' care. Administrative staff, clinic and patient care co-ordinators, surgeons, laser technicians, optometrists and nurses worked together to provide safe, patient-centred treatment.
- All staff we spoke with told us there was mutual respect between each staff group and all members of the MDT understood each other's role in ensuring the patient experienced excellent customer service as well as the expected clinical outcomes.
- The clinic had effective working relationships through service level agreements with external contractors, such as clinical waste management, to facilitate the effective running of the clinic.

Access to information

- Relevant authorised staff had access to details held on the electronic patient record. This included the whole range of records from initial consultation, test results as well as intra-operative documentation.

Consent and Mental Capacity Act

- A consent policy was in place at the clinic. The policy set out staff responsibilities for seeking and obtaining informed consent, in line with the Department of Health guidance: Reference Guide to Consent for Examination or Treatment, published in 2009.
- The policy included guidance on the Mental Capacity Act and how to apply the act in relation to gaining consent. However, we saw this policy was not up to date with the Royal College of Ophthalmologists professional standards (April 2017) for refractive eye surgery which states, "A minimum cooling off period of one week is recommended between the procedure recommendation and surgery." The policy was due for review in February 2018.
- The 'Guide to laser eye surgery booklet', which each patient was given when they first contact the clinic did refer to the Royal College standards (April 2017) for

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refractive eye surgery and the minimum cooling off period of one week. The guide states that if this is impractical for the patient, it should be discussed with the surgeon.

- Staff we spoke with were aware of the required cooling off period of one week and told us the clinic had a consent waiver form for patient to complete, should they wish to have their surgery sooner.
- We observed two consultations with the surgeons. We saw patients were given a thorough explanation of what to expect during surgery, their achievable outcomes as well as advice for the recovery period. However in both cases, the patients were asked to sign the 'cooling off period' waiver form, without any explanation from the surgeon.
- We discussed the cooling off period with the medical director, who informed us the patients receive a copy of their consent form at the first appointment with the optometrist and were asked to initial each page of the form to confirm that they had read and understood it. They then had a consultation with the surgeon and had the opportunity to ask questions and make an informed decision to proceed, prior to signing the forms with the surgeon. The surgeon explained that the patients had the 'cooling off period' between their appointment with the optometrist, where suitability for laser eye surgery was assessed and explained, and their consultation with the surgeon. However this was not in line with either the Royal College of Ophthalmologists standards or those of the General Medical Council (GMC) as the 'cooling off' period should be between the consultation with the surgeon and surgery day.
- The clinic managers told us they were auditing the number of patients who signed the cooling off period waiver form and this would be discussed at the senior management meeting. Data provided by the clinic showed 54% of patients undergoing surgery did not have the recommended one week 'cooling off' period between April and November 2017. This data and our observations of patient consultations with their surgeon during the inspection led us to conclude the 'spirit' or intent of either the Royal College's or the GMC's guidelines for the cooling off period was not being regularly observed at the clinic.

Are refractive eye surgery services caring?

Compassionate care

- Patients were greeted by staff on the reception desk and were treated with dignity and respect by all staff during their time at the clinic.
- We saw staff interacting with patients in a caring, kind and compassionate way. Patients told us staff were excellent and provided a good level of care.
- All staff at the clinic underwent training in customer service and the clinic managers told us the staff were proud to offer 'world class' customer care, which they felt set them apart from other refractive surgery services.
- We spoke to six patients during the inspection. The patients were at different stages of their treatment, some arriving for their pre-operative assessments, some on the day of surgery and others for their follow-up appointments. All six patients only had positive comments about the care and service they had received. One patient told us 'I did a lot of research before choosing this clinic and the care I received exceeded my expectation!' Another patient told us 'nothing is too much for the staff' and 'you are given clear information and are encouraged to ask questions all the time.'
- The clinic used an independent provider of reviews for healthcare and other services to gather feedback from patients about their refractive eye surgery. We saw that all reviews were consistently positive. One of the clinic managers regularly reviewed the feedback provided and responded accordingly.
- Each patient was allocated a patient care co-ordinator when they first contacted the clinic. The patient care coordinators then met the patient on their visits to the clinic as well as being a first point of contact for patients.
- During our time at the clinic, we observed several interactions between staff and patients. This ranged from first arriving at reception, pre-operative testing, and surgeon consultation to undergoing the procedure in the laser operating theatre. During all these interaction, staff were kind, respectful and treated each patient as an individual, providing explanation and reassurance when needed.

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- It was clear from our observation that customer service was important to each member of staff. Managers told us achieving 'world class' customer service was a key driver and all members of staff received customer service training from the manager of a five star hotel.
- The clinic had received 252 compliments from patient in 2017. The comments from the compliments included 'the entire process from the screening, procedure and after-care, is the most professional medical experience I have ever had and 'In comparison to other clinics I had visited in the search for something perfect, London Vision Clinic presented to me an unparalleled professionalism throughout each phase of the treatment.'

Understanding and involvement of patients and those close to them

- When patients contacted the clinic, the patient care coordinators explained the pathway and costs and each patient was sent a 'Guide to laser surgery' booklet. Patients also received a surgical information pack, which included information on the different type of lasers and the laser surgery pathway as well as the potential complications. Patients we spoke with told us the written information provided was very detailed and answered most of the questions they had.
- When patients attended for their pre-operative consultations, staff supported them to understand relevant treatment options, including risks, benefits and potential consequences. This was in line with NICE QS15 statement 5 and Royal College of Ophthalmologists professional standards for refractive surgery.
- Staff provided written information about aftercare and ensured that patients had the out of hours contact number if they had any questions or concerns following surgery.
- During the surgical procedures, we observed staff explain what was happening during each stage of the procedure and checked on the patient's welfare.
- We observed one of the surgeons explaining the surgical procedure to patients and ensured they understood the information provided, by supporting verbal information with the use of diagrams.

Emotional support

- The service allowed carers and family members to accompany patients to their appointments. Whilst in theatre, the team offered reassurance and support to the patient to keep them calm.
- Patients told us that staff took time to discuss their worries and fears about possible treatments and staff put them at ease by explaining procedures thoroughly. They told us they felt confident and reassured by the support provided by staff.
- All patients we spoke to told us that adequate time was given to consider treatments, to change their minds about surgery and discuss after care following surgery.
- Patient arriving for their surgery were taken to a relaxation room, where they were offered a neck and shoulder massage from the clinic co-ordinators to help them relax prior to surgery. Any additional questions they may have were answered by the nurses prior to administering pre-operative eye drops.
- The clinic aimed for patients to see the same members of staff during each visit. The managers told us this meant staff were able to build a relationship with each patient as well as ensuring continuity of care. During a three months follow-up appointment, we observed the optometrist knew the patient well and was able to ask specific questions about some of the issues the patients had expressed during the previous consultation.

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

Service planning and delivery to meet the needs of local people

- Refractive surgery was carried out Monday to Thursday at the clinic. This was to ensure all patients received a follow-up appointment with the surgeon the day after their procedure. If there was a special request from a patient or increased demand, then surgeries could be performed on Saturdays.
- All patients received an in-depth assessment, including the relevant scans, to ensure suitability for refractive surgery and to tailor the treatment to meet the needs of individual patients.
- All patients attended a consultation with the surgeon prior to their operation and patients always saw the same surgeon throughout, unless it was an emergency or the surgeon was away.

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- Patients attended the clinic from a wide geographical area as well as overseas. The patient care co-ordinators were able to offer advice to patient on booking accommodation for their stay in London.

Access and flow

- Patient self-referred to the clinic by making an enquiry by phone, email or via the clinic's website. Patient care coordinators then contacted patient and offered all the necessary information about the service provided and the patient pathway at the clinic. Patients then had the choice whether to book an initial consultation with the optometrist. All patients were self-funded.
- Surgery was cancelled on one day during the reporting period of December 2016 and November 2017. This was due to a fault with the laser machine, which required a new part to be ordered and fitted by an engineer. However we saw that all patients were rebooked for surgery the next day.
- Theatre lists were finalised in advance and patients were asked to attend at staggered times on the day of their operation. These ensured patients were not waiting for a long period of time for their surgery.
- There were no cases of unexpected returns to theatre or unplanned transfer to another healthcare organisation during the reporting period.
- The patient care coordinators sent reminders to patients the day before their appointments and would reschedule appointments, if patients were unable to attend. If a patient fails to attend, the patient care coordinators would contact the patient to enquire if they wanted to rebook. Currently the clinic did not collect DNA data but the clinic managers informed us that it was very rare for patients to not attend without informing the clinic.

Meeting people's individual needs

- Patients were offered a range of hot and cold beverages as well as snacks during their time at the clinic. These were readily available in the reception areas.
- Patients were asked about any mobility impairment prior to attending the clinic for their first appointment. This ensured staff could put in place a portable ramp to allow easy access up the front steps leading to the main door. A lift provided patient access to the different floors of the clinic, as required. There was a disabled toilet as

well as a consultation and testing room specifically designed for wheelchair users. The clinic did not have a hearing loop to facilitate communication with patients who wore a hearing loop.

- The clinic had a 'no manual handling policy' which meant that if patients required physical assistance, such as to transfer from a wheelchair to the operating table; they would have to bring their own carers to assist them. This was clearly explained in the patient handbook.
- The clinic had a range of patient information leaflets available, explaining the various conditions and treatments it offered, including pre and post-operative care instructions. However, all patient leaflets and documents, including consent forms, were in English.
- The clinic did not offer a translation service and patient were expected to bring in their own translators. This meant that relatives were often used to translate, including during the consenting process. This was not in line with best practice guidance.

Learning from complaints and concerns

- The clinic received 20 complaints from patients during the reporting period. We reviewed the complaints data and saw that 12 were related to customer service, three were from patients who were unhappy with their results and five were about the clinic fees.
- The clinic managers acknowledged all complaints within two days of receipt. They then carried out an investigation and provided a formal response within 10 days.
- The clinic managers were always available to speak to patients and were keen to attempt to resolve any dissatisfaction informally. If the complaint was in relation to the surgical procedure, the patients were offered an urgent review appointment with the surgeon, in the first instance.
- The complaint process was clearly explained in the patient guide and all patients we spoke with were aware of how to make a complaint.
- The clinic managers told us complaints, compliments and learning from incidents were shared at team meetings. Staff we spoke with confirmed this and also told us staff who were specifically mentioned in a compliment were congratulated during the meetings.

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Are refractive eye surgery services well-led?

Leadership and culture of service

- The senior management team consisted of the medical director, the managing director (who is also the registered manager) and the two clinic managers. The management team had the skills, knowledge, experience and integrity to lead the service.
- The management team was visible and approachable. Staff told us they felt supported in their roles and valued for the work they did. Staff were proud to work for the clinic and described their colleagues “like family”.
- Staff we met were welcoming, helpful and friendly. Many staff had worked at the hospital for a number of years, which demonstrated their job satisfaction. They told us they were happy and proud to work for the service.
- When asked what they were most proud of, staff members said, “the feedback they received from their patients, the quality of care and treatment they were able to provide, and the fact they were able to make a positive difference to patients’ quality of life through achieving good outcomes consistently.”
- The patient information leaflet explained the cost of treatment at the clinic was higher than in some of the high street chains, which meant that patients were fully informed when choosing to have their surgery at the clinic.
- We observed marketing to be honest, responsible and comply with guidance from the Committee of Advertising Practice. Patients were provided with written statements which detailed the terms and conditions of the service being provided and the amount and method of payment of fees. An interest free finance option was also available.
- The management team told us they promoted a culture of openness by speaking with staff and empowering them to suggest ideas for change.

Vision and strategy

- The mission statement for the clinic was to provide ‘personalised Laser eye surgery to world-class standards.’
- The core principles guiding the provision of services at the clinic were: to always act in accordance with our patients’ best interests; to be open and honest in all our

communications with patients; to enable our patients to make confident and informed choices; to explain every stage of treatment and aftercare to each patient; to provide the highest possible standard of clinical care; to provide excellent customer service, and to deal promptly with any complaints and to treat all patients and staff with fairness, dignity, and respect.

- The general manager told us that plan for the future included continuing to pioneer advancements in technology and research by sharing outcomes and to develop the cataract surgery service with two dedicated surgeons employed by the clinic. They also always strived to ensure the clinic was compliant with all relevant guidelines such as The Royal College of Ophthalmologists guidelines on refractive surgery.

Governance, risk management and quality measurement

- The registered manager and the clinic managers were responsible for the governance and day to day operational leadership of the clinic. They met weekly and we saw minutes of these meetings which showed standing agenda items were staff, patients, decision to drive long-term profitability and constant improvement. Staff training, patient feedback and learning from incidents as well as planning for the clinic’s future were discussed under these headings.
- There was also a monthly head of department meeting, where the leads for nurses, administrative staff, and patient care co-ordinators as well as the laser protection supervisor had an opportunity to meet with the senior management team and surgeons to discuss quality and safety performance of the service.
- Patient outcomes as well as research and publications were discussed at the quarterly quality management meeting. Staff we spoke with were fully aware of the patient outcomes as this information was regularly shared with staff.
- Risks were identified as a result of incidents reported or audits completed and were reviewed and investigated by the clinic managers. We saw that action was taken as a result of risks being identified through the audit process. For example an environmental audit identified a falls risks due to the step to a bathroom and during the inspection, we saw the appropriate notice was in place to alert patients and staff to the presence of the step.

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- The registered manager told us the main risks to the service was damage to their reputation, only having two permanent surgeons in post, equipment issues and only operating from one location. Some mitigating plans were in place, such as recruiting two clinical fellows but it was unclear how the service planned to mitigate the other risks.
- The clinic did not record all risks on a risk register and this meant the leadership team did not regularly discuss and review all risks to the service. There was also no process for identifying risks and how to mitigate these. Therefore risks we identified during the inspection such as those with the water system and the absence of safeguarding training and policy had not been considered and there were no mitigating plans in place.
- The clinic did not currently have a formal Medical Advisory Committee although the registered manager met regularly with the surgeons. The registered manager told us it was during these meetings that the decision to recruit two clinical fellows as well as granting practicing of privileges to the cataract surgeon was discussed and agreed. However these meetings were informal and therefore no minutes were available. The clinic had only granted practicing privileges to one cataract surgeon as all refractive surgery were carried out by the two surgeons employed at the clinic. The registered manager informed us there were no plans to grant additional practicing privileges as the clinic has now employed two cataract surgeons.

Public and staff engagement

- Staff completed feedback surveys to inform the management team of any areas they have identified for improvement and where they feel they may require more support. At the beginning of the year, during the staff meeting, staff were asked to reflect on the year's success but also highlight three areas for improvement.
- Patients completed satisfaction survey at their follow up appointment and the clinic had recently introduced a handheld electronic device where patients were asked to comment on specific areas such as cleanliness, customer service, and environment.
- The clinic managers gave us examples of how patient feedback has brought about changes to the service. Some patients reported they would have liked to spend more time in the post-operative relaxation room. The clinic has since established a second room to ensure patients were able to stay for longer without affecting

the theatre list. Another example was when patients reported they were unable to book appointments on their chosen day due to capacity; the clinic hired two additional optometrists and two patient care co-ordinators to provide more capacity and flexibility.

Innovation improvement and sustainability

- The clinic had a dedicated research team and contributed to ongoing research in the field of refractive surgery. The team at the clinic had published over 135 peer reviewed articles and were about to publish a book designed for trainees and fellows embarking on the refractive surgery speciality.
- The medical director had developed the first prototype of the high frequency ultrasound scan for the cornea. The surgeon then worked with a manufacturer to develop a high frequency ultrasound scanner. Patients at the clinic were offered this scan of their cornea if indicated during their assessment to better plan their surgery.
- The medical director also contributed to the development of the most commonly used laser machine and holds seven patents for techniques or technologies relating to refractive eye surgery.
- The clinic ran a charitable organisation providing refractive eye surgery in Nepal. Through this charity, surgeons at the clinic have been involved in the training of local surgeons and providing the equipment as well as electronic record software required to enable the clinic in Nepal to offer this service.
- The leadership team were keen to drive continuous improvement within their areas of responsibility. Staff were encouraged to share ideas, which improved the patient experience and the patient journey.
- The clinic was accredited by the Joint Commission International (JCI), which is a US based international body dedicated to improve patient safety and quality of health care in the international community by offering education, publications, advisory services, and international accreditation and certification.
- The clinic had achieved ISO9001:2015 quality management status, which demonstrated its ability to consistently provide products and services that met customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through the effective application of the system.

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- The surgeons at the clinic had pioneered the laser blended vision, which allows correction of both distant and near vision by adjusting one eye to focus at distance and the other close up.

Outstanding practice and areas for improvement

Outstanding practice

- The clinic had a dedicated research team to monitor patients' outcomes and assist the surgeons in publishing a large number of peer-reviewed articles on refractive eye surgery.

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that the water system is fully compliant with HTM 04-01 Safe water in healthcare premises.
- The provider must ensure a safeguarding adults policy is in place to guide staff, and ensure all staff are trained to a suitable level.
- The provider must ensure all risks to the service are recorded and mitigating plans are in place.
- The provider must ensure a Medical Advisory Committee is in place to provide oversight of the quality and safety at the clinic.

- The consent policy must reflect Royal College of Ophthalmologists professional standards 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Action the provider **SHOULD** take to improve

- The provider should remind staff to follow best practice with regard to infection prevention and control.
- The provider should offer patient information in the form of leaflets and documents in other languages apart from English.
- The provider should offer formal interpretation services for patients.

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	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: • The water system in the operating theatres did not comply with HTM 04-01 Safe Water in Healthcare premises and this had been known about since November 2016 but no action had been taken. • The clinic was not following the Royal College of Ophthalmologists professional standards for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon. • The clinic did not have an adult safeguarding policy in place, and the staff had not received suitable training. • The clinic did not have a risk register and some risks had not been identified. • The clinic did not have a Medical Advisory Committee to provide oversight over quality and safety at the clinic.