Optical Express - London (White City) Clinic

Quality Report

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

Overall summary

Optical Express Clinic White City is operated by Optical Express Limited. Optical Express is a nationwide company providing general optometric services. The service provides intra-ocular lens exchange, cataract and phakic intra-ocular lens implant surgery under local anaesthetic and intravenous sedation, for adults aged 18 years and above. Cataract and lens exchange procedures include the use of a laser machine.

The clinic is based on the first floor within Westfield's White City shopping complex, and is set over two floors. Facilities include a theatre, anaesthetic room, laser room, surgeon examination room, a pre-operative and post-operative room.

We inspected this service using our comprehensive inspection methodology. We carried out the inspection on 16 and 18 October 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.

Services we do not rate

We regulate refractive eye surgery clinics, 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:

- There was a positive culture of incident reporting and an effective process for the investigation of incidents. Shared learning was recorded and circulated to staff.Managers supported staff to deliver effective care and treatment, including through meaningful and timely supervision and appraisal.
- Staff were up to date with all core mandatory topics and had received an annual appraisal. Patient treatment was provided by competent, suitably trained staff. There was a clear and appropriate approach to support and manage staff when their performance was poor or variable.

Summary of findings

- All clinic staff we observed treated patients with respect and dignity throughout all interactions at the clinic. Feedback from patients was overwhelmingly positive about the caring nature of the staff looking after them.
- Facilities and premises were appropriate for the services being delivered. Services were available at the patient's convenience and were accessible to those who had disabilities.
- The clinic followed best practice guidelines and was determined to set realistic expectations for patient's outcomes after surgery.
- The governance arrangements in place meant there was oversight of quality, risks, and the challenges that needed to be address.

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

- The consent policy did not reflect Royal College of Ophthalmologists 2017 for 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Patient information leaflets were not available in different languages or formats.
- There were no formal interpreting services available and patients were asked to bring a family member or their own interpreter to the clinic with them.

Amanda Standford

Interim Deputy Chief Inspector of Hospitals London

Summary of findings

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Summary of this inspection

Background to Optical Express - London (White City) Clinic

Optical Express, White City clinic is operated by Optical Express Limited. The clinic opened in July 2009. The service primarily serves the communities of the London area. It also accepts patient referrals from outside this area. The clinic has had a registered manager in post since November 2016.

Our inspection team

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

The responsible interim head of hospital inspection is Helen Rawlings.

Information about Optical Express - London (White City) Clinic

Optical Express, White City, 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 first floor of a shopping centre complex. Patients are self-referring and self- funded. The clinic provides intra-ocular lens exchange, cataract surgery, and phakic intra-ocular lens implant under local anaesthetic and intravenous sedation.

The clinic provides the service between two and five days a week, frequency depending on patient

demand. They have five resident team members, including an ophthalmologist surgeon, two registered nurses and two clinical staff members. Clinical staff form part of a regional team covering London and the southeast area.

During the inspection, we visited the theatre, anaesthetic room, pre and post-operative rooms, laser room, dirty utilities and examination rooms. We spoke with eight members of staff, including the ophthalmologist surgeon, anaesthetist, registered nurses, and health care assistant and senior managers. We spoke with six patients. During our inspection, we reviewed six sets of patient records and the staff personal files including those of the ophthalmic surgeons.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The service had last been inspected in 2013, where it was found that the service was meeting all standards of quality and safety it was inspected against.

Activity:

In the reporting period June 2016 to June 2017 there were 2,734 inpatient and day case episodes of care recorded at the service. Of these, 2,687 were natural lens exchange cases, of which 2,599 required intravenous sedation and 47 cases were phakic lens implants, which also required intravenous sedation.

Track record on safety (June 2016 to June 2017)

- No Never events
- No clinical incidents
- No incidences of healthcare acquired meticillin-resistant Staphylococcus Aureus (MRSA), or healthcare acquired meticillin-sensitive Staphylococcus Aureus (MSSA)
- No incidences of healthcare acquired Clostridium difficile (c.diff)
- No incidences of healthcare acquired Escherichia coli (E-Coli)
- 26 complaints

Services provided at the clinic under service level agreement:

- Clinical and non-clinical waste removal
- Laser protection service
- Maintenance of medical equipment

Summary of this inspection

- Pharmacy
- Uninterrupted Power Supply
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- There were systems in place to manage incidents and staff had a good understanding of the processes to follow when reporting these.
- Staff received good training to enable them to fulfil their role. Staff were up to date with all mandatory core training topics.
- There were good laser safety measures in place.
- Equipment was readily available and serviced regularly.
- Medicines were managed safely and in accordance with the organisation's policy.
- Patient's records were fully completed and stored safely.
- There were systems in place to assess and respond to patient risk.
- There were sufficient levels and staffing mix to deal with patient's care and treatment.

Are services effective?

We found the following areas of good practice:

- Patients received care and treatment in accordance with recognised professional guidelines and national standards.
- Surgeons' outcomes were routinely measured and benchmarked.
- There was a system of auditing which allowed for the monitoring of quality.
- Staff sought consent from patients prior to surgery.
- There were suitably trained and competent staff to carry out the duties allocated to them.
- Additional training was provided to staff using laser equipment to ensure they carried out their role safely.

However:

- The consent policy did not reflect Royal College of Ophthalmologists 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Are services caring?

We found the following areas of good practice:

Summary of this inspection

- Staff were caring and treated patients with dignity and compassion.
- Patients were involved in the planning of their treatment.
- Patients were informed of all costs of the treatment prior to treatment.
- Staff were supportive of those patients who were emotional and anxious.
- The service received positive patient feedback.

Are services responsive?

We found the following areas of good practice:

- Patient appointments were flexible to accommodate patient preference.
- Suitable adjustments were made to accommodate patients with wheelchairs.
- There was a good system for the management of complaints. Complaints procedures were made clear to patients.

However:

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

Are services well-led?

We found the following areas of good practice:

- There were good governance arrangements to ensure the service had oversight of risks and quality.
- There was a clear organisational structure with defined roles and responsibilities.
- A patient feedback system allowed the organisation to measure patient satisfaction and benchmark against each location for improvements to be made.
- The organisation recognised staff through a weekly staff reward scheme.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

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.

Incidents and safety monitoring

- During the period 1 July 2016 to 30 June 2017 the clinic had not reported any 'never events' or other serious incidents. Never events are defined as 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.
- We spoke with three members of staff who were able to describe to us the clinic's incident reporting process. The clinic had an Incidents and Near Miss policy dated January 2017, which provided staff with reporting, escalation, and investigation processes. Staff completed written incident reports which the manager then uploaded to the electronic system. This meant the patient's electronic medical record was updated and available to authorised personnel with a complete history of the patient's treatment and any incidents or complications arising.
- Staff said information on incidents was fed back to them in the form of surgery directives from head office, which everyone had to read and sign. We asked for an example and they told us of an incident which had occurred at another Optical Express location we had inspected recently. This confirmed what we had been told by senior management that learning was shared throughout the company.
- We reviewed the seven reported non- clinical incidents at the clinic between 1 August 2016 and 31 July 2017 and saw that in all cases outcomes were recorded and where required, learning was circulated to staff. An example of this was a patient who had presented themselves incorrectly upon hearing another patient's name called for the femtosecond laser part of treatment. We saw evidence staff had been briefed on patient verification procedures and had signed to acknowledge the briefing. During the inspection we observed staff constantly checking patient ID at each stage of the treatment process.
- We reviewed minutes of the newly introduced monthly surgical team meetings and saw incidents were discussed and all staff had signed the completed minutes to acknowledge the information.
- 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. Staff received duty of candour training as part of their duty of care mandatory training and were able to convey their understanding of it to us during our inspection.

Mandatory training

- We saw that all staff who worked at the clinic had completed all mandatory training topics. This safety related training was renewed every three years and included core topics such as: information governance, conflict resolution, infection control prevention, fire safety, safeguarding children young people and adults, medicines management, health and safety, duty of care, consent, equality and diversity, and moving and handling. Consent training included the Mental Capacity Act 2005.
- The duty of care training undertaken by all staff included duty of candour training and additional training in relation to mental capacity and deprivation of liberty safeguards (DoLS) for patients.

- The staff personal records showed all had completed both basic life support (BLS) and immediate life support (ILS) training. The training was designed to provide them with the knowledge and skills required to treat patients in cardiac arrest until a paramedic attends. The anaesthetists who were supplied by an agency were trained to advanced life support level and some continued to work within the NHS.
- Staff also received anaphylaxis training. Anaphylaxis is the result of the body's immune system overreacting to a trigger, such as a bee sting or a nut or other allergy.
- Agency staff training was monitored and verified by the clinic.

Safeguarding

- Safeguarding was part of mandatory training. All staff were trained to level three for children's safeguarding procedures and level two for adults. The surgery manager was trained to level three safeguarding for children's and adults and was the safeguarding lead for the clinic.
- The clinic had a safeguarding policy, which described the types of abuse, and concerns staff should report. It was dated January 2017 and was version four of the policy. There were clear lines of escalation and contact details for the local authorities. We saw contact details displayed in a folder, which was easily accessible to all staff.
- The policy referenced the Care Act 2014, which included key changes to information relating to adult safeguarding.
- The safeguarding policy included information on the PREVENT strategy, which is a government directive. At the heart of PREVENT is safeguarding children and adults and providing early intervention to protect and divert people away from being drawn into terrorist activity.
- Staff we spoke with had an understanding of safeguarding. Any safeguarding concerns were reported to the surgery manager, who escalated these to the necessary local borough safeguarding teams.
- No safeguarding concerns were reported to the CQC during the year up to our visit.

Cleanliness, infection control and hygiene

- The clinic had an Infection Prevention and Control (IPC) policy, which was version three and dated January 2017. The policy referenced The Health and Social Care Act 2008 code of practice on the prevention and control of infections (DoH 2015), which provided staff with guidance and IPC procedures they should follow to minimise risk. Staff completed IPC mandatory training, which they refreshed every three years. All staff had completed this training. The surgery manger was the IPC lead for the clinic.
- The clinic's reception, clinical and staff areas were all visibly clean and tidy. We saw clinic cleaning lists for the last three months which were completed each day. Staff cleaned all clinic areas and signed as completed. This was checked by the clinic manager each day. There was also an end of day cleaning check list.
- Head office personnel conducted an overall infection, prevention and control (IPC) audit every six months. We saw that an action plan was produced as a result and dates were added when the actions were completed.
- Optical Express head office had sent out a sepsis awareness document to all of their locations and we saw it had been discussed at the surgical team meeting. Sepsis is a rare but serious complication of infection which requires swift diagnosis and treatment.
- We saw hand-sanitising gel was available at points of care in all clinic rooms. This was in line with Health Technical Memorandum (HTM) 'Infection control in the built environment.'
- During our inspection we observed staff adhere to the IPC policy. We saw staff wash their hands and change gloves before treating patients. Staff wore clean theatre scrub uniforms, suitable theatre shoes, masks and covered their hair.
- Staff used hand gel before entering the theatre area. We did note one hand gel container was empty; however, there were other full hand gel containers in the room and the container had been refilled by our next inspection day.
- We saw evidence of regular hand hygiene audits (17 over a four month period prior to the inspection), which showed an overall average 94% compliance. Most of the audits demonstrated reaching the target of 100% compliance. As part of the audit process staff were observed both individually and as a team. Individuals were given feedback if they fell below the standard and additional training was given.
- Hand hygiene posters were displayed throughout the clinic, which provided information on the 'five moments for hand hygiene' in line with World Health Organisation (WHO) guidance.

Refractive eye surgery

- We noted the sinks had elbow operated taps which was in accordance with the Health Building Note 00-09: 'Infection control in the built environment.'
- The clinic had a good supply of personal protection equipment (PPE), including disposable gloves and aprons which were used by staff.
- Clinical waste was properly deposited in orange clinical waste sacks and collected under contract by an external specialist company.
- Sharps bins were in place, dated, signed and off the floor in all areas we visited. This reflected best practice guidance outlined in the Health and Safety Executive (HSE) The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Sharps bins are used by clinical staff to safely dispose of used items such as, syringes, needles, and glass ampoules.
- Staff complied with the bare below the elbows policy.
- The majority of instruments used during the surgical procedures were single use disposable items. However, a small number of items required decontamination. We saw those items were individually coded and after being washed in the sluice area they were placed in a secure box ready for collection by the external decontamination company. We saw a record was kept in a dedicated ledger of the movement to and from the external company by the clinic. The clinic recorded the company's unique collection reference number alongside each item sent out.
- An annual legionnaire test was conducted and we saw the documentation; which showed the necessary checks had been made. Legionella is a water borne bacteria that can be harmful to people's health. The water tests for legionnaires disease complied with the Control of Substances Hazardous to Health Regulations 1989; Section 3(2) of the Health and Safety at Work Act 1974.
- The clinic's air conditioning system was maintained twice a year; we saw evidence of routine maintenance completed in October 2017. An annual airborne particulate check was completed in June 2017.

Environment and equipment

- The location was divided over two floors of a large retail unit at Westfield shopping centre. The ground floor was the general optical retail store and the first floor comprised the surgical treatment area. Some of the standard ophthalmic testing equipment was located in rooms on the ground floor and people having initial assessment eye checks and pre-surgery checks were taken to this area first before having further treatment related eye checks upstairs. Both areas were visibly clean and tidy.
- The clinic met the Royal College of Ophthalmologists (RCO) ophthalmic services guidance for theatres. The theatre and anaesthetic room were dedicated for ophthalmic use.
- Within the clinic, there were two lasers used for refractive eye treatments. The laser technician performed safety and calibration checks before each use. We checked the calibration log sheets for the previous three months and found them to be correctly signed and dated. The machines also had safety warnings and failsafe cut-outs built into the software. The Femtosecond laser was maintained under a contract, which provided for an annual service, a quarterly engineer's check and an emergency call out service.
- The clinic met the standards recommended by the RCO for a safe environment within the laser treatment room. There were suitable locks on the doors to prevent unauthorised entry, illuminated laser hazard signs to indicate the laser was in use and reflective hazards were minimised.
- The location had a contract with an external Laser Protection Advisor (LPA) who was responsible for undertaking risk assessments, providing advice, and training on laser safety training. They also drafted and issued suitable local rules and working practices and investigated adverse laser incidents. We noted the risk assessments and local rules were reviewed on a three yearly basis and the dates showed they were in order. We viewed the Local Rules for the laser machines. The rules contained information on the control of hazards, responsibilities, risk assessments, laser hazards, and gas hazards. Staff had signed the rules to show they had read and understood all the information.
- Staff attended core knowledge of training every three years with the LPA. We viewed staff records, which showed all staff had completed their training.
- The surgery manager at the location was the Laser Protection Supervisor (LPS) and directly supervised all optical radiation protection at the location in line with the Local Rules. The laser technicians were LPS trained and would assume the role when the LPS was not available.

- We checked the resuscitation equipment and saw it appeared to be in good condition. We saw the evidence of regular staff checks in the equipment log book. The emergency medicines were within their expiry dates.
- We saw oxygen cylinders stored safely in secure upright trolleys. The cylinders examined showed good levels of gas and were within date. The clinic had a contract, which provided next day delivery for medical gases.
- We saw the clinic's replacement lens stock was neatly stored in closed cupboards. Staff conducted monthly stock checks and all of the lenses were within their expiry dates.
- There were recording systems that allowed details of specific implants and equipment to be provided rapidly to the Medicines and Healthcare Products Regulatory Agency when needed. Theatre staff attached the packaging with unique identification label to the patient's paper record. This meant the clinic was able to identify which lens implant had been used for a patient's surgery should there be any issues after implantation.
- We observed electrical safety checking labels were attached to electrical items showing they had been tested and were safe to use.
- There was a red emergency cord in the patient discharge area to summon assistance if required.
- All flooring was easily cleanable and in accordance with Health Building Note (HTM) 00-10 part A: Flooring. All work surfaces appeared to be visibly clean and were clutter free.
- Ophthalmic diagnostic equipment not in use had appropriate covering to keep the machines clean and dust free.
- Emergency equipment was available and checked on operational days. All items were correctly stored and ready for use.
- The clinic had two defibrillator machines; a larger one and a smaller back up. Adefibrillatoris a device that gives a high energy electric shock to the heart through the chest wall to someone who is in cardiac arrest. On the days of our inspection the larger of the machines was away being serviced. As a result staff had been advised to monitor more closely any patients with pacemakers fitted because the smaller machine does not cater for such patients.
- The clinic had a collapsible wheelchair for use in emergencies.
- All storage areas; including the dirty sluice room were visibly clean and tidy.
- All fire exits and doors were kept clear and unobstructed. Emergency exits were clearly signed and easy to access.
- There was a lift for patients to use between the ground and first floor levels as well as a staircase.
- The fire extinguishers were clearly labelled, accessible and in date.
- The clinic had an installed and maintained uninterruptable power supply (UPS) which would switch on should the electrical power be cut off. It was capable of providing power for one hour; although the emergency policy stated in such a case any surgical treatment underway was to be completed which would normally only take a few minutes.

Medicines

- The clinic had a medicines management policy, which described the handling, storage, prescribing, recording, and safe administration, and disposal of medicines.
- The resident registered nurse was responsible for ordering, receiving, recording and storing of medicines and there was pharmacist support available by telephone. One pharmacy supplied all medicines for the clinic.
- We reviewed the clinic's drug order stock book and the medicines we checked were in date and reconciled with the records.
- The clinic used controlled drugs (CDs) during the conscious sedation procedures. These were kept appropriately and securely within a locked cabinet. We examined the CD register which was correctly completed and noted the entries had been signed by two members of staff as required. The CDs within the cabinet corresponded with the tally in the CD register. The clinic conducted a monthly CD audit.
- During one of the procedures we observed the anaesthetist administered the required amount of CD to the patient after which he disposed of the remaining drug according to the clinic's policy.
- The clinic did not use any cytoxic drugs.
- Medicines used during surgical procedures and given to patients to take home were prescribed by the surgeon that carried out the surgical procedure. There were prescription labels attached to each medicine package, with the patients name, date and instructions for dosage.

- Medicines requiring storage at cooler temperatures were kept in locked fridges. The clinic had three such fridges which would provide back up if one broke down. We examined the fridge logbooks for the previous three months and saw they had been completed correctly.
- We checked all the oxygen cylinders and found they contained safe levels of oxygen and were all within their expiry date. All oxygen cylinders were stored safely.

Records

- The clinic had an electronic medical record system and a paper copy of surgical records. The paper copy record was archived off site and a full time archivist managed these records. On receipt of the paper copy, it was scanned and saved. On the day of treatment, the information from the hard copy was entered onto the electronic file. The electronic record was, therefore, integrated with the hard copy file with the exception of the instrument traceability records and signed patient consent form. This information could be retrieved through the archivist who was able to send the scanned record.
- The electronic record was available to authorised staff at each Optical Express clinic, which meant staff could respond to any patient's post treatment concerns even if they were not at the treating clinic.
- We reviewed six sets of patient records and saw consent forms were signed and legible. Consent forms provided patients with information relating to risks associated with the procedure. The records we reviewed all showed patients had a two weeks or more 'cooling off' period before surgery had taken place. We saw prescription charts had been signed by the surgeon and registered nurse. Included in the records were the patients' medical history, eye tests, and scans taken. The examination included psychological testing and asking about the patient's motivation for having treatment. We saw informed discussions between the surgeon and patients were in-depth with discussed outcomes, expectations, risks, and recovery.
- Patients were consented for each eye surgery separately even though they may have chosen to have both eyes enhanced.
- The records contained lens product stickers showing the type and traceability codes for the replacement lenses used. Details of single use items were also present.
- The clinic conducted a quarterly audit of patient records including the World Health Organisation WHO checklists and we saw evidence of learning feedback to staff as a result.
- At initial consultation, the patient was required to indicate on their health questionnaire whether they consented to the clinic contacting their GP and we noted patients who consented provided their GP's details. The electronic system automatically sent a 'discharge' letter to the GP when the examiner had completed the patient's last examination record.
- The clinic maintained appropriate records of when each laser machine was operated. From our observations, speaking with staff and review of records it appeared the local rules for the safe operation of lasers were understood and complied with.

Assessing and responding to patient risk

- Patients were assessed for their suitability for treatment at the clinic prior to treatment. Checks included health questionnaires and eye examinations.
- The risks of treatment were explained to patients and we observed two consultations where health checks and eye tests were undertaken. Lifestyle questions were asked so the clinic could make an informed decision about the different treatments.
- We witnessed a pre-operative assessment during our inspection. The procedures and why the various tests were to be done were explained to the patient at every stage. We saw and noted during our review of patient records the results of the various questions, tests and scans were properly recorded.
- After the eye examination was conducted the patient was provided with information on likely outcomes, but it was explained they would need to see the surgeon who would make the final decision and discuss everything again and review examination results. We viewed six patient records, which showed there was sufficient time between the initial consultation and surgeon consent to allow patients a time for reflection and to decide whether they wished to proceed with treatment.
- Suitability guidelines also included other health associated issues. For example, patients with epilepsy had to confirm they had been seizure free for three months and had to have a letter from their GP to confirm this.
- Psychological issues were part of the assessment criteria. Patients with disorders such as depression also

required a supportive letter from their GP. Other checks included whether patients had rheumatoid arthritis, MRSA, whether patients had a pacemaker, and keratoconus, which is a non-inflammatory eye condition.

- The clinic used the World Health Organisation (WHO) five steps to safer surgery checklist, which included; sign in, sign out and time out. We observed the checklist in use during the procedures we watched, with patients' consent, and saw properly completed checklists in the patient records we reviewed.
- We saw evidence patient suitability and treatment criteria were discussed at the annual International Advisory Medical Board (IAMB) meeting. This meeting comprised of refractive eye experts who were independent of Optical Express.
- All staff were immediate life support (ILS) trained and anaesthetists were advanced life support (ALS) trained. The anaesthetist stayed at the clinic until the last patient was fit for discharge.
- During our inspection we observed a surgical procedure and saw the anaesthetist check and monitor his equipment and the patient throughout the process. The anaesthetist explained to the patient what he was intending to do and confirmed the patient was feeling okay.
- Once the surgery was complete the patient remained on the surgical bed until they were sufficiently recovered to transfer to a recovery lounger in the recovery room. They were monitored by a suitably trained member of staff and offered refreshments and snacks.

Nursing and medical staffing

- Nursing staff arrangements were dependent on when the clinic opened and this was dependent on patient demand. Therefore, there were no set days that the clinic opened, although the clinic state typically between two to five days a week.
- The staff present for treatment days included the surgeon, one or two scrub assistants, a laser assistant, a 'discharger', a co-ordinator, a health care assistant (HCA), an operating department practitioner (ODP) and a pre-operative nurse. For treatments requiring the patient to have conscious sedation an anaesthetist was also present. Conscious sedation is defined as 'a technique in which the use of a drug or drugs produces a state of depression of the central nervous system enabling treatment to be carried out, but during which verbal contact with the patient is maintained throughout the period of sedation. The drugs and techniques used should carry a margin of safety wide enough to render loss of consciousness unlikely.'
- The staffing levels and skills mix had been agreed by the Optical Express medical director and the medical advisory board. The team scheduler at head office produced a staff schedule for each of the clinics to ensure correct staffing on treatment days. The clinic surgery manager also reviewed and agreed the staffing arrangements.
- The anaesthetists were supplied by a specialised medical staffing agency. On the day of our inspection the agency anaesthetist also continued to work within the NHS.
- The clinic directly employed two ophthalmic surgeons; one full time and one on a part time basis. Both were registered with the GMC and we reviewed their CVs and qualifications.

Major incident awareness and training

- The clinic had its own fire and emergency response plan and staff received training as part of their mandatory training package. Each member of staff had a role to undertake and this was noted in their personnel record. Staff were also aware of what was required of them relating to the major incident response at Westfield shopping centre.
- The emergency exits were clearly marked and easy to access from the first floor surgical level.

The clinic had a UPS back-up system and protocols in place to inform staff of what to do should the main electricity fail.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Pre-operative assessments included screening against a defined set of criteria to ensure patients were suitable for the treatment. We observed staff discuss with patients any potential limitations of the proposed treatment as well as the potential benefits. Patients were asked to watch an informative video about the proposed treatment and asked if they had any

questions afterwards. Patients we spoke with told us they had been given enough reflection time before a procedure was carried out and they had not felt pressured or rushed.

- Policies and procedures we reviewed were aligned with recognised national standards and guidance. Pre and post-operative care followed the Royal College of Ophthalmologists Professionals Standards for Refractive Surgery April 2017.
- The provider employed a biostatistician to carry out an annual audit of all surgeon outcomes. These were presented during the surgeon's annual appraisal meeting and benchmarked against the Royal College of Ophthalmologists and the European Society of Cataract and Refractive Surgeons.
- Suitability guidance and treatment criteria were subject to critical review annually by the International Medical Advisory Board (IMAB). The IMAB comprised of refractive eye experts who had no link to the company. Guidance and any recommended changes were discussed and reviewed internally via their Medical Advisory Board (MAB). Any changes in guidance or protocols were disseminated to staff.
- We reviewed the IMAB meeting minutes dated October 2016. We noted the latest GMC guidance relating to refractive eye surgery was discussed as were a number of new technologies and continuing review of existing practices.
- 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.
- We noted the clinic's care pathways during our review of patient records. The pathways, developed by the medical advisory board and based on best practice guidance, described the care of the patient from first consultation to discharge.
- The clinic conducted regular audits for infection control, incidents, complaints, record keeping, maintenance of equipment, medicines management and health and safety. We viewed a variety of audits, which showed actions were taken against any areas of concern.

Pain relief

- Patients received dilation and local anaesthetic drops during pre-assessment and at the start of treatment. Patients were asked by staff to mention any discomfort experienced.
- During our inspection we saw a patient undergo conscious sedation. The anaesthetist explained through the procedure what he was going to do and checked how the patient was feeling throughout.
- Patients were prescribed pain relief medication to take home but advised to use it only if pain became unmanageable with over the counter paracetamol. We spoke to two patients who had undergone lens replacement surgery the previous day and had returned to have surgery on the other eye. Both reported virtually no pain either during or after the procedure.
- Patients were asked about the monitoring of their pain within the patient questionnaire.

Patient outcomes

- Each surgeon's clinical outcomes were monitored by the service on an annual basis. A full time biostatistician collated the information. Each year, the surgeon was presented with their clinical outcomes and they were discussed and evaluated as part of the surgeon's appraisal process. The biostatistician was able to extract mandatory information for analysis, such as the demographics of their patients in terms of patient age, gender, treatment type, and procedure type. The service was able to monitor efficacy, safety, estimated enhancement rate, and complications.
- Each surgeon's outcomes were assessed at the IMAB meeting. Any necessary changes to affect safety were reviewed and recommendations were made and discussed at the national Medical Advisory Board (MAB).
- Optical Express used data to monitor the efficacy and safety of treatment. Outcomes data was collected for every treatment undertaken including long term follow up data. This data was reviewed by the independent medical advisory board and the medical advisory board. Optical Express often presented studies, research, data and papers to the European Society of Cataract and Refractive Surgeons and the American Society of Cataract and Refractive Surgeons. Furthermore, they regularly published in peer reviewed reputable journals for the wider ophthalmic community.
- Optical Express compared their outcomes data with the data in the National Ophthalmic Database (NOD) but did not submit data to this database which only collects

data relating to NHS cataract procedures. This provided a means of benchmarking the treatment outcomes of individual surgeons. This data was used to conduct a yearly audit of the individual surgeon's outcomes which was made available to the registered manager.

- The clinic had provided information prior to our inspection regarding unplanned re-treatment and treatment enhancement following surgery. The figures provided for the period 1 july 2016 to 30 June 2017 totalled 214, broken down as 112 re-treatments relating to primary surgery within 12 months and 102 re-treatments relating to primary surgery undertaken between 2009 and 2016. The clinic stated the most common reasons for re-treatment were; intolerance of multi-focal lens implant induced halo/glare (quality of vision) – these were taken out and replaced with a monofocal lens, correction of residual refractive error – an additional lens implanted, and a cloudy lens.
- The clinic also reported 179 patients who experienced complications following surgery and required aftercare between 1 July 2016 and 30 June 2017. Those complications included posterior capsule opacification (PCO) which is "a complication that causes the back of the lens capsule (which holds your artificial lens in place) to thicken which causes cloudy vision. If this happens 'the patient' may need to have laser treatment to make vision clear again. Posterior lens capsule opacification (PCO) is fairly common and once it has been treated does not normally cause any long term problems with sight. The procedure to treat posterior lens capsule opacification is a painless process which is usually done in an outpatient clinic, and normally takes about 15 minutes." (Royal National Institute of Blind People (RNIB) website)
- The numbers reported appeared disproportionately high for the size of the clinic and this was investigated during our inspection. The White City clinic was viewed as a centre of excellence within Optical Express and the lead surgeon was very experienced in undertaking implanted lens replacement surgery, which often involves the delicate cutting of the 'haptic feet' on the lens which are designed to embed into the eye tissue. As a result patients requiring such re-treatment/ enhancements were often referred to this clinic from others within the chain.
- The clinic undertook implanted lens exchange up to many years later if there was a problem.

Competent staff

- Staff we spoke with and personal staff records we reviewed, showed staff had the skills and competencies to carry out the duties within their role. New staff attended an induction programme, which included completing competency assessments for each area within the clinic.
- We spoke with a new member of staff and saw evidence of the competency assessment checks completed in pre-assessment. The staff member was able to describe the induction programme, which included reviewing the policies and procedures of the organisation.
- We saw all staff had completed their annual appraisal. The surgery manager completed appraisals for all resident staff members and the medical director completed all surgeons' appraisals.
- Anaesthetists were agency based and generally worked within the NHS. The manager from the agency completed the training and updates, which was accessed by the organisation. We saw evidence that training, Disclosure and Barring Service (DBS) and insurance indemnity checks for the anaesthetists working at the clinic were up to date and in place.
- Appraisals looked at four core competencies, which included, clinical competency, whether they were a good team member, patient advocate, and mentor/ leadership responsibilities. We saw staff at the clinic had their appraisals completed, assessed and plans in place for development.
- The Laser Protection Supervisor (LPS) was a certified member of the association of laser safety professionals.
- Medical staff completed an induction programme and core knowledge training. Part of the induction included shadowing the company medical director and senior ophthalmologist. Upon approval by the medical director, they were entered onto a list of authorised users.
- The surgeons' files contained the following information; General Medical Council (GMC) registration, personal indemnity insurance certificate, DBS checks and references, continual professional development information and appraisals. The files also contained the surgeons' CV and copies of their professional training certificates.

- We reviewed the registered nurses' file and saw evidence of registration with the Nursing and Midwifery Council (NMC). Core skills competency assessments had been completed.
- The clinic kept checks of the review dates for nurse's revalidation. Nurses were supported with revalidation by receiving patient feedback and attending clinical meetings on refractive eye treatments to assist them.
- Most bank staff who worked within the clinic were exclusive to Optical Express and we saw evidence the same checks as permanent staff were collated for each bank staff member.
- Every three months the clinic carried out a simulated patient collapse scenario. We saw the report of October 2017 which showed staff had completed the simulation satisfactorily.

Multidisciplinary working

- We observed good interaction between the team at the clinic. Each person knew their role within the team and treated each other with respect.
- There was a morning team briefing where patient cases for the day were discussed before treatment started. Any concerns with the working day would be discussed at the briefing.
- 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.
- We saw a 'points of notice' displayed on the treatment door. This provided staff with details of staff allocation for the day, hygiene checklists and information on incidents. This was updated on a daily basis.
- The service had just started monthly team meetings, and staff told us they found the meeting informative and gave them an opportunity to discuss any concerns. Topics discussed in the first team meeting included incidents and complaints together with any associated learning, protocols to follow for suspected sepsis and the duty of candour.
- Staff told us how they would contact the LPA and the role they provided.

Access to information

- Patient records were mostly stored electronically, which meant staff at other clinics had access if the patient had an appointment there. Access to electronic records was for authorised staff and password protected.
- If the patient provided consent, a discharge letter would be sent to their GP, via the electronic system. The GP was able to access the patient's surgeon via the same telephone contact number given to the patient.
- The organisation's policies were accessible through the service's intranet. Hard copies were kept at the clinic.
- If patients called out of hours with concerns regarding their treatment and the on-call optometrist was unable to address their concerns, they had a direct line to the surgeon for assistance.
- Should the patient attend for post treatment care at another Optical Express location and experienced a post-operative complication, the examining optometrist completed the patient's electronic file. The post-operative record had a mandatory field where the optometrist indicated whether the patient had a complication, the nature of the complication and whether the patient needed to be referred back to the surgeon, or whether the patient file needed to be reviewed remotely (by the clinical services team in Head Office) for further advice.
- If the complication required urgent intervention, the examining optometrist was required to contact the clinical services team on their dedicated 'pre and post-operative advice' telephone line. The clinical services team co-ordinated and managed the patient's care; for example, a patient who attended with a post-operative infection. The examining optometrist called clinical services who then contacted the surgeon and liaised between the surgeon, optometrist and patient. All interventions and communications were recorded on the patients electronic file.

Consent and Mental Capacity Act

- Staff had received training for consent including the Mental Capacity Act (MCA) 2005. Staff understood consent and the decision making processes required before treatment could proceed. MCA training was included as part of the duty of care training, however the surgeon undertook a patient mental capacity assessment, if there were concerns regarding the patient's ability to consent.
- There was a consent policy ratified in January 2017, which stated it was the surgeon's responsibility to make

sure the patient understood the treatment plan including the finer details of risks associated with the treatment. The surgeon was responsible for ensuring the consent form was signed prior to treatment.

- At the initial consultation, the patient was provided with an information folder, which contained a copy of the consent form, the terms and conditions document, information on the procedure, which included the benefits and the risks. During the appointment, the patient watched a video, which reaffirmed the information provided during the consultation appointment.
- If the patient wished to proceed with treatment, they had a further appointment with the surgeon at least one week after the initial consultation appointment and at least three days before any treatment took place. The surgeon obtained written consent and conducted further diagnostic tests if necessary. The organisations policy stated a 'cooling off' period of three days prior to surgery procedures. This did not reflect Royal College of Ophthalmologists 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- For those patients who did not speak English, they were asked to bring somebody with them who could translate information. This was usually a family member or friend. However, for consent procedures, it is best practice for an independent interpreter to explain treatment and assist with consent, to minimise the risk of coercion and to ensure medical information is translated correctly.

Are refractive eye surgery services caring?

Compassionate care

- We observed care was given in a compassionate and dignified way. Staff were friendly, kind and treated patients with respect.
- Patient's dignity was respected. Staff were discrete and ensured patient discussions on treatment took place in private consultation rooms.
- We spoke with six patients. They told us staff were professional and had asked them throughout their care if they were comfortable.
- Patients were asked to complete an online survey at various points during their care. The surgery results were benchmarked against other clinics within the organisation.
- We reviewed the patient feedback data for the six months prior to our inspection. On average out of the 200 or so patients a month at the clinic the response rate was around 50%. In September 2017 for example under the care and welfare section there were 74 responses and for the vision and eye assessment section there were 105 responses. The feedback from the patients who completed the survey was overwhelmingly positive.

Understanding and involvement of patients and those close to them

- Staff involved patients in their pathway of care. We observed staff informing patients of what was happening to them during their treatment. Staff reaffirmed with the patient that they understood their procedure.
- The patients we spoke with told us they had been provided with good information regarding their treatment and staff had asked them if they understood everything to do with their care plan.

Emotional support

- We observed staff offering reassurance to those patients who were slightly anxious. They were calm, professional, and made patients feel relaxed.
- We observed staff providing supportive care in the theatre. Staff were sensitive and patients were given time to answer questions.
- Patients we spoke with said staff made them feel relaxed and did not pressurise them into going ahead with treatment.

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

Service planning and delivery to meet the needs of local people

- Patients accessed the service either through word of mouth or self-referral, through marketing or internet research. The clinic did not do any NHS work and did not receive referrals from the NHS.

Refractive eye surgery

- The clinic was open during the normal opening hours of the Westfield shopping centre, but surgical patients were able to gain early access in line with their appointment time.
- Patients were able to access other Optical Express clinics. The service did their utmost to ensure patients were treated at their preferred location.
- We spoke with six patients and they told us they had been provided with all the relevant information prior to treatment.
- The service was able to access the patient electronic system in other clinics. This allowed them to get the latest information on the patient's treatment and follow up information.
- The service ensured patients had an appointment with the refractive surgeon prior to the day of surgery and the refractive surgeon was available to examine the patient at the first post-operative appointment.

Access and flow

- Patients were self-referring and seen at the clinic at their own convenience. Appointments were also available at the weekends. Currently the service was performing approximately 50 surgical procedures a week.
- Patients gained access to the clinic through the main entrance of the shopping complex entrance. Access was via stairs, lift, or escalator.
- There were no unexpected returns for treatment. Returns for treatment were expected and normal in some cases, for example, to make minor enhancements.
- The service provided elective pre-planned procedures only. Emergency eye surgery was referred to the nearest NHS emergency eye care services.
- Waiting times were not routinely monitored, although patients we spoke with told us they had not encountered lengthy waits during their pathway of care.
- There had been no unplanned transfers of patients to another healthcare provider in the last twelve months.
- We were informed by the clinic that surgery was rarely cancelled. The clinic had systems in place to monitor cancellations and determine why surgery was cancelled, to include the specific clinical and non-clinical reasons.

Meeting people's individual needs

- The clinic was spacious and there was good access to accommodate those patients with wheelchairs.
- There were separate consultation rooms, which allowed discussions about patient treatments to take place in a private setting.
- There was a lift within the clinic for patients to use inbetween the different floors. The lift was spacious to accommodate wheelchairs and mobility scooters.
- A range of hot and cold drinks and biscuits were available in the reception area.
- There was a range of patient information leaflets available, explaining the different procedures, including pre and post care instructions. However, these were only available in English and no other languages. The organisation's website was informative and patient friendly to use. There was a good description of each procedure as well as patient feedback.
- Patient consent forms were only available in English, although they could be provided in large print format when required.
- There was no access to a translator, or interpreting services. Patients had to bring a friend or relative to explain details of the patient's treatment.
- The service did not treat patients with learning disabilities or patients with complex health conditions.

Learning from complaints and concerns

- The complaints policy described the process staff should follow in the event of a patient making a complaint. The principles of duty of candour were described in the policy but duty of candour was not referenced. Staff told us they knew how to manage a complaint and that information about complaints was shared during team meetings.
- The clinic had received 26 complaints in the reporting period 1 July 2016 to 30 June 2017 which had been managed according to the clinic's complaints procedure. Some of the complaints related to appointment issues at other Optical Express clinics prior to the patients attending White City but were managed by this clinic.
- The patient's consent form and terms and conditions document contained information about how to make a complaint. In the reception area, there was a notice with a summary of the process, which included who complaints should be raised with, addresses and also information about how to contact the CQC in the event of a breach in regulation.
- If a verbal complaint was made on the day of treatment, the designated surgery co-ordinator endeavoured to

resolve any issues and addressed the complainant directly. If the nature of the complaint was beyond the co-ordinator's ability to resolve quickly and locally, they engaged with the central clinical services department. They then took over the management of the process. The clinical services department team had a resident solicitor who assisted in the management of complaints.

- All written complaints were responded to by the clinical services team. The patient's electronic record was updated so the information regarding the complaint was accessible to the surgery manager who was then able to monitor progress.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was a clear leadership structure in place. Corporately, these arrangements consisted of the chief medical officer, operations director, clinical services team which consisted of the refractive operations manager, surgical services manager, and location surgery managers. Optometry directors also formed part of the corporate leadership team.
- Locally the clinic was led by the surgery manager. Staff we spoke with told us the manager was supportive, had an open door policy, and was good at listening and acting on concerns. Staff were able to tell us of the corporate management structure and who they reported to.
- Staff told us they enjoyed working at the clinic. They felt they worked well as a team and there was a good working atmosphere.
- The corporate surgery services manager regularly visited the clinic and staff told us they felt confident to raise concerns and talk about the clinic improvements with them.
- Staff performance was audited on a regular basis and we saw evidence of this in staff personal records. The surgery manager was able to describe the processes to manage poor performance. This involved using the organisation's appraisal process.
- We observed the organisation's marketing, in terms of information available to patients, to be honest and responsible. We found through observing and looking at documents and speaking to staff, the organisation complied with guidance from the Committee of Advertising. Patients we spoke with had not felt pressurised to go ahead with treatment and there had been no 'hard sell.'

Vision and strategy

- A vision for the organisation was provided that showed the objectives of the company. The chief executive officer for the company had a vision of expanding the business to provide international services.

Governance, risk management and quality measurement

- There were clear policies to support the governance structures. These included topics such as, incident management, information governance, risk management, medical management, and management of complaints. Staff we spoke with were familiar with the policies and were able to describe the finer points of some policies. For example, staff were able to tell us the systems they followed for the safe management of medicines.
- The clinical committee met on a monthly basis. The meeting was attended by the clinical services director, medical director, surgical services manager, and responsible officer. We reviewed recent minutes, which showed topics such as, clinical suitability guidelines, laser surgery outcomes, complications with surgery and new technologies were discussed. The minutes provided actions the organisation needed to take and information sharing.
- Quality indicators for the service covered incidents, local audits, and complaints. This information fed into the clinical governance committee and in turn to the Medical Advisory Board (MAB), of which the CEO headed. All surgeons and heads of departments were members of the board. The MAB had overall management of changing practices to surgery treatment techniques.
- The surgery manager had recently introduced monthly meetings. Staff we spoke with told us they found the meeting beneficial and looked forward to future meetings, so they could be involved in discussing quality improvements at the clinic. The surgery manager recognised the importance of having regular monthly meetings and how involving all staff in open discussion meant services could improve.

Refractive eye surgery

- The clinic managed risk well by using an integrated risk management process as set out in their 'welfare and safety of patients and the management of risk policy' dated January 2017. As described integrated risk management is the process of assessment, analysis and management of all potential risks and patient safety incidents bringing together all sources of information related to risk and safety.
- Risks were managed through risk assessments, which were colour rated, so the clinic were able to assess the severity of each risk. Red indicated a high risk, amber a moderate risk and green was a minor risk. Action plans were used as part of routine risk planning activity. We saw evidence of actions identified, dated, assigned to a particular person and completed.
- Risk management was also part of the newly introduced team meeting structure as set out in the above policy. Staff signed to agree they had read and understood the risks and the control measures in place.
- We saw evidence of a laser risk assessment by an external provider in which no current risks had been identified.
- The surgery manager monitored the quality of the service through regular audits. The quality management and clinical governance policy described how local managers provided contribution to the organisation's objectives of delivering safe and effective services to patients.
- The surgery manager fed back performance of quality through their regular meetings with the surgery services manager.
- Checks had been completed for the surgeons' personal file and indemnity insurance was in place. Clinical outcomes had been completed and an appraisal had taken place.
- The organisation had a medical advisory board, which had oversight of monitoring and managing surgeon's performance.
- Fit and proper persons checks had been adopted for the company's director, nominated individual and registered managers.

Public and staff engagement

- The clinic had conducted its first staff survey in October 2017, shortly before our inspection. Six members of staff completed the survey and the results were positive although some staff had difficulty expressing the organisation's vision and values strategy. We were told a Freedom to Speak Up Guardian would be appointed by the organisation in the near future and would conduct staff surveys on a regular basis.
- The service had recently introduced monthly staff meetings and staff were encouraged to provide feedback during the meetings.
- Patients were able to leave feedback at various points in their patient journey either whilst at the clinic or via the Optical Express website. The feedback rate was around 50% of patients attending the clinic.

Innovation improvement and sustainability

- A staff recognition scheme called 'wonderful Wednesdays' took place every week, where staff were nominated to receive awards such as spa days. The scheme was a way for the organisation to recognise valued members of staff.
- The surgical services manager was an expert panel advisor with the Optical Confederation, who were currently drafting new refractive eye standards for policies.
- The company developed the International Medical Advisory Board. The board was made up of specialists independent of Optical Express. They met annually to discuss outcome data and gave recommendations about any changes required.
- The medical director was one of the 11 members of the refractive surgery standards working group (Royal College of Ophthalmologists) who have recently published the latest guidance from RCO 'Professional Standards in Refractive Surgery' April 2017. The surgical services manager was an expert panel advisor with the Optical Confederation who were currently drafting new refractive surgery standards for providers.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The consent policy should reflect Royal College of Ophthalmologists 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider should offer patient information in the form of leaflets and documents in other languages apart from English.
- The organisation should offer formal interpretation services for patients whose first language is not English.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

This section is primarily information for the provider

Enforcement actions

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.