Optical Express - Nottingham 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 Nottingham Clinic is operated by Optical Express. Optical Express is a nationwide company providing general optometric services. The UK headquarters for Optical Express is based in Glasgow. Some corporate services are based there such as the clinical services team and the training team.

In addition to optometric services, Optical Express Nottingham Clinic provides laser vision correction procedures under topical anaesthetic and intra ocular lens (refractive) surgery for the treatment of cataracts and refractive errors under local anaesthetic to adults only, aged over 18 years. Treatment sessions take place approximately seven days per month. Between 15 and 20 patients are treated per session.

The clinic is set out over three floors. Facilities include an operating theatre, a laser treatment room, an anaesthetic room, pre and post-operative rooms, discharge room, dirty utility room and four examination rooms.

Patients are self-referring, self-funded patients with visual problems caused by a refractive error such as short sight, long sight, astigmatism and cataract. The treatment of refractive error is not classed as a medical condition so is not treated by the NHS.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 23 August 2017, along with an unannounced visit to the clinic on 3 September 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005

Services we do not rate

We regulate refractive eye surgery services 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:

Summary of findings

- Systems and processes were in place to keep staff and patient safe. Staffing levels were good and staff were competent to carry out their duties. There were good infection prevention and control procedures in place, all areas were visibly clean and well equipped. Patients received a thorough assessment prior to treatment, were monitored during treatment and were given emergency contact numbers following their discharge.
- Policies, procedures and treatments were based on nationally recognised best practice guidance. Regular audits were carried out on a range of topics. Patient outcomes were measured and benchmarked. There was a comprehensive staff training programme in place including laser safety. Robust consent procedures were in place.
- Care was delivered in a compassionate way and patients were treated with dignity and respect. Patient were kept informed throughout their care and encouraged to ask questions. Staff recognised when patient s may need additional support.
- Services were available at the patients convenience. Reasonable adjustments had been made for wheelchair users.
- Managers were visible and respected by staff. Staff felt valued. There was a culture of honesty and openness. Patient feedback was encouraged. Effective recruitment processes were in place.

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

- Duty of candour was not clearly described or defined in relevant policies and procedures.
- Some doors to rooms containing sharps, medicines or Control of Substances Hazardous to Health (COSHH) products were accessible to unauthorised persons.
- Patient information leaflets were not available in different languages or formats.
- Patient information on how to make a complaint did not include information about the Optical Complaints Consumer Service.
- There did not appear to be a vision or strategy in place.
- Staff engagement surveys were not taking place.

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

Heidi Smoult

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Refractive eye surgery;

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Background to Optical Express - Nottingham Clinic

Optical Express Nottingham Clinic is operated by Optical Express. The clinic opened in May 2006. The clinic primarily serves the communities of Nottinghamshire. It also accepts patient referrals from outside this area.The clinic has had a registered manager in post since 2006.

Our inspection team

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

Information about Optical Express - Nottingham Clinic

Optical Express Nottingham clinic is registered to provide the following regulated activities:

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

Patients are self-referring, self-funded; they attend an initial consultation with an optometrist followed by a consent appointment with the ophthalmic surgeon. Treatment takes place on a day case basis.

The team involved in the delivery of care includes ophthalmologist, anaesthetist, nurse, operating department assistant, health care assistant, surgical associate, optometrist and laser technician. The team works regionally across Nottinghamshire and Birmingham. Scheduling of the team is manged by a dedicated scheduler based at the Optical Express head office.

On our inspection day a laser vision correction clinic was taking place. On our unannounced inspection day intra ocular lens surgical procedures were taking place.

We inspected the operating theatre, laser treatment room, anaesthetic room, pre and post-operative rooms, discharge room, dirty utility room and examination rooms. We spoke with ten members of staff including; an ophthalmologist, a nurse, an operating department practitioner, a health care assistant, an optometrist, a laser technician and senior managers. We spoke with five patients and one relative. We also received 26 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed four sets of patient records and five sets of staff personnel files.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service was last inspected in October 2012. which found that the service was meeting all standards of quality and safety it was inspected against at that time.

Activity (June 2016 to May 2017)

- There were 1,961 procedures carried out at the clinic.

Track record on safety

- 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)

Summary of this inspection

- No incidences of healthcare acquired E-Coli
- Eight complaints.

Services provided to the clinic under service level agreement:

- Clinical waste removal including sharps and cytotoxic waste.
- Cytotoxic drugs service
- Medicines
- Laser protection service
- Decontamination of sterile 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 found the following areas of good practice:

- Policies and procedures were in place to manage incidents.
- MHRA safety alerts were acted upon.
- Staff received adequate training at induction and regular refreshers.
- Laser safety measures were in place and monitored.
- The clinic was visibly clean and staff followed policies and procedures in place for infection prevention and control.
- The environment was well maintained and well equipped.
- Medicines were managed safely and staff were competent to administer and dispense medicines.
- Patient records were completed fully and stored securely.
- Systems were in place to assess and respond to patient risk.
- Staffing levels and skill mix were in line with recommendations.

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

- Duty of candour was not clearly described or defined in relevant policies and procedures.
- Some doors to rooms containing sharps, medicines or Control of Substances Harzardous to Health (COSHH) products were accessible to unauthorised persons.

Are services effective?

We found the following areas of good practice:

- Policies, procedures and treatments were based on recognised national standards and guidance.
- Thorough processes in place for pre-operative assessment.
- Advertising and marketing was appropriate and responsible.
- Patient outcomes were measured and benchmarked.
- Audit took place regularly in key areas, improvements were identified and shared with staff.
- Staff were competent to carry out the duties allocated to them.
- Laser staff had additional training to carry out their duties safely.
- The ophthalmic multi-disciplinary team worked together effectively , good communication with patient's GP (with patient's consent).
- The surgeon had adequate patient information to advise on the most suitable treatment.
- Robust consent procedures were in place.

Summary of this inspection

Are services caring?

We found the following areas of good practice:

- Care was delivered in a compassionate way.
- Patients understood the information given to them and felt involved in their care.
- Consideration was given to patients who may require additional support.
- Staff recognised anxious patients and offered emotional support.

Are services responsive?

We found the following areas of good practice:

- Appointments for consultations were flexible and could be booked and changed easily. Additional consultations could be arranged if the patient needed further information.
- Reasonable adjustments were made for wheelchair users and people with restricted mobility.
- The complaints procedure was clear to patients and complaints were managed in line with the provider's policy by the clinic.

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

- Patient information on how to make a complaint did not include information about the Optical Complaints Consumer Service.
- Patient information leaflets were not available in different languages or formats.

Are services well-led?

We found the following areas of good practice:

- The management structure with roles and responsibilities was clearly defined.
- Staff demonstrated a culture of honesty and openness.
- Staff told us they were well supported and they were able to give feedback.
- Effective recruitment processes were in place, personal files contained complete and up to date information.
- A range of policies covered governance, risk management and quality measurement, local managers were aware of their role in these areas.
- A patient feedback system was in place which allowed the clinic to benchmark itself against other clinics in the organisation.
- There was a weekly staff recognition and reward scheme in place.

Summary of this inspection

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

- There did not appear to be a vision or strategy in place.
- Staff engagement surveys were not taking place.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

Are refractive eye surgery services safe?

Safe means the services protect you from abuse and avoidable harm.

Incidents and safety monitoring

- There were no never events and no serious incidents in the reporting period 1 June 2016 to 31 May 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- An incidents and near miss events policy dated January 2017 was in place. The policy clearly described the management of incidents including reporting, investigation and escalation procedures.
- The notifications policy dated January 2017 described the type of incident that should be reported to the Care Quality Commission (CQC).
- There were eight incidents in the reporting period. All were of low harm
- We saw in staff notifications and team meeting minutes where learning from incidents had been shared for example legionella checks had been increased following the discovery of mild levels of bacterium in the water. Legionella is a waterborne bacterium, which causes legionnaires disease. Staff described the incident management process to us and gave examples of incidents they had reported.
- 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 service were aware of the regulation but had not needed to use the process. Duty of candour was not clearly described in other relevant policies such as the complaints and incident management policies.
- Staff talked about being open and transparent with the public and we saw this reflected in the policies we reviewed.
- The clinic received safety alerts from the Medicine and Healthcare Regulatory Agency (MHRA). Managers told us they were relayed to staff in a quarterly staff bulletin unless they were more urgent in which case the information would be shared by e mail and staff bulleting straight away. We saw the MHRA safety alerts in the staff notifications file.

Mandatory training

- Mandatory training was renewed every three years and included the following topics, safeguarding children level one and two, conflict resolution, fire safety, health and safety, infection prevention and control, moving and handling, consent, safeguarding adults level two, duty of care, equality and diversity, medicines management and information governance. All staff were up to date with their mandatory training.
- All staff completed an on line training package annually which included Mental Capacity Act and consent.
- All staff attending laser vision correction procedures had basic life support skills; the operating department practitioner and nurse attending intra ocular lens surgery procedures had immediate life support skills.
- Staff who worked directly with the laser machines attended core knowledge training every three years and we saw evidence of this in personnel files, this included the surgical assistants and laser technicians.
- In the event the laser machine was upgraded or in light of new improved ways of working the machine manufacturer had a dedicated team of trainers who delivered training to staff.

- There was a named Laser Protection Advisor (LPA). The LPA reviewed the Local Rules every three years or more if required in response to any concerns with the lasers. Local Rules contain general guidance and instructions necessary to comply with legislation, standards and guidance for the safe use of lasers and/or other Light Therapy machine systems. If any changes were made to the Local Rules the changes were disseminated to staff via a directive and discussed verbally with staff. We saw the document in which staff had signed to say they had read and understood the rules.

Safeguarding

- The clinic did not treat patients under the age of 18 years.
- The safeguarding policy clearly described types of abuse and actions staff should take. It also informed staff where to find contact details for local safeguarding authorities. We saw the contact details displayed in the policy folder and staff told us they knew what to do if they became aware of a safeguarding event. The clinic had not reported any safeguarding events in the reporting period.
- All staff were trained to level two safeguarding procedures and the resident nurse was trained to level three. Staff compliance rate for training was 100%. If staff needed advice from a level four children's safeguarding lead they would access this through the local safeguarding board. Staff attended safeguarding refresher training every three years.

Cleanliness, infection control and hygiene

- All areas we inspected appeared visibly clean.
- A suite of policies and procedures dated January 2017 were in place to manage infection prevention and hygiene. Staff attended refresher training every three years and staff we spoke with were knowledgeable about infection prevention procedures.
- Staff wore disposable clothing during surgical procedures which complied with arms bare below the elbow principles. Theatre footwear was washable. Staff demonstrated good hand hygiene procedures.
- Personal protective equipment was available to staff and we observed staff using the equipment.
- The hand hygiene policy was based on the five moments for hand hygiene. The five moments for hand hygiene focuses on five moments when hand hygiene should take place, these are, before patient contact, before undertaking a clean or aseptic procedure, following an exposure risk, after patient contact and after contact with a patient's surroundings.
- We reviewed the hand hygiene audit for August 2017 which showed that staff compliance was 80% to 100%. Members of staff who had rated less than 100% had been informed and given additional training. Written hand washing guidance was visible at every sink.
- There had been no incidents of healthcare acquired infection in the reporting period. Patients were asked pre operatively if they carried Meticillin resistant staphylococcus aureus (MRSA). MRSA is a type of bacterial infection and is resistant to many antibiotics.
- Preparation of the operation/treatment site was described in the preparation of operation site procedure which was based on Royal College of Ophthalmology cataract surgery guidelines. We observed patients being told what to look out for after treatment such as signs of inflammation or infection.
- Most of the equipment used for surgery was disposable. The small amount of equipment that was multi use was decontaminated and sterilised by a authorised local company.
- The clinic did not perform bilateral intra ocular surgery, which is operating on both eyes on the same day.
- We saw completed and up to date cleaning schedules for all areas including monthly deep clean schedules.
- Legionella testing took place every seven to ten days along with water temperature checks, we saw an up to date record of the checks. Legionella samples were sent for analysis every three to six months. Legionella is a waterborne bacterium which causes legionnaires disease.
- Clinical waste was kept separate to non-clinical waste and stored appropriately in a dirty utility room. Sharp instruments and needles were disposed of safely and written guidance was displayed in the dirty utility room. Waste was removed by a authorised local company.
- There was a clear written procedure in place for what staff should do in the event of blood or bodily fluid spillage.
- Staff received training on infection prevention and control at induction and a refresher every three years.

Environment and equipment

Refractive eye surgery

- All areas we inspected were well equipped. Patient waiting areas appeared comfortable with the provision of TV, magazines and hot and cold beverages.
- The clinic had a laser safety policy dated January 2017 based on guidance from the MHRA which described staff responsibilities, health and safety and risk assessments. This was in line with the Laser Protection Advisor's latest report and was reflected in the local rules.
- A Laser Protection Supervisor was allocated by the central scheduling team for each laser treatment session; this was usually the laser technician. We saw the annual risk assessments of the laser treatment rooms were last completed in January 2017.
- We saw the list of authorised laser users and the signature list of staff declaring they had read, understood and would follow the local rules.
- The local rules also contained contact information for the Laser Protection Advisor. Staff could contact the LPA for personal queries such as safety precautions for pregnant members of staff.
- The clinic had a range of safety checks in place for equipment; all the check lists we reviewed showed that checks had taken place as scheduled and at the beginning of every treatment session.
- We inspected the intra ocular lens (IOL) operating room. The air handling unit in the operating room delivered 25 air changes per minute and there was a procedure in place informing staff what to do if the unit failed.
- The resuscitation trolley, defibrillator machine and suction machine were checked by the operating department practitioner on the day of surgery. Checks followed the resuscitation council checklist, we saw check list records had been signed and dated.
- Patient call bells were located in all rooms used by patients. Patients were not left alone following treatment but in the rare event that they were and needed assistance they were encouraged to use the call bells.
- We also inspected the laser treatment room and, with the patient's consent, observed a procedure taking place. All rooms where laser equipment was used were clearly signed with illuminated 'in use; do not enter' signs and were controlled by keypad entry. The room had controlled temperature and humidity this was checked prior to each procedure and recorded in the patient's notes and a separate log, we observed this being completed. There were no reflective surfaces in the line of the laser machine.
- The laser technician checked the calibration and the safety of the laser machine before each laser treatment session. The machine was also calibrated after every sixth eye procedure and we observed this taking place. Calibration and checks took place according to local rules.
- We saw the maintenance record for the laser machine. The machine was serviced at least twice a year. Any problems with the machine in between servicing would be referred to the manufacturer who sent an engineer within 24hrs.
- Other electrical equipment displayed portable appliance test (PAT) labels. We checked the labels on six pieces of equipment and all were within their servicing schedule. PAT labels show equipment has been routinely checked for safety and gives the date when the equipment is next due for routine servicing.
- Control of substances hazardous to health (COSHH) regulation 2002 risk assessments were in place for a range of chemicals including gases, mytomicin C and cleaning fluids. Mitomycin C is a cytotoxic drug which improves the result of refractive eye surgery. COSHH regulations state that employers should have risk assessments and control measures in place to reduce exposure to workers.
- Electrical sockets supported by an uninterrupted power supply (UPS) were coloured blue to distinguish them from others. The UPS was tested before each treatment session. If the power supply was lost the UPS provided enough power to complete the laser eye treatment or IOL procedure. The UPS system was also serviced annually and we saw a record of the last service.
- All electrical cables were safely positioned and did not show any signs of wear.
- Compressed gas warning signs were visible on the doors of all rooms containing gas cylinders.
- The extraction of plume was automatic via a small suction machine attached to the laser machine. Plume is the vapour produced during laser treatments which can be irritating to the eyes and smell nauseous.
- The clinic had a bariatric wheelchair. Bariatric equipment is specially designed for larger or obese patients.
- We saw a range of fire extinguishers strategically placed and within their expiry dates.

- The laser technicians were responsible for the laser keys which were kept in a locked key cupboard. We saw the laser technicians remove and return keys to the cupboard.
- Two rooms that contained sharps, drugs and COSHH products, on the main corridor of the laser treatment area, were not locked which meant they could be accessed by unauthorised persons.

Medicines

- The medicines management policy clearly described obtaining, prescribing, recording, handling, storage and security, dispensing, safe administration and disposal of the medicines held at the clinic.
- The resident registered nurse was responsible for the management of medicines at the clinic. A pharmacist was available by telephone for any queries.
- The clinic held a list of medicines with a stock count spreadsheet, we reviewed the spreadsheet numbers against the stock at the clinic and found the numbers were the same and all were within their expiry date. All medicines were supplied by one pharmacy.
- A separate policy for the administration of midazolam was in place. Midazolam is a schedule three controlled drug. It is a short acting sleep inducing medicine used for sedation purposes. Although Midazolam is exempt from safe custody regulation it was managed by the clinic as a controlled medicine. Appropriate checks were in place for the administration of midazolam and we saw these recorded in a log book. There was a named controlled drugs accountable officer. A controlled medicine is a prescription only medicine controlled under the misuse of drugs legislation.
- Mitomycin C was administered following refractive eye surgery. The use of Mitomycin C was explained clearly to patients and consent was obtained before the drug was administered. The procedure for the administration and disposal of Mitomycin C was described in a separate policy. The drug was premixed and had a very clear specific expiry time. Cytotoxic bins were used to dispose of the unwanted drug. Staff told us the bins were disposed of after each surgery session
- Medicines for sedation were only given by consent to patients undergoing intra ocular lens surgery. An anaesthetist administered the medication and was present at all times to monitor the patient. The operating department practitioner stayed with the patient during recovery and the patient was not discharged unless assessed as fit by the anaesthetist.
- Topical anaesthesia eye drops that numb the surface of the eye and local anaesthesia injections given around the eye to stop the eye moving were administered by the anaesthetist.
- Local anaesthetics and sedation were administered in line with the administration of sedation and local anaesthetic procedure January 2017.
- Prosthetic lenses used during intra ocular lens surgery were automatically restocked by the manufacturer using an electronic bar code recognition system. Each lens used was entered into a register along with the patient's details.
- Microbial protocols were not in place for antibiotics but managers told us the organisation followed the Royal College of Ophthalmologists and European Society of Cataract and Refractive Surgery guidance on antibiotic prescribing.
- We checked the medicines fridge temperature log and saw that it was up to date and temperatures were within the recommended range.
- A range of emergency medicines were stored on the resuscitation trolley and in a separate anaphylaxis pack. We checked the drugs and all were stored appropriately and were within their expiry date.
- Oxygen cylinders were stored safely. We checked all the oxygen cylinders; they contained safe levels of oxygen and were all within their expiry date.
- Only staff with the required competencies were administering and dispensing drugs. Eye drops were prescribed by the surgeon and checked by the registered nurse. Instillation of eye drops in the immediate post op/treatment period was delegated to a competent person. We saw in staff records that staff had been assessed as competent to give patients eye drops to take home and we observed during our inspection staff checking labels and verifying patient details.
- Medicines were managed according to the medicines management policy and staff attended medicines management training every three years.

Records

- The clinic used electronic and paper records for patient information. Paper records were stored securely at the

clinic until the patient was discharged and then archived off site by a dedicated archivist. The records could be retrieved by request if necessary, usually within three working days.

- At the initial consultation the patient was required to indicate on their health questionnaire whether they consented to information being shared with, or requested from their GP. If the patient had consented the electronic system automatically sent a discharge letter to the GP after the procedure had been completed.
- We reviewed four sets of patient records and saw that consent for procedure was completed, consent to contact GP was completed, allergies were recorded and a 'cooling off' period was given. A 'cooling off' period is recommended best practice and allows patients time to think about whether they wish to proceed with treatment or not.
- All records containing patient information were stored securely, electronic records were password protected.
- Each time the laser machine was used it was recorded in a log and in the patient's record, we observed this taking place.

Assessing and responding to patient risk

- Patients were self-referring and attended a series of appointments prior to treatment during which they completed a health questionnaire. The health questionnaire was completed electronically with the help of the optometrist if necessary.
- At each appointment the risks, benefits and limitations of refractive eye surgery were explained to the patient. We observed this as part of the inspection and witnessed the patient signing to declare they understood the information they had been given.
- The surgeon performing the procedure always performed a pre-operative assessment with the patient and a minimum of one week was given for the patient to change their mind – the cooling off period.
- Patients were only considered for treatment if they fulfilled the provider's suitability guidelines. We reviewed the criteria which not only assessed optical suitability, such as age related macular degeneration, but considered other health conditions. For example patients with epilepsy were considered suitable if they had been seizure free for three months, this had to be confirmed by a letter from the patient's GP providing the patient had consented to their GP being contacted.
- The suitability criteria also included psychological disorders. Patients with a psychological disorder such as depression or psychosis also needed a letter of support from their GP. We saw a copy of the medical practitioner letter of information which included the patient's authorisation to release medical information and a section for the GP to complete about their opinion of the suitability of the patient to go ahead with the treatment.
- For patients on warfarin the clinic had equipment on site to measure blood clotting levels. Warfarin is a drug which reduces the risk of blood clots forming. The provider did not carry out venous thrombo embolism assessments as the patients did not have a general anaesthetic and the treatment did not take longer than 30 minutes to complete. This was in line with Royal College of Ophthalmologists guidance.
- Patients were asked if they carried MRSA as part of the health questionnaire. An MRSA clinical directive October 2016 was in place which described the action staff should take if a patient carried MRSA or were at risk of carrying MRSA. For example all healthcare workers were prescribed a five day course of fucithalmic, an antibiotic, prior to their treatment.
- The surgical patient pathway included the completion of the five steps to safer surgery World Health Organisation (WHO) surgical safety checklist for intra ocular surgery. An amended version of the checklist was also used for patients undergoing laser vision correction. We observed the checklist being completed during our inspection. Compliance with the checklist was measured as part of the medical records audit; we saw the audit reports for April 2017 and July 2017 which showed 100% compliance.
- We observed staff following the procedure for surgical site marking and verification January 2017 which was based on National Patient Safety Agency guidance.
- The intra ocular lens (IOL) surgery team took part in a theatre brief before the start of the surgical list. This included sharing information such as patient numbers, patients with allergies, roles for the day and ended with a de brief at the end of the surgical list. We saw the completed theatre brief sheets at our unannounced inspection. The information was also displayed on a white board in the operating theatre.
- Post-operatively, sedated patients were monitored by the operating department practitioner until they were

assessed as fit for discharge by the anaesthetist. Monitoring included measuring pulse, blood pressure and oxygen levels as well as observing the patients general condition. Only patients having IOL surgery were offered sedation. There was always a member of staff who had immediate life support skills in attendance during IOL surgery clinics.

- Patients were given an out of hours telephone number to use if they had any concerns following treatment. They were also given detailed written instructions on aftercare and the time and date of their next appointment. The out of hours telephone was answered by an optometrist who had additional training in post-operative care complications. The optometrist had access to an on call ophthalmology surgeon.
- The surgeon was available in the 24 hour period following the procedure. Managers told us that there were back up surgeons available in the event that the operating surgeon was not available, for example to cover illness or annual leave.
- The need to transfer a patient to another health care provider had not occurred in the past 12 months. For medical emergencies, such as collapse, staff dialled the 999 emergency ambulance service. For optical emergencies, a system was in place to refer the patient to an emergency outpatient appointment with an ophthalmic specialist.

Nursing and medical staffing

- Surgical and laser treatment teams were allocated by a central scheduling team. This meant that the correct number of staff with the correct skills were allocated to each treatment session. A core team of staff worked across the Nottingham and other Optical Express clinics. Managers told us the clinics were organised in exactly the same way so staff were familiar with equipment and where to find it. Staff we spoke with confirmed this.
- The laser team consisted of a surgeon, laser technician, nurse or scrub assistant, surgery assistant and coordinator. The IOL surgery team consisted of a surgeon, an anaesthetist, operating department practitioner, two scrub nurses and two health care assistants. These staffing levels complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres and were in line with MHRA guidance on laser safety.
- Staff with the appropriate skills were on hand to administer medications such as local anaesthetics and sedation, and monitor the patients until they were fit for discharge.
- The Laser Protection Advisor (LPA) role for Optical Express Nottingham was provided by an external company. We saw a copy of the LPA's up to date certification and curriculum vitae.
- The clinic had a named Laser Protection Supervisor (LPS). The LPS had overall responsibility for the safety and security of the lasers including calibration of the lasers, safety checks, securing the area, making sure the lasers were shut down at the end of the treatment session, reporting incidents, reporting any technical problems with the lasers and ensuring other staff followed local rules on a day to day basis.
- In addition all the certified laser technicians undertook the role of deputy LPS when they were assisting the surgeon in the laser treatment room. This meant there was always a designated LPS present when treatments were taking place and all staff knew who was the designated LPS for the treatment session. Laser technicians had all attended core knowledge training.
- Patients were seen by the optometrist post operatively and care pathways were in place for referral of the patient to specialist advice if required. The care pathways ranged from contacting the ophthalmic surgeon for advice to liaising with other consultants or laboratory services if required. The surgeon retained overall responsibility for the patient following their treatment.

Major incident awareness and training

- An effective uninterrupted power supply system was installed in the treatment rooms. It provided enough power for staff to complete a procedure and was checked prior to each treatment session. We saw the annual maintenance report.

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

Are refractive eye surgery services effective?

Effective means that your care, treatment and support achieves good outcomes, helps you to maintain quality of life and is based on the best available evidence.

Refractive eye surgery

Evidence-based care and treatment

- 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.
- Pre-operative assessment included screening against a defined set of suitability criteria to ensure patients were suitable for the treatment. The surgeon discussed with the patient any potential limitations of the treatment as well as the potential benefits. We observed these discussions taking place on the day of our inspection. We noted from the patient notes we reviewed that a minimum of one week was given for them to reflect on their decision to go ahead with the procedure. Patients told us they were given several chances to change their minds if they wished.
- We reviewed the providers advertisements on the Optical Express website and those displayed in the waiting areas in the clinic. The costs were clearly outlined including the cost of medicines and follow up appointments. Patients we spoke with told us they were fully informed of the costs of the treatment and that there were no hidden extras.
- Managers told us there was an international medical advisory board in place made up of experts in ophthalmology who reviewed audits across the organisation. Any recommendations for change were discussed and agreed by the medical advisory board and information disseminated across the organisation. An example given was medical advisory board recommendations on which formulas to use when selecting the strength of the intra ocular lens implant. We saw the staff memo which contained the information.
- The provider had representatives on several national groups such as the Refractive Surgery Standards Working Group and the Optical Confederation. This meant that new and emerging best practice was shared within the organisation in a timely manner.
- We reviewed a sample of the care pathways, for example, natural lens replacement, management of patient with cataract and management of patient with dry eye. The pathways described the care of the patient from first consultation to discharge. Managers told us the pathways were developed by the medical advisory board and were based on best practice guidance.
- Treatment sessions took place throughout the day, between 15 to 20 patients were treated at each session. This was in line with best practice guidance.
- The surgeon working on the day of our inspection was employed by Optical Express.
- 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 Surgery.
- Regular monthly audits were completed for infection control, decontamination, air handling, incidents, complaints, patient satisfaction, record keeping, maintenance of equipment, personnel files, emergency equipment, medicines management, laser and laser room practices, quality management and health and safety. We reviewed the audit reports for May 2017 and June 2017. Areas of concern had been identified and action plans put in place with dates for completion. For example the records audit revealed that patient allergies were not always being recorded and hand basins were not always stocked with hand wash or hand towels. Information was shared with staff through staff notifications and re audit showed practice had improved.
- Anaesthetic eye drops or local anaesthetic injections were given prior to treatments to ensure patients did not suffer any pain or discomfort. We observed patients being asked if they were comfortable during treatments.
- Patients and staff told us that pain was only very mild following treatments. Patients were supplied with anaesthetic eye drops on discharge. These were only to be used in the unlikely event pain became unmanageable with over the counter medications such as paracetamol.

Patient outcomes

- At the time of our inspection independent health providers, such as Optical Express, were not able to contribute data to the National Ophthalmic Database (NOD) Audit. However the provider did benchmark Optical Express outcomes against the NOD audit which concluded 'Optical Express had a higher likelihood of excellent visual outcomes with a lower chance of

suffering either an intraoperative or post-operative complication. In addition, while the risk of vision loss is low for patients treated through the NHS, it is even lower for procedures performed at Optical Express.'

- In the past 12 months there were two unplanned returns of a patient to theatre following refractive eye surgery and two unplanned returns of a patient to theatre following cataract surgery.
- There was an expectation that approximately 5% of patients would need to return for further treatment enhancement. In the reporting period 165 patients had enhancement procedures, these were patients who had their first treatment between 2011 and 2016.
- In the reporting period June 2016 to May 2017, 28 patients had suffered complications following surgery. Most of these were minor eye conditions. One patient had suffered a post capsule rupture. Post capsule rupture is a recognised complication of cataract surgery. The rupture was recognised quickly, managed appropriately at the time and the patient referred to a retinal specialist for follow up.

Competent staff

- Staff we spoke with had the correct skills and competencies to carry out the duties required of them. All new staff attended a comprehensive induction programme including familiarisation of policies and procedures. Staff working with lasers worked alongside more senior staff until they had completed the core knowledge training.
- Managers told us some staff were multi skilled and could perform a variety of roles within the laser and intra ocular lens teams. As some of the roles were task orientated and repetitive this enabled staff to maintain interest and staff told us this improved job satisfaction. For example the surgery associates could perform diagnostic procedures, discharge patients and act as scrub assistants.
- Medical staff also completed an induction programme and the core knowledge training. They shadowed the medical director and senior ophthalmologist during a period of supervised practice. If satisfactory, they were approved by the medical director and entered onto the list of authorised users.
- Staff told us they attended an annual appraisal meeting with their manager and we saw evidence of this in the staff records we reviewed. All staff had attended an appraisal meeting within the last 12 months.
- We reviewed the personnel file of the surgeon working on the day of our inspection. It contained the following: Royal College of Ophthalmology Certificate in Laser Eye Surgery, General Medical Council registration, professional indemnity insurance, Disclosure and Barring Service checks, references, curriculum vitae, evidence of continuing professional development and patient feedback exercise.
- All staff working with lasers had attended the manufacturer's training as well as core knowledge training which was refreshed every three years. This meant they had received suitable laser equipment training and appropriate safety instructions. We saw the list of authorised laser users and staff had signed a declaration that they had read, understood and would follow the local rules.
- All staff attending laser vision correction procedures had basic life support skills; the operating department practitioner and nurse attending intra ocular lens surgery procedures had immediate life support skills. In addition the anaesthetist present at the intra ocular lens surgery procedures stayed at the premises until the last patient was fit for discharge home.
- Every quarter the clinic carried out a simulated patient collapse to refresh staff on how to deal with such an emergency, we saw the report for the July 2017 simulated event which indicated that staff had responded in a satisfactory way.
- The Laser Protection Adviser (LPA) support was provided by a recognised company. The LPA was a certificated member of the association of laser safety professionals. We saw a copy of the certificate which was due for renewal in 2020, along with a copy of their curriculum vitae. This showed they were knowledgeable in the evaluation of laser hazards and had the right skills and experience to perform the role.
- Optometrists had received additional training in pre and post-operative care. Training packages had been developed by the providers training department based at headquarters. We saw a copy of the training programme for post-operative care laser vision correction complications. The optometrist on duty told us they had attended the specialist training and we saw evidence of this in their personnel file.
- The laser technicians had attended additional competency based training in order to carry out the role of Laser Protection Supervisor. The competencies were reviewed every three years.

Refractive eye surgery

Multidisciplinary working

- We observed the refractive eye surgery and intra ocular lens surgery teams working effectively together. Each person knew their role within the team and what each member was responsible for. Staff told us they worked with each other regularly.
- We observed optometrists and ophthalmology surgeons liaising in the delivery of patient care.
- Staff understood the role of the LPA and knew how to contact the LPA if required.
- Staff responsible for managing out of hours queries from patients were clearly identified and understood escalation processes for referring patients to a higher level of care.
- Communication with the patient GP was encouraged and GPs were able to access the service through the out of hours telephone number.

Access to information

- Medical records were mostly stored electronically except for a paper record of the care and treatment carried out on the day of surgery. Electronic patient records were password protected. The details from the paper record were entered in to the electronic record following treatment. The electronic record was accessible in every Optical Express clinic which meant if a patient presented at a different clinic to where they received initial treatment their record could be accessed.
- At initial consultation the patient was required to indicate on their health questionnaire whether they consented to communication with their GP.
- Any health issues reported by the patient during their initial consultation were reviewed by the surgeon. If they required any further medical information they would ask the patient for permission to contact their GP. If the patient did not give consent for the surgeon to contact their GP the surgeon would not agree to carry out the procedure unless they were fully confident to do so.
- If the patient had consented to information about their treatment being shared with their GP the electronic system automatically sent a copy of the discharge letter. The GP could access the patient's surgeon if necessary via the same contact telephone numbers as given to the patient.

Consent and Mental Capacity Act

- The procedure for ensuring patients were able to make informed decisions about treatment and consenting to treatment was described in a consent policy January 2017.
- At the initial consultation with the optometrist the patient was given an information folder which contained; a copy of the treatment consent form, the terms and conditions document, information on the procedures available including the associated risks and benefits as well as the associated advice sheets. During this appointment, the patient was also required to watch a video which further explained the procedures and how they were carried out. The video detailed the potential risks and benefits of surgery. This meant the patient had sufficient information about the treatment to make an informed consent.
- The surgeon retained the responsibility for obtaining consent from the patient to proceed with treatment.
- Between seeing the optometrist and the surgeon for the consent appointment the patient was given a minimum of one week to reflect on their decision to proceed with the treatment, the cooling off period.
- Patient's capacity to consent to treatment was taken into account. It was the responsibility of the surgeon to assess whether the patient had capacity to consent. If there were any concerns the surgeon contacted the patient's GP.
- Patients were always asked for consent to communicate with their GP we observed this during a patient consultation and saw evidence of this in the patient records we reviewed.

Are refractive eye surgery caring?

Are refractive eye surgery services caring?

Caring means that staff involve and treat you with compassion, kindness, dignity and respect.

Compassionate care

- We observed care being given in a compassionate way. Dignity and privacy were respected, patients were seen in private rooms, patient information was treated with confidentiality. This was in line with the dignity, privacy, respect and human rights policy January 2017.

Refractive eye surgery

- We observed two procedures taking place. At both procedures the surgeon was talking to the patient, informing them what would happen, how they would feel and checking that the patient was comfortable.
- Patients told us staff helped them to feel relaxed and reassured.
- Patients were asked to complete an on line survey at the various consultation appointments they attended. The survey results were benchmarked against other clinics within the organisation. Nottingham clinic scored about the same as the organisation average for other clinics, scoring ten out of ten for the question 'did the surgery team make you comfortable and at ease?'
- Patients were given stress balls to squeeze during treatment, it is believed that squeezing and manipulating stress balls relieves stress and muscle tension. Patients we spoke with told us they found the stress balls helpful.

Understanding and involvement of patients and those close to them

- We observed staff interacting with patients before, during and after treatment. At each stage staff checked the patients understanding of the information they were given. Patients told us they were given enough information at a level they could understand and were encouraged to ask any questions at any time.
- There was clear information in patient leaflets and on the Optical Express website about the costs of treatment, aftercare and alternative treatment choices.
- Throughout policies reference was made to patients who may require additional support. For example the management of patients with restricted mobility was included in the consent policy.
- With the patient's consent, chaperones, friends and relatives were involved in the discussions about treatment and treatment outcomes. Information about chaperones was displayed in the waiting room.

Emotional support

- During our inspection we observed staff recognising when patients were anxious. Staff spent time talking with patients and in one case the anaesthetist prescribed sedation to an anxious patient.
- In the 26 feedback forms we received, comments were overwhelmingly positive with comments such as, "made me feel relaxed", "very understanding staff", "put me at ease" and "very thoughtful staff".
- Following treatment patients were instructed in post-operative care and how to instil eye drops. Relatives and carers were also involved at this point if the patient required their support with the aftercare.

Are refractive eye surgery responsive to people's needs?

(for example, to feedback?)

Are refractive eye surgery services responsive?

Responsive services are organised so that they meet your needs.

Service planning and delivery to meet the needs of local people

- Patients told us they were able to book and change appointments easily and had a good choice of treatment dates. In the event that the patient could not find a suitable appointment at the Nottingham clinic they could be referred to another clinic.
- Pre-operative appointments were flexible beginning with an initial consultation with an optometrist and followed by a preoperative consent appointment with the surgeon. If necessary additional pre-operative consultations could be arranged if the patient needed more information prior to the procedure. Post-operative review appointments were delegated to an optometrist trained to manage post-operative complications. The optometrist had access to the surgeon for advice in the event of any concerns with the patient's treatment.
- Patients we spoke with told us they were given full explanations of the treatment, expectations and post-operative care. This was backed up by patient information leaflets, contact phone numbers and an informative website. We observed patients being encouraged to ask questions.

Access and flow

- Patients were seen at the clinic at their own convenience, usually within four weeks of first enquiring about treatment. Appointments were also available at weekends. The clinic did not have a waiting list and in the reporting period there were no cancelled operations or treatments.

- There were no unexpected returns for treatment. Returns to treatment were expected and normal in some cases to make minor enhancements to the outcome.

Meeting people's individual needs

- The clinic made reasonable adjustments for wheelchair users/people with restricted mobility, however there were instances where patients with head and neck mobility restrictions could not be accommodated. This was because they were unable to lay flat.
- The clinic did not treat patients with complex health and social needs or learning disabilities.
- Patients did not have access to interpreters or translation services. The website did not hold information in different languages. Leaflets in different languages or formats were not available.
- All patient information leaflets had the crystal mark. The crystal mark is a seal of approval for information written in clear, simple English.
- An equality and diversity policy dated January 2017 was in place and staff attended training every three years.

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.
- We saw notices in the clinic and information in patient leaflets describing how to make a complaint. Information about how to make a complaint was also available on the website. Patient information on how to make a complaint did not include information about the Optical Complaints Consumer Service.
- Managers told us they would attempt to resolve verbal complaints on the day, more serious complaints were escalated to the clinical services director. Complaints could also be submitted via the website.
- The clinic had received eight complaints in the reporting period which had been managed according to the clinic's complaints procedure. We reviewed four complaints which had been managed according to the complaints policy. We saw evidence that learning had been identified from one of the complaints and shared with staff.

Are refractive eye surgery well-led?

Are refractive eye surgery services well-led?

Well-led means that the leadership, management and governance of the organisation make sure it provides high-quality care based on your individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.

Leadership and culture of service

- Clinic managers were visible, part of the team and took part in the day to day running of the services as well as managing the staff. Managers were supportive and encouraging to staff.
- On the day of our inspection we saw managers coordinating the refractive eye surgery team effectively.
- Most of the staff we spoke with had worked at the clinic for several years, they told us it was a good place to work and Optical Express a good organisation to work for.
- Staff were complimentary about their workplace and colleagues; we did not see and were not told of any conflict within the workplace however staff told us they were confident that managers could help to resolve conflict should it occur.
- Staff performance was regularly audited and we saw evidence of this in personnel files. If poor performance was identified managers told us this would be addressed through the appraisal process.
- A whistle blowing policy was in place, staff told us they were familiar with the policy and would be able to raise any concerns freely.
- Throughout our inspection by the things we observed, documents we reviewed and comments from staff and patients we spoke with, we determined the provider was responsible and honest in its approach to the treatment it provided. Patients told us there was no 'hard sell' and we did not see any evidence of irresponsible incentives.
- The principles of being open and honest were evident throughout policies we reviewed, however duty of candour was not clearly described in relevant policies such as incident and complaint management.

Refractive eye surgery

Vision and strategy

- The provider did not have a clearly defined vision and strategy and therefore this was not evident at the Nottingham clinic.
- Royal College of Ophthalmology standards are incorporated throughout policies and procedures.

Governance, risk management and quality measurement

- We saw that policies were in place for key governance topics such as information governance, incident management, risk management, management of complaints and staff recruitment. A theme throughout the policies was the importance the clinic placed on putting patients first in particular respecting equality and diversity and maintaining privacy and dignity. We saw the signature sheet where staff had signed to say they had read, understood and would follow the policies.
- Clinical committee meetings were held monthly by telephone conference. We reviewed recent minutes of the meetings, topics were relevant to the service and the minutes indicated where information should be shared across the organisation.
- The welfare and management of patients and management of risk policy dated January 2017, described risk assessment and action planning to mitigate against risk with reference to serious incidents and their management. The policy referred to staff training and the maintenance of local risk registers and described a safety culture.
- The clinic risk register contained risks which were relevant to the services provided at the clinic and were understood by staff working at the clinic. A rating system was used and actions identified to mitigate the risks.
- We reviewed the laser treatment risk register which identified potential risks, their severity and mitigating actions, risks identified were relevant to the environment and activity taking place. We also reviewed the LPA visit report January 2016 which had identified three actions which were all complete.
- We reviewed the surgeon's personnel file and were satisfied that all employment checks were complete, indemnity insurance was in place, patient feedback exercise had been completed in December 2012, annual audit of performance had taken place, and appraisal meeting within the last 12 months. Results of audit and patient feedback were benchmarked against the overall organisation results and this surgeon performed better in both. Revalidation was carried out by the responsible officer for Optical Express.
- The provider had a medical advisory board which equated to the medical advisory committee in NHS organisations. The medical advisory board was responsible for reviewing the performance of the surgeons working for the organisation.
- Local managers were involved in monitoring performance and audit and took action when required to make changes for improvement. The quality management and clinical governance policy described how local managers contributed to the organisations objective of delivering safe and effective treatment to service users.
- Although for the Care Quality Commission, fit and proper person checks only apply to directors, Optical Express applied the principles to nominated individuals and registered managers.

Public and staff engagement

- The clinic did not currently carry out staff surveys, however managers told us that the organisation was appointing a Freedom to Speak Up Guardian who would be commencing staff surveys once in post.
- Patients completed an on line survey at the clinic after the initial consultation, following the day of surgery, one week post operation and four weeks post operation.
- Information from patient surveys was collated across the organisation and trends identified. For example, patients were expressing anxiety on the day of treatment about the length of time they were in the clinic. In response the provider has improved its information for patients about what to expect on the day of treatment. Patients told us they understood that although the actual treatment took approximately 10 – 20 minutes other tests and checks needed to be carried out on the day and that they would be at the clinic between 2 – 3 hours.
- At the initial consultation with the optometrist the patient was given an information folder which included a copy of the terms and conditions, fees and information about methods of payment. We observed this information being discussed with a patient to check they understood it thoroughly.
- Staff were encouraged to give feedback at staff meetings and staff we spoke with told us they felt confident and

able to feedback on any aspect of the service. We reviewed the minutes of the most recent team meetings which included information about incidents, complaints, patient feedback and policy updates.

Innovation improvement and sustainability

- Optical Express audit and outcome data was shared with laser manufacturers to contribute to the development and improvement of the technology.
- The provider had contributed to the European and American academy meetings and published articles in the journal of cataract and refractive surgery 2016 on the outcomes and complications of excimer laser surgery in patients with collagen vascular and other immune-mediated inflammatory diseases.
- A staff recognition and reward scheme took place every Wednesday. Staff were nominated for the award by colleagues. Successful nominees were rewarded by a gift.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- Duty of candour requirements should be clearly and consistently described and defined in relevant policies and procedures.
- The provider should ensure rooms where sharps, medicines or Control of Substances Hazardous to Health (COSHH) products are stored are securely locked.
- The provider should consider providing patient information in different languages and formats.
- The provider should include information about the Optical Complaints Consumer Service in patient information about how to make a complaint.
- The provider should consider developing a vision and strategy for the service at Nottingham clinic.
- The provider should commence staff engagement surveys.