

Optical Express - Newcastle (St Nicholas) 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 - Newcastle (St Nicholas) Clinic has been established in its current city centre location since 2013 having previously traded from another location in the city centre for more than 10 years. The clinic is located on the ground floor of a multi-occupied office building. The clinic shares the location with an Optical Express optician which provide a general optical service including contact lenses, eye health screening and examinations as well as pre and post-operative intra-operative lens and laser vision correction assessments.

Patients are self-referring and self-funded. The clinic provides laser correction procedures under topical anaesthetic using Class 4 and Class 3b lasers and intra-ocular surgery to adults under local anaesthetic and conscious sedation. Ophthalmologists carry out the treatments. The clinic undertakes laser vision correction procedures approximately three times a month and intra-ocular lens procedures approximately four days a month.

All patients self-refer themselves to the clinic and they make enquiries via the website, by telephone via the Optical Express central customer services centre; they may be existing optical practice patients or in person in

the clinic. Following an initial consultation with an optical practice optometrist (at any branch), they patient must then book an appointment with a surgeon. As the surgery is not operational every day, the clinic has five resident team members who form part of a regional surgery team covering the North of England. Treatment days are staffed by the resident team members and supported by others within the regional team.

The clinic provides the following regulated activities:

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

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 12 December 2017, along with an unannounced visit to the clinic on 15 December 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's

Summary of findings

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:

- All areas of the unit were clean and tidy. The clinic provided a safe environment for patients, visitors and staff to move around freely.
- Medicines were safely stored in locked cupboards or fridges where appropriate.
- Staff stored intravenous sedation (Midazolam) in the controlled drugs cupboard. The stock was checked in accordance with the local policy and we found checks completed each day the clinic was open. The clinic manager completed bi-monthly controlled drugs compliance audits.
- There was collaborative team working observed at the Newcastle clinic involving surgeons, optometrists, nursing and administrative staff.
- We observed professional and caring interactions between staff and patients.

- Patients informed us that they were never pressurised to undergo laser eye surgery.
- The clinic made reasonable adjustments for vulnerable patients and those living with a disability.
- The clinic environment was spacious for ease of access for wheelchair users. There was access to disabled toilets and child changing facilities.
- Patients had access to a very informative website which provided company information, eye health information, guidance on procedures offered and patient testimony.

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

- We looked at five staff files and found that one file had no evidence of employee references and another file had no evidence of appraisal.
- The consent policy did not reflect Royal college of Ophthalmologists 2017 guidance for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider did not have any patient information leaflets for patients where English was not their first language. The provider was looking at ways to improve this.

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

Ellen Armistead

Deputy Chief Inspector of Hospitals (North Region)

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating

Summary of each main service

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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Optical Express (Newcastle)

Services we looked at

Refractive eye surgery

Summary of this inspection

Background to Optical Express - Newcastle (St Nicholas) Clinic

Optical Express - Newcastle (St Nicholas) Clinic is operated by Optical Express. The service opened in 2013 in its current location after operating for 10 years from another site in the city centre. It is a private clinic in Newcastle, Tyne and Wear. The clinic primarily serves the communities of Newcastle and the North East of England. It also accepts patient referrals from outside this area.

The hospital has had a registered manager in post since October 2014.

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 Lorraine Bolam, Interim Head of Hospital Inspection.

Information about Optical Express - Newcastle (St Nicholas) Clinic

Optical Express Newcastle provides treatment and care to adults only and the service runs over seven days. Opening times were flexible according to patient's treatments and appointments. There are no regular set day that surgery takes place. Surgery for laser treatment takes place approximately three times a month and intra-ocular lens procedures approximately four days a month. This meant there were days that the service did not open and staff were asked to work at another clinic across Northern England on a rotational basis.

The clinic has been operational in its current location since 2013 and is based on the ground floor of a multi-occupancy office building. It is shared with an Optical Express optician practice. The ground floor consists of:

- Laser treatment room. This room contained a Class 4 and Class 3b lasers and had two adjoining rooms; i.e. utility and clean room.
- Surgeon's examination rooms. Two rooms laid out as a typical ophthalmic examination room.
- Two discharge rooms. A laser discharge room which had no recliners and an IOL discharge room which contained two recliners.

- Consultation room. A small room used by patients if they want to discuss something private.
- Anaesthetic room. This is where patients receive their anaesthetic block and sedation. There is direct access from this room in to the theatre.
- The clinic also had other rooms used during the course of treatment.

The clinic undertakes refractive eye surgery on patients aged 18 and above. The clinic does not provide treatment and care for young people. The clinic does not offer any other services that are within CQC scope of registration.

As the service is not operational every day, the clinic has five resident team members only who form part of a team covering the North of England region. The clinic had one full-time and one part-time directly employed ophthalmologists as well as three part-time and one full-time other clinical staff. There are no current vacancies. In the last 12 months, no one joined or left the service.

Activity (reporting period October 2016 to September 2017)

- There were 964 laser eye surgery procedures performed

Summary of this inspection

- There were 164 intra-ocular lens procedures

Services provided at the service under service level agreement:

- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- Laser maintenance service
- 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 services.

We found the following areas of good practice:

- Staff followed the incident reporting policy. Staff completed an incident form. Staff sent the completed form to the surgery manager, the surgical services manager and clinical services directorate.
- All reported incidents were logged by Clinical Services where themes and trends are considered. Learning from submitted incidents and investigation outcomes are shared across the organisation by way of staff memos which are discussed at local team meetings.
- All areas of the unit were clean and tidy. The clinic provided a safe environment for patients, visitors and staff to move around freely.
- Access to all clinical areas was restricted through the use of key coded doors.
- Medicines were safely stored in locked cupboards or fridges where appropriate.
- Staff stored intravenous sedation (Midazolam) in the controlled drugs cupboard. The stock was checked in accordance with the local policy and we found checks completed each day the clinic was open. The clinic manager completed bi-monthly controlled drugs compliance audits.

Are services effective?

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

We found the following areas of good practice:

- Staff completed local compliance audits against key performance indicators, aligned to the patient journey along with specific audits covering topics such as infection prevention and control, documentation and medicines.
- The clinic manager completed these audits bi-monthly.
- Staff provided patients with anaesthetic eye drops post-treatment to assist with pain relief. Staff did not provide any systemic analgesia. Patients undergoing IOL procedure were given intravenous sedation which provided pain relief during and after the procedure.

Summary of this inspection

- The surgery manager completed staff appraisals annually where objectives were set. Staff also held informal discussions and reviews with their line manager throughout the year. Appraisals covered four key areas – clinical competency, trainer/mentor leadership, patient advocate and team member.
- Surgeon appraisals were overseen by the medical director and clinical services director. This included a review of individual safety and efficacy scores which underpinned performance review.
- There was collaborative team working observed at the Newcastle clinic involving surgeons, optometrists, nursing and administrative staff.

However,

- We looked at five staff files and found that one file had no evidence of employee references and another file had no evidence of appraisal.
- The consent policy did not reflect Royal college of Ophthalmologists 2017 guidance for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Are services caring?

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

We found the following areas of good practice:

- We observed professional and caring interactions between staff and patients.
- There was a genuine compassion and care partnership apparent between staff and patients.
- Patients informed us that they found Optical Express to be warm and friendly and they were informed about the benefits and risks of the surgery.
- Patients informed us that they were never pressurised to undergo laser eye surgery.
- Staff allowed patients who were nervous or anxious about their procedure to have a pre-visit and be shown around the clinic and meet staff.

Are services responsive?

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

We found the following areas of good practice:

Summary of this inspection

- The clinic made reasonable adjustments for vulnerable patients those living with a disability.
- The clinic environment was spacious for ease of access for wheelchair users. There was access to disabled toilets and child changing facilities.
- The clinic had wheelchairs suitable for bariatric patients however were constrained by the limitations imposed by existing equipment such as the laser bed.
- Patients had access to a very informative website which provided company information, eye health information, guidance on procedures offered and patient testimony.

However, we also found the following issues the provider needs to address:

- The provider did not have any patient information leaflets for patients where English was not their first language. The provider was looking at ways to improve this.

Are services well-led?

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

We found the following areas of good practice:

- The company vision, strategy and corporate objectives were displayed around the clinic in staff areas.
- Staff were aware of current roles, responsibilities and accountability; however, the clinical governance lead wanted to formalise the structure and make the current clinical governance processes more robust.
- The organisation had developed a new social media platform called 'My Eye Clinic' for public engagement targeting the 18 – 35 age group.
- A national line is in existence for prospective patients to speak to former patients about their experiences of laser eye surgery.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- There had been no never events or serious incidents reported in the clinic in the previous 12 months. 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.
- There had been four incidents reported at the clinic during the past 12 months. These related to suction loss during laser treatment (two incidents) and incomplete flaps (two incidents). These had been investigated to look for improvements to the service.
- The provider had policies in place for safety monitoring, reporting and investigating incidents. Staff we spoke with were aware of how to complete and respond to an incident or near miss. Incidents were reported on a form and sent to the surgery manager and surgical services director. The director liaised with patients regarding the incident and the surgery manager was responsible for investigating incidents. The surgery manager was trained in root cause analysis as part of their investigating duties.
- Learning from submitted incidents and investigation outcomes was shared nationally across the organisation by way of staff memo which was discussed at local team meetings. We reviewed team meeting minutes where incidents were discussed. Staff signed the memo to confirm read receipt.
- The staff we spoke with were aware of their responsibilities in relation to duty of candour requirements. There had been no duty of candour notifications reported in the previous 12 months.

- 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.

Mandatory training

- Mandatory training for staff included a range of core topics such as fire safety, manual handling, infection prevention and control, data protection and safeguarding. The training was updated every three years.
- Mandatory training was delivered via e-learning programmes. Records showed that all staff (100%) working at the clinic had completed their mandatory training. The corporate target for mandatory training completion was 100% compliance.
- All staff working at the clinic were trained and up to date with basic life support (BLS). The surgical services manager reported that some staff from other Optical Express locations were trained in intermediate life support (ILS) and could be utilised when working at the Newcastle clinic if required, as staff worked in several clinics.

Safeguarding

- The clinic had a safeguarding children and vulnerable adult's policy highlighted the process for staff to follow with issues or concerns regarding safeguarding. Staff understood how to identify and report safeguarding concerns.
- The clinic did not provide treatment to young people under the age of 18; however children attended the clinic with patients and relatives.

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- The surgery manager was the identified safeguarding lead. All staff had completed safeguarding training to level two for both children and adults.
- The service had not reported any safeguarding concerns in the last 12 months and there were no safeguarding issues reported to the Care Quality Commission.

Cleanliness, infection control and hygiene

- The provider had an 'Infection Control Policy' and local guidance on infection prevention and control (IPC) best practice.
- There had been no health-care acquired infections reported by the clinic during the past 12 months.
- The clinic was visibly clean, tiled and well maintained. Daily cleaning checklists were in place and we saw these were completed appropriately by staff.
- There were handwashing basins and wall mounted hand washes throughout the clinic. We observed staff washing their hands and using personal protective equipment (PPE) appropriately. All bins were hands free and there were handwashing facilities in the clinical areas and toilets.
- Staff used clean and dirty utility areas appropriately. Staff segregated and disposed of waste and sharps in accordance with local policy. The clinic had contracts in place with external providers for waste collection.
- The clinic did not decontaminate any reusable surgical instruments on site; however, they had arrangements with a local hospital for the collection, decontamination and return of such equipment requiring cleaning.
- The clinic employed domestic cleaners two days per week to undertake cleaning of the laser rooms and communal areas on the days the clinic was providing surgery.
- Infection control and hand hygiene audits were carried out at least every two months. Audit records between August and November 2017 showed a high level of compliance with cleanliness, hand hygiene and infection control guidelines. Remedial actions were put in place where areas for improvement were identified and these were followed up.

Environment and equipment

- The clinic was located on the ground floor of a multi-occupancy office building in Newcastle city centre. Clinic facilities included a large open plan reception and seating area, laser treatment room, two surgeon examination rooms, two discharge rooms, consultation room, two screening rooms, intra-ocular theatre, utility room, two post-operative rooms, anaesthetic room, pre-operative room and an optometrist's examination room.
- In the reception waiting area there were sofa chairs and settees for patient's comfort. There were also magazines and free access to hot and cold drinks. The reception area was clean and tidy. During the inspection, the toilets were being refurbished and thus patients had to use the toilets on the next floor of the building, where disabled toilets were located. There were two lifts for the use of patients.
- We followed the patient pathway through clinical and non-clinical areas from initial enquiry to aftercare. We found the environment suitable for the service offered and provided.
- We saw the clinic was well maintained and generally free from clutter. We found that staff had stored some shelving temporarily near to a fire exit, potentially causing an obstruction to the exit. We raised this with staff during the inspection and this was addressed immediately.
- Access to all clinical areas was restricted by way of key coded doors. The exterior doors to the laser rooms displayed controlled area warning lights.
- All clinic staff told us they had sufficient equipment to deliver patient care safely. This was crucial as the clinic carried out sedation of patients. Clinical areas were observed to contain equipment that was suitable for the assessment, diagnosis, treatment, recovery and aftercare for patients undergoing laser refractive eye surgery.
- Staff completed equipment and environment checking logs. The intra-ocular theatre log was completed daily when the clinic was open and covered all equipment and machinery. We also

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reviewed laser verification logs and calibration logs which had been completed in accordance with manufacturer recommendations, best practice guidelines and local policy.

- We reviewed maintenance files for external party checks covering air quality, air particulate measuring, manufacturer engineering reports, schedules and the local annual checklist. All equipment checks met with local policies and manufacturer recommendations.
- The laser room held the local rules which had been updated in June 2017. The local rules provided contact details of the laser protection supervisor, the laser protection advisor and details for the safe operating of the equipment. The laser protection advisor carried out a site visit and risk assessment every three years.
- The temperature monitor and humidity log were recorded daily on a laser log sheet. The laser equipment had a backup supply in the event of a power failure.
- Staff checked emergency (crash) trolley including oxygen and suction daily when the clinic was open. Staff recorded the check in a log book. The clinic also had 'emergency equipment' packs which staff also checked daily.

Medicines

- We found medicines were safely stored in locked cupboards and fridges where appropriate. Staff checked fridge temperatures daily when the clinic was open to ensure the safety and efficacy of medicines requiring refrigeration. Staff reported any temperature ranges outside the safe upper and lower limits to the maintenance team.
- Staff stored their intravenous sedation (Midazolam) in the controlled drug cupboard. The stock was checked in accordance with the local policy and we found checks completed each day the clinic was open.
- The clinic used cytotoxic eye drops (Mitomycin-C) and these were ordered into the clinic in a reconstituted format in a sealed bottle. The medicine was stored in a locked fridge prior to use. There was a local Mitomycin-c policy, a 'control of substances hazardous

to health' (COSHH) policy and a local risk assessment which staff were aware of. Staff completed training in the use of cytotoxic medicines as part of their laser competencies.

- Staff provided patients with medicines to take home. These were prescribed by the surgeon, dispensed by the registered nurse and handed to the patient by the healthcare assistants. Staff received training in dispensing as part of their medicines management training. Patients were advised how to administer the prescribed medicine correctly at home.
- Prior to leaving the clinic, patients were given verbal instructions, supported by a written leaflet explaining when and how to take the prescribed eye drops, what to expect in the first 24 hours and personnel aftercare.
- During the inspection, we saw that all medicines were labelled in accordance with national guidance to include patient name, name of medicine, dose, instructions on administration, safety points and the address where dispensed. Staff also provided patients with the medicine information leaflet.
- Medical gases were suitably labelled and were stored securely within the clean utility area in accordance with national guidelines. Used gas bottles and unused gas bottles were stored separately to avoid any confusion by staff.
- The surgery manager completed medicines management and controlled drugs compliance audits every two months. Audit records between August and November 2017 showed staff complied with the provider's policies and procedures.
- Prior to leaving the clinic, patients were given verbal instructions, supported by a written leaflet explaining when and how to take the prescribed eye drops, what to expect in the first 24 hours and personnel aftercare.

Records

- Access to confidential patient information was restricted to staff and held in secure areas. All paper records were stored in a locked room. Electronic patient information was stored on the provider database which was password restricted. All computer terminals were manned by staff or secured when not in use.

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- We reviewed the records of nine patients comprising five from laser procedures and four from lens replacement procedures. These were up to date and completed appropriately. All sets of records contained relevant consent forms, surgical safety checklist, prescription record, eye examination history and surgery management record (for laser surgery).

Assessing and responding to patient risk

- We observed patient consultations and saw that risks associated with the treatment were clearly outlined and discussed openly with the patient during pre-consultation, surgical assessment and treatment day.
- All patients completed a health assessment questionnaire as part of the pre-consultation and this was reviewed with the clinical staff. The health assessment questionnaire was refreshed on each visit in the event of changes which may impact on risk and safety.
- Staff informed patients of treatment options based on the combination of the health assessment questionnaire, eye examination results and surgeon review which were underpinned by professional guidelines.
- Staff followed an escalation policy in the event of patient deterioration, emergency or the need to escalate care. The clinic had local specialist NHS contacts for this purpose; i.e. numbers of the local A&E. In all cases, the clinicians on site and the clinical services director would be informed of any such events. Where these could not be managed internally, such as infections, a care management plan was discussed with the responsible clinician and the patient.
- In the event of patients' health deteriorating during surgery, staff would call an ambulance for the patient. There had been no instances where patients required transfer to hospital during the past 12 months. After surgery, patients could contact a 24-hour helpline in the event of any problems with their eyes.
- Patients that received sedation were taken to the post-operative room after surgery to recover from the effects of surgery. Also, they were collected from the clinic by a family member or relative rather than being discharged on their own.
- Staff completed a surgery register for each individual patient. This held information about patient demographics, eye operated on, the specific procedure and equipment batch numbers in the event of the need to refer back.
- Staff used an adaptive 'five steps to safer surgery' World Health Organisation (WHO) checklist. We observed the laser theatre team undertaking the 'five steps to safer surgery' procedures, including the use of the WHO checklist. The theatre staff completed safety checks before, during and after laser surgery and demonstrated a good understanding of the 'five steps to safer surgery' procedures.
- The WHO checklist record was stapled into the patient's notes to be used in surgery. We looked at four WHO checklists during our visit and found them to be completed appropriately. A WHO checklist audit was carried out to check staff compliance. We looked at recent WHO audit records which identified 100% compliance.
- In most cases, patients undergoing laser eye procedures had both eyes treated on a single visit. In the event of one eye being treated, the surgeon marked the eye and this was rechecked prior to the procedure.
- Staff escorted patients to the recovery room and into the comfortable chair after the procedure, where they were offered a drink and a snack. Patients remained in the clinic until a post-treatment review was completed. This included a check to see how the patient was feeling after the procedure, to ensure they could be safely conveyed home and to revisit post-procedure care instructions.
- The surgery manager informed us that they had carried out a sepsis awareness event in September 2017. The surgery manager had written a sepsis awareness policy and had sent this to regional surgery teams as well as optometrists. A sepsis flowchart based on NICE guidelines was also developed to provide guidance for staff.

Refractive eye surgery

Nursing and medical staffing

- We reviewed the staffing arrangements for the clinic. The clinic employed a registered manager. There were five members of staff that worked at the clinic who were part of a larger regional team covering other clinics in the region. There were no vacancies at the clinic and they had not used any agency staff in the last 12 months.
- There were two ophthalmologists (surgeons) directly employed by provider that carried out procedures at the Newcastle clinic. The theatre team consisted of the surgeon, nurse or scrub assistant, laser technician, discharger and a coordinator.
- After surgery, patients are taken to the post-operative room by a member of staff to recover before being discharged. Also, at this stage they are given pain relief eye drops and information on how to look after their eyes post-surgery.
- A full-time scheduler was employed at the head office who produced the staff schedule for every clinic, to ensure that the team had the correct level and skill matrix of staffing for each treatment day.
- The Laser Protection Superior (LPS) had been trained in the USA by the laser manufacturers during a one week course and certified as competent in the use of lasers and associated equipment. The service identified a number of technicians who were funded to train with the manufacturers' clinical application team in the USA. These were the Senior Refractive Trainers (SRT) and they carried out the laser competency assessments locally and supported technicians and LPS to ensure they remained skilled. They underwent competency revalidation every three years.
- The LPS were responsible for ensuring the lasers were calibrated, safety checks completed, the area was secure, lasers were closed down at the end of the day, all incidents were reported, laser performance issues communicated to the engineer, manager and head office and safe custody of the keys.
- Patients were given an out-of-hours number operated by optometrists on a rota basis. The patients were also given contact details and could phone the surgeon following their procedure.

- The surgeon attended the clinic on an 'as required' basis subject to patient demand. The surgeon remained on-site until all patients had safely departed the clinic.

Major incident awareness and training

- The clinic had an 'Equipment or mains services failure policy'. This detailed action to be taken in the event of equipment or power failure. Staff were aware of the policy and the action to be taken in the event of a local incident.
- The laser equipment had a backup supply in the event of a power failure.
- Staff had clear instructions for what to do in the event of a fire.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Care and treatment was delivered to patients in line with the provider's corporate national guidelines, Royal College of Ophthalmology (RCOphth) Standards for Laser Refractive Surgery and National Institute for Health and Care Excellence (NICE) guidance.
- All patients undergoing procedures had their needs assessed and their care planned prior to any treatment. All treatments offered were based on the clinical need of the patient and were delivered in line with evidence based guidance and professional standards. Where it was assessed that patients were unsuitable for a particular treatment or were more suitable for a treatment provided outside of the services at the Newcastle clinic, patients were duly advised and signposted accordingly.
- The suitability guidance and treatment criteria were subject to review each year by the corporate provider's International Medical Advisory Board (IMAB).

Pain relief

- Staff answered patient questions and concerns about pain associated with the procedures. Staff managed

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patient expectations around potential discomfort during and after the procedure. Staff also provided reassurance during the procedures to alleviate any anxiety.

- Patients undergoing laser eye surgery were treated under local anaesthesia. Anaesthetic eye drops were administered prior to treatment to ensure patients did not experience pain or discomfort. Patients were provided with a 'standard' pain relief regime following laser procedures.
- We spoke to patients returning for after care appointments. They informed us that they had experienced little or no pain during or after the procedure.

Patient outcomes

- The corporate provider had a full time biostatistics team based in the USA, who collected data, from patient electronic files to correlate the surgeons' annual outcomes. Each year, the surgeon was presented with their clinical outcomes, which were discussed and evaluated as part of the surgeon's appraisal process.
- Data collected included total number of treatments, male to female ratio, analysis by age group, vision comparisons pre operatively to post operatively, safety and efficacy, enhancement rate (when additional surgery was needed) and complications. We looked at the outcomes data for one surgeon operating from the Newcastle clinic, which showed their clinical outcomes were in line with the provider's average and national standards.
- Surgeons' statistics were recorded and compared to other surgeons within the organisation. The surgeon's establishment rate was the same as average for all surgeons within the organisation. Surgeons were given a score in relation to efficacy and safety. A score of 50 represented outcomes on par with expected Optical Express levels; a score above 50 represented an above average score. The surgeon's efficacy score (48) was slightly below average and safety score (45) was above average.
- The service expected to enhance approximately 5% of treatments. This meant that patients may have needed to return to the clinic to correct vision issues

or to achieve an outcome in which the patient was satisfied. Patients were aware of the potential need for enhancement at the start of their treatment so they were not unexpected. Some of the enhancements that were completed at the clinic had not had primary treatment within the last 12 months.

- The clinic completed 92 enhancement procedures over the past year; this included primary surgeries that were completed more than one year ago. Out of the 92 enhancements, 33 were completed following surgery that had taken place between October 2016 and September 2017. The reasons for enhancements were due to quality of vision issues and desired outcomes not achieved by the patient.
- The surgeon's enhancement rate was calculated and reviewed within their appraisal. The enhancement rate was calculated by determining the total number of primary procedures in a given time period that result in an enhancement within the first year. The surgeon's enhancement rate was 0.9%; this was better than the Optical Express expected range, where the average was 1.7%.

Competent staff

- Staff completed a corporate and role specific induction when they commenced employment. Staff were allocated a mentor and set learning objectives. The mentorship period was variable according to previous experience and the nature of the role. Staff also completed task based competencies and remained supernumerary until their competencies had been assessed.
- Staff told us they routinely received supervision and annual appraisals. Records showed all staff had completed annual appraisals. All eligible staff had validation of their professional registration completed within the last 12 months.
- The clinic employed two surgeons and one of two who performed refractive eye surgery held the Royal College of Ophthalmology Certificate in Laser Refractive Surgery.
- The Laser Protection Superior (LPS) had been trained in the USA by the laser manufacturers during a one week course and certified as competent in the use of lasers and associated equipment. The service

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identified a number of technicians who were funded to train with the manufacturers' clinical application team in the USA. These were the Senior Refractive Trainers (SRT) and they carried out the laser competency assessments locally and supported technicians and LPS to ensure they remained skilled. They underwent competency revalidation every three years.

- The LPS were responsible for ensuring the lasers were calibrated, safety checks completed, the area was secure, lasers were closed down at the end of the day, all incidents were reported, laser performance issues communicated to the engineer, manager and head office and safe custody of the keys.
- All staff completed detailed competency assessments every three years. These included pre-screening, preparing and assisting in theatre, patient discharge and laser technician duties. Staff informed us that all staff competencies were reviewed and monitored by the national training manager.
- The ophthalmologist surgeon completed three phases of training prior to working unsupervised. The ophthalmologist completed their induction programme with the medical director and clinical services director. The induction included detailed information about the procedures; diary and patient management systems; protocols and pathways. They also shadowed the medical director or a senior ophthalmologist so that they could appreciate the running of a treatment diary, each staff member's role and become familiar with the general flow and records system.
- When the surgeon's induction programme was completed, the medical director entered the surgeon on to the list of authorised users. This list was reviewed by the surgical services manager. The surgeon's performance in terms of outcome and complications was monitored centrally and through informal feedback from the surgery manager. Clinical outcomes were subject to an annual audit by the statistical team who reviewed outcomes and flagged up any issues in between appraisal times.
- We looked at five staff files and they showed that identity checks had been conducted and the files included records of mandatory training, disclosure

and barring service (DBS) checks and references. We found most files were complete and up to date; however, one staff file did not contain evidence of written references and one file had no evidence of staff appraisal.

Multidisciplinary working

- There was a strong and integrated team ethos at the Newcastle clinic. All grades of staff acknowledged their roles and responsibilities. Staff stressed the importance of effective team working to be fundamental to positive patient outcomes and the patient experience.
- The surgeon had overall responsibility for patient care; however, was fully supported by the clinic team (including the optometrist, the manager, supervisor and administrative staff). We observed professional and effective communications between staff.
- At the beginning of each surgery day, the team completed a team brief which discussed all staff's roles and responsibilities. The team brief also included information relevant to patients receiving surgery and an update on any specific issues or incidents.

Access to information

- The clinic had two systems of recording patient information; an electronic medical record (EMR) and for the surgery day only and a hard copy paper file which contained signed documents, prints of scans and laser treatments, instrument traceability labels and medication prescriptions.
- Patient electronic records held details of a patient's past medical history, medication, allergies, consent information, clinical notes, pre-assessment notes and surgeons' operation notes. This meant that information was readily available to all staff.
- The EMR system was accessible in every Optical Express practice. It was password protected and different grades of staff could view, access and add records which were appropriate to their role only.
- Staff had access to policies and procedures through the provider's intranet. Staff also had access to complete incident forms either electronically or paper copies.

Consent and Mental Capacity Act

Refractive eye surgery

- Patients attended an initial consultation with an optometrist. The optometrist discussed information regarding treatment options and included information on costs and methods of payment.
 - The optometrist completed an assessment of the patient's visual condition, taking in to account the patient medical history, views, experience and knowledge to identify which treatments were likely to result in overall benefit for the patient.
 - The optometrist explained the treatment options to the patient and recommended a particular treatment option, setting out the potential benefits, risks, burdens and side effects of the treatment options, including the option to have no treatment.
 - At the time of consultation, the patient received a 'patient 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. The patient was required to sign their medical record electronically at the end of the consultation to confirm that they had watched the video. They also confirmed that they had been provided with all the information they required, including the consent documents before proceeding to the next appointment.
 - All discussions were recorded in the patient's electronic and paper records, which were then made available to the operating surgeon.
 - If the patient wished to proceed, they were required to have a consultation with the surgeon who would be completing the surgery; this was either face to face or by telephone. On the day of surgery, the surgeon saw the patient and discussed the plan of care as well as the risks and benefits of surgery. Following this the patient completed another consent form.
 - The clinic had a 'consent to treatment' policy (September 2017) which provided guidance for staff on how to obtain patient consent. The policy stated it was a surgeon's responsibility to ensure the patient understood the purpose of the procedure and that consent had been completed.
 - Staff informed us that 'remote' telephone consent was obtained from patients prior to the day of surgery, followed by consent on the day of surgery. Patient records we looked at showed that patient consent had been obtained and planned care was delivered with their agreement.
 - The consent policy stated a "cooling off" period of three days was required prior to the procedure. However, the consent policy should reflect the Royal College of Ophthalmologists 2017 guidance for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
 - Where a patient lacked the capacity to make their own decisions (for example, patients with a learning disability), the surgeon liaised with the patient's GP and patient's representatives (who could make decisions on behalf of the patient) in order to determine if treatment could be offered. However this process could not be tested as the clinic had not received any patients lacking capacity.
 - Staff were aware of the Mental Capacity Act 2005 but no patient with dementia had been treated to date for surgery. If a person did lack capacity, the surgeon would need to be satisfied that the patient has understood consent.
 - The current policy was that patients needed to bring their own interpreter if English was not their first language. The clinic had a diverse workforce and often asked staff to interpret; however, the clinic was looking in to contracting with a professional interpretation services company.
- Are refractive eye surgery services caring?**
- Compassionate care**
- Staff were passionate about patient care and all were respectful towards patients.

Refractive eye surgery

- Staff welcomed patients when they arrived on the ground floor premises. We observed that the staff were professional and friendly.
- We observed that staff introduced themselves to patients and were kind and compassionate in delivering care.
- Privacy and dignity of patients was maintained at all times. The reception and waiting area was an open environment; however, consultation rooms were frequently used for private discussions. We observed positive and discreet conversations between staff and patients.
- Staff received positive comments from all the patients we spoke with. We spoke with nine patients during the inspection. One patient commented how she felt like a bionic woman since she had her eye surgery. She added how the service was “impeccable” and staff “lovely”. Another patient commented “the room was spotless where the procedure took place,” another patient stated “10 out of 10 for the service,” “very happy with the service.” However, one patient commented “after-care a bit slow; time gaps between appointments.”
- Patient’s confirmed their privacy and dignity was maintained at all times. Patients were provided with private areas for consultations, a private changing area and a private recovery area after treatments.
- All patients we spoke to were happy with the treatment received and care received. All patients told us they were informed of all the risks and benefits and had plenty of time to consider their surgery.
- Staff informed us that patients were asked to complete an online survey at various points during their care. The surgery experience survey was completed at the post-operative follow up appointment the day after surgery, if patients were willing to participate.

Understanding and involvement of patients and those close to them

- All patients were asked about their requirements and staff provided realistic expectations of the likely outcomes of their surgical procedure. Staff recorded these discussions in the patient notes.

- Staff invited and welcomed patient’s family involvement in care. Staff encouraged patients to be accompanied by relatives at appointments, in particular on treatment days.
- Patients were encouraged to ask questions about their care and treatment during consultations. We observed staff answering queries and concerns during these meetings.
- Staff took time to revisit and re-explain instructions to patients and their family members about post treatment care. This included medicines regimen, infection prevention, activities to avoid and after care reviews.
- Patients were aware of and informed of all costs associated with the proposed treatment. Staff discussed financial matters in a private consultation area.

Emotional support

- At initial consultation, staff introduced themselves by first name, their role and how they were there to assist. Staff asked patients how they would like to be addressed during their time at the clinic.
- Staff provided patients with necessary time and information to make care decisions. Staff confirmed patients could take any amount of time necessary and attend any number of pre-consult appointments before consenting.
- We observed staff giving reassurance to patients during consultations and at treatments.

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

Service planning and delivery to meet the needs of local people

- Optical Express Newcastle had been operating from its current site since 2013 having been trading for the previous 10 years at another location. The site served the population of Newcastle and the North East of England.

Refractive eye surgery

- Staff informed us that any person could attend any Optical Express nationwide as the service could access patient electronic records from every clinic.
- The service had direct access to patient electronic information in all Optical Express clinics. This meant that staff could access up-to-date information about patients.
- Staff informed us that all patients were offered a follow up appointment 24 hours after surgery, one week, one month and three months post-surgery. These appointments involved aftercare advice and follow up, assessment for risk of infections or side effects and the possibility of the need for enhancement procedures to refine outcomes.
- The clinic was open during weekdays. Surgery days were carried out approximately two to three times per month depending on treatment needed. This was dependent on patient demand and activity across the provider's other locations.
- During working hours, patients could contact the clinic if they had any additional questions or concerns. An out of hours contact number was available for patients to use after the service had closed.
- There had been two instances of cancellation on the day of surgery during 2017. One instance was due to a patient that did not attend and a follow up call was made to determine the reason patient did not attend their appointment. The second instance was due to an equipment failure and surgery and staff rearranged the procedure for another date.
- The clinic reported that there had been no incidence of an unplanned transfer of a patient to another health care provider in the last 12 months.

Meeting people's individual needs

Access and flow

- Patients were able to self-refer without a GP or optician's referral. Appointments were made to suit patient requirements. Patients could make enquiries via the Optical Express website, in person at the clinic, or they may already have been an optical patient at the practice and have discussed laser vision correction during their routine eye test and health check.
- Patients were advised to attend a free consultation with an optometrist. The Optometrist carried out an eye examination and used the Clinical Suitability Guidance document to make an initial assessment on the patient's suitability for a refractive procedure taking into account the individual's needs and expectations and ocular health and history.
- Staff told us patients could choose an appointment time that was suitable for them. Staff informed us that waiting times for clinic appointments were kept to a minimum and there was no waiting list for refractive eye surgery.
- Staff provided written literature to patients to aid their understanding of the treatment options to support care decisions.
- The clinic was situated in Newcastle city centre with ease of access by car and public transport. The clinic was located on the ground floor of a multi-occupancy office building.
- The clinic had an open plan reception and waiting area with comfortable settees, chairs, magazines, television and hot and cold drinks. There were areas for private consultation and discussion.
- The clinic was currently reviewing the facilities they provided for those patients with hearing difficulties. Staff were unclear if a hearing loop system had been installed at the clinic; however, this was under review.
- Patients whose first language was not English were advised to book their own interpreters; however, multilingual staff had been pro-active in interpreting where an interpreter was not available or had not been booked by patients. The clinic was looking to access the services of a professional interpretation company, the cost of which would be borne by the clinic.
- All the patient information leaflets were in English. The organisation was currently completing a scoping exercise to identify what languages would be best compiled and at which clinic location. This work was ongoing at the time of our inspection.
- Staff told us they had not treated any patients living with dementia or a learning disability; however, they made it clear they would take all reasonable steps to

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accommodate their particular needs whilst in their care. All patients had their level of co-operation and understanding assessed as part of the pre-consultation and consenting process.

- The computer used by patients to complete their health questionnaire was situated in the reception area and although situated away from view of other patients waiting in the clinic, the screen could be easily viewed from pedestrians and passers-by outside the clinic. This was brought to the attention of the clinic manager and we saw the screen had been moved away from the window during our unannounced visit.

Learning from complaints and concerns

- A summary of the complaints process was displayed in the reception area. This included details of how to escalate a complaint, the CQC's contact details and contact details of an impartial mediator. There were comment cards strategically placed for patients to complete and provide feedback about the service. Additionally, staff informed patients of the complaints procedure in their welcome pack and upon request. Staff attempted to proactively deal with patient concerns at a local level to avoid escalation but provided patients with head office details to further a complaint where necessary.
- The complaint policy stated that complaints should be acknowledged within 2 working days and respond to complaints with 20 working days.
- We reviewed the clinic complaints file which detailed 10 complaints between September 2016 and September 2017. Five of these complaints were managed locally by the clinic manager and the other five were co-ordinated by the clinical services team at the provider's head office. All the complaints were responded to in a timely manner.
- Most of the complaints were around patient expectations. The written complaint responses were detailed and contained lots of medical terminology which was not always fully defined. This meant that some patients may find the content of the letters difficult to understand.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was clear leadership and staffing structure within Optical Express.
- The corporate management structure consisted of Chief Medical Officer, optometry directors, managers and optometrists; operations director, managers and teams and the clinical services team, which consisted of the refractive operations manager, surgical services manager, location surgery managers and location surgery team.
- The surgeon's accountability was to the medical director and in turn the chief executive officer.
- The clinic was managed on a day to day basis by surgery manager (who was also the registered manager). The surgery manager was managed by the Optical Express surgical services manager, who attended the clinic periodically when required.
- Staff were clear about their reporting line within the management structure. They told us that local managers were honest, proactive and they felt confident to approach their line managers with any concerns.

Vision and strategy

- The company vision and corporate objectives were displayed around the clinic in staff areas.
- Senior staff told us that the strategy for the future included opening new locations, continuing to pioneer advancements in technology by sharing outcomes, maintaining and increasing the organisations profile by increasing influence in consultation processes and continuing to invest in electronic medical records system.

Governance, risk management and quality measurement

- The Optical Express governance structure and members included the clinical governance group,

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National Medical Advisory Board (MAB), services director, medical director and chief executive officer (CEO). All surgeons and key heads of department were members of the board.

- The corporate MAB met annually and reviewed data for all Optical Express locations and clinical protocols. The MAB managed changing practices to treatment, surgery techniques, or the introduction of new technology.
- The corporate clinical governance committee was headed by the clinical services director and included the managing director, responsible officer, refractive operations manager and surgical services manager. Local surgery managers did not attend these meetings but clinic staff informed us they received feedback from the surgical services manager.
- There was a risk register made up of 22 risks; these were all potential risks to the clinic, such as a needle stick injury, no registered nurse on site, wrong patient treated. Each risk had an impact, likelihood, what needed to be done and agreed actions. Staff had the ability to add specific risks to the location, if this was required.
- The clinic manager completed audits bi-monthly. We reviewed the findings of the local audit from August/September 2017 and October/November 2017. The local audit provided an overarching view of the clinic and included key performance compliance measures in a variety of areas such as infection control, emergency equipment and medicine management.
- There were also specific infection prevention and control (IPC) and controlled drugs audits. Auditors measured compliance against key measures and benchmarked against the provider's targets.
- We spoke with the head of clinical governance who had taken up post with effect during November 2017. The aim of the new clinical governance strategy was to move away from paper based activity and develop a more integrated clinical governance matrix to improve how the organisation communicated internally. Additionally, there was an objective to improve clinical sub-group cohesion and improve how this fed in to the management team.

- The clinical governance lead wanted to formulate the structure and make the current clinical governance processes more robust. There were a number of short and medium term projects in place and ongoing at the time of our inspection. These were to improve medical appraisals, review current workflows and strengthen competency frameworks for anaesthetic staff.
- The clinical governance lead planned to develop a clinical dashboard to encompass surgical outcomes and widen other quality indicators and key performance indicators. Additionally, there were plans to improve the clinical governance information flow from the clinic staff to management.

Public and staff engagement

- The provider obtained patient views and experiences of the service from a number of sources. This included patients completing an online survey prior to leaving the clinic, feedback through the Optical Express website and online surveys.
- We looked at the monthly survey results from September 2017 to November 2017. The number of responses ranged from 15 to 64 patients each month and the feedback was very positive, with most patients reporting high levels of satisfaction and almost all patients that responded to the survey reported they would recommend the clinic to friends and family.
- The provider had recently developed a new social media platform called 'My Eye Clinic' which had been set up like a forum to be more interactive for patients who utilised this type of technology. The platform was monitored by staff so they could respond to patient queries and comments.
- Patients had access to the provider's website which provided company information, eye health information, guidance on procedures offered and patient testimony. The site also provided a 'live chat' option for patients to ask questions from a customer services advisor.
- Patients were also invited and welcomed to attend the local clinic for a free consultation and to talk with a member of the clinical staff.
- The feedback from patient surveys and complaints was analysed to identify any trends and identify

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service improvements. An example of a recent improvement was to increase the font size of the terms and conditions document given to patients following feedback from patients.

- We reviewed minutes of local monthly team meetings. These included a detailed agenda, thorough notes, actions and outcomes. There was reference to safety, risk, quality and governance issues. Staff signed the accompanying read receipt to confirm they had read the minutes.
- The organisation had recently launched a 'Wonderful Wednesday' initiative for staff. This was to promote

and acknowledge members of staff or staff groups work and achievement. Staff were asked to nominate each other in recognition of their work. Prizes included a restaurant voucher and spa days.

- The clinic did not conduct any staff surveys.

Innovation improvement and sustainability

- Staff informed us of a new online social media programme to target bloggers and promote online marketing.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- All staff files should include relevant information such as employee references and appraisal records.
- The consent policy should reflect the Royal college of Ophthalmologists 2017 guidance for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Written information should be made available for patients where English is not their first language.