

# Optical Express - Leeds (Albion Street) Clinic

## Quality Report

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

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

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

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

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

# Summary of findings

## Letter from the Chief Inspector of Hospitals

Leeds Albion Street Clinic is operated by Optical Express. Optical Express is a nationwide company providing general optometric services. The clinic provides laser vision corrective procedures under topical anaesthetic, for adults aged 18 years and above.

The clinic has been operational since September 2013 and is based on the sixth floor of an office block.

Part of the clinic is dedicated to the provision of the optometric service which includes sight tests, eye health screening and examinations, pre and post-operative cataract examinations, pre and post-operative refractive surgery examinations. The remaining part of the clinic accommodates the treatment suite where the regulated activities take place. The clinic provides laser vision correction procedures under topical anaesthetic using Class 4 and Class 3b lasers.

Facilities include a laser treatment room where the surgery is completed, surgeon examination room, consultation room and two rooms where patients receive aftercare advice and medicines following surgery.

The clinic was not operational every day, therefore there was only one staff member based there, which was the surgery manager. The surgery manager was on an extended absence of leave for one year from the clinic and another surgery manager was covering. Treatment lists were staffed by a regional surgery team that travelled and covered the Manchester, Liverpool, Sheffield and Newcastle areas who visited the clinic on surgery days.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 23 November 2017, along with an unannounced visit to the clinic on 8 December 2017.

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

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

### 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:

- Staff were aware of how to report incidents. Incidents were discussed across the North region to aid learning.
- Staff received level two training for both safeguarding children and adults. A policy was in place and staff were aware of the responsibilities in reporting any safeguarding concerns.
- The clinic was visibly clean and monthly cleaning logs were in place. There was accessibility to clean disposable theatre attire and hand washing facilities.
- Laser safety was well managed and records were appropriately maintained. Equipment was serviced regularly and all electrical tests had been completed.
- Medicines were prescribed and administered to patients appropriately ensuring that they understood how to administer them.
- Records were appropriately written and contained all the relevant consultations, health questionnaires and consent forms.

# Summary of findings

- A team brief session took place at the beginning of each surgery day to discuss the patients and any issues. Prior to the patient's surgery an adaptive 'five steps to safer surgery' World Health Organisation (WHO) checklist was completed. WHO audits were completed to ensure that practice was embedded.
- Scenario based training sessions were completed on specific surgery days to support staff in managing and dealing with untoward situations.
- Staffing was managed by a central schedule and we saw that the appropriate number of staff were present on surgery days.
- Care and treatment reflected current legislation and national guidance.
- Patients received adequate pain relief and were advised how to manage their pain on discharge.
- The surgeon's statistics were reviewed to identify their establishment rate and safety score and compared against the organisation.
- Staff had received an appraisal that reviewed their performance.
- We saw evidence of good multidisciplinary working and staff reviewed patients at the beginning of the surgery day.
- Patient information could be accessed across all the Optical Express locations; this allowed information to be viewed at any clinic.
- Patients consented to the treatment several times prior to their surgery. We looked at seven records and found them all to have consented more than seven days before their surgery.
- Staff treated patients with dignity and respect. Feedback from patients was consistently positive. Patient satisfaction surveys identified that patients were satisfied with the treatment and care they received.
- Patients were reassured at all times during their treatments and we saw that staff were compassionate.
- Patients told us they felt involved in the decision making process and were encouraged to ask questions. We saw that the consultant drew pictures to ensure that patients understood the process.
- Services were planned to meet the needs of patients, based on their own choice and preference. They could attend any Optical Express clinic for their post-surgery aftercare.
- Extra surgical lists were created to support the demand for surgery. There had been no cancellations for non-clinical reasons.
- Patient's individual needs could be met. These included spacious areas for wheelchair users and adjustable height chairs.
- There was a process for the reporting, monitoring and learning from complaints.
- The clinic had a clear leadership structure in place from the chief executive office to local leadership. A generic risk register was in place.
- Staff were aware of how their role fed in to the vision of the organisation albeit they did not fully understand the overall strategy.
- The clinic had a lead for governance and quality monitoring. Staff attended meetings and provided with minutes that they signed to identify they had been read.
- Appropriate checks had been completed for staff, these contained references and Disclosure and Barring Service (DBS) record.

# Summary of findings

- The organisation recognised and rewarded staff through their weekly staff reward scheme.  
However, we also found the following issues that the service provider needs to improve:
- The consent policy did not reflect Royal College of Ophthalmologists 2017 guidance for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The clinic did not have access to any interpreting services and patients were asked to bring their own interpreter. This meant that staff may not be clear if patients had fully understood the risks and benefits of the surgery.

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**

# 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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### Summary of this inspection

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# Optical Express - Leeds (Albion Street) Clinic

**Services we looked at**

Refractive eye surgery

# Summary of this inspection

## Background to Optical Express - Leeds (Albion Street) Clinic

Leeds Albion Street Clinic is operated by Optical Express. The service opened in September 2013. It is a private clinic in Leeds, West Yorkshire. The clinic primarily serves the communities of the West Yorkshire area. However it also accepts patient referrals from outside this area.

The hospital has had a registered manager in post since September 2013.

## Our inspection team

The team that inspected the service comprised a two CQC inspectors and a specialist advisor with expertise in refractive eye surgery. The inspection team was overseen by Lorraine Bolam, Interim Head of Hospital Inspection.

## Information about Optical Express - Leeds (Albion Street) Clinic

Optical Express, Leeds is registered to provide the following regulated activities:

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

The clinic occupies the sixth floor of an office block which is accessible by passenger lift or stairs. Part of the clinic is dedicated to the provision of the optometric service which includes sight tests, eye health screening and examinations, pre and post-operative cataract examinations, pre and post-operative refractive surgery examinations. The remaining part of the clinic accommodates the treatment suite and regulated activities.

The clinic is only operational for approximately four days a month, therefore there is only one staff member based there, which was the surgery manager. The surgery manager was on an extended absence of leave for one year from the clinic and another surgery manager was covering in their absence. Treatment lists are staffed by a regional surgery team that travelled and covered the Manchester, Liverpool, Sheffield and Newcastle areas.

During the inspection, we visited the laser treatment room, surgeon's examination room and other small consultation rooms. We spoke with nine staff members

including the ophthalmic surgeon. We spoke with 15 patients and relatives. During our inspection we reviewed seven sets of notes and the staff personal files, including the ophthalmic surgeons and registered managers.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The clinic has not received any previous inspection since registration in September 2013.

### Activity

- In the reporting period August 2016 to July 2017, there were 805 day case episodes of care recorded at clinic. The clinic offered two different types of refractive eye surgery all which required topical anaesthesia.

### Track record on safety

- No never events
- Two clinical incidents with no harm
- No serious injuries
- No incidences of hospital acquired Methicillin-resistant *Staphylococcus aureus* (MRSA) or Methicillin-sensitive *staphylococcus aureus* (MSSA)



# Summary of this inspection

- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- Nine complaints
- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- Laser protection service
- Maintenance of medical equipment
- Pharmacy

**Services provided at the clinic under service level agreement:**

# Summary of this inspection

## The five questions we ask about services and what we found

We always ask the following five questions of services.

### Are services safe?

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

We found the following areas of good practice:

- Staff were aware of how to report incidents. Incidents were discussed across the North region to aid learning.
- Staff received level two training for both safeguarding children and adults. A policy was in place and staff were aware of the responsibilities in reporting any safeguarding concerns.
- The clinic was visibly clean and monthly cleaning logs were in place. There was accessibility to clean disposable scrub uniforms and hand washing facilities.
- Laser safety was well managed and records were appropriately maintained. Equipment was serviced regularly and all electrical tests had been completed.
- Medicines were prescribed and administered to patients appropriately ensuring that they understood how to administer them.
- Records were appropriately written and contained all the relevant consultations, health questionnaires and consent forms.
- A team brief session took place at the beginning of each surgery day to discuss patients and any issues. Prior to the patient's surgery an adaptive 'five steps to safer surgery' World Health Organisation (WHO) checklist was completed. WHO audits were completed to ensure that practice was embedded.
- Scenario based training sessions were completed on specific surgery days to support staff in managing and dealing with untoward situations.

Staffing was managed by a central scheduler who ensured that the appropriate number of staff were present on surgery days.

### 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:

- Care and treatment reflected current legislation and national guidance.

# Summary of this inspection

- Patients received adequate pain relief and were advised how to manage their pain on discharge.
- The surgeon's statistics were reviewed to identify their establishment rate and safety score and compared against the organisation.
- Staff had received an appraisal that reviewed their performance.
- We saw evidence of good multidisciplinary working and staff reviewed patients at the beginning of the surgery day.
- Patient information could be accessed across all the Optical Express locations; this allowed information to be viewed at any clinic.
- Patients consented to the treatment several times prior to their surgery. We looked at seven records and found them all to have consented more than seven days before their surgery.

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

- 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:

- Staff treated patients with dignity and respect. Feedback from patients was consistently positive. Patient satisfaction surveys identified that patients were satisfied with the treatment and care they received.
- Patients were reassured at all times during their treatments and we saw that staff were compassionate.
- Patients told us they felt involved in the decision making process and were encouraged to ask questions. We saw that the consultant drew pictures to ensure the patient understood the process.

## 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

- Services were planned to meet the needs of patients, based on their own choice and preference. They could attend any Optical Express clinic for their post-surgery aftercare.
- Extra surgical lists were created to support the demand for surgery. There had been no cancellations for non-clinical reasons.
- Patient's individual needs could be met. These included spacious areas for wheelchair users and adjustable height chairs.
- There was a process for the reporting, monitoring and learning from complaints.

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

- The clinic did not have access to any interpreting services and patients were asked to bring their own interpreter. This meant that staff may not be clear if patients have fully understood the risks and benefits to the surgery.

## 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 clinic had a clear leadership structure in place from the chief executive office to local leadership. Staff had an oversight of the location. A generic risk register was in place.
- The clinic had a lead for governance and quality monitoring. Staff attended meetings and were provided with minutes that they actioned to identify they had read.
- Appropriate checks had been completed for staff, these contained references and Disclosure and Barring Service (DBS) record.
- The organisation recognised and rewarded staff through their weekly staff reward scheme.

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

- Staff were aware of how their role fed in to the vision of the organisation albeit they did not fully understand the overall strategy.

# 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 in the 12 months from August 2016 to July 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.
- The clinic had an incidents and near miss events policy in place from January 2017 which was due to be reviewed in three years. The policy stated the surgery manager was responsible for identifying and reporting any incidents and managing the process. Part of the process was to ensure that other staff were able to understand and report incidents in the absence of the surgery manager.
- We spoke with staff who confirmed that they were aware of how to complete and respond to an incident or near miss. The incident severity was completed by the surgery manager who reviewed this whilst investigating the incident.
- There had been two incidents reported at the clinic from August 2016 to July 2017, both of these were in response to patients fainting in and outside the clinic. We reviewed the incident forms and found that they contained the relevant information.
- The surgical services manager and clinical services director reviewed the incident reports for the North region and shared any learning that was required with other locations. Incidents were discussed at regional team meetings and within the team brief; staff confirmed that they reviewed the minutes.

### Mandatory training

- Staff received mandatory training on various subjects, these included; basic life support, safeguarding, consent, duty of care, conflict resolution, information governance, moving and handling, health and safety and fire. The majority of training was completed on line through a recognised company. A staff member provided face to face basic life training and attended meetings to complete this, for example they attended the surgeon's conference meeting.
- The surgical services manager had an overview of the staff's mandatory training within the North region and this was shown to us during our inspection. Mandatory training compliance was also kept in individual staff members personal files and reviewed during their appraisal.
- As the surgery manager for the clinic was on leave, we reviewed the training record of both the surgery manager who was temporarily overseeing the clinic and the ophthalmic consultant. We saw that they had completed the relevant mandatory training and their record was up to date.
- We looked at five records of the regional surgery team that provided care to patients at the clinic; we saw that they had completed basic life support training within the year. They had also completed all the relevant mandatory training.

### Safeguarding

- The clinic did not provide treatment to young people under the age of 18; however children attended the clinic with patients and relatives. Safeguarding training was required for both adults and children.
- The clinic had a safeguarding children and vulnerable adult's policy in place from January 2017 and was to

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be reviewed in three years. Within the policy it highlighted the process for staff to follow with issues or concerns regarding safeguarding. Staff were aware of the process and who to escalate their concerns to.

- The surgery manager was on leave therefore we reviewed the training for the surgery manager that was overseeing the clinic. The surgery manager was trained to safeguarding level two for both children and adults. Staff at the clinic were not trained to a higher level. The policy highlighted that staff would refer any incidents to the local safeguarding board and would access people trained to a higher level via the local authority.
- There had been no safeguarding concerns at the clinic from August 2016 to July 2017.

## Cleanliness, infection control and hygiene

- There had been no incidences of a healthcare acquired infection at the clinic from August 2016 to July 2017.
- The clinic was visibly clean, monthly cleaning logs were in place; we reviewed the records from April to October 2017 and found them to be completed correctly. We saw that the treatment room had been deep cleaned on a regular basis. In addition, all areas of the clinic were cleaned regularly, including the pump dispensers, clocks and other equipment.
- We saw that daily checklists took place on the day of surgery. These included checking staff were wearing the appropriate uniform and adhering to the clinic policy. In addition, cleaning of the treatment room, surgeons' room and clean and dirty utility areas were completed at the end of surgery.
- We saw that staff washed their hands effectively and wore appropriate personal protective equipment when required. Hand sanitising solutions were readily available around the clinic. Staff wore disposable scrub uniforms which complied with the bare below elbows principle.
- Hand hygiene audits were completed at the clinic; we reviewed the audits between August 2017 and November 2017 and found they were 95% compliant. The audits included an action plan which highlighted areas for further learning and compliance.
- All the equipment used in the clinic was single use and was disposed of correctly. There was a clinical waste file that identified when the waste was collected, this was signed and dated correctly. The clinical waste was collected every two weeks.

## Environment and equipment

- The clinic was spacious and well maintained. The clinic was on the sixth floor and accessible via the lift or stairs. The waiting area was pleasant with comfortable seating, TV, magazines, hot and cold beverages.
- The clinic had various rooms that contained relevant equipment; these included scanning machines to examine the eye prior to surgery. The laser treatment room, where patients had their laser surgery, was the largest room and contained two laser machines required to complete the surgery.
- There was a laser warning light on the laser treatment room door which was in working order to inform individuals not to enter the room. The appropriate warning signs were also on the door to advise staff when the room was occupied. A key pad was on the door to control entry into the area.
- Optical Express employed their own team of maintenance specialists such as plumbers and electricians. The maintenance of the laser machines was completed by the laser manufacturer's own engineers. The maintenance spreadsheet was completed every two to three months due to the low activity at the clinic. The two laser machines had a backup supply in the event of a power failure. Staff told us that the maintenance team attended in a timely manner to respond to any issues within the clinic.
- The temperature monitor and humidity log were recorded daily on a laser log sheet. We checked these and found that they were recorded appropriately.
- There was an equipment register which identified timeframes for regular servicing, when it was due and when it was completed. We saw that the register was up to date and reflected the current needs of the service.
- Both smoke and fire alarms were checked every six months. Regular fire alarm tests were completed and

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staff were aware of the evacuation process. Information was on the wall to identify where the meeting point was after evacuating the building. We saw that fire extinguishers were around the clinic in areas such as the laser treatment room.

- The clinic was not required to have a resuscitation trolley and in the event of an issue the team contacted the emergency services. The clinic did have access to an anaphylaxis box which contained all the relevant equipment that was needed. Other equipment was available such as spillage packs and eye wash packs. Staff at the clinic checked the contents and expiry dates.
- The clinic had a laser safety policy in place from January 2017, for review in three years. The clinic had a contract with an external Laser Protection Advisor (LPA) who provided advice on laser safety as well as completing laser risk assessments. A site visit and risk assessment was completed every three years by the LPA who then would re-issue the Local Rules or validate the existing Local Rules. No issues were raised at the clinic from the last visit by the LPA.

## Medicines

- The clinic had a medicine management policy in place from January 2017, for review in three years. This described the handling, storage and security, ordering and disposal of medicines.
- No controlled drugs were stored or administered at the clinic. The clinic had a narrow range of eye drops held at the location. The surgery manager was responsible at a local level for ensuring that the policy and processes with regards to handling medicines; were followed and adhered to.
- It was the responsibility of the surgery manager to review the stock levels and order the prescribed medicines. We checked some stock levels and found them to be correct and within the expiry date.
- Patients were prescribed eye medicine by the surgeon which was administered during their surgery. When patients were discharged, they were given multiple eye medicines. One staff member on each surgery day

had the responsibility of discharging all the patients and discussing the medicines with them. Staff were trained appropriately to discharge patients and discuss their medicines.

- Each patient was discharged with an information leaflet that explained when and how many times a day the eye medicines needed to be administered. We observed three patients being discharged, the staff member explained thoroughly with the leaflet, when to administer the eye medicines.
- Patients were discharged with their own prescribed medicines. We looked at the medicines and found them to be labelled with the patient's name and date of discharge. All medicines were checked and the medicines were within their expiry date.
- Mitomycin C was a cytotoxic drug that was sometimes required to be used in specific patient's laser surgery. The drug was used 'off license' during superficial laser treatments and was required to be explained to the patient why it was required. This was agreed by the surgeon and the patient completed the relevant section on the consent form.
- The clinic did not use Mitomycin C regularly; however when this was required it would be ordered in for the specific patient from the central support services for the company. This was delivered to the clinic already prepared and ready for use. We looked at the operations register when Mitomycin C was used, the details were recorded such as; patients name, expiry date and batch number.
- Pharmacy support was available for staff to contact in the event of a query.

## Records

- The clinic had an information and records management policy in place from January 2017, for review in three years. This described the processes when completing notes, storage of notes and destruction of records.
- Each patient had both electronic and a paper set of records. All the electronic information was printed into the paper set of notes to be used on the day of surgery. This allowed the surgeon and team to identify that all the relevant paperwork had been seen and completed. After the patient's surgery all the



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information was then scanned onto the patient's electronic record. As patients may have chosen to have their post 24 hour check up in a different location, this information was available to be reviewed.

- Each patient completed a health questionnaire at their initial consultation which identified any risks associated with the laser surgery. We saw that these were completed with relevant information, for example it highlighted patient's hobbies that may impact on their post discharge care.
- Some patients had telephone consultations with the surgeon, the surgeon had remote access to the computer which allowed the document to be uploaded following the call. We saw that these were thoroughly completed and printed off within the notes.
- We looked at seven records, which contained all the relevant information. The traceability sheets for the equipment used were in place. Consultant notes were present if the patient had visited somewhere else prior to the day.
- We saw that patient's records were stored securely when not in use. They were stored within a locked room that was not accessible to patients.
- The clinic completed records audits every three months, a random selection of five records were chosen and reviewed. The audit results were 100% against the questions asked, with suggestions for improvements.

## Assessing and responding to patient risk

- All patients self-referred and attended a series of appointments prior to their surgery day. Patients were seen several times post-surgery. A health questionnaire was completed to highlight any issues that may impact the need for laser surgery. Some patients were required to contact their GP to provide more information regarding their health and medical conditions, the GP then completed a letter for the surgeon to review before surgery. We were told that surgery did not take place if the patient did not attend with the letter and the information required from the GP.
- A team brief took place at the beginning of each surgery day. Information was documented within the team brief that highlighted specific concerns with individual patients such as known allergies, diabetic patients and consideration of the GP's letter. We reviewed the team briefs and found that they contained relevant information.
- Staff used an adaptive 'five steps to safer surgery' World Health Organisation (WHO) checklist which had commenced in July 2017. We observed the WHO checklist being carried out in the treatment room and found the correct checks were completed. The WHO checklist 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. At our unannounced visit we looked at two WHO checklists and found that they did not contain the patient's name or date. We discussed this with staff who said it was an oversight and corrected the information.
- We saw that the WHO checklist was completed in the laser treatment room and a second identity check was completed when the surgeon entered the room.
- The WHO checklist was audited to provide assurance and ensure that it was used correctly. We reviewed the WHO audits which identified 100% compliance; areas for any improved practice were documented. We saw that paper audits of the WHO checklist had been completed, but observational audits had not been conducted.
- There was access to an emergency support system for urgent cases where the clinical services team co-ordinated care between the surgeon and optometrist, for example, if the patient presented with an infection. Staff could also co-ordinate external services such as an external referral to another consultant or laboratory services. A referral system was in place for less urgent cases where the optometrist wanted to refer the patient back to the surgeon for direct post-operative care.
- When patients received their discharge advice, patients were given contact details of who to contact, these also included out of hours emergency numbers. Out of hours the calls were transferred to an on call optometrist who provided support. The calls were



# Refractive eye surgery

triaged and the operating surgeon was contacted for advice if the issue appeared to be urgent. Telephone numbers were detailed within their aftercare advice leaflet and also on the website. Patients were provided with a next day appointment for their treatment to be reviewed. We observed three patients being discharged after their surgery who had all received relevant information.

- There had been no unplanned transfer of patients to another health care provider in the previous 12 months.

## **Nursing and medical staffing**

- As the clinic was only operational for approximately four days a month, only one staff member was based at the clinic, this was the surgery manager. The surgery manager was on extended leave at the time of inspection, therefore another surgery manager was overseeing the clinic. On surgery days staff from the regional surgery team attended the clinic; this consisted of four or five staff members with the inclusion of a registered nurse.
- The roaming team consisted of 13 staff that covered all locations in the North of England, these included: Sheffield, Leeds, Manchester, Newcastle and Liverpool.
- A central scheduler determined the minimum and optimum number of staff required on the day of surgery, dependant on the type of patients that were booked in for surgery. The staffing level and skill mix requirements had been agreed by the medical director and Medical Advisory Board.
- The team consisted of the surgeon, nurse or scrub assistant, laser technician, discharger and a co-ordinator. Part of team brief identified which staff were completing the specified roles.
- The medical director completed the surgeon's GMC revalidation and appraisal. The ophthalmologist was employed by Optical Express and held the Certificate in Laser Refractive Surgery; this was evident in their employment file.
- An external company provided the Laser Protection Advise role (LPA); the clinic's Local Rules document listed the contact information for the LPA, address, email and mobile phone number. Staff could contact

the LPA for laser safety advice at any time. All staff had attended core of Knowledge training which was provided by the LPA. Staff told us that the LPA was accessible and provided advice when needed.

- All certified laser technicians undertook the role of Laser Protection Supervisor (LPS) on the day that they were allocated the role of assisting the surgeon in the treatment room. A designated LPS was in the room whilst treatments were taking place. They were responsible for ensuring that the lasers were calibrated, safety checks completed, the area was secured and lasers were closed down at the end of the day.
- The surgery managers were leads for laser safety, however all technicians supporting the surgeon during treatment acted as the LPS at that time.

## **Major incident awareness and training**

- Regular fire alarm tests were completed and staff were aware of the evacuation process. Fire escapes were marked throughout and clearly identifiable. Information was on the wall that identified where the meeting point was after evacuating the building. We saw that fire extinguishers were around the clinic in areas such as the laser treatment room.
- The clinic had backup generators in the event of a power supply failure which allowed the procedure to be completed that had already commenced.

The team undertook scenario based training sessions on surgery days. These involved role play and had involved situations where patients had fainted, collapsed, received a head injury or had an anaphylactic reaction.

## **Are refractive eye surgery services effective?**

### **Evidence-based care and treatment**

- Care and treatment was provided in line with current legislation and national guidance. These included the Royal College of Ophthalmology standards for laser refractive eye surgery. Policies referenced the appropriate guidance and were evidence based.

# Refractive eye surgery

- Sepsis information was available and displayed as a prompt for staff. Staff were aware of sepsis and the steps to take to ensure the patient was treated promptly and effectively.
- The service used suitability guidelines for refractive surgery to ensure that patients were appropriate for surgery. The document identified the various types of refractive eye surgery and whether individual patients were suitable for the surgery.
- The suitability guidance and treatment criteria were subject to review each year by the International Medical Advisory Board (IMAB). We saw that the document in use had been revised in August 2017.
- Between August 2016 and July 2017, 78 procedures were performed on patients between 18 and 20 years of age. Within this age group the service's suitability guidelines identified that any refractive errors needed to be stable before surgery was performed. Surgeons advised young patients that they may need the treatment to be repeated at some stage in the future. During our inspection we saw a young person, between 18 and 20 years old, who wanted to have refractive eye surgery, we saw the surgeon discuss these implications with the patient.
- The medical director for the organisation was one of eleven members of the Refractive Surgery Standards Working Group (Royal College of Ophthalmologists) who had recently published the latest guidance from the RCO 'Professional Standards in Refractive Surgery' June 2017.
- The surgical services manager was an expert panel advisor with the Optical Confederation, who was currently drafting new 'Refractive Surgery Standards for Providers'.
- Surgeons attended the relevant ophthalmology conferences both internationally and in-house. Surgeons had an annual meeting and conference calls every 12 weeks where they discussed new methods of surgery and any issues raised. The surgeon we saw discussed the last event they had attended and the learning they had put into practice.
- Patients were seen post-operatively by an optometrist at a location of their own choice. There were also a

number of pathways that staff could use for medical advice and support. The optometrist was able to call or email the operating surgeon directly in the event of any queries.

## Pain relief

- During consultations patients were advised that there may be some discomfort before they had surgery. This ensured that patients were prepared and understood what to expect.
- 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. This enabled patients to remain fully conscious and responsive. We observed that staff asked patients during their laser treatment surgery if they had any discomfort and acted accordingly.
- We saw that patients were given advice on pain relief and how to manage their pain after discharge. Anaesthetic eye drops were given to patients to take home and use to relieve pain if required. Information leaflets were given to patients that identified what symptoms were normal to have after surgery. This identified that there may be some pain and discomfort for the first few days.
- Patients told us they did not feel pain during their procedure and were informed prior to surgery that they may feel some discomfort. We observed three patients being discharged who felt that the staff member had clearly discussed how to their pain, once they were at home.

## Patient outcomes

- The clinic was not required to contribute to the National Ophthalmic Database Audit (NODA) as this only collected data relating to NHS cataract procedures.
- The clinic had a full time biostatistician who collated the data for each surgeon's outcome. These were collated and used as part of the surgeon's appraisal process. We reviewed the surgeons clinical outcome compiled data, which included patient feedback. The

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data collected enabled the clinic to monitor the demographics of their patients in terms of gender, age, treatment type and provided comparisons of eyesight both pre and post operatively.

- Surgeons' statistics were recorded and compared to other surgeons within the company. 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 scores were better than average with an efficacy score of 52 and safety score of 59.
- 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 78 enhancement procedures over the past year; this included primary surgeries that were completed more than one year ago. Out of the 78 enhancements, 26 were completed following surgery that had taken place between August 2016 and July 2017.
- The surgeon's enhancement rate was calculated and reviewed within their appraisal. The surgeon's enhancement rate was 1.7%; this was in line with Optical Express expected range, where the average was also 1.7%.
- From August 2016 to July 2017, 21 patients experienced complications following refractive eye surgery. The surgeon's complication rates and overall performance were monitored and then reviewed annually at their appraisal. The surgeon's overall complication rate was slightly higher at 0.60% compared to Optical Express' average score of 0.52%.
- Audits were completed every two to three months. These included records, WHO checklists, patient

satisfaction, complaints, infection control and maintenance of equipment. We saw action plans had been completed where improvements needed to be made.

## Competent staff

- Staff we spoke with had the correct skills and competencies to carry out the duties required. Staff completed an induction and training prior to working unsupervised.
- The surgeon had the Royal College of Ophthalmology Certificate in Laser Refractive Surgery. The medical director attended occasionally, on surgery days, to review the surgeon's practice. The surgeon attended routine conferences and participated in three monthly conference calls with the medical director to be updated with knowledge and information.
- We looked at four personal files; these had information on clinical competencies that had been attained. These included staff that were part of the regional surgery team that provided cover at the clinic.
- The laser protection supervisor (LPS) was always a certified laser technician; this included a one week course in the use of lasers and associated equipment followed by a period of competency assessments. Competency was reviewed every three years to ensure that staff's skill and knowledge remained current and competency was maintained. 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.
- Staff completed a Core of Knowledge course; this was a national certificate in laser safety. We looked at five records of staff within the regional surgery team and saw that this training had been completed in June 2017.
- The Laser Protection Adviser (LPA) was a certified member of the association of laser professionals. Staff had attended training with the LPA and knew how to contact them.
- Within the team brief at the beginning of surgery, staff were designated roles that they were competent to perform. We were told that no staff felt they had been asked to complete duties outside of their roles.

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- Every three months the team undertook scenario based training sessions on surgery days. These involved role play and had involved situations where patients had fainted, collapsed, received a head injury or had an anaphylactic reaction. Staff received feedback in how they had managed the situation. We reviewed the feedback and found the scenarios provided positive information to staff.
- Appraisals had been completed for both the surgeon and surgery manager overseeing the clinic.

## Multidisciplinary working

- We saw good multidisciplinary working and communication between the team at the clinic.
- 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.
- The team had a co-ordinator on each surgery day that took the lead and managed the clinic. On some occasions the co-ordinator was required to complete other roles such as scanning patients prior to surgery, however staff said that this was manageable to complete.
- Staff worked as part of a regional team and attended the clinic periodically when scheduled to work. All the staff we spoke with had been to the clinic many times and were aware of how the clinic was set up and managed.
- Staff attended team meetings, any staff that could not attend were requested to read and sign the minutes. We saw that staff signed to say they had read the minutes of meetings.

## Access to information

- Patient information was recorded on an electronic medical record (EMR) and printed off on the day of surgery. This contained documents that had been signed, consent forms, copies of scans and laser treatments. The information from the surgery was then updated onto the patient's EMR to be viewed the next day when the patient returned.
- Any Optical Express clinic could access a patient's record, therefore if the patient returned to an

alternative clinic for their 24 hour post-operative check, the information could be viewed. We saw that information was uploaded onto the record. The optometrist could complete on the patient's post-operative EMR to indicate whether the patient had a complication and be referred back to the surgeon.

- The patient's EMR was password protected and available to different grades of staff to view access and add records which were appropriate to their role only.
- As part of the suitability guidelines for refractive surgery, it allowed for communication with the patient's GP if they had indicated certain medical conditions. Patients signed a disclaimer to allow the release of their medical records to assess their suitability to have the procedure.
- Patient's GPs were not routinely informed of the surgery unless it had been identified that the patient's consent had been sought.
- Staff had access to policies and procedures; these could be viewed on line. Staff also had access to complete incident forms either electronically or paper copies.

## Consent and Mental Capacity Act

- Patients attended an initial consultation with an optometrist where they w
- The patient was required to have a consultation with the surgeon who would be completing the surgery; this was either face to face or by telephone. We saw that these were documented fully and included information about the risks and benefits of the surgery. These were evident in the patient's electronic medical record.
- 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. We saw that the surgeon completed this and thoroughly explained the risks and benefits.
- We spoke with patients who all said they had been asked several times regarding consent and if they

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wanted to continue with the surgery. All patients felt that they had not been coerced into having surgery and felt that the surgeon had their best interests in place.

- The clinic had a consent to treatment policy in place from January 2017. The policy identified the process and procedure ensuring that consent was obtained and understood. It was clear in the policy that it was a surgeon's responsibility to ensure themselves that the patient understood the purpose of the procedure and that consent had been completed.
- The consent policy stated a "cooling off" period of three days was required prior to the procedure. Staff also undertook remote telephone patient consent. However, the new Professional Standards for Refractive surgery (April 2017) recommend a "cooling off" period of one week and that consent should not be conducted by telephone.
- We looked at seven records and found the consent forms to be correctly completed. The cooling off period was within the standards of more than one week.
- If patients were required to have Mitomycin C administered during surgery that this was consented for by the patient within the relevant section. This was due to the medicine being used off license and patients were required to be aware of this before it was used. Staff were aware of this and showed us within the consent document where this needed to be completed.

## Equality and human rights

- The clinic had an equality and diversity policy in place from January 2017.

## Are refractive eye surgery services caring?

### Compassionate care

- We saw that patients were treated with dignity and respect during our inspection by clinical and non-clinical staff.

- We spoke with 15 patients who felt that staff provided excellent care for them, many described staff as friendly and welcoming. Staff took time to interact with patients and relatives in a respectful and considerate manner.
- We saw staff support and position patients both during their surgery and whilst having investigations prior to their surgery.
- We observed interactions between staff and saw that patients were spoken to with warmth as individuals and all members of staff listened to and addressed patients' needs immediately. Patients were continuously reassured at several points during consultations and surgery.
- Patients completed a patient satisfaction survey, with 10 being the optimum score. The results were collated. We reviewed the survey from May 2017 to October 2017, 117 patients responded. The results were positive with 100% response rate for a warm and friendly atmosphere.
- We accompanied patients, with their consent, through their surgery and observed that all staff treated them kindly and compassionately. We saw the consultant re-assess the patient and gave clear explanations of what to expect, and talked the patients through the procedure step by step.

## Understanding and involvement of patients and those close to them

- All patients that we spoke with felt involved in the decision making, some patients told us that the risks and benefits of the surgery were discussed several times from the initial consultation up to the point of the surgery. None of the patients felt pressurised into having the surgery and felt they had made an informed decision.
- We observed two consultations with the surgeon, where the treatment options were discussed with the patient. The consultant drew pictures for patients regarding the surgery and gave them information in a way that they could understand. The surgeon stressed the importance to one patient who was 21 years of age who wanted to undergo the surgery and comprehensively explained the risks and consequences.



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- The patient satisfaction survey identified that the majority of patients felt the surgeon answered all of their questions, with most either answering with a nine or 10 score.
- We observed three patients that were discharged following their surgery, each patient was involved in the discharge process and staff ensured that the patient had understood the information given.

## Emotional support

- Staff reassured patients continually throughout their surgery and provided the opportunity for patients to ask questions. We saw that after completing surgery on one eye, the surgeon confirmed that the patient wanted to continue with the second eye.
- The patient satisfaction survey identified that 100% of patients felt comfortable and at ease during their visits to the clinic and their surgery.
- Patients who had surgery on their eyes a few months earlier told us the surgeon was friendly and they had received thorough explanations about the benefits and risks of the surgery.

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

### Service planning and delivery to meet the needs of local people

- Services were planned to meet the needs of the patients, for example patients could attend various other clinics for their consultations and then attend the Leeds clinic for their surgery. This allowed patients to be flexible and attend clinics to near where they lived or preferred. We spoke to one patient who had their first consultation at a clinic in London but preferred to have their surgery at the Leeds clinic.
- Services were flexed to meet the demand required. The clinic did not complete any NHS work, patients self-referred and paid privately for their treatment. Extra surgical lists were created if there was a demand.
- The clinic was open seven days a week with a flexible appointment system. Surgery was conducted at the weekends if surgeons were available.

## Access and flow

- The clinic did not have a waiting list for refractive eye surgery; patients would choose an appointment that was suitable for them. There had been no cancellations from August 2016 to July 2017 for non-clinical reasons.
- Appointments and clinics were chosen and scheduled to fit around the patients' individual needs and preferences.
- Patients had telephone consultations with the surgeon which were documented within the patient's file. These were then followed up with a face to face consultation with the surgeon prior to surgery. A patient told us how their own schedule had been arranged to fit around a sporting activity.

## Meeting people's individual needs

- The clinic had good access and enough space for wheelchair users and for people with a disability. Patients and staff reached the clinic by a lift from the ground floor; the clinic was on the sixth floor. Two lifts were available and in the event of a mechanical fault with both lifts alternative appointments could be made.
- Patient's individual needs were discussed at the initial consultation and communicated with the surgery team. For example, wheelchair users were assessed to identify if they could undergo the required diagnostic scans, transfer to the laser couch unaided, or lie flat. We were told that patients with diabetes would be identified and preferred to be treated first.
- We saw that equipment could be adjusted to meet the patient's height in order for the patient to undertake investigations correctly and comfortably.
- Staff informed us the clinic did not provide interpretation services. Instead they identified any staff who could interpret; otherwise they asked patients to bring their own interpreter, which was not best practice. Surgeons were expected to make a judgement that patients had understood all the information provided in order to give consent.

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- The reception area had a range of patient information leaflets available, explaining the various treatments the clinic offered. However, all the patient leaflets were in English. Staff did say they could access other languages if required.
- The clinic had an acceptance criteria and did not treat patients with complex health and social needs or learning disabilities.
- All areas we inspected were well equipped. Patient waiting areas were suitable, with the provision of magazines and hot and cold drinks.

## Learning from complaints and concerns

- Patients were given complaint information in the document pack at their initial consultation. There were no complaint leaflets in the clinic; however, there was a notice on the wall at reception with a summary of the process. In addition, information was available on the clinic's website to direct patients how to complain. However it did not identify other services to complain to if patients were not satisfied by the response from Optical Express.
- Staff were aware of the complaints process and could talk us through the steps to take. Verbal complaints made on the day of surgery were managed by the co-ordinator in order to resolve the complaint quickly and discuss with the patient.
- The majority of complaints were submitted centrally through the organisation's head office, rather than locally. Staff had specific roles in overseeing the management of complaints with regards to responses and documenting the outcome. On line negative feedback was monitored and followed up by Optical Express' head office, with the individual service, to ask for further information.
- We saw nine complaints had been received over the past 12 months; these included the price of the surgery and lack of improvement in eye sight. Optical Express had investigated and answered all the complaints within the expected timeframes. We saw that complaints were discussed in the regional surgery team minutes.
- There was learning outcomes from two of the complaints, for example the importance of providing realistic timescales to prevent frustration to patients.

The second learning outcome was from a complaint where a patient was given medicines with another patient's details on. The complainant received an apology and the clinic reviewed the incident and processes. Staff were informed and we saw complaints were discussed in team meetings and team briefs.

- The clinic had a managing complaints and concerns policy in place from August 2016. The policy described the process and timescales required to respond to a complaint.

## Are refractive eye surgery services well-led?

### Leadership and culture of service

- There was a clear leadership structure in place. Staff identified that the chief executive officer was open, approachable and honest. Optical Express had held a conference call in May 2017 updating staff on the company and minutes were circulated for all to read.
- The surgeon was accountable to the medical director who reported to the chief executive.
- The surgery manager was managed by the Optical Express surgical services manager. The clinic was managed on a day to day basis, by the surgery manager. The surgical services manager attended periodically when required.
- The surgery manager for the clinic was on extended leave and the location was being overseen by another surgery manager. We did not see the temporary surgery manager at either inspection day. We telephoned the surgery manager who told us that they would attend the clinic periodically.
- Staff that performed and assisted with the surgery were part of the regional team that moved around locations. At the beginning of each surgery day a co-ordinator was assigned who would lead the team and ensure that all staff completed their responsibilities. We spoke with the co-ordinators who felt that good practices were in place and told us they felt supported. The co-ordinators could tell us who they would contact in the event of an emergency.

### Vision and strategy

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- A vision for the organisation was provided that showed the objectives of the company. The chief executive officer for the company had a vision of expanding the business to provide international services.
- The surgical services manager identified that staff might not fully understand the overall strategy but that they would understand their role and how the quality of their work affected the overall patient experience in terms of satisfaction, safety and efficacy. Staff told us they were aware of the principles of the company and that they wanted to provide a high quality service to patients.
- Annual International Medical Advisory Boards (IMAB) were set up with worldwide refractive eye experts with no link to Optical Express. The IMAB was financed through the company and met annually to review the data and clinical protocols. We saw minutes of the meetings which recorded medical advisors challenging or agreeing on the procedures completed by Optical Express.
- The Optical Express lead for governance and quality monitoring had been assigned as a temporary surgical services manager in the absence of the substantive surgery manager. The surgical services manager had an oversight of the clinic, which included the quality monitoring and audits that had been completed.
- We reviewed the clinical and surgical services conference call minutes from April 2017. The minutes were succinct discussing changes to the company, however there was no ownership or timeframes within any actions identified. It highlighted the Royal College of Ophthalmologists Professional Standards for Refractive Surgery in April 2017 and the impact they may have.
- Optical Express held annual medical advisory board meetings. Refractive eye surgery and outcomes were reviewed and discussed with the board members.
- Staff attended regional meetings which included a set agenda where incidents, complaints, compliments and ongoing issues could be discussed. In November 2017, the surgery manager overseeing the Leeds clinic identified that staff at the clinic were up to date with mandatory training. Minutes were circulated to staff that could not attend and they were expected to read and sign the minutes as confirmation that they had been read.
- The surgical services manager would often send emails to all staff to inform them of any information that they were required to know. This included any lessons learnt and incidents from other clinics around the region.
- Checks had been completed for the surgeon's personal file and indemnity insurance was in place. Clinical outcomes had been assessed and an appraisal had taken place. We reviewed the personal files for the surgery manager overseeing the clinic; the appropriate checks were in place, including Disclosure and Barring Service (DBS) record, training and references.
- Staff completed patient scenario roles every three months, this involved the whole team and the approach they undertook. An evaluation of the situation was completed and staff received feedback.

## Governance, risk management and quality measurement

- Relevant policies were in place to support the governance of the company. These included information governance, medicine management, safeguarding and consent. The policies provided staff with clear guidelines and processes to follow.
- All the policies had dates set for when to review the information contained. A document management policy was in place that detailed the process in updating policies. We were told that additional and revised policies were made available to staff. Staff also signed to identify that they were aware of the changes to specific policies.
- The clinic had a risk register made up of 22 risks, for example; 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. There was no specific individual risks identified for the Leeds location that needed to be added. Staff did have the ability to add specific risks to the location if this was required.

## Public and staff engagement



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- Staff felt they could make suggestions that impacted and improved patient care. These included changing operation and waiting times to be more efficient. More administration staff had been created to support staff to complete more clinical care.
- Staff were encouraged to provide feedback at staff meetings. Staff told us that they would feel confident to discuss any issues at meetings or generally to the co-ordinator or surgery manager.
- Staff did not participate in staff surveys however staff felt that they would discuss any issues or concerns at the time with the management team.
- The font size within the written terms and conditions document was increased in response to information received that patients may not have read or understood the document. The document received a Crystal Mark standard, a recognised standard of approval for the clarity of a document.
- Patients completed questionnaires at several points during their procedure which asked if they had been satisfied with their care and treatment. Questionnaires at the clinic had scored consistently highly, therefore there had been no specific changes made as a result of patient feedback.
- A staff recognition scheme called 'wonderful Wednesdays' took place every week, where staff were nominated to receive awards such as spa days. The scheme was a way of the organisation recognising valued members of staff.
- The medical director and surgical services manager participated in working groups to provide guidance for refractive eye surgery.
- The company developed the International Medical Advisory Board. The board was made up of specialists independent of Optical Express. They met annually to discuss outcome data and gave recommendations about any changes required.
- The company had invested financial resources in research and patient outcomes were used worldwide to inform laser manufacturers and to drive technology. The company had several articles published in the professional press and outcomes were presented annually at the European and American Academy meetings.
- We were told that the clinic was to receive the latest diagnostic equipment; the equipment could take more specific measurements and was designed to interpret the readings at a higher level.

## **Innovation improvement and sustainability**

# Outstanding practice and areas for improvement

## Areas for improvement

### Action the provider **SHOULD** take to improve

- The consent policy should reflect Royal College of Ophthalmologists 2017 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 should offer patients access to interpreting services instead of relying on individuals that attend with the patient.