

Optimax Laser Eye Clinics - Leeds

Quality Report

47 The Headrow,
Leeds,
West Yorkshire
LS1 5RB
Tel: 0113 2342898
Website: www.optimax.co.uk

Date of inspection visit: 3 and 27 October 2017
Date of publication: 01/02/2018

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

Ratings

Overall rating for this location

Are services safe?

Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

Overall summary

Optimax Laser Eye Clinic – Leeds, is operated by Optimax Clinics Limited. Optimax hold the lease for part of the building situated on the third floor. Facilities include reception, a main central waiting area, topography room, three consultation rooms, one treatment room, preparation room and a recovery room. There is in addition, a manager's office, optometrist room, doctor's room, staff kitchen / rest room, patient toilets, filing room, laser technician's room, and electrical cupboard. Loft access was through a small staff only room.

All patient areas / rooms had disabled access and the building benefits from a lift.

The service provides refractive eye surgery only. If a patient required further care or surgery using anaesthesia or sedation, as an example, lens replacement surgery, patients were referred for private surgery to another Optimax Clinics Limited branch. If patients had lens surgery in another Optimax Clinics Limited branch, the Leeds location provided pre and post-operative care. The

Summary of findings

clinic recently started to offer Mibo-Thermoflo (a process in which the eye is massaged through ultrasound, as an aid to dry eyes), which is outside of our scope of regulation.

We inspected refractive eye surgery.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 3 and 4 October 2017 along with an unannounced visit to the location on 27 October 2017. This was due to the clinic holding only two surgical days per month.

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 Optimax Clinics Limited 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. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- There were low numbers of incidents and complaints.
- Staff members were positive about their working experience feeling supported to be part of a team and had worked in the service for a number of years.
- Patients spoken with and feedback to the service were positive about their experience and the outcomes from their surgery.
- All staff at the clinic had received an annual appraisal.
- Medicines were managed and administered in a safe and appropriate manner.
- Most staff were up to date with mandatory training.

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

- There was a lack of consistent registered general nurse cover, during surgical treatment days.

- Maintenance issues were not given priority by senior managers. Some of these issues had the potential to impact on patient care and treatment.
- Risks registers were not reflective of clinic issues and risks were not identified during environmental audits.
- General support for the clinic manager was poor.
- Clinical competencies for the extended role had not been reviewed, to ensure safe clinical practice.

Following this inspection, we issued a letter of concern and told Optimax Clinics Limited that it **MUST** take some actions to comply with the regulations and that it **SHOULD** make other improvements. We also issued Optimax Clinics Limited with two requirement notices for regulations breached. Details are at the end of the report.

Summary of findings

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

Contents

Summary of this inspection

| | Page |
|--|------|
| Background to Optimax Laser Eye Clinics - Leeds | 7 |
| Our inspection team | 7 |
| Information about Optimax Laser Eye Clinics - Leeds | 7 |
| The five questions we ask about services and what we found | 8 |

Detailed findings from this inspection

| | |
|--|----|
| Outstanding practice | 26 |
| Areas for improvement | 26 |
| Action we have told the provider to take | 27 |

Optimax Laser Eye Clinics - Leeds

Services we looked at

Refractive eye surgery

Summary of this inspection

Background to Optimax Laser Eye Clinics - Leeds

Optimax Laser Eye Clinic – Leeds, is operated by Optimax Clinics Limited. The clinic opened in 2000. It is a private service in Leeds city centre. The service provides refractive (laser) eye surgery for patients over the age of 18. The service receives patients from throughout the North area of England and is part of Optimax Clinics Limited.

The registered manager has been in post for three years.

The service is registered to provide the regulated activities of diagnostic and screening, surgical procedures and treatment of disease, disorder and injury.

Our inspection team

The team that inspected the service comprised a CQC Inspection Manager, lead inspector, two additional inspectors and a specialist advisor. The inspection was overseen by Sandra Sutton, Head of Hospital Inspection

Information about Optimax Laser Eye Clinics - Leeds

The service is located in the centre of Leeds, on a busy main road. There are no parking facilities directly outside of the clinic, but there is a public car park nearby, which is in walking distance. It is on a main bus route and a short walking distance from Leeds rail station. The service receives patients from throughout the North area of England and is part of Optimax Clinics Limited

All patients are privately funded, referring and paying for their refractive (laser) eye surgery themselves. Surgery days are planned twice a month on a Friday and Saturday with other days used for consultations and aftercare. There are no overnight facilities with opening times from 8am until 6pm.

During our inspection, we reviewed three sets of patient electronic records. We spoke with five patients in total who were attending for pre and post-operative assessments and laser surgery. Additionally we spoke with seven members of staff about their views and experiences.

In the last 12 months, the service performed 460 refractive eye surgery procedures.

The service has not been subject of any external review or investigation by the CQC at any time during the 12 months before the inspection.

There have been no Never Events or serious incidents reported in the preceding 12 months.

There were no incidences of hospital acquired infection such as Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), E-Coli or Clostridium difficile (c.diff) in the last 12 months.

In the preceding 12 months, the clinic had received eight written complaints.

Services provided at the location under service level agreement:

- Clinical and or non-clinical waste removal
- Interpreting services
- Laser protection service
- 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 where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Patients told us that that all risks and benefits were discussed with them prior to surgery and that they received good discharge and aftercare information.
- Incidents were recognised and addressed with staff understanding the importance of incident reporting.
- The clinic used a surgical checklist to ensure safe treatment for their patients.
- Laser safety was well managed and records were appropriately maintained.
- Medicines management processes were robust and had recently been reviewed.

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

- The clinic had been without a registered nurse for some time and the clinic manager had not received any form of clinical supervision since completing the extended role training.
- Maintenance issues were not actioned in a timely manner. Specific safety concerns were not prioritised or captured in risk assessments.
- The transportation of confidential records was not monitored and arrangements were not robust at the time of inspection.

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:

- Patients receiving care at the service were screened for suitability to ensure correct laser surgery was provided.
- Staff worked well together to ensure they maximised the patient experience.
- We saw comprehensive patient records held electronically, which was accessed securely by staff at the clinic.
- All staff at the clinic had received an appraisal in the last 12 months.

Summary of this inspection

- We saw clear medical protocols to support the patient treatment journey.

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:

- All patients we spoke with told us they found the clinic staff helpful and friendly.
- The clinic received consistently positive feedback from the annual patient survey.
- All comments cards we received provided positive feedback about the service.

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:

- Patients were able to access the clinic easily and found staff to be supportive.
- Staff worked flexibly to accommodate the patient appointment times.
- We saw examples of adjustments that staff had made to accommodate patients with specific needs.
- Complaints were managed in a timely manner and learning identified and shared with staff.

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 issues that the service provider needs to improve:

- Support for the clinic manager was poor. Escalation processes were weak and there were failings to address potential health and safety issues by senior managers.
- Governance processes did not capture issues within the clinic and risk registers were not reflective of current concerns.
- There was a lack of visual presence by members of the senior management team.

Summary of this inspection

- Audits were limited and lacked professional curiosity in order to drive improvement.

However, we also found the following areas of good practice:

- There was a clear leadership structure from service level to senior management level.
- All staff we spoke with reported they had good local relationships with their colleagues, within the clinic.
- There was positive staff surveys results undertaken to assess staff motivation, experience and well-being.

Refractive eye surgery

| | |
|------------|--|
| Safe | |
| Effective | |
| Caring | |
| Responsive | |
| Well-led | |

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The provider was currently developing an updated policy for the reporting of incidents and near misses during our announced inspection dates. We spoke with the compliance manager who was on site during our visit. We were told that a policy was currently being developed following advice from recent inspections on other Optimax sites and the policy was due to be finalised in a couple of weeks.
- All staff were familiar with the process for reporting incidents and could describe the actions they should take, despite the lack of a formalised policy.
- We saw the provider had developed the policy 'Adverse Event and Near Miss Reporting, Investigating, Analysing and Learning Policy', upon an unannounced return visit. It included guidance relating to serious incident reporting and never events. This policy had been shared with the clinic manager and was to be discussed with clinic staff that same week. The policy stated that it was created in October 2017 and was due to be reviewed in October 2019.
- All staff we spoke with told us there was a culture of reporting and learning from incidents amongst staff working within the clinic. Staff we spoke with understood their responsibility to report incidents and were able to speak with the clinic manager openly about incidents. Clinic staff told us that incidents were recorded electronically on the incident report form, by the clinic manager and investigated.
- A member of staff told us that all patients were asked if they had ate, prior arrival to the clinic. This was due to two incidents, in which patients felt unwell during treatment, as they had not eaten before attending the clinic. In addition to this, we saw the introduction of patient documentation audits following incidents specific to documentation gaps. For example, no date of birth recorded for two patients.
- There had been no never events or serious incidents in the preceding twelve 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.
- In the same period, we saw there had been 11 incidents recorded at the clinic. Three incidents related to incorrect information documented onto patients records, three related to environmental issues, such as blocked drains. Two involved patients feeling unwell during treatment, one regarding a patient fall, one regarding poor staff communication and another regarding a wrong lens laid out for a patient prior to treatment.
- We saw that all incidents were categorised. All incidents we reviewed were classified as near miss incidents. We reviewed staff meeting minutes during the periods in which incidents occurred and we saw that incidents were discussed with the clinic staff attending the meeting. Staff told us they were not informed of incidents that occurred in other Optimax clinics.
- Records reflected that the Compliance Manager for Optimax Clinic Limited reviewed incidents to ensure that the detail and quality of the incident report was sufficient. We reviewed the annual independent incident audit dated January to December 2016 and saw that Leeds Optimax experienced one of the lowest numbers of actual incidents across all Optimax clinics. Proactive reporting was evident as Leeds showed the highest number of near miss incidents, with 17 recorded across the year.

Refractive eye surgery

- A 'Duty of Candour and Being Open' policy was available; a review of records and information supplied prior to the inspection showed that the service had no duty of candour concerns. 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. Discussions with staff and the clinic manager showed that they were aware of their responsibilities to act on any duty of candour concerns.

Mandatory training

- All staff were required to complete a programme of induction, which included mandatory training modules appropriate to their role.
- The clinic manager told us that staff were nurtured and developed from the point of joining the organisation. Staff were encouraged to work across all roles to fully understand the organisation and the company's values before moving into more skilled roles such as assisting in the laser room.
- Mandatory training for staff included a range of subjects such as fire safety, manual handling, equality and diversity, data protection and safeguarding. Registered nurses were also expected to complete basic life support training each year. Training was delivered through a mix of classroom sessions at the Peterborough clinic and online training sessions.
- Training was delivered on an annual, or two yearly basis, dependent on the topic. For example, data protection, manual handling, duty of candour were completed annually and health and safety, fire safety, laser core knowledge were completed every two years.
- We reviewed the clinic training spreadsheet, which showed training for the staff working in the Leeds clinic and when training was due. Online and off site training was shown separately for clarity.
- Mandatory training was largely up to date. We saw two members of staff were overdue with some of their training, but were currently on maternity leave.

Safeguarding

- We were provided with a copy of the service's safeguarding policy named 'Vulnerable Adult Protection Policy' prior to the inspection. The document showed it was created in September 2011 and was reviewed in September 2017.
- The provider had also developed a child protection policy. The document showed that it was due to be reviewed in August 2017 and was part of the on-going policy review process.
- The designated lead for both adult and children's safeguarding was the clinic manager. The manager told us they had completed level three safeguard training for both adults and children and clinic staff level two adult and children's safeguarding. All staff we spoke with, were clear whom their safeguarding lead was and which local authorities they would need to contact to raise an alert. This was in line with the intercollegiate guidance document "Safeguarding Children and Young People" (2014)
- Information from the service showed that they did not treat patients under the age of 18 years old. The service had limited contact with young people. Staff members told us that they were provided with basic (level one) safeguarding training for both adults and children.
- There were two safeguarding training days, which staff were required to attend. Standard safeguard training (level two), which all staff completed and leading safeguarding (level three), which was completed by the clinic manager and involved a greater understanding of safeguarding issues.
- The service had not reported any safeguarding concerns since its opening in 2000 and there were no safeguarding issues logged with CQC. The manager confirmed that there had never been a safeguarding concern in the service.
- Records reviewed showed that staff members at a minimum of two yearly intervals undertook safeguarding training. The manager monitored training in order to make sure that staff received the latest and most up to date training.
- Staff underwent disclosure and barring checks just prior to appointment but there was no policy or process in place to revisit these. The provider told us that any changes affecting the disclosure and barring checks would be discussed at appraisal each year and new applications submitted for staff names changes or new job roles.

Refractive eye surgery

Cleanliness, infection control and hygiene

- There were clear infection prevention control (IPC) protocols and hygiene arrangements for staff to follow. We saw the provider had developed an 'Infection Prevention Control' policy, which had been reviewed in August 2017.
- There was a 'Cleaning policy for clinics'. This detailed equipment to be used and cleaning schedule to be followed'. This policy was created in 2007 and had recently been reviewed within the last two months.
- Upon entering the clinic, we noted that there was a strong sewage like smell. We saw that the clinic manager had escalated the concern relating to the strong smell several times to the properties and facilities team. The compliance manager was also aware of these concerns. We heard patients waiting in the reception area discussing the smell and this indicated that it had been a problem for some time.
- We also saw that there were some significant maintenance issues across several areas of the clinic. For example, we saw flaking ceiling paint across a large crack in the ceiling in the topography room, a ceiling tile missing in the cleaner's room, significant water stains on the wall and ceiling in the recovery room, and water damage to plastered wall in the clinic stairwell.
- All of these concerns had been raised by the clinic manager to the properties and facilities team and escalated to the compliance manager. We reviewed several emails escalating the severity of the concerns and requesting urgent maintenance work. No action had been taken to rectify these concerns by the provider during the six months of escalation made by the clinic manager.
- We advised the clinic manager to alert a senior manager of our concerns. They attended the clinic the same day and assured the inspection team that immediate action would be taken to address all of our concerns raised.
- We returned to the clinic the following morning and saw that repairs to all areas were in progress and the areas affected were made safe for patients to access.
- Following inspection, we were advised that the local authority were in attendance on the day of our announced visit, to address the problem of the sewage type smell. The senior management team had not made the clinic manager aware of this visit.
- Records viewed reflected that the service had not had any reported infections in the last 12 months. All staff we spoke with told us they were aware of the procedures for reporting and identifying infections.
- The provider developed a document had been developed by the provider to identify eye infections. Staff told us it was the responsibility of the surgeon or the optometrist to identify eye infections but were aware of the supportive guidance.
- The clinic manager told us that the clinic did not screen for infections specifically but any information specific to infections in the patient healthcare questionnaire, would be investigated further.
- We saw that the clinic manager carried out legionella water tests.
- We saw a compliance audit was completed by a senior manager each year. The audits were intended to identify what actions the service needed to take in order to reduce any potential risk of infection and assess overall clinic quality compliance. We reviewed the audit completed in June 2017. None of the maintenance issues were identified as part of this audit visit.
- Records we reviewed and conversations with staff confirmed that staff received and completed training in infection control. Staff also completed questionnaires following their training to confirm that they understood the training and were able to put the training into practice.
- We reviewed the training matrix and saw that all staff, except one who was on maternity leave, had completed infection control training.
- We observed that personal protective equipment (PPE) to help reduce the spread of infection, such as gloves were available, and observed to be used appropriately. All bins were hands free or pedal bins, soap in bathrooms was liquid soap and there was access throughout the service to hand sanitiser.
- Throughout the service, we observed that there were "sharps" boxes used for the safe disposal of items such as used needles. The service had a contract with an external organisation for the removal and replacement of sharps boxes in order to maintain safety.
- We saw that the service utilised "single" usage surgical equipment. These were appropriately disposed of following surgery and the provider had developed a policy to support this.

Refractive eye surgery

- We reviewed the cleaning schedule for the laser room and saw that there were daily and weekly audits that the manager undertook. We reviewed the cleaning records for October and saw that they were up to date.

Environment and equipment

- The clinic consisted of a central waiting / reception area. Three consulting rooms, a laser and preparation room, recovery room and a doctor's room.
- We reviewed clinical areas and experienced the full patient journey from first entering the clinic to consultation and treatment.
- All clinic staff told us they had sufficient equipment to deliver patient care safely. Clinical areas were observed to contain equipment that was suitable to the diagnosis, laser surgery and recovery of patients.
- Records available indicated that the service had an ongoing maintenance scheduled that checked the equipment available, and made sure that routine maintenance was in place including the lasers used for surgery. The clinic manager reported any equipment needed to be repaired or replaced.
- The service had an optical radiation safety policy and local rules were available for staff to follow. We saw appropriate signage displayed when lasers were in use.
- Local rules were stored in a folder in the registered manager's office. There was a list of authorised users and staff had signed to state they had read and understood them. Staff were clear regarding the safety arrangements within controlled laser areas.
- The local rules also contained contact information for the Laser Protection Advisor. The LPA was external to the service and based in London.
- We saw records and spoke with staff regarding their training in laser safety. Training was available and supported by a Laser Protection Supervisor (LPS) within Optimax Clinics Limited and a Laser Protection Advisor (LPA). Staff confirmed they knew whom to contact if they had any concerns about the safety of the laser equipment.
- Staff completed documents to record humidity and temperature in the laser room and they checked on a daily basis in order that these were correct and maintained the safety of patients.
- We saw the clinic had appropriately raised an automated safety alert to advise that the temperature within the laser room had increased above usual temperature parameters. We reviewed the actions taken by the clinic manager and saw that new temperature and humidity sensors were ordered as the equipment was found to be faulty.
- The clinic manager told us the LPS provided training and support both on a yearly basis and as and when needed.
- Laser assistants were trained by senior and experienced staff on how to calibrate and assist with the laser machine. They had also attended a core of knowledge' laser safety course
- We observed a staff only area, which led to a small corridor. Doors led off from this corridor opened into several rooms. These included the laser technician's room and a spare room, which contained an old treatment machine.
- We saw within the spare room, loft ladders, which were in full extension into the open loft at the time of inspection.
- We brought this to the clinic managers concern immediately as, there was a potential fire risk and general risk of patients wandering down to into the corridor. We reviewed the unlocked laser technician's room and saw that there were gas cylinders unsecured to the wall and electrical cables hanging loose above them. Again, these issues were brought to the senior manager's attention during the visit and we were assured, the concerns would be attended to straight away.
- We reviewed these areas during our unannounced visit and saw that a key coded lock had been added to the spare and laser technicians room. Cables had been removed and cylinders were secured to the wall appropriately and had been clearly marked for identification.
- We observed waiting and treatment areas to be tidy and well maintained; they were free from clutter and provided a visually clean environment for patients, visitors and staff to move around freely.
- We observed what appeared to be a CCTV camera in the patient waiting area. We spoke with the compliance manager who told us that it was no longer in use, as it was part of an old surveillance system. This camera had been removed when we returned for our unannounced visit.
- We observed equipment stock in the storage areas was CE marked, which means they complied with European

Refractive eye surgery

standards. These included protective eyewear, needles and other surgery devices. This ensured that all equipment was approved and compliant with relevant safety standards.

- We reviewed several pieces of equipment, found them to be in clean working order, and had been regularly serviced.
- We saw the resuscitation trolley was regularly checked by the clinic staff and all equipment was in date. All members of staff were aware of the emergency equipment and how to use it. There have not been any occasions in the last 12 months in which the emergency equipment had been required.
- We saw waste was handled and segregated appropriately.

Medicines

- We reviewed the medicines management policy. We saw a new document 'Policy for prescribing, Dispensing, Administering Medication, Competency and Training of Company Medical and Clinical staff'. This document was created in September 2017, and gave clear protocols for the dispensing of medicines for staff.
- The service had a policy regarding the use of cytotoxic medicines, which included the management of risk. These are medicines that contain chemicals, which are toxic to cells, preventing their replication or growth. There were appropriate risk assessments, policies and protocol associated with the handling of the cytotoxic medicines. We saw that cytotoxic medicines were ordered corporately and a spillage kit and appropriate waste disposal arrangements were in place.
- We saw that medicines were stored safely, within lockable cupboards. Access was limited to the key holder and there was only one set of keys available in order to make sure the medicines were accessed appropriately.
- The training spreadsheet showed that staff had received a medicines management course as part of their training. However, this did not detail if staff had been trained in dispensing medicines that patients took home to take later, known as To Take Out (TTO) medicines. We reviewed the electronic medicines training module and saw that no guidance was provided for TTO medicines.

- The clinic manager told us that all TTO medication was pre-prepared, which mitigated any risk against the wrong dose of medicines being dispensed and administered.
- The registered manager told us that only the consultant or registered nurse gave medicines such as eye drops and this was recorded appropriately in patient notes with dose, site and strength of medicine given.
- We looked at two patient's records, which detailed current medicines, any allergies and a medical history in order to make sure that any medicines prescribed by the consultants were safe to be given.
- Staff carried out monthly stock checks to ensure medicines remained safe to use. Fridge temperatures were checked and recorded daily to ensure that medicines, which required refrigeration, remained suitable for use. Staff knew what to do if the fridge temperatures went out of range.

Records

- The service used a combination of paper and electronic records. Electronic records were comprehensive and contained all the patients' details including assessments, surgery and medicines given. We looked at this system for two patients. These recorded information such as full details of the patient's medical history, previous medications, consultation notes, treatment plans and follow-up notes in order to keep the patient safe and determine the suitability of surgery.
- The clinic manager told us that patient records were transported by a clinic member of staff to the Huddersfield site, when specific patients were referred. Documents were not stored securely and were taken home by the member of staff if it was too late in the day to return back to the Leeds clinic. There was a potential data and confidentiality breach. The provider, purchased secure lockable storage and arranged for documents to be transported by a recognised delivery firm, took immediate action. We saw that the compliance manager had also developed a protocol, when we return for the unannounced inspection visit.
- The service retained all copies of the patient records and supplied patient information as needed to external professionals. We observed post laser surgery letters were given to patients to provide to other healthcare professionals as they wished.
- The clinic manager carried out documentation audits on a quarterly basis. We reviewed the data from the last

Refractive eye surgery

audit completed in October 2017. Ten patient records were audited and we saw comments by the manager relating to actions needed to be taken. These related to missing blood pressure records and there were meetings with staff to improve this.

Assessing and responding to patient risk

- Prior to commencement of laser surgery, patients were assessed for their suitability for laser surgery at the service. We saw that pre assessment data included a health questionnaire and eye tests were performed to assess suitability. Any pre assessment issues were highlighted to the Optometrist, who took the final decision in consultation with the surgeon.
- We observed two patient consultations and saw that risks associated with the treatment were clearly outlined and discussed openly with the patient.
- We saw that the provider had developed a system of 'Medical Protocols', which followed the stages of the patient journey through to treatment. The protocols provided guidance to staff, to ensure consistency and safety, within each element of the clinics care. There were 18 protocols, which covered induction through to discharge of the patient.
- All staff we spoke with understood the patient's journey and the importance of the appointment with the Optometrist prior their laser surgery, to examine the patient at the first post-operative appointment.
- We saw all patients were reviewed again prior to treatment to check for infection or complication by the surgeon.
- Surgical checklists were used on surgery days. The checklist had been recently developed and was based the World Health Organisation (WHO) surgical safety checklist. Due to the fact these had recently been introduced, there were no audits completed for the checklists at the time of inspection.
- Staff informed us that patients remained in the service until they felt well enough to go home. We reviewed the recovery room for patients and observed patients escorted to the room. Patients were supported, with sufficient time to rest and recovery.
- Once discharged, we saw aftercare information discussed with patients. As the surgery did not involve general anesthesia or sedation, patients did not require any observations post operatively.
- We spoke with three members of staff who were all able to clearly define what actions to take if a patient

became unwell. Information provided as part of the Optimax Clinics Limited' assessment of their services, showed that the most common issue post-surgery was patients fainting. Staff described how they would address this, and if necessary, they would call an ambulance for the patient.

- We reviewed the clinics 'Emergency After Care Cover Guidelines' and saw that staff were provided with clear guidelines.
- The service had a service level agreement with the local hospital in the event of complications. In the previous 12 months, there had not been any complications for patients that required a patient to transfer to hospital.
- We saw that staff provided patients with an emergency telephone number for out of hours use. These calls were managed by the patient's surgical consultant. The information was written on the aftercare advice leaflets, which staff discussed with patients.

Nursing and medical staffing

- We reviewed the staffing arrangements for the clinic. We saw that all Ophthalmologists working within the clinic were self employed. There were 5.8 whole time equivalent 'other' staff who supported the full time clinic manager.
- The clinic manager told us that a registered nurse had been appointed, but was currently off sick. There was no agreed date of return for this nurse at the time of inspection.
- We reviewed the rotas for the last 12 months and saw that a registered nurse was present for only 7% of treatment sessions at the clinic.
- The clinic manager had completed extended role training which meant the manager could complete the registered nurse role within the laser room. Records showed that the manager, laser technician and a registered nurse from another clinic supported the surgeon in the laser room. The compliance manager told us it was not necessary to always have a registered nurse on suite due to the low risk nature of the treatments but this practice was not in line with 'The Royal College of Ophthalmologists' guidance document 'Roles within the Refractive Surgery Team' April 2017.
- Monitoring of staffing levels was based upon the numbers of patients requiring refractive surgery and

Refractive eye surgery

aftercare in the service. Clinics and surgery was scheduled dependant on the amount of patients and staff available in order that patients' safety was maintained.

- A review of staffing files showed that all staff had received a DBS check (police check) to make sure that none of the staff had a past criminal record. Additionally all staff had completed a healthcare check and immunisation check to make sure that they did not place patients at risk.
- We reviewed four staff recruitment files for other staff. We saw references and recruitment checks were in place as required. The company did not have a policy to determine how often DBS checks should be repeated but did encourage staff to disclose any new issues during appraisal.

Major incident awareness and training

- We saw the provider had developed a major incident, policy and procedure. The document stated it had recently been reviewed in August 2017. The document had not been completed to show where the assembly point was in the event of a major incident but all staff we spoke with were able to explain the procedures.
- During our initial tour of the clinic, we highlighted several areas of concern, which may have presented a fire risk to the clinic. These were addressed immediately and were all fully actioned upon our unannounced visit.
- We were told by the compliance manager, during our unannounced visit, that a new fire alarm system was to be added to the clinic. The fire alarm was reviewed in November 2017, which identified that only minor work was required, which was carried out.
- Backup generators were in place specifically for the laser equipment and were checked daily.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- The provider had developed policies and procedures, which were developed in line with relevant best practice guidance such as National Institute for Health and Care Excellence (NICE) and The Royal College of Ophthalmologist (2017 RcOph guidance) .

- The clinic manager told us that Optimax has a Medical Advisory Board, which sets standards for all of the surgeons and optometrists across the company.
- Records reviewed, and discussions with management, demonstrated that the service utilised both national policies and procedures developed by Optimax as well as local policies.
- We saw the compliance manager completed a compliance audit of the clinic, but this did not monitor clinical practice against best practice or national guidance.
- We spoke with the compliance manager, who was present during the inspection, who told us that policies were being reviewed following advice and discussion from recent Optimax inspections at other sites.
- We saw a number of policies such as the incident reporting and mandatory training policy were recently re-written (October 2017), to ensure they provided comprehensive guidance and were reflective of recent national guidance and best practice. However, a number were not in date at the time of inspection.
- We saw that guidance relating to patient care 'Medical Protocols', provided sufficient detail in which to safely care for and support patient treatment plans.
- We saw records that showed that patients were advised that they needed a "cooling off period" time to think about the surgery and its implications before any surgery was scheduled. This was in line with industry guidelines and was a minimum of 7 days.

Pain relief

- Patients were not routinely assessed for pain and the clinic provided limited forms of pain relief at pre and post-surgery consultations, in the form of anaesthetic eye drops. This was in line with usual practice within refractory (laser) eye clinics.
- We observed two patient consultations and saw that patients were advised on pain relief during discharge discussions.
- Records available and staff discussion showed that patients were given a 24-hour helpline number to contact if they needed pain relief. All patients were given discharge information that if the pain was severe they should go to their local accident and emergency department.
- Patients returning for after care appointments informed us that they had experienced little to no pain and knew to contact if they had experience any discomfort.

Refractive eye surgery

Patient outcomes

- We saw the clinic monitored patient outcomes through a series of predicted results called 'Patient Forecast', which were developed for each patient. We saw these results were collated electronically and clinic managers were able to see if there were trends in the results. If results outside the predicated range were identified this was discussed at the Ophthalmologists appraisal. Significant deviation would be logged and investigated.
- The clinic manager told us that the patient forecast was given to the patient to take home following consultation. It explained the treatment outcomes with similar prescriptions and age, and then a print out of the aftercare check afterwards.
- This data from patient predicted outcomes and the Ophthalmologist results were discussed at the Medical Advisory Board (MAB) to determine the results for patients' of the laser surgeries provided and safety. In the event that recommendations for change were made, senior managers reviewed the recommendations internally via the national MAB and when changes were required; the information was disseminated to all staff in the organisation. This was undertaken in order that the service continuously reviewed and improved the results that patients achieved.
- We reviewed the minutes of the March 2017 MAB minutes and saw that there were discussions around patient's expectation specific to lens treatment.
- We reviewed information sent to us prior to inspection by the provider, which stated that all surgeons have their treatment outcomes audited for the purpose of revalidation by the diary department at head office. We saw evidence of this within the surgeons staff file.
- Outcomes were measured in addition through patient satisfaction surveys and through the surgeon's yearly audit.
- We were not assured that this data was routinely used to drive and improve patient treatment and care quality.
- Staff informed us that the Optimax Clinics Limited reviewed and audited incidents, outcomes and complications by each Ophthalmologist. By involving the corporate clinical services team, the Optimax Clinics Limited were assured that the patient received consistent continuous care, which was delivered at the time it was needed.
- Information sent to us before the inspection recorded that out of the 460 patients treated in the previous 12

months, 10 required retreatments/enhancements. The reasons for retreatment/enhancement were due to quality of vision issues and desired outcome not achieved by the patient. Staff informed us that patients were made aware of the potential need for retreatment/enhancement at the start of their laser surgery and we observed this during consultation. We did not see any internal benchmarking

- We saw the compliance manager audited the patient experience surveys. We reviewed the most recent survey dated November 2017, which showed over 98% of patients thought they had a good experience with a good result. The service had a consistently high patient satisfaction rate, with October scoring 99%, with no serious incidents and no infection rates.
- We asked the clinic manager if they submitted any data to PHIN, but the clinic were not submitting data at the time of inspection.

Competent staff

- There was a comprehensive training programme available for staff. All staff were encouraged to learn very basic skills, prior to moving through the job roles. The clinic manager told us it was important that staff learnt all elements of the patient journey.
- Staff told us that they had good access to training regarding their professional development. Training was offered either as an electronic module or as face-to-face training in Peterborough clinic in the training centre. Training records reflected a variety of training including health and safety, safeguarding, moving and handling and laser safety.
- The clinic manager was the services' Laser Protection Supervisor (LPS), with overall responsibility for the safety and security of the lasers and generally attended the laser room during procedures. Records reflected that the service ensured that all the laser technicians had undertaken laser safety training and this was renewed at a minimum of every two years.
- Minutes of meetings showed that Laser Safety was discussed at team meetings. An external Laser Protection Advisor (LPA) was available for training and advice and supported as needed.
- The clinic manager had also completed extended role training. This training ensures that the manager was competent to fulfil some of the clinical elements of the registered nurse role.

Refractive eye surgery

- We saw that a registered nurse had provided the extended role training to the clinic manager in 2011, but there had been no clinical supervisor or competency review completed since this training.
- The clinic manager told us that staff were allocated to specific roles each morning. Only staff that had completed specific laser room training were assigned to assist. If someone fell sick, staff were requested from nearby Optimax clinics such as Newcastle.
- The clinic manager supported all staff within the clinic and told us it was important that they understood every aspect of the patient journey. Staff worked independently once all their competencies were signed off. There was no time period for competencies to be completed by, but all new staff had a six-month probation period.
- We saw that there was always at least one member of staff on duty during surgery days that were BLS (basic life support) trained. Only registered nurses were required to undertake ILS intermediate life support (ILS) training. Staff informed us that as a single speciality service that did not use anaesthesia or sedation, the risk to patients was low.
- The service had a policy in relation to sepsis, discussion with nursing staff and Optometrists showed that they were aware of the signs of potential sepsis and how to escalate any concerns they had in order that the patient received treatment.
- We spoke with three staff working in and around the treatment areas. All were able to clearly articulate the signs and symptoms of sepsis.
- All staff spoken with and records reviewed indicated that 100% of staff had received an appraisal within the last 12 months. Staff told us that they found the appraisal sessions helpful and were supported with specific training requests.

Multidisciplinary working

- All staff told us that everyone worked well as a team. We observed clear communication between the staff working in the clinic, within a positive working environment.
- The surgeon had overall responsibility for patient care and reviewed patient outcomes reports and proposed treatment plans. Any patient concerns, such as suitability for treatment including health issues would be discussed and agreed by the surgeon.

- The clinic manager told us that staff meetings were held monthly. Most staff attended the meetings, although some staff may not be allocated to work on those days. Minutes of meetings were recorded and retained in a file in the clinic manager's office.
- We reviewed the minutes of the last three meetings and saw that discussion included audit results, clinic security, patient feedback, and clinical knowledge updates.
- The clinic manager told us that telephone conference calls (TC's) were also held by senior managers, to share learning across the company. For example, we saw a TC was arranged to discuss the new style risk assessment document, to be completed by the clinic managers.
- All patients were provided with a treatment overview letter upon discharge. Patients were asked to share this with their GP.

Access to information

- We saw that patient details were held electronically, and were accessible for each appointment during laser eye surgery, and for staff to monitor patients after their laser surgery.
- We observed pre-treatment patient questionnaires were completed by clinic staff and patient medical questionnaires were reviewed by the optometrist prior to all eye examinations.
- All staff told us they would speak with the optometrist or surgeon if they had any queries. Information was given to patients prior to any treatment, which outlined the risks and advantages of the surgery.
- Patient records detailed current medicines, any allergies and a medical history to make sure that any medicines prescribed by the consultants were safe to be given.
- We saw that electronic records enabled those patients who came to Leeds for assessment and after care to have these records accessed from another Optimax Clinic sites.

Consent and Mental Capacity Act

- Consent to treatment means a person must give their permission before they receive any kind of treatment or care. An explanation about the treatment must be given first. The principle of consent is an important part of medical ethics and human rights law. Consent can be given verbally or in writing.

Refractive eye surgery

- We saw the provider had a policy specific to patient examination or treatment consent, which was reviewed, in July 2017.
- We saw that a patient questionnaire was used as part of the consent process and was also a guidance tool, which assisted staff in identifying the patient's understanding of the information provided to assist in making an informed consent.
- In addition, we reviewed three surgery agreement and consent forms specific to surgical treatment and all were found to be fully completed and in line with professional standards. We observed staff seeking verbal consent prior to undertaking care and treatment.
- Staff demonstrated a clear understanding of the legal requirements of the Mental Capacity Act 2005 (MCA) and Deprivation of Liberty Safeguards. The staff members spoken with gave examples of when patients might lack the capacity to make their own decisions and how this would be managed. In general if a patient lacked capacity to make the decision they were not offered the laser surgery. This was because the individual paid for the laser surgery themselves and the best interests requirements of the MCA were not likely to be met.
- We spoke with the optometrist, who gave us a clear example of a patient who had visited the clinic and displayed capacity issues. The optometrist was able to clearly articulate the support that this patient required and the sensitivity shown in that specific situation.
- We observed records that demonstrated that the mental capacity of a patient to consent to laser surgery was reviewed by the Ophthalmologist and staff during consultation and the pre-operative assessment stage.
- Records reviewed showed that all patients were given time and information to reflect on the decision this was a minimum of seven days.

Are refractive eye surgery services caring?

Compassionate care

- We spoke with five patients during our inspection. All patients we spoke with told us staff were kind, knowledgeable and made them feel relaxed. We observed patients were treated with compassion, dignity and respect.

- Privacy and dignity of patients was maintained. The waiting area was an open environment; however, patients were escorted to consultation rooms to enable private discussions. We observed positive and discreet interaction between staff and patients.
- The last patient survey in the clinic, completed in November 2017 showed 98% of patients felt satisfied. The clinic scored consistently high overall with October showing 99% patient satisfaction.
- We received eight completed comment cards from patients; all were positive and reflected the satisfaction figures within the patient survey. One patient said 'The service throughout has been excellent. The staff and the surgeon were amazing'.

Understanding and involvement of patients and those close to them

- All patients we spoke to told us that they were given realistic expectations of the outcomes of their surgical procedure. We saw evidence in patient records of realistic outcomes following surgery being discussed.
- Patients informed us that they had sufficient time to consider the information provided about their proposed surgery, including any risks and benefits. Patient told us they "felt welcomed" and "fully informed" about their laser surgery.
- We saw that patients were encouraged to ask questions about their care and treatment and were given direction regarding treatment options.
- Leaflets were provided to patients explaining the benefits and risks of the treatment. We did not see leaflets provided in different languages but we were told that these could be requested by staff, through head office.
- We observed staff taking time to clearly and carefully explain instructions to patients and to answer any questions patients had following surgery. This included how to insert eye-drops at home, cleaning around the eye to prevent infection and activities following surgery.
- Staff told us they would make reasonable adjustments to patients visiting the clinic. One member of staff gave us an example of a patient with mobility issues. They described how furniture would be moved to ensure the patient had sufficient space to move freely around the clinic.

Refractive eye surgery

- Another member of staff told us that some patients are uncomfortable using computers and find the electronic questionnaire system strange. The staff member spoke of the support that was provided and paper versions of the questionnaire that were offered if patients preferred.

Emotional support

- We spoke with patients who told us they felt supported and staff members were warm and welcoming. One patient told us they were given good written and verbal information and at no point in time felt pressured into treatment.
- The clinic asked patients to complete an electronic questionnaire following each visit. Patients were asked about their experience of the clinic and whether they had any concerns they wished to raise. The clinic manager told us that concerns would trigger an electronic flag to the manager, and the issue could be resolved quickly.
- Throughout our visit we observed staff giving reassurance to patients with additional support given when it was required, especially if patients were apprehensive. One patient comment card said 'I felt safe in their hands, no pressure'.
- We saw that patient's dignity was respected and maintained at all times. Patients passed through the reception area when leaving the laser room but none of the patients we spoke with, told us this was an issue.

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

Service planning and delivery to meet the needs of local people

- Optimax Leeds opened in 2000 and provided private laser eye surgery for the immediate and local population and across Leeds and the North of the region. The clinic manager informed us, that any patient could attend any of the Optimax Clinics Limited services nationwide as the service could access electronic patient records from every service.
- For patients requiring surgery that could not be accommodated at the clinic, such as lens replacement, referrals were shared with other Optimax clinics, which patients could access.
- All of the appointments for the clinic were managed at a central location known as the diary team. This team

took calls from prospective patients who wanted an appointment to assess if they were suitable and for all consecutive appointments. The clinic manager told us that this service worked well and there were positive relationships between the clinic and the diary team.

- Information sent to us prior to inspection and available on the services website showed that the service opened Monday to Saturday from 8am to 6pm with the exception of Thursday when the service was open until 8pm. If necessary, some appointments could be made for Sunday in order to meet patients' needs.
- We saw a loop system was installed at the reception area for people who required additional support with hearing and translation services.
- In the reception/waiting areas, we saw that there were "easy clean" chairs for patients to use whilst waiting for laser surgery. There were also magazines and a hot drinks machine available.
- We spoke with staff and management regarding the arrangements for patients where English was not their primary language. We were informed that this was addressed in a variety of ways including patient support from relatives, and a translator attending the clinic in order to support individual needs. Additional charges were applied for these services.

Access and flow

- Patients were able to self-refer without a GP or optician's referral.
- We saw that the clinic did not monitor waiting times for patient appointments but all patients told us they were seen quickly upon arrival. We observed this during inspection and patients were informed if there were any delays.
- We reviewed information sent to us by the provider prior to inspection and saw that there were no incidences of unplanned transfer of a patient to another health care provider in the last 12 months. This meant that the service was able to recognise and address any potential complications to maintain quality of care to patients.
- There was no waiting list for treatment at the clinic and staff we spoke with said this was consistent. There were no cancellations due to non-clinical reasons in the last 12 months.
- Staff told us that it was the services policy to try to make sure that patients received an appointment of their choice. All staff we spoke with told us they work flexibly to accommodate patient's requests.

Refractive eye surgery

- The clinic manager told us that patients who cancelled appointments were followed up with a telephone call. Subsequent missed appointments would be managed by issuing a letter to those patients.
- We asked how cancelled surgery dates were managed and were informed that surgery was rarely cancelled. However, there were no monitoring systems in place to determine how often surgery was cancelled or the reasons that it could be cancelled.

Meeting people's individual needs

- The clinic did not offer car parking facilities as it was adjacent to a busy main street but there was a private car park within a short walking distance from the clinic.
- Patients who had additional needs such as those living with dementia, or who had challenging behaviour were not treated at the clinic.
- We spoke with five patients. All told us they had found the facilities comfortable and relaxing with drinks facilities, magazines and information leaflets available.
- Several of the patients we spoke with first contacted the clinic through the website. They told us that accessing the clinic was straightforward and they received a call back quickly.
- The service did not provide an emergency eye surgery service. They provided elective and pre-planned procedures only. Any emergency cases were referred to the appropriate emergency eye care services.
- The clinic manager told us that carers, patient friends, and family members were welcomed. Particularly where patients felt anxious or nervous about their treatment.
- Information leaflets were available within the clinic entrance and in the reception waiting area. We asked staff and patients if information was available in different formats such as braille, large print or other languages. Staff and management confirmed that different formats were available if requested, but were not accessible on site. The availability of information in formats to meet the needs of people with impaired sight would benefit patients in their understanding and involvement of the laser surgery they were to receive.
- The manager and staff confirmed that the service only undertook laser surgery on patients aged 18 and above. Information sent to us prior to the inspection recorded that six patients aged 18-21 years had undergone laser surgery during the last 12 months. The service did not have a policy on laser vision correction specifically for

this age group but told us that the usual patient medical protocols were followed. The staff confirmed that younger patients were advised that further laser surgery may need to be repeated at some point.

- We saw information that was given to patients advising them of post-operative care and details of the 24 hour helpline should they have concerns following discharge.

Learning from complaints and concerns

- The provider used a complaints management policy and procedure, which set out the process and staff responsibilities for handling compliments, comments, concerns and complaints. The policy defined the severity of complaints and set out a 20 working day timescale for the response to complaints and concerns. The clinic manager was responsible for ensuring complaints were responded to within the policy's timescales.
- We reviewed the patient's information booklet provided to patients by staff at the clinic. The booklet did not include information for patients about how to make a complaint but we saw the patient guide and statement of purpose, contained the full complaints procedure, which was on show in the reception of the clinic. Suggestion forms were also printed and available to patients in a clear display holder at reception.
- We saw that complaint forms were behind the desk at reception and saw that information about the complaints process was included in the new patient handbook. Patient complaints could be made verbally, in writing, by email or online.
- We saw that information regarding complaints was made available as part of the discharge information given to patients. This outlined how to make a complaint and included a copy of the patient survey.
- The clinic manager told us that patient complaints were also noted through the electronic questionnaire system. An electronic flag was sent to the clinic manager should a patient answer a particular question which gave a negative response.
- We saw within the minutes of clinic staff meetings that patient feedback was discussed including complaints and how to improve services.
- The service received few complaints. Information submitted to us prior to the inspection showed five complaints in the last 12 months. We reviewed the complaints file and saw that an additional three

Refractive eye surgery

complaints had been recorded for the last 12 months. Five complaints were in relation to patient expectations and three were about consent and explanation of the procedures.

- All staff we spoke with, told us that clear information is provided to the patients to ensure they are well informed and disappointments are avoided.
- The clinic manager responded to all complaints within the 20 day period and we saw discussion around these complaints within staff meeting minutes.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was a clear leadership and staffing structure within Optimax, both locally and within the wider organisation. The clinic manager had worked for several years within the organisation, initially as a patient advisor and then supervisor before progressing into the registered manager role. The full time manager was supported by a compliance manager and reported directly to the Director of Operations.
- The clinic manager told us that the company was established in 1991 and the founder stayed with the company throughout its growth and development. It was clear that staff felt proud about the company.
- Morale within the clinic was good and all staff we spoke with told us that they enjoyed their job. One member of staff told us 'It's a good place to work. The team make it a good place to work and the manager is very supportive'.
- There was a friendly culture, and the manager was visible and approachable. The atmosphere was relaxed and we saw positive dialogue between staff and patients. Staff were clear whom they reported to.
- Support for the clinic manager by the senior management team, was poor. We reviewed emails, which were sent to the properties and facilities team in relation to the maintenance issues and health and safety concerns by the clinic manager. We saw that emails were sent across a ten month period and were gradually becoming more urgent in tone during each correspondence. We were not assured these issues were taken seriously by the senior management team and it was clear that the clinic manager was expected to resolve these concerns.

- In one particular email, we saw that the clinic manager had taken photographs of the ceiling, which was cracked and potentially unsafe, as it was sited above tomography equipment. We saw the clinic manager frequently shared correspondence with senior managers about these concerns.
- We were not assured that these issues were taken seriously by senior managers.

Vision and strategy

- The organisation mission was 'to be the first choice in the UK for laser and lens surgery procedures'. All staff we spoke with understood the mission and felt engaged in the development of the clinic.
- The clinic manager was clear about the plans for the future of the clinic, which included offering new treatments, building on the current reputation and continues to pioneer advancements in technology by sharing outcomes, maintain and increase the organisations profile by increasing influence in consultation processes and continued investment. The providers values were for staff to:
 - Be committed and proud of their work
 - Be recognised for their efforts
 - Feel responsible and accountable for what they do
 - Be well trained and managed
- All staff we spoke with were aware of these values and felt part of the organisations mission.

Governance, risk management and quality measurement

- There was a governance framework in place, which, was intended to support staff delivering care and managing the clinic. For example, the clinic manager was overseen by the compliance manager and lead by the Director of Operations.
- The clinic manager told us there was no formal timetable for either the compliance manager or Director of Operations visits but both members of the team were available to contact via telephone.
- We saw the compliance manager visited the clinic regularly and conducted environmental compliance audits.
- We were not assured that these audits captured current issues and concerns within the clinic. For example, we

Refractive eye surgery

reviewed the audit completed in June 2017 and saw that none of the on-going maintenance, fire risks and odour in and around the clinic had been identified. It was clear upon reviewing correspondence that these issues had been active at the time of the audit.

- We asked the clinic manager about patient outcomes and key performance targets that the clinic was asked to report and monitor upon. We saw that outcomes were financially focused and patient outcomes were limited. For example, we saw there were targets around the number of patients who converted from enquiry stage to treatment.
- We were not assured that the provider monitored outcomes to improve the patient treatment experience. We saw limited audit activity and benchmarking within the clinic.
- The majority of the medical professionals were working under practicing privileges at the service. All staff working in this manner were monitored by the corporate Medical Advisor Board (MAB) to make sure they maintained the correct skills and before they started working they were checked as suitable by the MAB. The clinic manager did not have oversight of these meetings and we did not see evidence of these checks at the clinic, as they were held centrally.
- All staff members we spoke with were aware of the governance arrangements and told us that the clinic manager took a proactive role in audit activity. We saw that local audit results, for example documentation were discussed with staff and we saw clear action plans developed by the clinic manager.
- Staff were not clear about what risks had been identified within the clinic and what measures were in place to reduce the risks.
- We reviewed the risk register for the clinic. We were told by the clinic manager that it was currently being reviewed and therefore the document was not current. We saw that the risks were based on a standard list of risk and risk assessments relating to refractive surgery and did not reflect local risk issues or related to local incidents. Senior staff informed us that there was no national risk register. We also spoke with the compliance manager who told us the new register would be available very soon.
- The compliance manager told us that teleconferencing was arranged to discuss the new risk register with the clinic managers nationally.

- We were informed that alert information from Medicines and Healthcare products Regulatory Agency (MHRA) or Health and Safety Executive (HSE) were screened as relevant by the Compliance manager and cascaded to the service. These were further reviewed by the manager and discussed at team meetings. Where actions were needed, the manager included these on a risk assessment and monitored the effectiveness of actions taken. We saw examples where the relevant alerts had been cascaded to staff.
- We were informed by the manager and saw that a business continuity plan was in place, which covered potential risks such as dealing with crisis event management, bomb threats, IT system and hardware failures, clinical equipment failure and utilities failure. We reviewed the major incident policy and although staff we spoke we were not clear of the detail, they could explain where to find the policy and who to contact.

Public and staff engagement

- The service had a website where full information could be obtained about the laser surgery available for patients. This included information about costs and finance. It also outlined the suitability criteria, and explained the laser eye surgery. The website also included information regarding a free consultation and lifetime after care as needed.
- Feedback from patients undertaken as part of their assessment and aftercare was examined and discussed with managers. The information was then utilised to increase the performance of the service and inform future developments.
- We saw that patients were asked if they would be happy to talk to potential patients about their experience with Optimax and explain how they felt throughout the patient journey.
- Information was also available in other social media. The feedback viewed was positive with patients recommending the service and describing positive results.
- The service undertook staff surveys yearly; the results of these were positive. Staff generally felt valued and enjoyed working for the company.

Innovation improvement and sustainability

Refractive eye surgery

- The clinic manager told us about a number of improvements that were being made at the clinic. Text messaging was to be introduced in the very near future to confirm patient appointments and treatment dates.
- Expansion plans for the clinic included cataract and lens exchange treatments. This would see the use of additional floors within the building.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- Ensure registered nurse cover is in place for each surgical treatment day in accordance with The Royal College of Ophthalmologists' guidance document 'Roles within the Refractive Surgery Team'. April 2016.
- The provider must ensure the World Health Organisation (WHO) surgical safety checklist for intra ocular surgery is audited in order that it can assure itself that the risk of error during surgical procedures is minimised as far as possible.
- The provider must review its governance processes to ensure all staff are supported within the clinic.
- The provider must ensure identified risks are properly assessed, consistently monitored and reflected in the service's risk register.
- Provide competency review processes against all clinical practice.
- Develop a robust audit programme, which drives improvement and recognises gaps in the quality of its service.

Action the provider **SHOULD** take to improve

- The provider should ensure audit processes are robust and identify the key areas of improvement with the clinic environment.
- The provider should ensure that patients receive clear information and guidance in relation to raising complaints.
- The provider should ensure information for patients is readily available in a variety of different formats.
- The provider should continue to develop information governance practices to protect patient records.
- Ensure appropriate support processes are in place to fully support all clinic staff.
- Address maintenance concerns promptly to ensure premises are safe and appropriate for patient care and treatment.
- Support and monitor clinical practice with the introduction of clinical competencies.
- The provider should consider formal pain screening processes to establish whether pain relief for patients was adequate.

Requirement notices

Action we have told the provider to take

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

Regulated activity

Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

- Registered nurse cover was not in place in the clinic, on all surgical treatment days.

Care and treatment must be provided in a safe way for service users. Ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely;

Regulated activity

Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

- Systems and structures were not in place to fully support the staff working at the clinic.
- The World Health Organisation (WHO) surgical safety checklist for intra ocular surgery was not being audited.
- Arrangements for identifying, recording and monitoring the on going management of risk were not effective.
- Risk assessments had not always been undertaken for known risks within the service.
- The risk register was not tailored to risks identified within the service.
- Competency reviews were not carried out in relation to the extended role.
- Audits were not robust and did not capture areas of concern within the clinic.

This section is primarily information for the provider

Requirement notices

Systems or processes must be established and operated effectively to ensure the provider to assess, monitor and improve the quality and safety of the services provided

in the carrying on of the regulated activity and assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity.