

# Optimax Laser Eye Clinics - Manchester

## 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

# Summary of findings

## Letter from the Chief Inspector of Hospitals

Optimax Laser Eye Clinics - Manchester is operated by Optimax Clinics Limited. Facilities include four floors with no disabled access. The reception, main waiting room, topography room and two consultation rooms are located on the ground floor; the first floor has a waiting area, managers', office, two storerooms, counselling room and doctor's room. The second floor is a staff only area with kitchen. The basement has public and staff toilets, waiting area, preparation, recovery, laser room and staff changing rooms.

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 are referred for private surgery to another Optimax Clinics Limited branch. If patients had lens surgery in another Optimax Clinics Limited branch the Manchester location provided pre and post-operative care. We inspected refractive eye surgery.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 03 August 2017 along with an unannounced visit to the location on 11 August 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 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:

- All areas of the service were tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff to move around freely.
- There were minimal incidents and complaints. Staff members were aware of how to raise incidents and feedback from patients in relation to their experience was followed up.
- 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.
- A system of risk and quality management was in place that centred on ongoing meetings and communication within the location and the organisation.
- Patients spoken with and feedback to the service were positive about their experience and the outcomes from their surgery.
- A number of audits were in place with action plans that were monitored in order to progress areas of improvement.

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

- The arrangements for dispensing medicines were not sufficient to provide safe management of medicines. As there was no policy or procedure to support staff practice and no competency or training for staff to ensure that they had the correct skills.
- References were not consistently available for employed staff and those working with practicing privileges. Specific qualification information was not available in all personnel files.
- A complaint for a patient allocated to the Manchester branch who received surgery in another Optimax Clinics Limited branch had not been investigated for lessons learnt.
- Policies and procedures were not all up to date or available to consistently deliver a quality and safe service.

# Summary of findings

Following this inspection, we told Optimax Clinics Limited that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued Optimax Clinics Limited with two requirement notices for regulations breached. 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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# Optimax Laser Eye Clinics - Manchester

**Services we looked at**

Refractive eye surgery

# Summary of this inspection

## Background to Optimax Laser Eye Clinics - Manchester

Optimax Laser Eye Clinics - Manchester is operated by Optimax Clinics Limited. The service opened in 1994. It is a private service in Manchester. The service provides refractive (laser) eye surgery for patients over the age of 18. The service receives patients from throughout the North West area of England and is part of Optimax Clinics Limited.

There is no registered manager at present. However, the manager has applied for registration with CQC. At the time of the inspection this application was being processed and the manager had been invited to attend an interview.

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 lead inspector. The inspection was overseen by Lorraine Bolam, Interim Head of Hospital Inspection.

## Information about Optimax Laser Eye Clinics - Manchester

The service is located in the centre of Manchester opposite the Town Hall. There are no parking facilities. It is on a main bus route and within easy walking distance from major rail stations. The service receives patients from throughout the North West 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 Friday and Saturday with other days used for assessments and aftercare. There are no overnight facilities with opening times from 8am until 6pm.

The service does not offer any other services other than refractive (laser) eye surgery. If a patient required further care or surgery using anaesthesia or sedation, as an example, lens replacement surgery, patients are referred for private surgery to another Optimax Clinics Limited branch. The service provides pre and post-operative care for patients referred for surgery at the alternative clinic.

During our inspection, we reviewed five sets of patient electronic records. We spoke with six 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 526 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. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers

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, there were 11 complaints one which had not been investigated at the time of inspection.

### **Services provided at the location under service level agreement:**

- Clinical and or non-clinical waste removal

# Summary of this inspection

- 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:

- All areas observed at the service were clean and tidy. Records recorded that equipment was suitably maintained and monitored in order to provide a safe environment for patients.
- 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. Incident patterns and trends could not be identified at a local level as there were minimal incidents occurring.

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

- The service did not use a surgery checklist or equivalent before, during or after surgery treatments. However, on our unannounced visit, staff had developed a surgery checklist, which had not yet been implemented.
- The dispensing of medicines was not well managed, as staff did not have the competency and guidance to do this safely.
- Clinics could be cancelled without consultation with the manager and were not logged as an incident in order to utilise the learning.

### 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:

- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional.
- Information about the outcomes of patients' care and treatment was collected and audited annually to review quality care and patient outcomes.

Patients receiving care at the service were screened for suitability to ensure correct laser surgery was provided.

# Summary of this inspection

## 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 asked reported that staff members were caring and respectful.
- All patients we spoke to were very happy with the care and treatment they had received.

We observed good staff/patient interaction and communication.

## 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:

- Patient feedback was positive.
- Every patient had individualised records and a plan to make sure their individual needs were met.

## 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:

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

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

- Although a local risk register was in place, it was 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.
- Several policies were either not in existence or had insufficient information to guide staff.

## Summary of this inspection

Staff members were not consistently appropriately recruited and there was limited information regarding staff members' professional qualifications.	
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# Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

## Are refractive eye surgery safe?

### Incidents and safety monitoring

- We reviewed the records of incidents for the preceding 12 months. There had been nine incidents none of which related to clinical issues. Staff spoken with explained how they reported incidents and confirmed that incidents were discussed at team meetings for lessons learnt.
- A duty of candour 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 senior management showed that they were aware of their responsibilities to act on any duty of candour concerns. Staff members spoken with were able to give examples as to when they thought duty of candour was relevant.
- 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. Discussion from the Compliance Manager's review was available in the minutes of managers and senior managers meetings. Actions were recorded as taken both at a local and national level in order to maintain patient safety.
- The service had reported no 'never events' for the preceding 12 months. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers.
- The manager told us that the service had a team of staff external who were responsible for undertaking booking

for patients both before and after surgery. There have been occasions when the team had cancelled a clinic day due to insufficient people attending. We were given one example where this would have been a delay to the patients after care treatment. The organisation did not class cancelled clinics as an incident and the manager was not consulted for their views prior to the clinic being cancelled.

- We asked to see a copy of the incident policy that outlined what an incident was and how staff members were to make sure that incidents were correctly recognised and graded. We were informed that although there were incident reports forms available. However, there was no policy or procedure that supported the usage of incident forms. Without this guidance there may be occasions when incidents go unrecognised or are not correctly managed.

### Mandatory training

- Staff spoken with and records viewed confirmed that mandatory training was undertaken in order to develop and maintain staff skills. The training included areas such as fire training, moving and handling, safeguarding, Duty of Candour, infection prevention and mental capacity.
- The manager provided up to date records that demonstrated that all staff training was monitored in order to make sure that staff had the training to maintain the safety of patients, visitors and themselves.
- Records reviewed reflected that all staff members were trained and up to date with Basic Life Support (BLS). Two members of staff had training to immediate Life Support (ILS) level. This training was in place in order to ensure that if a patient required life support staff would have the skills to intervene appropriately. The service

# Refractive eye surgery

had no incidents that warranted life support since opening in 1994. The service did not provide surgery under sedation and anaesthesia, which would warrant Advance Life Support (ALS) training.

## Safeguarding

- We were provided with a copy of the services safeguarding policy prior to the inspection. In discussion with staff they were aware of what concerns could potentially be a safeguarding and how to raise them.
- Information from the service showed that they did not treat patients under the age of 18 years old. As such, the service had limited contact with young people. Staff members told us that they were provided with basic safeguarding training for both adults and children. They provided child safeguarding training as children rarely attend waiting areas with their relatives.
- The service had not reported any safeguarding concerns since its opening in 1994 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 that staff received training in order to make sure that they received the latest and most up to date training.

## Cleanliness, infection control and hygiene

- Records viewed reflected that the service had not had any reported infections in the last 5 years. We observed all areas to be visibly clean and tidy.
- We saw a copy of the service infection control policy dated August 2017 and the two most recent infection control audits, including hand washing audits. The audits identified what actions the service needed to take in order to reduce any potential risk of infection. An audit had identified that some of the furniture was not sufficiently clean. The manager developed an action plan, which included discussion with the external cleaning company and cleaning checklists. The audit following the implantation of these actions recorded that there had been an improvement and the issue had now resolved.
- 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 observed that personal protective equipment (PPE) to assist in the reduction of 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. These actions were in place to assist in the prevention of the spread of infection via touch. We observed staff practice throughout the inspection and saw that staff washed their hands appropriately and used PPE as needed. Staff practice assisted in reducing any risks of the spread of infection within the service.
- 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.
- The manager confirmed and we saw that the service utilised “single” usage surgical equipment. These were appropriately disposed of following surgery.

## Environment and equipment

- We looked at clinical areas including examination rooms, consultation rooms and the laser room. 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. Any equipment or areas of the environment that needed to be repaired or replaced was actioned rapidly in order to maintain the safety of patients.
- All areas were observed 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.
- 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.

# Refractive eye surgery

- Security measures were in place that meant that staff had to allow access to visitors and could observe them arriving in the building.
- We observed equipment stock in the storage areas was CE marked. For example, protective eyewear, needles and other surgery devices. This ensured that all equipment was approved and compliant with relevant safety standards.
- We looked at emergency equipment including emergency medicines. These were checked by the manager weekly, all were in date, and all equipment was in working order. Staff members spoken with 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 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) who was part of an external company. Staff confirmed they knew who to contact if they had any concerns about the safety of the laser equipment.
- Records recorded that humidity and temperature in the laser room was checked on a daily basis in order that these were correct and maintained the safety of patients.
- Records from the LPS recorded that they gave training and support both on a yearly basis and as when needed.
- 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.
- We looked at patients 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.
- The service had an emergency medicines box containing non-controlled drugs for use in an emergency. There was a list on the outside of the box to alert staff to expiry dates. Restocking of drugs was through the service drugs ordering systems.
- We saw that the staff members were giving out medicines for patients to take home in a manner that did not always maintain the safety of patients. This was because medicines given to patients did not include vital information they needed such as cautionary labels attached to the medicine container and patient information leaflets (PILS) for one medicine. On our return, the manager had made sure that all medicines dispensed had a copy of the PILS. The PILS described any side effects to the medicine of contra-indicators, such as other medical conditions or medicines to inform patients
- Records 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). We spoke with the manager and staff who confirmed that they had not received training that covered dispensing of medicines and had not been assessed for competency to do this safely. Following the inspection, we received information outlining how the manager had reduced the risks and that arrangements were to be made for appropriate training for staff.
- Prior to inspection we were given a copy of the services medicines management policy. Staff confirmed that this policy was available to them on the services computer system. This policy did not cover the dispensing of medicines but did cover the administration of medicines by all staff. Following the inspection the provider sent an updated policy and procedure which included guidance for the dispensing of medicines.
- During our inspection we confirmed that staff members were giving TTO to patients without guidance as there

## Medicines

- 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 spoke with the manager regarding the management of these toxic medicines. The service purchased these medicines at a maximum of three weeks before surgery for single usage only. We were shown how these medicines were disposed of safely in line with the policy and appropriate equipment was used to protect staff.

# Refractive eye surgery

was no information in the medicines policy for the dispensing of medicines and no written protocols or standard operating procedure to guide staff as to how to undertake this action safely.

- We saw that were optometrists or consultants gave medicine such as eyedrops. They recorded the strength of the medicine given but did not record the dose and site of the medicine. Following the inspection the manager confirmed that staff had been instructed to record dose of medicine in the patient records.

## Records

- The service used electronic medical record system known as optic. This contained all the patients' details including assessments, surgery and medicines given. We looked at this system for five 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. Copies of post laser surgery letters were given to patients to provide to other healthcare professionals as they wished.
- The service retained all copies of the patient records and supplied patient information as needed to external professionals.
- Records were audited externally to the service, by a representative of the Optimax Clinics Limited. However these audits had not noted the lack of recording for dose of medicines. Additionally the system used a "stamp" system where by staff indicated that they had given the patient medicines to take at home. This recorded a single entry of medicines given. It did not record that the medicines had been discussed what medicines had been given or what instructions staff had given regarding the medicines. Following the inspection, the manager informed us that the Optimax Clinics Limited was reviewing this system in order to make a sure that a full record of medicines and any advice given was made.

## 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 Ophthalmologist who took the final decision about treatment the patient undertook. The Optometrist could call or email the operating Ophthalmologist directly in the event of a query.

- We saw records and this was confirmed by staff that patients have an appointment with the Ophthalmologist prior their laser surgery, to examine the patient at the first post-operative appointment.
- Staff informed us that they did not use a surgery checklist on surgery days. Staff informed us that they verbally checked the correct patient name, date of birth, allergies and correct procedure with the patient prior to surgery commencing. However, this was not documented in any patient records. A surgical safety checklist is designed to reduce the number of errors and complications resulting from surgical procedures by improving team communication and by verifying and checking essential care interventions. Without this system risks to patients of receiving incorrect surgery had not reduced. Following the inspection the manager informed us that she had developed a temporary checklist and was working with the Optimax Clinics Limited to produce a suitable checklist based on the World Health Organisation (WHO) surgical safety checklist. However, this was not yet embedded into practice or opportunities available to monitor its effectiveness.
- Staff informed us that patients remained in the service until they felt well enough to go home. Once discharged and aftercare information had been discussed with patients, and they were confirmed as visually well, they were supported to leave with appointments for follow up confirmed. As the surgery did not involve general anesthesia or sedation, patients did not require any observations post operatively. However, a staff member explained that they were aware of 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.
- 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.



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- We saw that staff provided patients with an emergency telephone number for out of hours use. The information was written on the aftercare advice leaflets which staff discussed with patients.

## Nursing and medical staffing

- Records and discussion with the manager showed that the service employed an Optometrist part time, a nurse who was also the manager and two technicians. Other staff members were a patient support member of staff, an Ophthalmologist and three Optometrists. The Ophthalmologist and Optometrists were self-employed and worked under practicing privileges. The granting of practising privileges is a process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic.
- During surgery records and discussion with staff reflected that the surgeon was supported by a qualified nurse and a laser technician.
- Monitoring of staffing levels was based upon the numbers of patients requiring refractive surgery and 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. Non-medical staff told us that they worked exclusively in the service in Manchester. The majority of medical staff worked in other services.
- We were informed that there was one current vacancy for a reception member of staff. The manager had been interviewing prior to the last day of inspection for a new member of staff to assist the current staff team.
- Staff and the manager told us all new staff shadowed a senior member of the team until they felt confident. 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.
- 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 the files for practicing privileges for the Ophthalmologist and Optometrists. We were unable to locate references for two of the staff employed and evidence of their qualifications. We requested from the service copies of how medical staff members were

recruited under practicing privileges and checked that they were suitable. We were informed that this was undertaken at the Medical Advisory Board (MAB). We saw a policy on the process to recruit doctors that supported safe recruitment.

- We reviewed recruitment files for other staff. None of the staff working at the time of the inspection had worked in the service for less than three years. The staff files reviewed did not contain two references for all staff as described in the services HR recruitment guide. As such staff had not been consistently recruited in accordance with the services policy. The policy also stated; "two satisfactory references needed to be obtained. There was no definition in the policy as to what constituted a satisfactory reference in order that managers recruiting staff could do this safely.

## Major incident awareness and training

- We saw that all exit fire doors were unobstructed and fire escapes were clear. The manager had recently updated the fire risk assessment and staff members spoken with were aware of the action to take in the event of a fire. Fire drills were recorded as being undertaken twice yearly. Staff spoken with confirmed that they found the drills of use and felt confident that they would be able to evacuate the building safely in the event of a fire. All fire equipment including extinguishers were checked and up to date.

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

### Evidence-based care and treatment

- Records reviewed, and discussions with management, demonstrated that the service utilised both national policies and procedures developed by Optimax as well as local policies. Clinical guidance that was incorporated in policy was reviewed at a company national level as well as at local level to maintain continuity of care and support and develop consistent implementation.
- The policies we reviewed cited and included relevant best practice guidance such as National Institute for Health and Care Excellence (NICE) and The Royal College of Ophthalmologist (2017 RcOph guidance) .
- We saw that patients receiving care at the service were screened and assessed prior to any laser surgery. This



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was undertaken to make sure that the procedure was suitable and could meet their needs. Staff gave us examples where they had refused laser surgery to patients who would have not gained a reasonable result or were contra-indicated for the laser surgery.

- Records and staff confirmed that when patients did not attend appointments or dropped out of laser surgery they were reviewed and contacted to determine if they still required the appointment.
- We saw that the service had a policy that patients start their laser surgery following a clinical assessment, which involved a review by an optometrist prior to being seen by the ophthalmologist. Where a patient was deemed unsuitable for laser surgery an explanation in writing was provided to them. This was undertaken in line with best practice guidelines in order to maintain patient safety.
- 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

- The service provided limited forms of pain management and no formal pain screening process. The only form of pain relief given at pre and post-surgery consultations was anaesthetic eye drops.
- We were informed by staff that patients were advised on pain relief during discharge discussions. However these discussions were not recorded in patients’ notes in order to determine and record that the best advice and support had been given.
- 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. There were no incident records available that showed any patients had experienced severe pain after discharge.
- Patients returning for after care appointments informed us that they had experienced little to no pain.

## Patient outcomes

- 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 was assured that the patient received consistent continuous care, which was delivered at the time it was needed. The provider assessed its own services against each other in order to measure the quality and increase performance as needed.

- As part of a large organisation the service had access to significant data that monitored patient outcomes. As a result each patient was assessed and using the data they were predicated as to the results that they would receive from the surgery. We saw copies of patients’ individual predicted outcomes and how this was used to monitor their individual outcome from the surgery.
- Records we saw recorded that on a quarterly basis the Ophthalmologists’ results were assessed against the predicated outcomes of individual patients in order to make sure that the expected results were achieved. If results outside the predicated range were identified this was discussed at the Ophthalmologists appraisal. Significant deviation would be logged and investigated.
- This data from patient predicted outcomes and the Ophthalmologist results was 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.
- Information sent to us before the inspection recorded that out of the 526 patients treated in the previous 12 months, 42 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. Some of the retreatment/enhancements undertaken at the service were for patients who had laser and lens surgery at another location and/or several years after their primary laser surgery.
- Staff told us that the quality of the service was good and the Ophthalmologist achieved good results. The service audits on patient experience showed that over 97% of patients thought they had a good experience with a good result. The service had a high patient satisfaction

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rate, no serious incidents and no infection rates. The Compliance Manager for the organisation audited these and other results in the service at quarterly intervals. The results of these were discussed at staff meetings in order to monitor the quality of the service provided.

## Competent staff

- Staff told us that they had good access to training regarding their professional development. Training records reflected a variety of training including health and safety, safeguarding and Laser Safety. The service had a 100% rate for staff undertaking their training and showed that staff and the service were invested in providing suitable training for staff.
- The manager was the services' Laser Protection Supervisor (LPS), with overall responsibility for the safety and security of the lasers. The manager was a qualified nurse 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.
- Staff informed us and from duty rotas we observed, there was always at least one member of staff on duty during surgery days that were BLS (basic life support) trained. One staff member was ILS (intermediate life support) trained. 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. In the entire time the service has been in operation there have been no incidents of sepsis.
- All staff spoken with and records reviewed indicated that that 100% of staff had received an appraisal within the last 12 months. Staff told us that they found this of use and that there was ongoing informal supervision that assisted them in identifying areas of skill they wished to develop.
- We spoke with staff dispensing medicines and reviewed the Optimax Medicines policy dated April 2016. Staff spoken with and management confirmed that specific

training and assessment of competency to undertake the dispensing medicines had not been undertaken. The Optimax Medicines Policy did not contain any information regarding the dispensing of medicines. As a result staff members were undertaking an activity for which they had not been determined as competent to do. The manager confirmed that this would be addressed as a priority.

- We requested on three occasions copies of the Ophthalmologist qualifications. We were informed that these were retained at a central location. The copy of Ophthalmologist qualifications from Royal College of Ophthalmology Certificate in Laser Eye Surgery was not made available. Therefore we do not have evidence that the surgeons have relevant qualifications in line with Royal College of Ophthalmologists guidance.

## Multidisciplinary working

- Records showed and staff confirmed that a team meeting was held on a monthly basis, which included staff from across the disciplines. The purpose of the meeting was to enhance shared learning and build team collaborative working.
- As a larger organisation information at a multi-disciplinary level was also discussed and senior management meetings. This again was undertaken to share best practice and enhance learning for all staff.
- All staff we spoke with told us that all the disciplines worked well together and there was a mutual respect for each other's profession.

## Access to information

- We looked at how information needed for staff to deliver safe treatment was made available. We saw that patient files were electronic, and were accessible for each appointment during laser eye surgery, and for staff to monitor patients after their laser surgery.
- Records showed that information was given to patients to provide to any external professionals that they wished to be informed about their surgery.
- Discharge information we reviewed did not consistently include relevant information about medicines. Patients were given verbal information, on when and how to take the prescribed medicine. However this was not recorded in the patients' records in order to make sure that this information was consistent and fully understood by the patient.

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- We saw that electronic records enabled those patients who came to Manchester for assessment and after care to have these records accessed from another Optimax Clinics Limited branch when they undertook surgery at that service. It also assisted the Manchester office to review the records for an individual following surgery and assisted the service to provide continuity of care.

## Consent and Mental Capacity Act

- 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 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.
- 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.
- We saw that consent was ongoing throughout the patients' journey. As an example consent for eyedrops was discussed by the Optometrist prior to being given and consent for surgery was undertaken by the Ophthalmologist prior to surgery.
- Staff explained that one of their biggest hurdles regarding consent was managing the expectations of patients. We saw documentation that showed where patients were informed of their likely results and any complications in order that they had sufficient information to make a decision.
- Records reviewed showed that all patients were given time and information to reflect on the decision this was a minimum of 7 days. This was also confirmed by patients spoken with. This was undertaken in order to make sure that patients were able to determine if they had sufficient information to make an informed choice and allow them an opportunity to discuss their decision fully.

## Are refractive eye surgery caring?

### Compassionate care

- We observed staff interaction with patients these were positive. Some patients returned frequently to the service for aftercare appointments and the familiarity of staff with individual patients was observed as warm and welcoming. Patients spoken with told us that, "Staff are very lovely and welcoming", "I was given every chance to discuss my concerns", and "staff are very friendly and professional"
- We saw positive interaction from staff, consistently throughout the inspection. Staff members were kind towards patients, joking and smiling with them and putting their minds at ease.
- Patients spoken with told us that they were treated with dignity and respect by all staff members. All patients we spoke with said they found the staff polite, friendly and approachable.
- We observed that staff respected patient confidentiality and ensured discussion took place in laser rooms. At reception patients were not asked to provide confidential information.
- Staff told us and we observed that patients' relatives were supported to attend appointments as needed.
- The service undertook questionnaires from patients. The results of these were reviewed and shared with the manager. We were shown a copy of the latest results. Overall patients were very positive about their experience, where issues were identified the patient was contacted by the manager to provide additional support.

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

- 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 supported" and "fully informed" about their laser surgery.

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- 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.

## Emotional support

- We spoke with patients who told us they felt supported and staff members were warm and welcoming. Records showed and was confirmed by patients that they were given verbal information and support regarding their laser surgery.
- Throughout our visit we observed staff giving reassurance to patients with additional support given when it was required, especially if patients were apprehensive.
- We saw that patient's dignity was respected and maintained at all times.

## Are refractive eye surgery responsive to people's needs? (for example, to feedback?)

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

- The service covered laser surgery for the immediate local population and across the North West of England region. Staff 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 service such as lens replacement, support to access the another Optimax Clinics Limited branch was in place. Patients were offered the opportunity to choose where they would prefer to receive any pre and post-surgery support.
- All patients we spoke with told us, they felt comfortable in the waiting areas at the service, where drinks facilities, magazines and information leaflets were available.
- We spoke with patients and staff who confirmed that all appointments were planned in advance. As such, the service was able to plan laser surgeries and appointments with this information. All of the appointments for the Optimax Clinics Limited 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.

- Information sent to us prior to inspection and available on the services website showed that the service opened Monday to Saturday from 8 am to 6 pm 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 spoke with staff and patients who informed us that there was assistance for people who required additional support to communicate such as a loop system to assist in hearing and translation service for patients who would benefit from these services. We saw that loop system equipment was available.
- We observed that information was available to patients about who to contact if they had any concerns about their care. Additionally there was a wide variety of information leaflets available in waiting areas. 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 readily available 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.
- 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 patients support from relatives, phone based translation services and a translator attending the service in order to support individual needs.

### Access and flow

- Patients were able to self-refer without a GP or optician's referral.
- Management and staff spoken with confirmed that the service did not monitor waiting times, both prior to an appointment being arranged or when the patient arrived for their appointment. Patients told us that they did not wait long before they got an appointment.
- Records reviewed and discussion with the manager showed that there were no incidences of unplanned

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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.

- We were told by staff that it was the services policy to try to make sure that patients received an appointment of their choice. The staff and the manager told us that sometimes patients' appointments were cancelled by the diary team without consultation with the manager. This could on occasions be disruptive in particular for patients who needed an appointment on a specific date. The manager explained that this had been discussed with senior management and if necessary she was able to make sure that the appointments went ahead.
- Staff and patients confirmed that where patients missed any appointments the service contacted them within 48 hrs to follow up and rearrange an appointment as needed.
- The manager and Compliance Manager confirmed that there were no arrangements in place to monitor the amount or frequency of aftercare that was needed. As such the service had no means to determine what the amount or duration of aftercare was needed or how this impacted on the available appointments. The manager told us that on average, patients needed 4 months aftercare but this was based on her experience and was not supported by any monitoring.
- Staff told us they would like more control and have more say over their input into the appointments diary. The appointments were managed by a national team; staff thought that the team did not liaise with them fully prior to clinic cancellations. However, they did think that the diary team supported new appointments for people well, and patients often had suitable information discussed with them prior to attending an appointment. Following the inspection we were informed that no clinic would be cancelled without 10 days' notice in order that staff could make sure patients have appropriately rescheduled appointments.
- 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.
- 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 waiting area was spacious with separate offices that supported staff to have private discussion if needed. The service also had private consultation and assessments rooms, which enabled staff and patients to have private discussions.
- Staff informed us that patients with communication restrictions such as hearing, language or literacy issues were advised to bring someone with them for every appointment. The service loop system did not extend to the laser room where the laser surgery took place. The manager stated that this had not caused any issues but would review the possibility of expanding the system.
- The service had a range of patient information leaflets available, explaining the various conditions and laser surgeries it offered, including pre and post care instructions. However, all patient leaflets and documents, including consent forms, were in English.
- 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 21 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. The staff confirmed that younger patients were advised that further laser surgery may need to be repeated at some stage in the future due to changes in eyesight commonly experienced with age. The suitability and laser surgery criteria protocol was the same for patients of all ages.
- We saw information that was given to patients advising them of post-operative care and details of the 24 hour contact details of the treating surgeon should they have concerns following discharge.
- We saw that the building for the service did not meet the Equality Act as there was no wheelchair access. This information was made clearly available to patients on the services website and when they contacted the service for an appointment. Where patients needed wheelchair access they were directed to one of the other services in the country where this could be accommodated.

## Meeting people's individual needs



# Refractive eye surgery

- The service was unable to correct this restriction as the building that the service operated from was a listed building and could not be adapted for wheelchair access.

## Learning from complaints and concerns

- The service had a complaints policy. The policy gave the same level of importance to verbal complaints as it did for written and determined that all complaints needed to be responded to within with-in 20 working days.
- 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.
- Any concerns raised in patient surveys were logged and addressed as a complaint. On receiving the information the manager contacted the individual to determine the nature and scope of the complaint. A copy of any complaints and the actions the manager had taken to investigate and resolve the complaint was available in the service and the outcomes discussed at team meetings in order to improve the service.
- We were informed that complaints were discussed and addressed at senior management meetings and if necessary the information was also referred to the Medical Advisory Board (MAB)
- The services complaints policy dated July 2017 incorrectly stated that complaints could be directed to CQC. Whilst CQC will take information they do not investigate individual complaints as such the policy was not correct as to the role of CQC.
- The service received few complaints. Information submitted to us prior to the inspection recorded 11 complaints in the last 12 months. This conflicted with the records viewed which showed a total of six complaints. One complaint had been submitted to the service in June 2017, this had not been fully investigated within 20 working days or any findings taken forward for potential learning.
- Although the complaint was regarding lens surgery at another Optimax Clinics Limited branch it is the policy of Optimax Clinic Limited that the complaint is addressed by the service undertaking the original referral. Further information as to the progress of this complaint was requested on three occasions this was not made available. The remaining complaints were not made regarding clinical outcomes or concerns and had

all been addressed in accordance with the services policy. Following the inspection we were informed that Optimax Clinic limited would review its current arrangements for managing complaints.

## Are refractive eye surgery well-led?

### Leadership and culture of service

- We were informed that an individual owned Optimax Clinics limited having established the company in 1991. The same individual has been in control of the company since its advent and was well respected by staff spoken with.
- Staff members spoken with were aware of the corporate management structure and were clear about who they reported to within the structure. Staff told us that management were honest, proactive and they felt confident to approach their direct manager with any concerns.
- Records and staff reflected that a compliance manager attended the service every six months in order to review the quality of the service and make sure that staff working in the service were appropriately supported.
- There was a full time manager based at the service; they did not work elsewhere. At the time of the inspection they were applying for registration with CQC.
- Staff told us they felt supported and were able to raise any concerns with their manager and senior managers. The staff members told us there was a good sense of teamwork and this was the reason that the majority had worked there for several years.
- We observed information available was honest, responsible and complied with guidance from the Committee of Advertising. Patients received a statement that included, terms and conditions of the service being provided, the cost, and method of payment for the laser eye surgery.

### Vision and strategy

- Staff members spoken with informed us of the vision and strategy of Optimax Clinics Limited as this was discussed at team meetings and in training. Staff told us that plans for the future included opening new locations, continue to pioneer advancements in technology by sharing outcomes, maintain and increase the organisations profile by increasing influence in consultation processes and continued investment.

# Refractive eye surgery

## Governance, risk management and quality measurement

- The majority of the medical professionals were working under practicing privileges at the service. All staff working in this manner were monitored by the 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
- All staff members we spoke with were aware of the governance arrangements that monitored and improved the quality of the service. Staff described how management audited the quality of the service including quarterly checks from the compliance manager and daily audits from the service manager. Staff were clear and meetings records we reviewed reflected that where improvements needed to be made this was discussed. This included local meetings, managers' nationwide meetings, senior manager meetings and Medical Assessment Board (MAB) meetings.
- Staff informed us that they felt as a single speciality service, the risk to patients was low. We discussed a number of policies and procedures that although up to date had gaps that needed to be addressed. Examples of this included a medicines policy which did not cover dispensing of medicines and the lack of an incident policy that outlined and determined what an incident was and how to address it.
- We saw that the service had risk assessments that were updated and reviewed monthly these covered areas such as moving and handling and fire risks. Each risk assessment contained action plans as to how to reduce the risks. Changes to these risk assessments were discussed at meetings throughout Optimax Clinics limited.
- Staff spoken with confirmed that they were aware of what risks had been identified and what measures were in place to reduce the risks. They also confirmed that they knew how to raise any areas that they thought needed to be identified as a potential risk.
- 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.

- The service had a risk register in place for the service. Risk registers are a management tool used to fulfil any regulatory responsibility and acting as a repository for all risks identified, Risk registers include information about each risk such as; the nature of the risk, who has responsibility to monitor the risk and any measures in place to reduce the risks. We were informed that these were identical for every service and contained a list of all risk assessments.
- We reviewed the risk register and saw that it was not tailored to the specific risks of the service, nor monitored to make sure that risks were addressed. We were informed that alterations to the management of risk registers would be made in the future in order to make sure that they were specific to the risks and were appropriately monitored.
- 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.

## 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 life time 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.
- 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. The main concern from staff was

# Refractive eye surgery

their salary and bonuses which they felt could be better. Staff spoken with said as a small team they had an ongoing communication and felt that they were well engaged with the manager.

## **Innovation improvement and sustainability**

- Although we found no evidence of innovation at this location, staff informed us of the corporate plans to improve the services they offered.



# Outstanding practice and areas for improvement

## Areas for improvement

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

- The provider must put into place safe arrangements to manage the dispensing of medicines.
- The provider must make sure that staff are competent to undertake the safe dispensing of medicines and are supported to do safely.
- The provider must review its arrangements to recognise gaps in the quality of its service and address areas of improvement.
- The provider must review its policies and procedures in order to support the staff to consistently deliver a quality and safe service.

- The provider must ensure that it has systems and process in place that recognise risk and act on that risk promptly.

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

- The provider should make sure that staff members are correctly recruited at all times.
- The provider should retain evidence of professional qualifications.
- The provider should address any outstanding complaint in line with its own policy.
- The provider should continue to implement and monitor the use of the surgical safety checklist.

This section is primarily information for the provider

## Requirement notices

### Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment  The provider must ensure that care and treatment is provided in a safe way for service users.  The provider must ensure that medicines are managed in a safe way.  Regulation 12 (1)
Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance  The provider must ensure that systems or processes are established and operated to assess, monitor and improve the quality and safety of the services.  The provider must ensure that they evaluate and improve their practice with regards to policies and procedures, guidance to staff in order to manage and reduce risks.

This section is primarily information for the provider

## Enforcement actions

### Action we have told the provider to take

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