Optimax Clinics Limited

Optimax Laser Eye Clinics - Southampton

Inspection report

16-17 Kings Park Road
Southampton
SO15 2AT
Tel: 02380634828
www.optimax.co.uk

Date of inspection visit: 29 April 2021
Date of publication: 06/07/2021

This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

Safety was not managed well. Equipment was not always maintained. The service did not always control infection risk well and staff did not always follow the provider's infection prevention and control policies or national guidance. Staff mostly assessed risks to patients, acted on them and kept diligent care records. The service managed safety incidents well but learned lessons from them were not widely shared with staff. Staff collected safety information but did not always use it to improve the service.

The clinic manager's responsibilities had changed since the redundancy of the clinic's qualified nurse. The clinic manager reported to us that they were unable to perform some of their responsibilities due to operational pressures. There were limited opportunities for staff to develop their skills. Not all staff felt respected, supported and valued. Not all staff were clear about their roles and accountabilities. Not all staff had received a formal appraisal.

Flammable materials and substances that could cause harm were not stored securely.

Leaders and teams did not always use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and recognise actions to reduce their impact.

Actions from audits which showed non-compliance were not always actioned.

The clinic manager did not monitor the effectiveness of the service. Patient outcomes to improve care and treatment were not monitored by the clinic manager.

We saw incorrect use of personal protective equipment (PPE).

Staff did not always follow policies; some policies did not reflect national guidelines.

Rooms throughout the clinic had not been risk assessed to establish the maximum number of people that could occupy the room whilst maintain social distancing in line with government guidelines.

Staff did not challenge a contractor handling soiled linen incorrectly.

However:

On the day of the inspection the service had enough staff to care for patients and keep them safe. Staff had training in key skills and understood how to protect patients from abuse.

Staff treated patients with compassion and kindness, respected their privacy and dignity, and helped them understand their conditions. They provided emotional support to patients at all stages throughout their treatment. Staff were focused on the needs of patients receiving care.

Staff provided safe care and treatment, offered them refreshments, and gave them pain relief when they needed it. Patient feedback was used to monitor the effectiveness of the service. Staff worked well together for the benefit of patients, supported them to make decisions about their care. Services were available six days a week between 08:30am and 5:30pm Monday to Friday and between 09:00am and 5:30pm on Saturdays.

Summary of findings

People could access the service when they needed it and did not have to wait too long for treatment.

The service used systems and processes to safely prescribe, administer, record and store medicines.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery	Requires Improvement 	See summary above.

Summary of findings

Contents

Summary of this inspection

Background to Optimax Laser Eye Clinics - Southampton

Optimax Laser Eye Clinics Southampton is operated by Optimax Clinics Ltd. It provides services for patients who self-refer and pay for their own treatment.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice unannounced inspection on 29 April 2021.

Optimax Laser Eye Clinics - Southampton is an independent eye clinic, registered with the CQC to provide the following regulated activities:

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury care

The clinic is set over two floors, with disabled access to the clinic and toilet facilities. Patient facilities are all on the ground floor, which include one treatment room, a recovery area, one topography room, two consultation rooms, a counselling room and toilets.

The clinic provides laser eye surgery, refractive lens exchange, implantable contact lenses and intraocular surgery for cataracts, under local anaesthetic. The clinic does not offer treatments to patients under 18 or people with certain medical conditions.

The clinic manager is also the registered manager who has been in post since 2008.

This service was last inspected in August 2017, we did not have a legal duty to rate refractive eye surgery services at that time. Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached. During this inspection we found not all these improvements had been made.

How we carried out this inspection

We spoke to six members of staff and five patients and reviewed three patient records. After the inspection we undertook a meeting with the nominated individual and the Director of Operations to follow up on some concerns found during inspection.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take to improve:

Summary of this inspection

We told the service that it must take action to bring services into line with legal requirements. This action related to refractive eye services.

The service must ensure substances subject to The Control of Substances Hazardous to Health Regulations are stored securely. Regulation 12 (1) (a)

The provider must ensure they follow policies and national guidance in assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated Regulation 12 (1) (h)

The provider must ensure there is oversight, manage ongoing incidents, manage performance and risk, and assess and respond to patients' care. The provider must ensure governance systems are able to benchmark patient outcomes against other services. Regulation 17 (2) (b)

Action the service SHOULD take to improve:

We told the service that it should take action because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall.

The provider should ensure that action taken to ensure fire escapes and firefighting equipment are not blocked and easily accessible in the event of a fire is maintained.

The service should ensure electrical equipment undergoes electrical safety testing in line with the provider's policy.

The provider should ensure the premises and the environment are suitable for their purpose and review storage arrangements within the clinic.

The provider should review the patient information available to ensure it meets the needs of patients who are visually impaired.

The provider should ensure actions from audits are completed and consider how to reinstate clinic meetings.

The provider should consider how to ensure clinic staff have oversight of patient outcomes.

The provider should consider if training provided meets the needs of staff.

The provider should consider collecting and submitting data to The National Ophthalmic Database Audit and the Private Healthcare Information Network.

The provider should review their website to ensure it clearly signposts patients on how to make a complaint.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Refractive eye surgery	Requires Improvement	Good	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Good	Good	Good	Requires Improvement	Requires Improvement

Requires Improvement

Refractive eye surgery

Safe	Requires Improvement
Effective	Good
Caring	Good
Responsive	Good
Well-led	Requires Improvement

Are Refractive eye surgery safe?

Requires Improvement

Mandatory Training

Staff received and kept up to date with their mandatory training. Staff told us that most training was completed electronically. Staff told us that they did not always have training on new policies they were expected to read the relevant policy and confirm in writing that they had read the policy and understood it. For example, the cleaning policy that was implemented after the clinic had been closed due to the COVID-19 pandemic. Managers monitored mandatory training and alerted staff when they needed to update their training.

All staff working within the clinic had received basic life support training, to enable them to respond to an emergency. This was updated annually. Nurses who worked at the clinic on the days surgical procedures were undertaken received intermediate life support training. We reviewed the records of two staff members which showed all training was up to date. Oversight of mandatory training for staff not directly employed by Optimax Clinics Limited was undertaken at corporate level.

Safeguarding

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse and they knew how to apply it. The training records we examined showed that clinic staff were appropriately trained to level 2. The clinic manager was the location lead for safeguarding and had undertaken level three adult and children safeguarding training and level two safeguarding children training. We saw training records which confirmed training was up to date.

None of the staff we spoke with could recall the need to raise a safeguarding concern. Staff knew procedures to follow and staff knew who their safeguarding lead was should they have any concerns. We saw there was contact information for the Local Authority information available should they need to contact them.

In addition to the local safeguarding lead (clinic manager) there was a corporate safeguarding lead available to provide advice and oversight.

Infection Control

The service-controlled infection risks. However, staff did not always follow Optimax infection prevention and control policies, there was no evidence that this resulted in an increase of infections. Staff mostly used equipment and control measures to protect patients, themselves and others from infection. Staff kept equipment and the premises visibly clean.

Patients and staff did not undergo COVID-19 testing, despite twice weekly lateral flow testing for staff being available. Optimax Clinics Limited had a coronavirus policy which was last updated in January 2021.We found staff were not always following the policy. The policy stated that all patients should have a courtesy call before attending the clinic to ask if they currently had any COVID-19 symptoms or have been in contact with a person who had symptoms or tested positive for COVID-19. Staff told us that they did not always have time to undertake these calls. We spoke to a patient who told us that they had not had a courtesy call prior to attending but did receive written information regarding not attending the clinic if they had symptoms of COVID-19.The clinic manager was only aware of one patient who had subsequently tested positive for COVID-19 after attending the clinic and there had been no staff outbreaks .

We saw there was a buzzer entry to the clinic to restrict access, there were posters reminding patients not to enter the clinic if they had symptoms of COVID-19.

We observed when a patient or visitor enters the clinic, staff completed and recorded forehead temperature readings as part of the routine assessment prior to seeing the patient. At this point patients and visitor were also asked if they had any symptoms of COVID-19 prior to entering the clinic.

Patients were not allowed to bring in visitors unless there was an essential need for example a patient required an interpreter. Any visitors had their contact details recorded so they could be contacted if needed. Optimax Clinics Limited provided information on safe COVID-19 practices on their website.

We found that rooms throughout the clinic had not been risk assessed to establish the maximum number of people that could occupy the room whilst maintain social distancing in line with government guidelines.

We observed staff wore personal protective equipment (PPE) in line with Optimax Clinics Limited coronavirus policy. However, the policy was not in line with Public Health England guidance as staff were wearing gloves and aprons when not providing clinical care. We observed one member of staff was not bare below the elbows and wearing two masks which was not in line with Optimax Clinics Limited policy or national guidance.

We observed a contractor collected dirty linen from the clinic without putting them in a bag, this was an infection control risk and was not challenged by clinic staff.

We saw fabric chairs which could not be cleaned effectively and storage on the floor which meant items could become contaminated.

An external company undertook cleaning of the whole clinic three times a week and we reviewed records which confirmed this. On days when procedures were undertaken the clinic administration staff cleaned the procedure room prior to procedures starting and we saw records which confirmed this. All areas we visited were visibly clean.

We saw there were no handwashing sinks in any of the consultation rooms. Staff and patients could only clean their hands in the toilets and within theatres. The provider told us that the risk was mitigated as staff could wash their hands on arrival at the clinic and before seeing patients, using PPE and alcohol hand gel.

We observed staff undertook cleaning in between patients to minimise the risk of infection. Some staff did not feel that appointments times were staggered enough to allow for extra cleaning between patients. Not all staff felt the training on cleaning was sufficient and there was an over reliance on reading a policy rather than have bespoke training. We reviewed the Optimax Clinics Limited policy which did not reference any national guidance.

We reviewed an infection prevention and control audit undertaken in January 2021.The audit showed full compliance. Staff explained that infection prevention and control guidance was monitored by the compliance team and any changes communicated to clinic managers. We reviewed the minutes of conference calls which showed changes to guidance were communicated during these and confirmed by a follow up email.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. The clinic posed a fire safety risk and dangerous substances were not stored securely.

We observed in the upstairs area of the clinic fire exits and fire extinguishers were blocked by chairs and empty cardboard boxes. This meant staff would not be able to exit the building easily in the event of a fire or have access to firefighting equipment. Since the inspection we have been supplied with photographs which show the fire exits were clear and fire safety equipment was accessible.

We saw some electrical diagnostic equipment had not been checked for electrical safety since July 2019. This was not in line with Optimax Clinics Limited maintenance policy which stated electrical equipment should undergo electrical safety checks annually. We saw correspondence which confirmed the issue had been raised by the clinic manager. We were told, due to financial issues, the contractor only undertook electrical safety testing at one clinic at a time and once payment was received the engineer could visit another clinic. Since our inspection we have received confirmation that all equipment has undergone electrical safety checks.

We saw the recovery area where patients sat immediately after their procedure for a period of observation was also used as a storage area, which did not provide a relaxing environment for the patient.

We saw the cupboard containing substances subject to the Control of Substances Hazardous to Health Regulations was not locked. This meant patients and visitors could potentially access dangerous substances.

We saw that all areas had warning signs as required; for example, the procedure room had laser safety signage and an external illuminated light when the laser was in use to alert staff and patients. Access to the lasers and laser room was restricted to authorised staff.

There was one procedure room where refractive lens exchange, cataract surgery and laser refractive eye surgery was performed. The room was spacious, fit for purpose and clutter free. In line with guidance the air-handling unit in the operating room delivered 20 air changes per minute.

Both humidity and room temperature were recorded within the operating room daily. We saw that there were no missed checks and the recording of both humidity and temperature were monitored on a weekly basis by the clinic manager.

The laser protection advisor was external to the clinic, they carried out a risk assessment of the laser-controlled environment every three years or when equipment was changed. Staff were trained every two years in laser safety and we saw that all staff were up to date with their training.

Support and advice were available from the laser protection supervisor (the clinic manager) or the laser protection advisor. All staff we spoke with were able to tell us who they would contact if they had any concerns regarding the laser equipment. Staff told us that if the laser failed then they could move the patients to another clinic.

Local rules were in place for both types of lasers used at the clinic. Local rules summarised the key working instructions intended to restrict exposure in radiation areas. We saw on inspection, most staff had read and signed the rules and further evidence supplied after inspection confirmed completion by all staff.

Staff we spoke with were aware of the maximum weight of trolleys and whether the equipment was suitable for bariatric patients. This was an improvement since our last inspection when staff were not aware.

Staff segregated and disposed of clinical waste safely. The clinic had a service level agreement with an external waste management company who collected clinical waste weekly.

Staff carried out daily safety checks of specialist equipment. Lasers were checked daily and calibrated; both checks, and calibration were recorded within separate logbooks. We saw that checks were completed consistently, and they were monitored by the clinic manager. We saw that the emergency equipment included a portable automated external defibrillator. The emergency equipment was checked monthly and recorded on log sheets. The automated external defibrillator was checked daily and we saw records which confirmed this.

Assessing and responding to patient risk

Staff completed risk assessments for each patient and removed or minimised risks. The clinic had an inclusion and exclusion criteria to ensure only patients whose needs could be met attended the clinic.

Patients were assessed for their suitability for a procedure at the clinic by an optometrist and a doctor; a minimum of seven days before the surgical procedure took place. This was in line with National Institute for Health and Care Excellence guidance.

All patients completed a health questionnaire and underwent specialised diagnostic eye examinations and any issues identified by the optometrist were esculated. Optometrists could contact the operating ophthalmologist with any concerns and the final decision for treatment was made by the ophthalmologist. Patients were reassessed by the ophthalmologist on the day, prior to surgery. Consultations were a mixture of virtual and face to face to minimise the time a patient spent in the clinic.

The clinic had an acceptance criteria which excluded patients who were not safe for treatment at the clinic. This included certain eye conditions, contraindicated medicines, and high-risk clinical conditions.

The patient's blood pressure was measured as part of the diagnostic tests undertaken. Patients with high blood pressure were referred to their GP for further treatment before surgery was agreed.

On the day of surgery, staff undertook pre-operative assessments such as a general health check, blood pressure and heart rate and a prescription check to ensure patients were still suited to the surgery selected.

The surgical patient pathway included the completion of a surgical safety checklist that had been adapted from the World Health Organisation (WHO) surgical safety checklist. We observed staff used the checklist and we saw completed WHO surgical safety checklists in patient records.

The service undertook WHO surgical safety checklists to monitor compliance, we reviewed these audits which showed 100% compliance consistently.

As part of the surgical safety checklist a safety huddle took place prior to surgery and a debrief took place following surgery. The checklist included a requirement to ensure the planned refractive outcome was checked, as well as the lens model and power to be used and that the correct lens implant was present, and a spare lens was available if needed.

We saw additional safety checks and measures were undertaken if a patient was having a bilateral procedure performed. For example, separate instruments were used for each eye and different batch numbers of instruments where possible.

After their procedure, patients were given detailed written instructions on aftercare and the time and date of their next appointment and we observed this during our inspection.

Patients were given the contact number of the ophthalmologist who they could contact for the first 24 hours after their procedure, after this time they could call the clinic directly or the Customer Services Team. We observed staff showing patients the contact information within their discharge information.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

The clinic manager told us since the permanent nurse role at the clinic had been made redundant, they felt added pressure as they did not have clinical knowledge and had to undertake responsibilities the nurse used to carry out. However, on refractive eye surgery days, a staff member who had undergone additional training assisted at the clinic they came from another clinic. On days when refractive lens exchange and cataracts were undertaken days two nurses and another member of staff usually based at other clinics would attend. This complied with Royal College of Ophthalmology guidance on staffing in ophthalmic theatres.

Surgeons undertaking laser refractive surgery held the Royal College of Ophthalmology certificate in laser refractive surgery. Surgeons undertaking refractive lens exchange and cataract surgery were on the general medical council (GMC) specialist register.

The central human resources team held and maintained an electronic register of checks on medical staff to ensure that they met the requirements of revalidation and maintained the appropriate membership to the professional body.

The service employed three ophthalmologists and one optometrist under practising privileges. It also directly employed one full time and one part time patient advisor/treatment assistant, one part time patient advisor/laser assistant and a full-time clinic manager. However, all staff remained on flexi furlough working and only attended the clinic on treatment days and consultation days. The clinic manager also undertook one administration day.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care. The service used their own electronic patient administration system. The system

contained all information; for example, patient details, assessments, medical notes and prescriptions. The system was used throughout all the providers clinics. This was important because patients may choose to have their follow up at a different clinic and their notes could be assessed immediately. Similarly, if a patient contacted the Customer Services Team staff they were able to access the patient's records.

Traceability documentation from theatre such as the type of lens was uploaded; immediately after surgery, onto the electronic system. Patients were given a card with details of the lens they had, should it be needed for traceability purposes.

Of the three patient records we reviewed, we saw that each had been completed accurately and

contemporaneously including; consent, medical notes, pain relief advice and health questionnaires. The service regularly audited their medical records, an audit from April 2021 showed full compliance.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines. All prescribing was completed using the electronic patient administration system. Records we reviewed showed staff checked and documented each patient's allergies and these were reconfirmed before any procedure. Only staff with the required competencies administered

and dispensed medicines.

Staff followed systems and processes when prescribing, administering, recording and storing medicines. A member of staff demonstrated the process to us, the ophthalmologist prescribed the medicines on the system, the nurse prepared the medicines and checked them, and the ophthalmologist undertook a second check of the medicines. Medicines for the patients to take home followed the same process with the ophthalmologist giving the patients the medicines on discharge. We observed that patients were given manufacturer's patient information leaflet with each medicine they were given to take home. We saw staff took time to explain how to instil eye drops and the importance of hand hygiene before instilling the eye drops.

An overall medicine stock check was carried out once a month by the clinic manager, previously this was undertaken by the nurse employed at the clinic. Medicines were ordered based on the remaining stock levels and the number of surgical and follow-up appointments booked. This was monitored centrally by the national team. Advice and support were available from an external pharmacist via a service level agreement.

Medicines were stored safely and securely; within locked cupboards or fridges, in restricted access areas, in line with national and manufacturer guidance. We reviewed records which showed that fridge temperatures were monitored and recorded daily. Certain medications must be kept at; or between, required temperatures for them to remain effective and safe for use. All medicines we checked were in date with batch numbers recorded. If patients were undergoing a bilateral procedure different batch numbers of medicines were used.

The clinic did not use any cytotoxic medicines or controlled drugs. Emergency medicines were available and regularly checked.

Incidents

Requires Improvement

Refractive eye surgery

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents but did not always share lessons learned with the whole team. This was because the staff were still flexi furloughed and only worked on procedure days or consultation days and staff meetings were not being undertaken.

When things went wrong, staff apologised and gave patients honest information and suitable support. We saw an example of this when we reviewed incidents during the inspection. Managers ensured that actions from patient safety alerts were implemented and monitored. For example, we saw an alert regarding defective surgical face masks had been actioned by the clinic manager.

Every six months the clinic manager undertook a review of all incidents. We saw confirmation of this within the incident report folder. This was also shared with the compliance lead which enabled them to have oversight.

Staff raised concerns and reported incidents and near misses in line with the provider's policy. Nurses told us that when they reported an incident they were informed of the outcome and any learning. Due to a lack of clinic meetings wider learning from incidents from other clinics was not shared.

The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The clinic manager had received training on the duty of candour regulation, and we saw confirmation of this within their training log.

Are Refractive eye surgery effective?

Good

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The service had a range of policies to support the delivery of care and treatment. We reviewed a sample of these. All those we reviewed were mostly version controlled, reviewed by the provider in a reasonable timeframe and contained references to national guidance, best practice documents such as National Institute of Health and Care Excellence (NICE) Clinical guidelines and Royal College of Ophthalmologists (RCoO). The only exception to this was the provider's coronavirus policy which did not always reference national guidance.

The Medical Advisory Board (MAB) meeting minutes we reviewed contained information regarding how compliance to national standards and guidance was monitored throughout the organisation.

The service undertook a variety of audits, which were all undertaken at different intervals throughout the year. Audits included medicines, infection control, consent and environmental. Most audits had been completed, however the clinic manager told us that some were behind due to staff remaining on flexi furlough and the redundancy of the clinic nurse.

Nutrition and hydration

Staff gave patients appropriate food and drink to meet their needs. Patients did not spend a long time in clinic but there was a selection of drinks and light refreshments available. Patients all had local anaesthetic for their surgery therefore were not required to fast before surgery.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.

Patients undergoing ophthalmic surgery were treated under local anaesthesia. Anaesthetic eye drops were instilled prior to treatment to ensure patients did not experience pain or discomfort. This enabled patients to remain fully conscious and responsive. Although there was no formal pain tool used, we observed patients being asked if they were comfortable during treatment. We observed staff clearly informed patients about the expected level of pain after discharge and to contact the clinic if the pain became severe.

Patient outcomes

The clinic did not directly monitor the effectiveness of care and treatment. Each ophthalmologist maintained a log of procedures undertaken to monitor patient outcomes, this information was monitored at corporate level. We were not assured that the clinic manager was aware of how to review individual ophthalmologists' audits. Findings from these audits were not shared with clinic staff as monthly clinic meetings were not undertaken. Complications from surgery were identified by staff during aftercare appointments and the clinic manager was informed.

We saw findings from patient outcome data was discussed at MAB to make improvements and achieve good outcomes for patients. For example, changes were made to the World Health Organisation safety checklist following an audit. However, staff were not able to tell us outcomes or actions from the national collection of patient outcome audits.

Treatment outcomes were measured in terms of the individual ophthalmologist success rate and the patient satisfaction with their treatment journey. The treatment outcomes for all ophthalmologists working for Optimax Eye Clinic Limited were monitored. This data was used to conduct a yearly audit of the individual surgeon's outcomes, which was discussed with the ophthalmologist at their appraisal. We reviewed an example of an appraisal which confirmed this.

We reviewed three ophthalmologist's yearly audits for 2019.The provider told us that 2020 Audits have been completed but they have been delayed due to the COVID-19 pandemic.

Outcomes for patients were positive, consistent and met expectations, such as national standards. Out of 346 treatments recorded in the last year at the clinic there had been no reported complications. Out of the 346 treatments within the last 12 months the provider told us that there were no patients requiring visual enhancements. The Royal College of Ophthalmologists (RCoO) recommendation is under 15%. Visual enhancement is undertaken when the vision is not acceptable to the patient after surgery. Low enhancement rates indicated consistently good and predictable outcomes.

On completion of all the diagnostic tests, the results were inputted into a bespoke computer system. The computer system predicts the overall patient visual outcome based on patients of a similar age, same treatment and same eyesight prescription. We saw that patients were given a copy of this prediction. In addition, the computer system recommended which type of laser treatment would be optimal. This meant although there was no guarantee the patients vision after the procedure would match the forecast, patients were informed of expected outcomes.

Requires Improvement

Refractive eye surgery

The service did not contribute to the National Ophthalmic Database Audit (NODA) or the Private Healthcare Information Network (PHIN). This meant they could not compare patient outcomes against similar services.

Competent staff

The service mostly made sure staff were competent for their roles. The clinic manager had not had an appraisal in the last two years. All other staff had an appraisal in the last 12 months, and we reviewed records which confirmed this.

The clinic manager told us that their role and responsibilities had changed since the clinic nurse was made redundant. In addition, staff remaining on flexi furlough provided increased pressure for the clinic manager. The clinic manager told us they sometimes felt out of their depth as they did not have a clinical background and did not understand all the clinical aspects such as equipment requirements. However, a nurse we spoke to during our inspection said nursing support was available and that they allowed extra time to get equipment ready and check they had everything needed.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients according to their role. Consultant expertise and competence was checked through review of the main employers' annual appraisal; this was held within their personal file.

The service did not use agency staff, but utilised staff from other clinics when required. These staff were familiar with the provider's policies and procedures.

On refractive eye surgery days an extended role staff member from another clinic assisted the ophthalmologist. Extended role clinic staff had undertaken a specific training programme and completed competencies supervised by a registered nurse before they could work independently. Extended role clinic staff always worked under the direct supervision of an ophthalmologist or optometrist.

The service had dual role members of staff who were patient advisors and laser assistants. Managers made sure staff received any specialist training for their role. Staff were trained to be laser assistants by a qualified nurse. They had also attended a core of knowledge laser safety course. Laser safety update training was included in mandatory training programme.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide safe care. The team worked well together, with care and treatment delivered to patients in a co-ordinated way.

Staff did not hold meetings to discuss both clinical and business matters. They were a small team who told us they had constant communication. However, we saw that Optimax Eye Surgery Limited undertook a variety of multidisciplinary meetings of which the meeting minutes were shared with clinic staff.

Staff told us they had good working relationships with all disciplines of staff and that they worked hard as a team.

Patients gave consent for their GP to be contacted when required. All patients were given a letter to give to their GP's post procedure; it was the patients' responsibility to ensure that the GP received this letter.

Seven-day services

Requires Improvement

Refractive eye surgery

The service was open six days a week to support timely patient care. The clinic was open Monday to Friday 8:30 to 5:30pm and on Saturday's between 8:30am and 5pm. Patients were given a phone number to call for 24 hours after their procedure to access a surgeon for advice if they had any concerns. After the first 24 hours patients could call the clinic directly or call the Customer Services Team.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. Due to the COVID-19 pandemic the service had developed other methods for gaining consent.

Optimax Eye Surgery Limited had a consent to examination and treatment policy, which was in date and set out the standards and procedures for obtaining consent from patients or them to be examined or treated. We saw this policy had been reviewed recently and changes agreed at a MAB to reflect the need for additional COVID-19 consent.

Optimax Eye Surgery Limited had implemented an additional COVID-19 consent process which informed patients that they were at an increased risk of catching COVID-19 within a healthcare facility.

Optimax Eye Surgery Limited undertook audits to check for compliance with the additional COVID-19 consent. The audit asked two different questions and compliance monitored against each question. Audit findings for the clinic showed in December 2020 one ophthalmologists was non-compliant in one of the questions, the action was to talk to the ophthalmologist and remind them to fully complete the COVID-19 consent and to check records at end of the day to monitor compliance. However, the same audit was undertaken in February 2021 and the ophthalmologist was still not compliant.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. The consent forms we reviewed were appropriate and thorough. Staff made sure patients consented to treatment based on all the information available. Patients would have their initial assessment for suitability of surgery completed and if deemed suitable would be given a consent form and information for them to review in advance of their virtual consultation with an ophthalmologist. During the consultation with the ophthalmologist both the patient and ophthalmologist would sign the consent form after discussing the risks and benefits. Consent was reaffirmed by the ophthalmologist on the day of surgery.

Optimax Eye Surgery Limited had a variety of pre-populated consent forms specific to the procedure being undertaken which detailed the likelihood of certain complications and the possible need for further procedures. Patients undergoing bilateral surgery complete a consent for each eye.

Records showed that all staff received and completed Mental Capacity Act training.

The Deprivation of Liberty Safeguards did not apply to this service.

Are Refractive eye surgery caring?

Good

Compassionate Care

Refractive eye surgery

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff were discreet and responsive when caring for patients. Staff followed policy to keep patient care and treatment confidential. All staff ensured patients privacy and dignity was maintained. Patients remained fully clothed during their procedure.

All patients were requested to complete service and satisfaction surveys after treatment, at each follow-up visit to ascertain their response to the care and treatment they received. This formed part of the Optimax Eye Clinic Limited Southampton annual survey.

Patients said staff treated them well and with kindness. One patient told us their care had been “exemplary”. During our inspection, we saw staff interacting with patients in a polite and courteous manner.

Results from the 2019 to 2020 patient survey showed 90% of patients felt they were treated with respect and dignity.

In the same patient survey over 80% of patients said they would recommend Optimax Laser Eye Clinics - Southampton to family and friends.

Emotional support

Staff provided emotional support to patients, to minimise their distress. They understood patients' personal, cultural and religious needs. Patients underwent a full assessment of their work and social interests to recommend the most suitable treatments.

Staff gave patients emotional support and advice when they needed it. We observed the ophthalmologist maintained a reassuring conversation with a patient during surgery. Talking to the patient and explaining when they were likely to experience sensations such as pressure in the eye.

Staff were available to meet and greet patients on arrival. We saw staff introduce themselves and explain their role. Results from the 2019 to 2020 patient survey in answer to the questions how well did clinic staff help you throughout your consultation? Seventy percent of patients said excellent and 20% said good.

Optimax Eye Clinic Limited website included videos of patients who had undergone laser eye

surgery, this meant perspective patients could hear the experiences of others who had undergone surgery.

Understanding and involvement of patients and those close to them

Staff supported and involved patients and families to understand their condition and make decisions about their care and treatment. The patient’s family was able to be present for virtual consultations if the patient wished so they understood the treatment and aftercare.

Staff made sure patients understood their care and treatment. Staff told us they were honest when discussing different treatment options that fitted their own specific needs and did not let patients have inappropriate procedures.

Requires Improvement

Refractive eye surgery

Staff ensured patients were able to make informed decisions about their treatment. After the initial consultation treatment recommendations were made and patients were given the relevant information to take home and read. The information included the cost, potential complications and expected outcomes so this was clear from the first consultation.

We saw staff give the patient comprehensive written and verbal information about their on-going care. This included eye care, follow-up appointments, hobbies and counselling on medicines.

This helped patients understand how to care for themselves and recognise any post-operative

complications.

In response to the question how would you rate the overall approach of the surgeon in the 2019 to 2020 patient survey. Seventy percent of patients rated it as excellent and 20% as good.

During our inspection, due to COVID-19 we did not see that any patients were accompanied by a friend or relative. However, we did observe that staff checked patients had somebody collecting them from the clinic and escorting them home.

Are Refractive eye surgery responsive?

Good

Service delivery to meet the needs of local people

The service had limited ability to provide care in a way that met the needs of local people and the communities served as all appointments were arranged centrally.

Not all the facilities and premises were appropriate for the services being delivered. The recovery area where patients went for a short observation period was also used as a storage area. There was no parking available at the clinic but there were public car parks within easy walking distance.

Follow up appointments were offered to all patients, on the day after surgery. These appointments involved aftercare advice, assessment for risk of infection or side effects.

Laser eye surgery was undertaken two or three times a month and refractive lens exchange and intraocular surgery for cataracts once a month. The number of outpatient clinics depended on demand.

Appointments, including follow up could be undertaken at any of the Optimax Eye Clinics Limited depending on patient choice.

Patients could either self-pay or use private health insurance. Patients could self-refer or be referred by another healthcare agency for example an optician.

We saw in Medical Advisory Board meeting minutes which we reviewed, discussions regarding new ophthalmologists who undertook different procedures. We saw these were considered by the Medical Advisory Board and we saw examples of when they were implemented. This provided different treatment options for patients and more flexibility.

Meeting people's individual needs

The service took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services.

Patients with mobility difficulties could access the clinic as it was all on one level, there was an accessible toilet with an emergency alarm for wheelchair users.

The service had interpreting facilities available. Staff told us that they rarely had patients who attended whose first language was not English and required an interpreter. Patients had to pay for interpreting service if required. If patients required British Sign Language translation this was provided free of charge.

The service had a strict criteria with regards to the patients that could be treated at the clinic. The clinic was designed to provide low risk procedures under local anaesthetic only. Patients who required procedures outside the criterion could be offered this at a different clinic or signposted to local private hospitals where there was more support in case of any complications arising.

Information leaflets were only available in English and in one format they were not available in large font for patients who were visually impaired.

The clinic provided an induction hearing loop in the reception area. A hearing loop is a sound system for use by people with hearing aids.

Patients were provided with information about aftercare and a post-operative appointment. This included contact details.

Access and flow

People could access the service when they needed it and received the right care promptly. Patients told us they did not have to wait long for an appointment, and they were given a choice of day and time.

Staff worked to make sure patients did not stay longer in the clinic than they needed to. Some staff told us that the number of procedure and appointments had not been staggered enough to allow for the additional cleaning needed.

All appointments were managed at a central location where the diary was maintained. Patients self-referred to the service through a variety of methods, for example, on-line, calling the clinic directly or through the corporate call centre or by visiting the clinic.

Patients received courtesy reminder calls, texts and emails to remind patients of their appointments.

As there were only two ophthalmologists who worked at the clinic, this meant that all patients had continuity of care throughout their procedure and aftercare.

Requires Improvement

Refractive eye surgery

All patients had consultations with the ophthalmologist prior to the day of treatment. Postoperative appointments were held with the optometrist. However, if the optometrist had concerns, they could refer the patient for an ophthalmologist consultation.

Learning from complaints and concerns

It was easy for people within the clinic to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them but did not always formally share lessons learned with staff.

In the last 12 months the clinic had received three written complaints. However, one complaint did not relate to this clinic. There was information displayed in the clinic about how to raise a concern in the patient areas. However, we were unable to find out how to make a complaint on the Optimax Eye Clinics Limited website. We asked the provider about this who told us that they do not deal with complaints via the website, people could call or write to the customer service team. We reviewed the Optimax Eye Clinics Limited website which had contact information for the customer service team.

Complaints were dealt with at source or escalated to the clinic manager. There were rooms available to allow privacy to discuss the patient's concerns. All verbal concerns, complaints and comments were listened to and acted upon immediately if possible. If the patient was still unhappy and the complaint was, unresolved patients were advised on how to make a formal complaint to Head Office. Verbal complaints were recorded on a verbal complaints document log, there was also a complex patient log sheet for ongoing complex patients, this included complex referral patients.

The clinic manager was responsible for investigating complaints, liaising with patients and head office with the outcome of the complaint. The Optimax Laser Eye Clinics Head of Compliance & NHS had oversight of all complaints and outcomes.

Staff were not able to give examples of learning from complaints. Complaints were a standard agenda item on the Medical Advisory Board meetings and compliance meetings.

Are Refractive eye surgery well-led?

Requires Improvement

Leadership

The clinic manager who was also the registered manager for this location had identified a lack of some skills, abilities and time to run the service they had additional responsibilities since there was no longer a clinic nurse. We saw the clinic manager had tried to manage the priorities and issues the service faced but this was not always supported corporately. They were visible and approachable in the service for patients and staff.

There was a clear leadership structure from service level to senior management level.

Optimax Eye Clinics Limited had a chief executive and chair, who linked into the senior management team, which was made up of six people, these were part of eight different support role groups, supporting Optimax Clinics Limited Clinic Teams.

The clinic manager was responsible for a team of Optimax Eye Clinics Limited employees. Ophthalmologists and optometrists worked under the direction of the clinic manager whilst working in the clinic however, they were self-employed working under practising privileges. Nurses were sourced internally to cover days when they were required. It was company policy for staff from other clinics to fill staffing gaps for annual leave or sickness. The clinic manager was responsible for these staff whilst they were on site at the Optimax Eye Clinics Limited Southampton. This meant there were clear lines of accountability which staff understood.

The clinic manager received regular communication from the corporate team to understand how the service was performing, its plans and the challenges it faced.

We were told that the clinic manager was accessible and available to support staff. Staff told us clearly about their lines of reporting. We observed positive working relationships between

staff. Due to the small size of the clinic, everyone knew each other, and we observed friendly interactions between staff at the clinic.

Vision and Strategy

The strategic vision and strategy was determined at a corporate level. The Optimax Eye Clinics Limited vision was to be the UK's first choice for laser and lens surgery procedures and to provide high quality state of the art clinics and working conditions. We saw the vision was displayed within the service.

Culture

Most staff felt respected, supported and valued. They were focused on the needs of patients receiving care. There was limited opportunities for career development of staff working at the clinic.

Not all staff were confident they could raise concerns safely without fear of punishment. However, staff working at the clinic felt they could raise concerns safely within the clinic setting but were not confident to raise concerns with head office or human resources. The service had an up-to-date whistleblowing policy which included clear guidance about how staff would be supported to raise concerns. Staff understood the importance of raising and recording incidents.

Most staff were positive and proud to work at the service. They enjoyed supporting patients through their patient journey. Staff had supportive working relationships with their colleagues. They worked together as a team to achieve the best outcomes for patients.

The culture within the clinic was centred around the needs and experiences of people who used the service. People using the service were provided with information that included terms and conditions of the services being provided to the person and the amount and method of payment of fees. Prices for different treatments were clearly advertised on the service's website. We saw discussions regarding the fees within the patients notes.

Governance

The clinic manager did not operate effective governance processes, throughout the service, the reason for this may have been due to a lack of time due to staff remaining flexi- furloughed. Not all staff were clear about their roles and accountabilities and did not have regular opportunities to meet, discuss and learn from the performance of the service.

Requires Improvement

Refractive eye surgery

Our findings from the other key questions did not always demonstrate that governance processes operated as effectively as they should have done and some of these issues were outstanding from our previous inspection.

The clinic manager understood the governance processes and was able to articulate what they thought the main challenges and risks were to the service were, but these did not reflect our inspection findings.

There were some gaps in the processes and accountability to support standards of infection

prevention and control including patient COVID-19 questions prior to attending the clinic.

There were some gaps in audits including the monitoring of actions to improve compliance, these were not documented in the audit documentation or followed up on.

Staff said they found policies and procedures around infection prevention and controls were not

easy to follow and no additional training was provided.

However, there was a clear policy about the introduction of new techniques. Applications were reviewed with the local medical advisory board corporately to ensure the supporting evidence was sufficient to ensure the safety and effectiveness of the procedure. They had to set out the risks and benefits to patients of the procedure, as well as the costs.

The service had effective governance systems ensuring appropriate recruitment checks to grant staff practicing privileges. Practising privileges is the process by which a medical practitioner is granted permission to work in an independent hospital or clinic. Practicing privileges were managed and monitored by Optimax Eye Clinics Limited Head Office department. To maintain practising privileges, staff had to provide evidence of an annual whole practice appraisal, indemnity cover, an up to date Disclosure Barring Service check and evidence of completed training. Clinic managers were notified if a member of staff was not up to date with the requirements to maintain their practicing privileges.

Management of risk, issues and performance

Leaders and teams did not always identify and escalate relevant risks and issues and identify actions to reduce their impact. The service did not regularly review and action the local risk register. The clinic manager thought their main risks were not being present all the time to keep on top of the governance and risk processes and the lack of a permanent nurse at the clinic. However, they did not identify more immediate risks such as fire safety and secure storage of harmful substances. The risk assessments associated with Control of Substances Hazardous to Health (COSHH) items had not been updated in line with the provider's policy. We highlighted the fire safety concerns at the time of our inspection and have received photographs which show these issues have been addressed.

Although we found issues with the identifying, monitoring and managing issues and risk we did not see any evidence of this impacting patients. The service had not reported any infections, serious incidents, never events, cases of COVID-19 or complaints from patients.

We reviewed the clinic's risk registers which did not show when they were last reviewed or what actions had been taken to mitigate the risk. For example, there was an entry for the lack of handwashing sinks in the consultation rooms but did not detail what measures had been put in place to mitigate the risk. One entry stated that the risk was due to be reviewed in 2019 but it was only added to the risk register in May 2021.

Optimax Eye Clinics Limited had a corporate risk register which included 19 risks all of which had been reviewed within the last 12 months. Each risk had control assurances, actions and risk owner.

The service had up-to-date policies to support the service's risk monitoring. For example, the service had a clinical governance and risk management policy. This policy detailed the types and frequency of meetings that should take place, and the topics that should be discussed within the meetings. We reviewed meeting minutes of some of these meetings which showed they were well attended and followed a set agenda. However, we noted that the clinic manager only attended one compliance conference call out of 13 between June 2020 and May 2021.

The same policy also stated that local clinic team meetings should occur monthly to discuss complaints, incidents and near miss reports, clinic key performance indicators (KPIs), conference call actions, emails from head office, training, and development. However, these were not being undertaken due to availability of staff. This meant learning was not shared with staff to prevent a reoccurrence of incidents.

Monthly senior management team meetings away from the local clinic supported clinical governance and risk management. We reviewed meeting minutes and saw that KPIs and training and development, complaints, incidents and near miss reports were discussed.

We reviewed meeting minutes from the medical advisory board meeting and saw these followed a set agenda set out in the clinical governance and risk management policy.

The service promoted risk assessments of all staff and took action to reduce the risk to staff, including those at higher risk of COVID-19 and staff who required reasonable adjustments. We saw an example of a reasonable adjustment made for a member of staff who was not able to wear a mask.

The service did not always comply with the Government guidance on COVID-19. There were posters displaying wash hands, cover face, make space. Temperature checks were in place at reception and we observed all staff wearing a facemask but not always correctly. In addition, there was no guidance on how many staff were suitable in an area or room at any one time to comply with social distancing.

Information Management

The service collected reliable data using a bespoke computer system. The data was collated and monitored centrally. However, it was not clear if the clinic was using this data to monitor its performance and use the findings to improve their service. The information systems were integrated and secure. Data was not submitted to external national audits.

Staff could easily access patient records to ensure they had access to all information needed to provide safe patient care. The service used mostly electronic records. Nursing and medical patient records were combined within the same record. This meant all health care professionals could follow the patient pathway clearly at every clinic location.

The service had a website where people could access information about the different procedures available which would be useful when deciding which clinic to attend.

Requires Improvement

Refractive eye surgery

Staff had access to the intranet to gain information relating to policies, procedures, professional guidance and training.

Staff across the hospital described information technology systems as fit for purpose. However, staff reported problems with the recent change over of computers as they did not feel they had the skills and knowledge to install them.

Engagement

Staff actively and openly engaged with patients. Patients were encouraged to complete a survey every time that they attended the clinic. However, staff were unable to give us examples of how feedback was used to improve the service.

Most staff were engaged and said that they felt supported by the company throughout the COVID-19 pandemic. There was a variety of courses available for staff to support their mental wellbeing. Due to many staff being on flexi-furlough for a long-time, opportunities to engage with staff had been limited.

The service had an up to date website which gave information about the service and procedures. The service monitored feedback it received on social media and review websites. All the reviews and comments we saw were positive.

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 Diagnostic and screening procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose **The service did not ensure that The Control of Substances Hazardous to Health Regulations are stored securely. Regulation 12 (1) (a)** **The provider did not follow policies and national guidance in assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated Regulation 12 (1) (h)**

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **The service did not have oversight, manage ongoing incidents, manage performance and risk, and assess and respond to patients' care. The provider must ensure governance systems are able to benchmark patient outcomes against other services.**