

Optimax Laser Eye Clinics - Peterborough

Quality Report

172 Lincoln Road
Peterborough
PE1 2NW
Tel: 0800 093 1110
Website: www.optimax.co.uk

Date of inspection visit: 15 November 2017 and 22
November 2017
Date of publication: 09/02/2018

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optimax Laser Eye Clinics Peterborough is operated by Optimax Clinics Limited and was established in 2006. The service is set over two floors and facilities include two reception areas, three consultations rooms, pre and post treatment areas, and a laser treatment room.

The service provides laser vision correction treatment under topical anaesthesia to adults only. If a patient required further care or surgery using anaesthesia or sedation, as an example, lens replacement surgery, patients were referred for private surgery to another Optimax Clinics Limited branch. If patients had lens surgery in another Optimax Clinics Limited branch, the Peterborough location provided pre and post-operative care. Patients are self-referring and are self-funded.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 15 November 2017, along with an unannounced visit on 22 November 2017.

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

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

Services we do not rate

We regulate refractive eye surgery, but we do not currently have a legal duty to rate them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

We found the following areas of good practice:

- Staff received a three-day induction and refresher training.
- Laser staff had additional training to ensure they were competent to perform their duties safely.
- Laser safety measures were in place and were monitored.
- Staff were competent to carry out duties allocated to them.
- The service managed staffing effectively and had processes in place to ensure that staff had the appropriate skills, experience, and training to keep patients safe and to meet their care needs.
- 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.
- The process for obtaining consent was in line with the Royal College of Ophthalmologists (RCOph) guidelines.
- The clinic was visibly clean and well maintained.
- Access to the service and booking appointments was easy.
- Interpreter services were available for patients whose first language was not English.
- The provider collected patient feedback and analysed this to make improvements/changes to the service.
- When informed of concerns throughout the inspections the service took timely action to mitigate risks.

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

Summary of findings

- We found the inside of the medication cupboard in the laser room was dusty.
- We found unlabelled medicine in the medication cupboard that did not show the name of the medicine or an expiry date.
- We found three single use instruments that were out of date.
- We found an identified risk that had not been properly assessed, monitored and reflected in the service's risk register.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve.

Heidi Smoult

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

There was an 'out of hours' emergency call system providing patients with a 24 hour mobile number following their discharge.

Staff were competent to carry out duties allocated to them.

Laser safety measures were in place and were monitored.

Staff maintained the privacy and dignity of patients.

The clinic received consistently positive feedback from the annual patient survey.

Access to the service and booking appointments was easy.

The provider had a clear leadership structure from senior management level to service level.

Summary of findings

Contents

Summary of this inspection

	Page
Background to Optimax Laser Eye Clinics - Peterborough	7
Our inspection team	7
Why we carried out this inspection	7
How we carried out this inspection	7
Information about Optimax Laser Eye Clinics - Peterborough	8
The five questions we ask about services and what we found	9

Detailed findings from this inspection

Overview of ratings	12
Outstanding practice	26
Areas for improvement	26

Optimax Laser Eye Clinics - Peterborough

Services we looked at:

Refractive eye surgery

Summary of this inspection

Background to Optimax Laser Eye Clinics - Peterborough

Optimax Laser Eye Clinics Peterborough is operated by Optimax Clinics Limited. The service opened in 2006. It is a private clinic situated in a residential area of Peterborough, Cambridgeshire. The clinic primarily serves the communities of Ely and Peterborough. It also accepts patient referrals from outside this area.

The clinic has had a registered manager in post since 2006. The current registered manager has been in post since 2008.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector, and one other CQC inspector. The inspection team was overseen by Fiona Allinson Head of Hospital Inspection.

Why we carried out this inspection

The service was last inspected in December 2013, which found all standards of quality and safety it was inspected against were met. There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 15 November 2017, along with an unannounced visit on 22 November 2017.

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

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

During our inspection, we visited the consultation room, laser treatment area and the pre and post treatment areas, we spoke with three patients, six members of staff; including a registered nurse, laser assistant, the registered manager, the compliance manager, the optometrist and the engineer. We reviewed seven sets of paper patient records and three electronic patient records. We placed comment boxes at the clinic before our inspection, which enabled staff and patients to provide us with their views. We received six 'tell us about your care' comment cards, which patients had completed prior to our inspection.

Summary of this inspection

Information about Optimax Laser Eye Clinics - Peterborough

Optimax Laser Eye Clinics Peterborough is operated by Optimax Clinics Limited and was established in 2006. The service is set over two floors and facilities include two reception areas, three consultations rooms, pre and post treatment areas, and a laser treatment room.

The service provides laser vision correction treatment under topical anaesthesia to adults only. If a patient required further care or surgery using anaesthesia or sedation, as an example, lens replacement surgery, patients were referred for private surgery to another Optimax Clinics Limited branch. If patients had lens surgery in another Optimax Clinics Limited branch, the Peterborough location provided pre and post-operative care.

Optimax Laser Eye Clinics Peterborough is registered to provide the following regulated activities:

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

Patients are self-referring and self-funded; they attend an initial consultation with an optometrist followed by a consent appointment with the ophthalmic surgeon. Treatment takes place on a day case basis. The provider undertakes surgery twice a month on a Thursday and Saturday with other days used for consultations and aftercare. There are no overnight facilities; the clinic is opened Monday to Saturday from 8am until 6pm.

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 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 an 'out of hours' emergency call system providing patients with a 24 hour mobile number following their discharge.
- Staff maintained patient records ensuring they were, legible and up to date.
- Laser safety was well managed and records were appropriately maintained.
- Staff carried out an infection control audit in March 2017 which showed the service was 100% compliant in the areas of clinical practice, use of protective clothing, decontamination, care of equipment, handling of sharps and waste disposal.
- The service had a major incident plan, reviewed in August 2017. The policy covered potential risks such as dealing with a bomb alert, fires, gas leaks and flooding.

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

- We found medicine in the medication cupboard that was not labelled with the name of the medication or an expiry date.
- We found three single use instruments that were out of date.

Are services effective?

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

We found the following areas of good practice:

- Staff were competent to carry out the duties allocated to them.
- Laser staff had additional training to carry out their duties safely.
- Procedures for obtaining consent were in line with Royal College of Ophthalmology (RCOph) national standards and guidance.
- Surgeons who performed refractive eye surgery at the service held the RCOph certificate in laser refractive eye surgery.
- All staff received an appraisal in the last 12 months.

Summary of this inspection

Are services caring?

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

We found the following areas of good practice:

- Staff maintained the privacy and dignity of patients.
- All CQC comments cards we received provided positive feedback about the service.
- The clinic received consistently positive feedback from the annual patient survey.
- Staff gave patients transparent and accurate information about all the costs of potential treatment.

Are services responsive?

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

We found the following areas of good practice:

- Access to the service and booking appointments was easy.
- The provider offered interpreter services if patients did not speak English as their first language.
- The provider managed complaints in a timely manner and identified learning shared with staff.

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

Patient information leaflets were not available in different languages.

Are services well-led?

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

We found the following areas of good practice:

- The provider had a clear leadership structure from senior management level to service level.
- Staff we spoke with reported that they worked well as a team.

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

- The providers' visions and values were not displayed in the patient areas.
- Governance processes did not capture issues within the clinic and risk registers did not reflect current concerns.

Summary of this inspection

- Audits were limited and lacked attention to detail, influencing how the service improved.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Refractive eye surgery	N/A	N/A	N/A	N/A	N/A	N/A

Refractive eye surgery

Safe

Effective

Caring

Responsive

Well-led

Are refractive eye surgery safe?

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.

Incidents and safety monitoring

- The provider had a policy in place for the reporting of incidents and near misses, which was due for review in October 2019.
- In the 12 months prior to our inspection, there had been no serious incidents requiring investigation. Serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response.
- All staff we spoke with told us there was a culture of reporting and learning from near misses/ incidents amongst staff working within the clinic. A member of staff described to the inspection team an incident that had occurred at another Optimax Clinic Limited location and the learning outcome from this incident.
- Staff understood their responsibility to report incidents and told us they were able to speak with the clinic manager about incidents. Clinic staff told us that the clinic manager recorded incidents electronically on the incident report form, and investigated these, which we reviewed.
- On the day of our announced inspection, the team met the Compliance Manager for Optimax Clinic Limited, whose role was to review incidents and ensure that the detail and quality of the incident

report was sufficient. We reviewed the annual independent incident audit dated January 2016 to December 2016 and noted that Optimax Peterborough had reported no clinical incidents.

- The registered manager undertook six monthly audits of incidents. Between September 2016 and August 2017, there had been eight near misses reported. There were no particular themes identified. A near miss is an unplanned event that did not result in injury, illness, or damage; but had the potential to do so. We reviewed staff meeting minutes and noted these near misses were discussed with the clinic staff attending the meeting.
- A Duty of Candour and Being Open Policy was available with a review date October 2019. The registered manager and staff had all undertaken duty of candour training and were aware of their responsibilities in relation to duty of candour. 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. In the reporting period September 2016 to August 2017, no incident met the threshold for managing it in line with this regulation.
- The provider monitors its surgeons' results, infection rates and complications on a six monthly basis. A copy of the audit for each Surgeon is given to the company Medical Directors who review them, against the standards set by the Royal College of Ophthalmologists (RCOph).

Mandatory training

- The provider had recently introduced a mandatory training policy and staff accessed details relating to mandatory training from the service's staff handbook.

Refractive eye surgery

- The provider delivered annual mandatory training courses as part of refresher training and development, including 'face to face' training and 'e-learning' modules. These included topics such as data protection, fire safety, violence and aggression, equality and diversity, introduction to safeguarding, disability and discrimination awareness, infection control, medicines training, manual handling, first aid, automated external defibrillation and basic life support and legionella and water safety. Up to September 2017, figures provided showed mandatory training compliance for all staff was 92%, with outstanding training booked to be completed by the end of November 2017.
- Staff we spoke with confirmed they received mandatory training annually, and we reviewed evidence of this in staff records.
- The registered manager maintained a training matrix, to monitor staff training and ensure staff compliance with their training requirements.
- All relevant staff received training in basic life support (BLS). The service had no incidents that required basic life support since it opened in 2006. The service did not provide laser corrective surgery under sedation, which meant the staff, did not require advanced life support training.
- The service had not reported any safeguarding concerns since its opening in 2006 and there were no safeguarding issues logged with the CQC. The manager confirmed there had never been a safeguarding concern in the service.
- The service had a vulnerable adult's protection policy, updated in August 2017. The policy defined what constituted a vulnerable adult, what constituted abuse and detailed the local authority contact should a safeguarding referral need to be made. The vulnerable adults' protection policy also explained that staff should complete annual awareness training to enable them to understand how to respond to a potential safeguarding risk. Records demonstrated, annual awareness compliance for all staff was 100%.
- Although the service did not treat patients under the age of 18 years, it had a child protection policy, reviewed in August 2017. The policy was in place to provide guidance for staff around children visiting the premises with an adult.
- Staff underwent disclosure and barring checks just prior to appointment but there was no policy or process in place to revisit these.

Safeguarding

- The registered manager was the designated local lead for both adult and children's safeguarding. The registered manager told us they had completed safeguard training for adults and level three safeguard training for children whilst clinic staff had completed safeguard training for adults and level two children's safeguarding training, we reviewed staff training records and saw evidence of this. All staff we spoke with knew their safeguarding lead and which local authorities they would need to contact to raise an alert.
- Records reviewed showed that staff members received safeguarding training at two yearly intervals. The manager monitored the staff training in order to make sure that they received the latest and most up to date training.
- The provider had an infection prevention and control (IPC) policy as well as protocols, and hygiene arrangements for staff to follow. The policy provided staff with guidance on appropriate IPC practice such as hand washing, the use of personal protective equipment (PPE) and dealing with spillages. The policy was in date and due for review in August 2019.
- The provider had an up to date 'cleaning policy for clinics'. This detailed the cleaning equipment for use by staff and the cleaning schedule. We reviewed completed and up to date cleaning schedules for all areas
- All areas we inspected were visibly clean. We reviewed the cleaning schedule for the laser room and noted that the manager completed daily and weekly audits. We reviewed the cleaning records for the three months prior to our inspection and found they were up to date.
- The service used single use (disposable instruments) and a policy was in place to provide guidance to staff

Refractive eye surgery

on the safe use and disposal of these instruments. However, we found three single use items that were out of date. When this concern was brought to the attention of the registered manager, the instruments were immediately disposed of. We were told that these particular instruments were not now used, the registered manager showed us five boxes of single use disposal instruments that were now used, and we noted all instruments were in date.

- Adequate supplies of hand sanitiser, liquid soap and aprons and gloves were available throughout the clinics. All waste bins were hands free or pedal bins.
- Throughout our inspection, staff working in the clinical areas complied with best practice regarding hand hygiene. However, we noticed no hand washing facilities in the topography (scanning) room. We spoke about this with the registered manager who told us they used hand sanitising liquid between patient contact and they used the handwashing facilities in the recovery area which was next door should they need to wash their hands. Although the provider mitigated this risk, as staff had access to hand sanitising liquid, we noted this had not been formally risk assessed or included on the service's risk register.
- The provider conducted an infection control audit in March 2017, which showed the service was 100% compliant in the areas of clinical practice, use of protective clothing, decontamination, care of equipment, handling of sharps and waste disposal. However, the audit showed an 82% compliance rate for the environment, there was no action plan in place to improve the results of this audit.
- Hand hygiene audit results for the months of March 2017 showed that 92% of staff complied with hand hygiene guidance. This audit included all grades of staff. The audit identified that a good handwashing technique should be included in the new staff induction programme. We requested additional hand washing compliance audits from the provider but did not receive any.
- There had been no reported healthcare associated infections for this service in the 12 months prior to our inspection.

- There had been no incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA) or healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).
- There had been no incidences of healthcare acquired Clostridium difficile (C.difficile) or healthcare acquired Escherichia coli (E-Coli).
- Throughout the service, sharps bins complied with the UN 3291 clinical waste standards. Staff used the bins for the safe disposal of items such as needles. The service had a contract with an external company for the removal, disposal, and replacement of sharps boxes.
- The provider had a service level agreement with an external waste management company who collected clinical waste once every two weeks.
- Staff received training on infection prevention and control at induction and had a refresher every year as part of the mandatory training. As of September 2017, the compliance rate for this training was 100%.
- The inside of the medication cupboard in the laser room was dusty. When we brought this concern to the registered manager, a member of staff was instructed to clean the cupboard. On the day of the unannounced inspection, the cupboard was clean.

Environment and equipment

- On the day of each laser surgery list staff completed a number of checks. These checks included cleanliness and equipment checks completed and signed by staff. We reviewed the check sheets and noted that staff completed and signed these.
- The service had an up to date optical radiation safety policy in place and local rules were available for staff to follow.
- Local rules were stored in a folder in the laser room. There was a list of authorised users and staff had signed to state they had read and understood them.
- The local rules also contained contact information for the Laser Protection Advisor (LPA). The LPA was external to the service and based in London. Staff could contact the LPA for personal questions such as safety precautions for pregnant members of staff.

Refractive eye surgery

- Laser assistants received training from a senior and experienced member of staff on how to calibrate and assist with the laser machine. They had also attended a core of knowledge laser safety course.
- Staff recorded the humidity and temperature in the laser room on a daily basis to ensure these were correct and to maintain patient safety.
- The laser technician checked the calibration and the safety of the laser machine before each laser treatment session. Calibration and checks took place according to local rules. We viewed the check sheets and noted they were completed, signed, and dated by staff.
- The laser-controlled area was clearly defined with a warning sign stating 'do not enter' when the laser was in use. This could be seen from the pre and post treatment rooms.
- Access to the laser room was by a key coded pad.
- All procedures were undertaken within a standard laser treatment room. The room was spacious and clutter free.
- The extraction of plume was through a small suction machine attached to the laser machine. Plume is the vapour produced during laser treatments, which can be irritating to the eyes and patients can feel nauseated.
- When the lasers were not in use, the keys to operate the laser machines were kept in the managers office, in a locked cupboard, which was accessed by a key coded pad.
- The provider held risk assessments for a range of chemicals including gases and cleaning fluids in line with the Control of Substances Hazardous to Health (COSHH) regulation. We noted that all items were stored correctly and securely.
- The service had a maintenance policy in place. On the day of our unannounced inspection, we met the engineer responsible for maintaining the medical equipment. The provider employed four engineers to service equipment. The engineer was able to describe how equipment maintenance was scheduled, how they provided an on call 24 hour service to respond to any serious issues, and the training they received.
- We reviewed the maintenance records for the laser and noted it had been serviced in May 2017.
- We checked seven pieces of equipment, including the automated defibrillator, slit lamps, and the topography machine. All had an up to date servicing history and displayed labels to state they had all been safety checked.
- Emergency equipment was available in the treatment area. Staff checked this on a weekly basis. All equipment was in date and in working order. We reviewed the checklist records for the three months prior to our inspection and found they were signed and dated.

Medicines

- We reviewed the medicines management policy and noted a new document 'Policy for prescribing, dispensing, administering medication, competency, and training of Clinical staff'. The policy was created in September 2017 and gave clear protocols for the dispensing of medicines for staff, which was the responsibility of the operating surgeon. The service had a policy regarding the use of cytotoxic medicines, which included the management of risk and patient information. Cytotoxic medicines are medicines that are toxic to cells, preventing their replication or growth. We noted in the patients consent form that a clear explanation of cytotoxic medication and its actions were given and the rationale for the use of cytotoxic medication was clearly described. The provider held appropriate risk assessments, policies, and protocols associated with the handling of the cytotoxic medicines. Staff ordered cytotoxic medicines corporately and a spillage kit and appropriate waste disposal arrangements were in place.
- We checked the medicines fridge temperature log and noted it was up to date and temperatures within the recommended range. Staff also monitored ambient room temperatures.
- Staff stored medicines safely, within lockable cupboards. Access was limited to the key holder on duty to restrict any unauthorised access.
- Qualified staff received medicines management training. In September 2017, the compliance rate for this training was 100%.

Refractive eye surgery

- Optometrists, nurses, or ophthalmologists administered medication such as eye drops and staff recorded this appropriately in patient notes with dose, route, and strength of medicine given.
- We looked at 10 sets of patient records, which detailed current medications, allergies, and patients' medical history in order to make sure that any medications prescribed by the ophthalmologist were safe to be given.
- On the day of the announced inspection, we found medicine in the medication cupboard that were not labelled with the name of the medicine or an expiry date. When we informed the registered manager of our concerns, the unlabelled medication was immediately removed and disposed of. On the unannounced inspection, we noted that all medications were labelled with the name and expiry date. The registered manager had discussed the incident with the member of staff and had put into place actions to mitigate the risk.
- The registered manager undertook a monthly stocktake of all medicines within the service.
- The clinic had an emergency medicines box containing non-controlled medication for use in an emergency. There was a list on the outside of the box to alert staff to expiry dates. Re-ordering of medication was through the pharmacy service level agreement.

Records

- The provider held patient records electronically and in paper format. The electronic system contained all the patients' details including assessments, surgery, and medicines given. We looked at six patients medical records held on this system. These included the consultation and surgeons pre-operative assessments, the laser procedure, post-operative information, and follow-up notes.
- We reviewed 10 sets of electronic and paper based patient records and saw that consent for procedure was completed, consent to contact general practitioner (GP) was completed and a 'cooling off' period was given. A 'cooling off' period is a recommended best practice standard and allows patients time to think about whether they wish to proceed with treatment or not.
- The registered manager carried out documentation audits on a quarterly basis. We reviewed the data from the last audit completed in October 2017. Ten patient records were randomly selected and audited against specific prompts. The audits showed the records were completed well with no required actions.
- Staff stored all records containing patient information securely and electronic records were password protected.
- Each time the laser machine was used staff logged this in a central register and in the patients' records.

Assessing and responding to patient risk

- All patients using this service were self-referring and attended three appointments prior to treatment during which they completed an electronic health questionnaire. The questionnaire consisted of 40 questions relating to the patients' medical history, treatment day requirements such as ability to lie still and flat for thirty minutes and whether the patient agreed to the clinic disclosing details of their treatment to their GP are some of the questions. If a patient required assistance with completing the health questionnaire, a member of staff would help.
- Patients' who experienced photosensitivity or epilepsy were referred to their GP. Patients with epilepsy were only considered suitable for treatment if they were seizure free for two years.
- Patients were only considered for treatment if they met the provider's criteria. This criteria included a psychological assessment. Patients, who presented with a psychological condition such as depression, were required to have an assessment of their mental health status prior to being considered for treatment.
- Patients who were taking warfarin (an anti-coagulant that makes the blood cells less sticky) were required to have a blood test to check their clotting levels, two days prior to the procedure. This was organised with the patients GP.
- Throughout our inspection, we observed the risks, benefits, and limitations of laser refractive eye surgery explained to the patient, before the patient signed to declare they understood the information provided.

Refractive eye surgery

- On the day of the procedure, patients had baseline observations of pulse, respiration, and blood pressure pre procedure performed as part of their medical assessment.
- In most cases, patients undergoing laser surgery had both eyes treated on the same day. If the surgeon was performing laser treatment on one eye, the eye to be treated would be marked to ensure treatment took place on the correct eye. In all cases, the surgical team checked the treatment parameters, before undertaking the laser treatment.
- The patients' pathway included the completion of a modified surgical pause checklist. This was a process for ensuring staff completed a number of safety checks including patients' identity, completed consent, allergies and identifying and marking the operated eye for surgery prior to the procedure. This modified checklist was not audited separately but as part of the quarterly medical records audit. The patients' medical records audit for October 2017 did not include the modified checklist. This meant we did not receive assurance the checklist was always completed.
- Post procedure, a nurse took each patient- to a recovery area, with recliner chairs and stayed with the patient until they felt well enough to return home. Staff did not take any post treatment observations as laser refractive surgery did not involve sedation or general anaesthesia. Staff told the inspection team the most common complication post-treatment was fainting, and were able to explain the steps they would take to address this.
- On discharge, the nurse supplied patients with an emergency card, which contained their treating ophthalmologist contact details, in case of any queries or concerns out of hours. Staff told patients that during clinic opening times, they should call the clinic direct for advice over the telephone or arrangements could be made to return to the clinic for a review with either the optometrists or treating ophthalmologist.
- Prior to discharge staff gave patients verbal information that was reinforced with written instructions on aftercare and the date and time of their follow up appointment.
- The service did not have a service level agreement with the local NHS hospital in the event of the need to transfer a patient due to a the event of patient deterioration or collapse, they would telephone the emergency services whilst providing basic life support.
- Staff trained in basic life support were available during treatment days. At the time of the inspection, all nursing and medical staff were 100% compliant for basic life support (BLS) training.

Nursing and medical staffing

- The service employed ophthalmologists and two optometrists under practicing privileges. It also directly employed one registered nurse, and one full time laser technician, supported by the registered manager who has been in place for nine years and is a laser technician as part of this role.
- The provider planned staffing levels based upon the number of patients requiring laser treatment surgery, post treatment follow-ups, and consultations. If additional staff were required, they were transferred from surrounding Optimax clinics. Staff also told us they frequently travelled to other Optimax clinics and were familiar with the teams. Due to the provider, having standardised protocols throughout the organisation staff felt comfortable with this arrangement and did not identify any concerns with this work pattern. The provider did not use bank or agency staff.
- On both inspection days, there were no laser refractive treatments taking place. However, the registered manager told us there were always adequate numbers of suitably trained staff available on treatment days. We viewed the formulae used to meet the clinics staffing requirements, and skill mix and found they met the requirements of the Royal College of Ophthalmologists (RcOph).guidelines.

Major incident awareness and training

- The service had a major incident plan, reviewed in August 2017. The policy covered potential risks such as dealing with a bomb alert, fires, gas leaks and flooding.
- The service had emergency backup generators that would be initiated if there were a power failure.

Refractive eye surgery

- Staff undertook resuscitation drills on a quarterly basis. We reviewed documentation and confirmed these drills took place in July 2017 and October 2017.
- Staff had received fire training and were 100% compliant.

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

Evidence-based care and treatment

- Patients had their needs assessed and their care and planned and delivered in line with evidence based
- The optometrist told us that Optimax had a Medical Advisory Board (MAB), which set standards for all surgeons and optometrists across the service to work to. The inspection team viewed minutes of these meetings and noted that Royal College of Ophthalmologists (RCOph) recommendations and NICE guidelines were standard agenda items.
- Twice a year meetings were held at provider level where ophthalmologists', optometrists, the chief executive, chair of the board and the medical compliance manager, attended. At this meeting, information from the MAB, such as changes to protocols or the introduction of new treatments from the MAB was shared.
- Patients were given a one week 'cooling off period' to think about the surgery and its implications before any surgery was scheduled. This was in line with the RCOph guidelines.

Pain relief

- Patients undergoing laser refractive eye surgery received treatment under local anaesthesia. Staff administered topical eye drops into the eye prior to the procedure as a method of pain relief. This was in line with joint guidelines from the Royal College of Anaesthetists (RCA) and the RCOph (2012). Staff did not routinely offer patients pain relief post-surgery. However should patients require analgesia then their consultant could prescribe it.
- Patient information leaflets were used to advise patients about what pain relief may be required once they returned home.

- The medical records audits and the patient feedback cards indicated no concerns from patients with regard to pain management.

Patient outcomes

- The clinic monitored patient outcomes through a series of predicted results called 'Patient Forecast', developed for each patient. Staff collated the results electronically and clinic managers established if there were trends in the results. If results fell outside the predicated range, senior clinical staff investigated these and discussed the results at the ophthalmologist's appraisal. The registered manager told us that staff gave the forecast to each patient following their consultation.
- Data from patient predicted outcomes and the ophthalmologist results were discussed at the provider meetings. In the event that recommendations for change were made, senior managers reviewed the recommendations internally through the national MAB and the information was shared with all staff in the organisation. This was to ensure the service continuously reviewed and improved patient outcomes.
- We reviewed evidence of benchmarking against other Optimax clinics, within the data stored on the shared drive. The registered manager told us the corporate clinical team reviewed and audited each individual ophthalmologist outcomes, complications and incidents, which we viewed.
- Part of the patient satisfaction questionnaire asked patients how satisfied they were with the results of the treatment. Results for the service showed 96% of patient responses rated the service as good or excellent. It is to be noted, that the survey did not specifically break down areas of satisfaction however, feedback relating to patient experience and outcomes was consistently positive.

Competent staff

- Staff we spoke with had the correct level of skills and competencies to carry out their role. All new staff attended a comprehensive induction programme, which included familiarisation with policies and procedures.

Refractive eye surgery

- Staff working with lasers worked alongside more senior staff until they had completed their core knowledge training.
- The laser technicians received training to assist with laser treatment and completed the core of knowledge training.
- The registered manager was the services' Laser Protection Supervisor (LPS), with overall responsibility for the safety and security of the lasers. The laser technicians undertook the role of deputy LPS when they were assisting the surgeon in the laser treatment room or if the registered manager was not on site. Records reflected that the service ensured all the laser technicians completed laser safety training every two years. An external Laser Protection Advisor (LPA) based in London was available for training, advice and support as needed.
- The clinic manager supported all staff within the clinic and told the inspection team it was important that new members of staff understood every aspect of the patient journey. Staff worked independently once senior staff signed off their competencies. There was no time period for competencies to be completed, but all new staff had a six-month probation period. However once these competencies had been completed there were no formal assessments in place to reassess staff knowledge.
- All staff we spoke with told us that they had received an appraisal within the last 12 months, this was confirmed when we viewed the staff records.
- A member of staff told us they had recently attended the annual Optimax nurses meeting in London where staff discussed new treatments and protocols.
- All of the surgeons who performed refractive eye surgery at the service held the Royal College of Ophthalmology certificate in laser refractive eye surgery.

Multidisciplinary working

- We observed good interactions and communications within the team. Staff told us they worked well as a team and enjoyed working within a supportive environment.

- Overall responsibility for patient care and patient outcomes were the ophthalmologist' responsibility.
- We observed the optometrists and an ophthalmologist liaise effectively in the delivery of patient care.
- Staff understood the role of the LPA and knew how to access the LPA if required.
- The service offered consultations and treatments Monday to Saturday and provided clinics on Sundays when required.

Access to information

- Patient records were held electronically with some elements such as consent forms in paper format. Records were accessible for each appointment during laser eye surgery, and for staff to monitor patients after their laser surgery.
- All relevant staff could access patients' electronic notes from any Optimax clinic if required.
- We observed clinic staff completed pre-treatment patient questionnaires and the optometrist reviewed patient medical questionnaires prior to all eye examinations.
- All staff told us they would speak with the optometrist or ophthalmologist if they had any queries. Staff gave information to patients prior to any treatment, which outlined the risks and advantages of the surgery.
- Patient records detailed current medicines, any allergies, and a medical history to make sure that any medicine prescribed by the consultants was safe to administer.
- Staff gave patients clear verbal and written instructions regarding necessary precautions before and after surgery. Ophthalmologists gave clear predictions of what vision the patient would be likely to achieve following their surgery and explained how long they would need to wait before this vision was available to them.
- Following surgery, staff gave all patients a letter detailing the procedure they had undergone and a

Refractive eye surgery

post-operative medication regime to take to their general practitioner (GP). Staff gained permission from patients at the consultation stage, to enable the service to contact their GP if required.

- GPs could access optometrists and ophthalmic surgeons for advice if this was required.

Consent and Mental Capacity Act

- The service had a policy for consent to examination and treatment, which set out the standards and procedures for obtaining consent from patients prior to examination or treatment.
- We reviewed 10 sets of patient records all demonstrated that staff gave patients time and information to reflect on the decision, we noted the provider gave the patients a minimum of seven days.
- Training data provided by the service indicated that staff had not received any training on obtaining consent or the Mental Capacity Act. The registered manager told us that Mental Capacity Act training was part of the safeguarding training; however, we were unable to evidence this.
- It was the responsibility of the surgeon to assess whether the patient had capacity to consent. If there were any concerns, the surgeon would contact the patient's GP.
- Staff always asked patients for consent to communicate with their GP we observed this during a patient consultation and saw evidence of this in the patient records we reviewed.

Equality and human rights

- The service had an equality and diversity policy. In addition, staff received equality and diversity training as part of their induction and as part of their on-going mandatory training. Up to September 2017, staff compliance for this training was 100%.

Are refractive eye surgery caring?

Compassionate care

- Staff maintained the privacy and dignity of patients. The waiting area was an open environment; however, staff escorted patients to consultation rooms to enable private discussions. We observed positive and discreet interaction between staff and patients.
- We observed an optometrist speaking to a patient who had undergone surgery the previous week. The optometrist explained how to clean the eye, and the importance of putting in the eye drops and ensured the patient was able to instil the drops correctly. We spoke to the patient who stated the care provider had been "brilliant, can't fault the service, everyone has been extremely nice".
- We received six completed CQC comment cards from patients; all were positive and reflected the satisfaction figures within the patient survey. One patient said, "The service has been absolutely amazing, excellent customer service, everything explained".
- The last patient survey in the clinic completed December 2016 showed 97% of patients felt satisfied.

Understanding and involvement of patients and those close to them

- Patient advisors gave patients information about what to expect from laser surgery. This information was shared during one to one face-to-face consultations when patients were allocated ample time to ask questions. During this initial consultation, staff gave patients transparent and accurate information about all costs of potential treatment.
- We spoke too three patients who said staff gave them realistic expectations of the outcomes of their laser procedure. We reviewed evidence in patient records of staff discussing realistic outcomes following surgery.

Emotional support

- Patients were asked to complete an electronic questionnaire following each visit. The questionnaire asked patients about their experience of the clinic and whether they had any concerns they wished to raise. The registered manager told us that concerns would trigger an electronic flag, and the issue could be resolved quickly.

Refractive eye surgery

- Staff got to know patients during their appointments prior to their surgery and this relationship helped to put patients at ease. Where possible, the same patient advisor saw patients at all stages of their journey. All patients we spoke with agreed that staff made them feel comfortable and safe.

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 clinic provided private laser eye surgery for the immediate and local population and across the Cambridge area. The clinic manager told us that any patient could attend any of the Optimax Clinics Limited services nationwide as the service could access electronic patient records from every clinic.
- For patients requiring surgery not available at the Peterborough clinic, such as lens replacement, staff shared referrals with other Optimax clinics, which patients could access.
- The provider managed all appointments for the clinic at a central location known as the customer service team. This team took calls from prospective patients who wanted an appointment to assess if they were suitable and for all consecutive appointments. The clinic manager told us this service worked well and there were positive relationships between the clinic and the customer service team.
- Information sent to us prior to our inspection and available on the services website showed that the service opened Monday to Saturday from 8am to 6pm.
- Another member of staff told us that some patients were uncomfortable using computers and found the electronic questionnaire system strange. The staff member spoke of the support provided and paper versions of the questionnaire offered if patients preferred.

- Patients brought their relatives into the clinic and they were involved in the discussions where this had been the patients wish. A patient told the team that staff showed their partner how to instil eye drops as they found this very difficult.
- Optimax did not treat patients under the age of 18, or those who were pregnant or breast-feeding.
- The service provided pre-planned elective services only, which meant they were able to control the numbers of patients they could accommodate each day.
- The service did not provide an emergency eye surgery service. They provided pre-planned procedures only

Access and flow

- Patients self-referred to the service through a variety of methods, for example, on-line, through the corporate call centre or by visiting the clinic.
- In the 12 months prior to our inspection, the provider did not cancel any refractive eye treatments.
- At the time of our inspection, there was no waiting list for refractive eye surgery. This meant patients did not have to wait for their treatment.
- Information sent to us by the provider prior to inspection demonstrated there were no incidences of unplanned transfer of a patient to another health care provider in the 12 months prior to our inspection.
- The registered manager told us that staff contacted patients who cancelled appointments with a telephone call. Staff followed up any subsequent missed appointments by issuing a letter to those patients.
- The service did not monitor patient waiting times prior to arranging appointments or when patients arrived for their appointment.

Meeting people's individual needs

- Each patient received an initial courtesy call to confirm their appointment to establish an initial rapport with them and to ascertain any special requirements whilst attending the service.
- The service made reasonable adjustments for wheelchair users and people with restricted mobility.

Refractive eye surgery

For example, staff held consultations for patients with mobility issues on the ground floor. Doors and corridors were wide enough to accommodate a wheelchair and there was an accessible disabled toilet on the ground floor for patients who required this facility. One member of staff gave us an example of how the team had accommodated a patient with mobility issues. Staff carried out the patients' consultation on the ground floor and moved furniture to ensure the patient had sufficient space to move freely around the clinic.

- The registered 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 one patient aged 18-21 years had undergone laser surgery during the last 12 months. The service had recently introduced a policy on laser vision correction specifically for this age group. We reviewed the policy and noted it was in date July 2017 but it did not have a review date. Staff confirmed that younger patients were advised they might need further laser surgery repeated at some point.
- Staff gave information to patients advising them of post-operative care and an emergency card with the ophthalmologists' details so they can contact them directly overnight if they have any concerns or queries.
- Interpreting services were available for patients who required this service. Staff we spoke with knew how to contact the interpreting service and how to arrange support.
- The provider had installed a hearing loop system at the clinic reception area for people who required additional support with hearing and translation services.
- 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. We did not see any of the patient leaflets and documents including consent forms in any other languages however, staff told us these could be requested through head office.

- The service screened patients' suitability for treatment at an initial consultation, if a patient had complex health and social care needs, this would be taken into account at this stage.
- All areas we inspected were well equipped. Patient waiting areas were suitable with the provision of magazines, information leaflets, and hot and cold drinks.
- The clinic offered car-parking facilities; it was also adjacent to a busy main street with an accessible bus route.

Learning from complaints and concerns

- The service had a complaints policy, reviewed in September 2017. The policy detailed that staff would deal with complaints within 20 days of their receipt. The policy gave the same level of importance to verbal complaints as it did to written complaints.
- Information regarding how to make a complaint was available within the clinic but this information was not available to patients in the printed patient information guide or as part of the printed aftercare advice guide given to patients on discharge.
- Staff asked all patients to complete surveys at each visit in order to gauge their satisfaction with the service they received.
- Between September 2016 and August 2017, the service had received 71 written compliments and two complaints. Both complaints related to patients dissatisfaction with the results of their treatment and were managed under the formal complaints procedure and resolved.
- Where possible staff dealt with complaints and concerns at source and could raise these with the registered manager where necessary. If it was not possible to resolve the complaint, staff advised patients to make a formal complaint at corporate level.
- We did not see any evidence that the provider shared learning from complaints within the wider organisation.

Refractive eye surgery

- The registered manager responded to all complaints within the 20-day period and we noted discussion around these complaints within staff meeting minutes.

Are refractive eye surgery well-led?

Leadership and culture of service

- At location level, the registered manager who was responsible for a team of three Optimax employees led the service. Ophthalmologists and optometrists worked under the direction of the registered manager whilst working in the clinic but they were self-employed working under practising privileges. It was company policy for staff from other clinic locations to fill staffing gaps during the treatment days. The registered manager was responsible for these staff whilst they were on site at the Peterborough clinic.
- The registered manager had the skills, knowledge, and experience, to lead the service with support from the central governance team. The registered manager had been in post nine years and had a good understanding of the service.
- There was a clear leadership structure from service level to senior management level.
- Staff told us that following establishment of Optimax Clinics Ltd in 1991 one individual had owned the business. They explained the founder was well respected, accessible, and approachable.
- Staff knew the corporate management structure and were clear about lines of reporting. Staff told us that senior managers were visible and approachable and the registered manager was readily available and often worked clinically alongside them.
- Staff told us they felt able to raise concerns with the registered manager. The team was small but well established and there was a good sense of teamwork.
- The provider audited staff performance and we reviewed evidence of this in personnel files. If the provider identified poor performance, they addressed this through one to one meetings and the appraisal process.

- The Optimax central corporate team directed all marketing campaigns. We observed information available was honest, responsible, and complied with guidance from the Committee of Advertising Practice. Patients received a statement that included, terms, and conditions of the service, the cost, and method of payment for their treatment.

Vision and strategy

- The strategic vision and forward vision of the service 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.
- Staff we spoke with had not been involved with the development of the vision and values and was not aware of them. The provider did not display the vision and values within the service.

Governance, risk management, and quality measurement

- The service had a clinical governance and risk management policy. This policy detailed the types and frequency of meetings required, and the topics within the meetings. The policy indicated that staff should discuss complaints, incidents, and near miss reports, clinic key performance indicators (KPIs), conference call actions, emails from head office and training and development at these meetings.
- The monthly compliance teleconference was attended by the compliance manager, the director of operations, the customer services team, the lens surgery lead and registered managers of clinics across the country.
- Monthly senior management team (SMT) meetings supported clinical governance and risk management. We reviewed the minutes of the March 2017, April 2017, May 2017 SMT meetings and noted that KPIs, training, and development were discussed but there was no evidence that staff discussed complaints, incidents, and near miss reports. This meant there could be a risk that the SMT may not be fully aware of themes and trends relating to complaints, incidents, and near misses at location level.
- The service had a risk register that contained a list of 30 generic risk assessment titles. The risk register did not include the date for review, details of mitigating

Refractive eye surgery

actions or persons responsible for ensuring action plans for mitigation were completed. 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 responsible to monitor the risk and any measures in place to reduce the risks.

- We found an identified risk that had not been properly assessed, monitored and reflected in the service's risk register
- The registered manager had completed the risk register to identify potential and actual risks but staff had not reviewed the risk register to monitor and address risks.
- We looked at the minutes of team meetings, compliance conference calls and senior leadership team meetings and found there was no discussion relating to the risk register. We were therefore not assured that governance processes were robust in relation to risk within the service.
- The provider employed medical professionals such as the optometrist and ophthalmologists under practising privileges. Practising privileges mean that the provider does not directly employ the medical staff but they have permission to practise there. All medical practitioners working under practising privileges had professional indemnity insurance in their personnel file.
- The provider checked all staff working under practising privileges for suitability and monitored them on an annual basis by the Medical Advisory Board (MAB) to make sure they maintained the correct skills to undertake their role.
- There was a lack of governance around disclosure and barring (DBS) checks for staff working under practising privileges. All staff had a DBS check undertaken at the beginning of their employment, however it is

recommended that periodic rechecks are undertaken at a frequency appropriate for the role, the inspection team did not receive assurances that this was taking place. It was noted that in the personnel records of a member of staff their professional registration had expired 2015, when we raised this concern with the registered manager the staff member was able to demonstrate that their registration was current by accessing the professional register. The registered manager was unaware whose responsibility it was to ensure members of staff professional registration was current.

- The compliance manager visited the clinic regularly and conducted environmental compliance audits.

Public and staff engagement

- The service had a website where patients could obtain information about the types of treatment available for patients. This included information about costs and finance. It also outlined the suitability criteria, and explained the laser eye surgery. The website also included information regarding a free consultation and lifetime after care as needed.
- The provider sought patient feedback following their treatments. The feedback viewed was positive with patients recommending the service and describing positive results.
- The registered manager told us the service did not undertake staff surveys. As a small team, staff told us they had on going communication and felt well engaged within their team.

Innovations improvement and sustainability

- Plans for the clinic included relocating all clinical services to the ground floor with training and human resource services transferred to the first floor. The registered manager told us that this was to improve the patient's journey and have all clinical services in one place.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should ensure that the modified surgical checklist is audited separately and not as part of the quarterly medical records audit.
- The provider should ensure audit processes are robust and identify the key areas of improvement with the clinic environment.
- The provider should ensure that identified risks are properly assessed, consistently monitored and reflected in the service's risk register.
- The provider should review how assurance is sought in regards to DBS checks and professional registration.
- The provider should ensure patient information leaflets are available for patients whose first language is not English.
- The provider should ensure staff receive adequate Mental Capacity Act training.
- The provider should display its vision and values where as many people as possible are able to see them.