Optimax Laser Eye Clinics – Newton Abbot

Quality Report

34-42 Queen Street
Newton Abbot
Devon
TQ12 2EH
Tel: 01626 356744
Website: www.optimax.co.uk

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

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

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

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

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optimax Laser Eye Clinics – Newton Abbot provides laser eye surgery for adults who pay privately for their care and treatment. No NHS funded work was completed at this clinic. Optimax Laser Eye Clinic Newton Abbot (hereafter known as 'the clinic') was operated by Optimax Clinics Limited (hereafter known as 'Optimax'). The service provides refractive eye surgery and intraocular lens surgery for day case adult patients. There are no inpatient facilities. All surgery is carried out using topical anaesthesia. Refractive lens surgery is undertaken on one day per month, intraocular lens replacement surgery is carried out on two days per month. All patient activity is part of the surgery pathway.

Several elements of the pathway occur prior to the day of surgery including initial measurements and topography scans with the patient advisor, optometrist assessment, patient advisor consultation to explain fees and terms/conditions, and surgeon assessment. On the day of surgery the patients are seen by the surgeon for a pre-surgery review and for a post-operative check, the nurse for a pre-operative assessment and medication talk. One to two days after the surgery, patients are seen by the optometrist or the surgeon for a review, and then the optometrist reviews the patient at intervals of one to three months until the episode of care is completed, usually approximately six months post-surgery.

Patients are seen for initial consultation without the requirement of a referral from a healthcare professional. Patients are accepted for surgery if they meet admissions criteria and if the optometrist and surgeon agree that surgery is a viable treatment option. During January to December 2016, there were a total of 1847 patient activities including 279 pre-surgery consultations, 476 eye surgical procedures and 1092 aftercare appointments.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 11 and 12 August 2017 along with an unannounced visit to the hospital on 16 August 2017.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to patient's needs, and well-led? Throughout the inspection, we took account of what patients told us and how the provider understood and complied with the Mental Capacity Act 2005.

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

We found the following areas of good practice:

- Openness and transparency about safety was encouraged. Staff understood and fulfilled their responsibilities to raise concerns and to report incidents and near misses. Lessons were learned and communicated widely to support improvement in other areas as well as services directly affected.
- There were clearly defined and embedded systems to prevent and protect patients from a healthcare associated infection. There had been no incidences of infection during the twelve months preceding our inspection.
- Prior to surgery, risks to patients were assessed and managed. Staff used clear admission criteria to ensure that patients were suitable for surgery and patients underwent a thorough assessment process prior to the decision to treat. There were reliable systems to ensure that laser equipment was set and gauged effectively. The laser controlled area had been risk assessed, risks were clearly defined and protocols for the use of laser equipment were available and accessible to staff.
- Staffing and skill mix were planned and implemented to keep patients safe at all times. Any staff shortages were responded to quickly and adequately. There were adequate numbers of suitably trained staff to operate laser equipment safely. Staff had adequate awareness of laser protection protocols. Staff employed at the clinic were supported to meet their competencies and received a yearly appraisal.
- Patients care and treatment was planned and delivered in line with current evidence based guidance. This included thorough pre-operative assessment and attentive care post-surgery. The medical advisory board set standards and protocols in line with national guidance and staff at the clinic followed these.

Summary of findings

- Information about patient's treatment outcomes was routinely collected and monitored via a patient satisfaction survey and a yearly audit of individual surgeon outcomes. Post-surgery complications were monitored closely and investigated. Learning was shared at the location and across the company.
- Staff could access the information they needed to assess, plan and deliver care to patients. All recorded patient information was available to staff during the patient journey. Records were stored securely. However, important sections of the pre-surgery assessment record were not always completed by the attending surgeon.
- Consent to care and treatment was obtained in line with legislation and guidance. Staff ensured that patients gave consent that was fully informed at every stage of their treatment journey.
- Feedback from patients was positive about the way staff cared for them. Staff spent time talking to patients. Staff built effective relationships with patients. Patients told us they felt comfortable and safe with staff. Surgeons spoke in a reassuring way to patients throughout the duration of their surgery as recommended in the Royal College of Ophthalmology professional standards for refractive surgery.
- Patients were involved and encouraged to be partners in their care. Staff took time to explain the expected outcomes and limitations of surgery in a way that patients understood. There was a culture of honesty regarding costs of treatment
- The premises and facilities met the needs of the service being delivered. There was flexibility within the company to offer patients a choice of location and dates and times of appointments. Waiting times, delays and cancellations were minimal and were managed. Patients were kept informed of any disruption to their care or treatment. The service was responsive to feedback from patients and informal complaints were resolved promptly.
- The registered manager was visible and approachable for staff and for patients. The manager modelled and encouraged cooperative supportive relationships amongst staff so they felt respected and valued.
- The leadership was knowledgeable about quality issues and priorities. Quality was discussed at local and corporate level. Staff felt able to raise concerns and these concerns were taken seriously. Audit processes functioned well and had a positive impact in relation to quality governance with evidence of action to resolve concerns. Risks were investigated and mitigated.

We found the following issues that the service provider needs to improve:

- The duty of candour had not been fully embedded within the processes of the organisation. At the time of our inspection staff did not receive training in the duty of candour and staff did not demonstrate a working knowledge of this regulation. However the registered manager was supported by a central compliance team that assisted with all investigations of incidents and there had been no requirement to employ the duty of candour at this location. Shortly after our inspection duty of candour training was arranged for key staff.
- Systems, processes and standard operating procedures for dispensing of medicines were not reliable to keep patients safe. Nursing staff and patient advisors were dispensing medicines and they were not trained for this extension to their role. Dispensing labels did not include specific warning notices or storage instructions. Shortly after our inspection, a new policy for the dispensing of medicines was introduced and dispensing labels were changed to include necessary warnings and instructions.
- Registered managers monitored the mandatory training compliance of staff on practising privileges. However, this system was not robust. We checked the staff files of staff engaged via practising privileges and found that half of these did not contain evidence of mandatory training completed. At the time of our inspection, two permanent staff members had not completed the safeguarding adults and children course.
- During surgery, some sections and processes of the National Patient Safety Agency Surgical Safety checklist for cataract surgery adapted from the World Health Organisation Safer Surgery checklist were omitted and the checklist was not completed according to guidelines published by the Royal College of Ophthalmology. Following our inspection a safety pause protocol and checklist was introduced.
- Staff told us they felt involved in decisions, however this engagement was not formalised. There had been no staff survey and team meetings were not recorded.

Summary of findings

- The processes in place to identify and monitor current risks were not comprehensive. The processes of assurance around risk were not documented in a complete risk register.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with three requirement notice(s) that affected Optimax Laser Eye Clinic – Newton Abbot. Details are at the end of the report.

Professor Edward Baker
Chief Inspector of Hospitals

Overall summary

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

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Summary of this inspection

Background to Optimax Laser Eye Clinics – Newton Abbot

Optimax Laser Eye Clinics – Newton Abbot (hereafter known as 'the clinic') is operated by Optimax Clinics Limited. The hospital/service opened in 2011. It is a private clinic in Newton Abbot, Devon. The clinic primarily serves the communities of the South West. It also accepts patient referrals from outside this area.

The clinic provides laser eye surgery for adults who pay privately for their care and treatment. No NHS funded work was completed at this clinic.The service provides refractive eye surgery and intraocular lens surgery for day case adult patients. There are no overnight facilities. All surgery is carried out using topical anaesthesia. Refractive lens surgery is undertaken on one day per month, intraocular lens replacement surgery is carried out on two days per month. All patient activity is part of the surgery pathway and is carried out at the clinic premises.

The registered manager was in post since November 2011. The service was inspected previously on two occasions, in November 2012 and in April 2014. At the most recent previous inspection in April 2014, the service was found to have met the standards inspected. These included: respecting and involving people who use the service; care and welfare of people who use the service; cleanliness and infection control; safety, availability and suitability of equipment; requirements relating to workers.

Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Catherine Campbell, Inspection Manager and Mary Cridge, Head of Hospital Inspection.

Information about Optimax Laser Eye Clinics – Newton Abbot

Optimax Laser Eye Clinic Newton Abbot is part of the Optimax Clinics Limited Company which specialises in private laser eye and lens replacement surgery with nationwide facilities. The clinic opened in 2011. Patients are aged 18 and over. The regulated activities at this location are diagnostic and screening procedures; and treatment of disease, disorder or injury and surgical procedures.

In the 12 months preceding our inspection, there had been no refractive eye surgery performed on patients less than 21 years of age. There had been one patient aged 21. The total number of surgical procedures carried out during the period June 2016 to May 2017 was 275. No patients stayed overnight at the facility.

During the inspection, we visited the clinic. We spoke with ten staff including; registered nurses, patient advisors, medical staff, the registered manager and the compliance manager. We spoke with four patients and two relatives. We also received two 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed four sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service has previously been inspected two times, and the most recent inspection took place in April 2014 which found that the service was meeting all standards of quality and safety it was inspected against.

During January to December 2016, there were a total of 1847 patient activities including 279 pre-surgery consultations, 476 surgical procedures and 1092 aftercare appointments.

Summary of this inspection

There were no never events or serious incidents reported in the12 months preceding our inspection. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers.

There were no incidences of hospital acquired infection such as methicillin-resistant Staphylococcus aureus (MRSA), methicillin-sensitive Staphylococcus aureus (MSSA), Escherichia-coli (E-coli) or Clostridium difficile (c.diff) in the 12 months prior to the inspection.

In the12 months preceding our inspection, there were two complaints, both of which had been investigated at the time of inspection.

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 found that

- The systems to ensure the safe dispensing of medicines were not adequate. Nursing staff and unregistered patient advisors were dispensing medicines. Nurses and patient advisors did not have specific competency based training to dispense medicines and their competencies in this task were not evaluated or monitored. The medicines management policy did not include sufficient detail regarding the dispensing of medicines. Dispensing labels did not include specific warning notices or storage instructions. Following our inspection the policy and labels were changed to include necessary details.
- Registered managers monitored staff compliance with mandatory training. However this system was not robust as 50% of staff files we checked did not contain evidence of mandatory training completed by staff employed via practising privileges. At the time of our inspection, two permanent staff had not completed safeguarding adults and children training.
- During surgery, some sections and processes of the National Patient Safety Agency Surgical Safety Checklist for Cataract Surgery adapted from the World Health Organisation Safer Surgery checklist were omitted and the checklist was not completed following guidelines published by the World Health Organisation. Following our inspection a safety pause protocol and checklist was introduced.
- Patient records were available to clinicians and stored securely, however important sections of the patient pre-surgery assessment record were not always completed by the attending surgeon.

However,

- There were clearly defined and embedded systems to prevent and protect patients from a healthcare associated infection. There had been no incidences of infection during the twelve months preceding our inspection.
- Staff understood how to report incidents and safeguarding concerns. Lessons from incidents were learned and communicated widely to support improvement.
- There were clearly defined and embedded systems to ensure that laser equipment was calibrated effectively. The laser

Summary of this inspection

controlled area had been risk assessed, risks were clearly defined and local rules were available and accessible to staff. There were adequate numbers of suitably trained staff to operate laser equipment safely.
- There were reliable systems to ensure that patients were suitable for surgery. There were clear admission criteria. Patients underwent a thorough assessment process prior to the decision to treat. Patients received comprehensive care after their surgery.

Are services effective?

We found that

- Clinicians planned and delivered evidence based care. The medical advisory board set standards and protocols in line with national guidance.
- Patients received thorough pre-operative assessment and care. Post-surgery complications were monitored closely and investigated.
- Staff followed evidence based protocols for treatment. Treatment outcomes were carefully monitored via a patient satisfaction survey and a yearly audit of individual surgeon outcomes.
- Staff had adequate awareness of laser protection protocols. Staff employed at the clinic were supported to meet their competencies and received a yearly appraisal. However, this assurance regarding the competency of staff was not extended to those staff dispensing medicines.
- Staff processes for seeking patient consent were followed in line with best practice and legislation. Staff ensured that patients gave consent that was fully informed at every stage of their treatment journey. Staff could access all recorded patient information at every stage of the patient journey

Are services caring?

We found that

- Feedback from patients was positive about the way staff cared for them. Staff spent time talking to patients. Staff built effective relationships with patients. Patients told us they felt comfortable and safe with staff. Surgeons spoke in a reassuring way to patients throughout the duration of their surgery as recommended in the Royal College of Ophthalmology professional standards for refractive surgery.

Summary of this inspection

- Patients were involved and encouraged to be partners in their care. Staff took time to explain the expected outcomes and limitations of surgery in a way that patients understood. There was a culture of honesty regarding costs of treatment.

Are services responsive?

We found that

- The premises and facilities met the needs of the service being delivered. There was flexibility within the company to offer patients a choice of location and dates and times of appointments. Waiting times, delays and cancellations were minimal and were managed.
- Patients were kept informed of any disruption to their care or treatment. The service was responsive to feedback from patients and informal complaints were resolved promptly.

Are services well-led?

We found that

- The leadership was knowledgeable about quality issues and priorities. Quality was discussed at local and corporate level. Staff felt able to raise concerns and these concerns were taken seriously. Audit processes functioned well and had a positive impact in relation to quality governance with evidence of action to resolve concerns. Risks were investigated and mitigated.
- The registered manager was visible and approachable for staff and for patients. The manager modelled and encouraged cooperative supportive relationships amongst staff so they felt respected and valued.

However

- The processes in place to identify and monitor current risks were not comprehensive. Not all risks had been identified and mitigated. The processes of assurance around risk were not documented in a complete risk register.
- Staff told us they felt involved in decisions, but this engagement was not formalised. There had been no staff survey and team meetings were not recorded.
- The processes in place to identify and monitor current risks were not comprehensive. The processes of assurance around risk were not documented in a complete risk register.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

Incidents and safety monitoring

- The service monitored safety performance in terms of the competency of its staff, the incident reporting system, adherence to infection control policies, rates of infection post –surgery, maintenance and calibration of equipment and the safe requisition and stock control of medicines. The team used the incident reporting system and regular audits to highlight risks to safety in the service. There had been no incidences of infection during the 12 months preceding our inspection. There had been no serious incidents during the 12 months preceding our inspection.
- Staff understood their responsibilities to raise concerns and knew how to record safety incidents. Staff told us they were actively encouraged to complete incident reports. During January to December 2016, the team had reported 18 incidents that were all categorised as low harm. Managers looked for trends within incident reports. There had been two incidents where surgeon intervention had been incorrectly documented. The surgeon was informed of these mistakes and the procedure was changed to ensure that staff checked patients' notes prior to surgeons leaving the clinic to ensure the records were correct and complete. An annual incident report audit was conducted by an independent safety consultant; this report was fed back to the clinics for review and learning. This report did not highlight specific learning for the Newton Abbot clinic.
- When things went wrong, investigations were carried out and lessons were learned and shared beyond the affected team. For example, a patient had stumbled when standing up from a wheeled chair within the clinic. This had resulted in a change to the method staff used to assist patients.
- 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) ofcertain 'notifiable safety incidents'andprovide reasonable support to that person. The duty of candour had not been fully embedded within the processes of the organisation and staff did not demonstrate adequate understanding of this regulation. Staff did not complete any training in relation to duty of candour. However, an in-house online course was due to be launched in September 2017.

Mandatory Training

- Staff employed at the clinic were offered mandatory training in systems and practices designed to keep patients safe. This training included a range of topics including introduction to safeguarding adults and children, introduction to equality and diversity, data protection, infection control, medicines, manual handling, automated external defibrillator and basic life support, first aid, fire safety, violence and aggression, display screen equipment, hazardous substances, slips and trips, identifying and managing personal stress, health and safety, personal health and safety.
- In addition staff completed mandatory training specific to their role. All staff completed the laser core of knowledge training day. The registered manger completed learning on child protection and fire risk assessment training.
- At the time of our inspection, staff were up to date with the mandatory training in most subjects. However, whilst allowing for one member of staff on maternity leave, the compliance rate for completion of some important training was low, including introduction to safeguarding adults and children (50%), introduction to child protection (50%), disability and discrimination awareness (50%).

- The mandatory training compliance of staff engaged via practising privileges was not effectively monitored.These staff completed training at their NHS trust and supplied evidence of the completion of this training. We were told that all staff working under practising privileges were up to date with mandatory training requirements. However, on the day of our inspection, records of mandatory training were not evident in two of the staff files we checked.

Safeguarding

- All staff we spoke with understood their responsibility to recognise and report safeguarding concerns. The registered manager demonstrated knowledge of local systems for reporting safeguarding concerns and all staff knew where to go for further advice if a safeguarding concern arose.
- No children were treated at the clinic and staff advised patients not to bring children to the clinic. There were two staff trained in safeguarding children level one and two these included the registered manager and a trained nurse.
- Staff were offered training in introduction to safeguarding adults and children. However, at the time of our inspection, two permanent members of staff had not completed this training.

Cleanliness, infection control and hygiene

- Reliable systems were in place to prevent and protect patients from a healthcare-associated infection. Standards of cleanliness in the laser treatment room/ were ensured. Cleaning schedules were in place that reflected the standards and guidance from the Royal College of Ophthalmology. The operating theatre and treatment areas were thoroughly cleaned at the beginning of each day of surgery and then deep cleaned once per week. Cleaning was undertaken by the staff employed at the clinic. Checklists were completed to evidence that cleaning was completed regularly and consistently.
- Intraocular refractive surgery was completed within a standard ophthalmic operating theatre environment. Laser refractive surgery was performed in a minimal access intervention operating environment with a log of temperature and humidity conditions. Temperature and humidity conditions were maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used.
- There were systems in place to ensure that staff could identify sepsis and take timely action when required. Surgeons and optometrists were trained to recognise early signs of infection. If this occurred, optometrists instigated emergency post-operative care at the initial aftercare appointment which was between 24 and 48 hours after surgery.
- Optimax deemed that pre-surgery screens for methicillin-resistant staphylococcus aureus (MRSA) or other communicable infections were not required as universal precautions were used during all procedures.
- There were systems in place to ensure that the equipment used in patient treatment was clean. There was a service level agreement with a nearby acute hospital for the sterilisation of non-disposable equipment used within intraocular lens implant surgery. All other instruments used within the theatre were single patient use.

Environment and equipment

- All surgical equipment could be traced. Theatre staff attached unique identification stickers from every surgical instrument to the patient record and also wrote the numbers in ink in case the stickers became dislodged. This included details of the lens implants used.
- There were systems in place to ensure that surgery was performed using calibrated laser equipment. The service used two different types of laser and these were calibrated according to the manufacturer's recommendations.
- Where calibration data was out of normal range, there were safe systems to ensure that surgery did not proceed. As staff inputted calibration data, the information technology department of the corporate office monitored the data and immediately contacted the theatre room directly. If equipment did not calibrate satisfactorily, engineers were informed and surgery did not proceed. Patients were offered surgery at alternative clinic locations or alternative surgery dates.
- The theatre environment was temperature and humidity controlled. When staff inputted recordings of this data the electronic system provided an alert if humidity increased above 60% or was significantly different to the previous reading. Staff were able to alter the air conditioning and calibrate the machines more frequently if any concerns arose.

- Not all surgical equipment had been serviced and checked for electrical safety within the twelve months preceding our inspection. At the time of our inspection, the last service for the microscope used for the intraocular lens surgery was not recorded and the portable appliance test was overdue for completion in June 2017. This was brought to the attention of the manager who promptly arranged for it to be serviced and electrical safety tested on 22 August 2017.
- The laser protection advisor completed a detailed risk assessment of the laser controlled area in November 2015. This was reviewed every three years or when any changes to equipment or the environment occurred. All actions from the previous assessment had been actioned. Staff had signed to confirm they had read this document.
- Local rules for laser protection were in place. Staff knew where to find these and were cognisant with the safety precautions contained within the local rules. There was a stand-alone policy for optical radiation safety available to staff on the intranet. The laser protection supervisor tried whenever possible to be present on site during treatment days. When this was not possible a laser protection supervisor from another clinic attended the clinic. The laser controlled area was clearly defined. Illuminated warning notices were clearly visible. There was a key pad securing entrance to the laser treatment room.
- There were safe systems for the disposal of all waste including disposal of cytotoxic waste.

Medicines

- Medicines were stored securely. However, the service could not be assured that medicines had been stored in accordance with manufacturer's instructions. Staff did not record minimum and maximum temperatures of the medicines cupboards in the operating theatre. The temperatures of medicines fridges were checked daily for minimum and maximum temperatures reached. These had been recorded as reaching as high as 11 degrees Celsius. The fridge had not been reported as faulty and staff were unclear as to what action they would take if fridges recorded high maximum temperatures. In addition, patients were not advised of storage instructions for medicines prescribed for them to take home. Following our inspection a new protocol for cleaning the fridge was introduced to reduce variation in fridge temperature recordings.
- There were systems for the safe use of medicines by optometrists. Optometrists did not prescribe any medicines but if a patient presented with diffuse lamellar keratitis (DLK), a sterile inflammation of the cornea which may occur after refractive surgery, they could amend medicines already prescribed following set protocol for diffuse lamellar keratitis management. Optometrists administered some medicines in order to complete their examinations and to remove the contact lens bandage following surgery. As all registered optometrists may use diagnostic agents or topical anaesthetics, a patient group directive (PGD) was not required.
- There was a corporate policy for the ordering, receipt, storage disposal and administration of medicines; for the safe use of cytotoxic drugs, and for the signing in and out of medicine cabinet keys. These policies served as guidelines for staff to follow. No controlled drugs were stored or administered as part of the service provided. The service did not use sedation.
- The systems for dispensing of medicines were not adequate to ensure patient safety. The medicines policy referred briefly to dispensing responsibilities but lacked the detail required to guide practitioners in their dispensing duties or to guide managers in their responsibilities to train staff in this extended role. Current practice did not reflect the policy and the policy had not been audited to gauge compliance.
- The policy stated that the prescribing doctor was responsible for the dispensing of the medicines. At the time of our inspection, medicines were dispensed by either the nurse or the patient advisor. Although some training was undertaken for these duties, the registered manager acknowledged this was not sufficient to provide assurance of clinical based competency required for this extension of the nursing role.
- The printed medicine label attached to prescription only medicines did not contain warning messages as detailed in the current edition of the British National Formulary and did not identify specific storage requirements. All patients were given written medication instructions that were specific to each surgeon and the particular surgical procedure, but this also did not contain the specific warning messages or storage requirements.

Records

- Records were stored securely. Electronic records were password protected. Paper records were stored in locked filing cabinets in a non-patient area of the clinic. We saw that no paper records were left unattended at the time of our inspection.
- Records were maintained each time a laser was operated. We saw that staff inputted a contemporaneous record of laser operations for every patient.
- Audits of the patient electronic record were completed every three months. A high level of compliance was achieved on the most recent audit. Any learning from the audit was shared at the team meeting, for example staff were reminded to complete the data protection consent form. Learning was also shared with the wider Optimax team, for example the manager emailed other clinics to suggest that blood pressure measurements be recorded on the health assessment questionnaire.
- Patients undergoing intraocular lens replacement surgery followed a pathway that was recorded on paper format on the day of treatment. This should have included the surgeon's assessment of the patient's biometry which indicated the reasons for the choice of implant and the surgeon decision as to which eye should be treated first. We looked at the records of eight patients who had undergone intraocular lens surgery. In four of these records, the surgeon's biometric assessment of the patient had not been recorded by the surgeon.

Assessing and responding to patient risk

- Prior to the decision to treat, clinicians used the patient admission criteria to ensure that only patients well enough to undergo surgery were accepted for refractive eye surgery and intraocular lens implant surgery. These criteria included refractive parameters, the thickness of the eye cornea, the curvature of the anterior surface of the cornea, particularly for assessing the extent and axis of astigmatism, contraindicated medications such as warfarin, contraindicated ocular conditions such as previous retinal detachment, systemic contraindications such as pregnancy. Patients with high blood pressure were referred to their GP for further treatment before surgery was agreed. Treatment did not proceed if patients were not able to give informed consent to treatment.
- On the day of surgery, pre-operative assessments completed by the nurse and the surgeon ensured that patients were still suited to the surgery previously selected. These checks included blood pressure and pulse, general health, biometry, a check to make sure the patient had conformed to the pre-operative regime, for example practising wearing one contact lens for those patients undergoing surgery on one eye only, and confirmation of the type and location of surgery to be completed. The surgeon also reviewed the risks associated with the surgery and reminded the patient of the aftercare regime.
- There was an increased risk of error during intraocular lens implant surgery because the theatre staff team did not thoroughly complete the minimum safety checks recommended by the World Health Organisation (WHO) at the time of the surgery for every patient. This was because the surgical team followed an Optimax 'intraocular lens theatre management day of surgery' protocol for the intraocular lens surgery patients which did not comply with WHO guidelines for use of safer surgery checklists. Shortly after our inspection a new policy was introduced and the protocol was changed to include use of a safety pause checklist.
- When compared to the safer surgery checklist for cataract surgery which is adapted by the Medicines and Healthcare Products Regulatory Agency (MHRA) from the WHO safer surgery checklist, the Optimax protocol did not include all equivalent checks, most notably omitting the 'sign out' check. World Health Organisation guidelines for use of the surgical safety checklist confirm that all sections of the checklist including the 'sign in' before anaesthesia is commenced, the 'time out' before starting surgery, and the 'sign out' before any member of the team leave the operating room must be completed. The protocol did not require staff to read aloud from a standardised checklist. This does not comply with the recommendations from the World Health Organisation which advise that reading from the checklist for every case helps ensure that teams consistently follow critical safety steps and thereby minimize the most common avoidable risks endangering the lives and well-being of surgical patients.
- We observed two intraocular lens implant operations and saw that safety checks were not 'read aloud' from the checklist, the 'time-out' checks were not completed with the undivided attention of all members of the

team and the records of these checks were not completed at the time of the check. A member of nursing staff completed the record at a later point during the patient's surgery.

- For refractive eye surgery, the surgical team completed the verbal checks stated in the Royal College of Ophthalmology standards for refractive eye surgery. However, the team did not record that these checks had occurred.
- There were suitably qualified staff available for the care of patients following surgery. A trained nurse monitored the patient in recovery, the surgeon reviewed the patient prior to them leaving the clinic, the optometrist reviewed patients one to two days after their surgery and then again at regular intervals until discharge. Patients were given the mobile telephone number of the surgeon who could be contacted between 6pm and 8am on the night of treatment.
- Patients were carefully monitored to check for any sign of inflammation, irritation or infection post-surgery. Any patient complications were documented in the electronic records and recorded on an incident form. The treating surgeon was notified the same day. There had been three cases of diffuse lamellar keratitis in the twelve months preceding our inspection.
- During clinic opening times patients were encouraged to call the clinic direct for advice. If necessary patients returned to the clinic for review with either the optometrist or treating surgeon. All patients were supplied with an emergency card for their surgeon, so they could contact the surgeon directly outside of clinic opening times on the evening following the surgery in case of any queries or concerns.
- Staff described how they would recognise a patient who had a deteriorating condition. The protocol was to call for an ambulance. All staff were trained in basic life support and two members of staff per shift were trained in advanced life support. At the time of our inspection, the system for ensuring that resuscitation equipment was in safe working order was not entirely robust. There were two resuscitation trolleys, one on the ground floor and one on the first floor directly outside the operating theatre. Resuscitation trolleys contained an automated external defibrillator, oxygen, emergency treatment for anaphylaxis a resuscitation mask and slide sheets. Staff told us they checked these devices daily, but were only required to record these checks on a weekly basis. When this omission was highlighted to the team during our inspection, it was immediately rectified.
- Staff participated in regular resuscitation drills. At the last resuscitation drill, the team identified that some reception staff did not feel confident taking a lead role if they were first on scene. Action following the drill focussed on improving the confidence of staff to feel empowered to control the scene.

Nursing and medical staffing

- There were adequate numbers of suitably trained staff on duty on treatment days. Staffing numbers and skill mix complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres.
- Staffing included two ophthalmologists employed on a zero hours contract, one optometrist employed on a zero hours contract, two full time patient advisors and one part time patient advisor plus two full time nurses, one of whom was also the registered manager. At the time of our inspection there was one patient advisor on maternity leave and no vacancies. There had been no staff sickness at the Newton Abbot clinic during the three months preceding our inspection.
- There was an effective system for engaging staff at short notice from other Optimax clinics to cover sickness or annual leave. All protocols were standardised throughout the company and staff felt at ease travelling to other sites to assist with surgery in their role. Staff were familiar with the teams in other sites and identified no concerns with this pattern of work. There was also a small 'bank' of staff for each clinic that the registered manager could request to cover surgery days as required.
- The team could access advice from a laser protection advisor via telephone if needed.

Major incident awareness and training

- Laser treatment was not compromised if power failed mid-treatment. There were back up batteries in theatres for the laser equipment and these were checked weekly.
- The team were well equipped and trained to keep patients safe in the event of a fire. Staff participated in fire evacuation drills. An evacuation chair was available

and staff practiced using this equipment during fire drills which occurred every six months. Fire extinguishers had been serviced within the twelve months preceding our inspection
- In the event of clinic closures or the whole business closing, there was a corporate closure strategy, which ensured that patients continued to receive aftercare as required.

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

Evidence-based care and treatment

- Patients had their needs assessed and their care planned and delivered in line with evidence based guidance and standards. There was a medical advisory board, which set standards for all surgeons and optometrists according to National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery and recommendations from the Royal College of Ophthalmology Standards for Laser Refractive Surgery and Royal College of Surgeons' Professional Standards for Cosmetic Surgery. Minutes of these meetings showed that clinical protocols were discussed and amendments to current practices made to be in line with evidence-based practice. For example, members of the committee agreed that it was necessary to see patients for aftercare one day post-surgery. They also discussed the risks associated with treating patients with type-one diabetes.
- Clinical meetings were held twice a year. These were attended by the surgeons, the optometrists, the chief executive, chair of the board and the medical compliance manager. At this forum, information from the medical advisory board was shared such as changes to protocols or the introduction of new treatments.
- Technology and equipment were used to enhance the delivery of effective care and treatment. All lasers were equipped with the latest software.
- The service ensured that patients who were requesting laser refractive surgery received thorough pre-operative assessment and thorough discussion of their needs with both the optometrist and the surgeon. This complied with guidance from the General Medical Council and the Royal College of Ophthalmology professional standards.
- There were reliable systems to provide assurance that staff followed protocols for best practice as identified by Optimax policies. The compliance manager completed an audit of the clinic every six months. This focussed on the regulations within the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.The most recent audit preceding our inspection highlighted some areas of non-compliance which were collated on an action plan for the location. For example, ensuring the staff disclosure and barring service checks were evident in staff files.
- The registered manager also completed spot check audits and completed spot-check observations of patient consultations with patient advisors. The team had acted upon the results of internal audits. For example, an audit of the medicines had shown that the clinic held excessive stock of certain medicines. This was discussed amongst the team and future orders were reduced.

Pain relief

- Patients undergoing ophthalmic surgery were treated under local anaesthesia. They were fully conscious and responsive. Staff were able to monitor their pain throughout the procedure. Staff clearly informed patients about the expected level of pain during and after the surgical procedure. Patients told us they did not feel pain during their procedure and they felt informed regarding the best way to manage any post-operative pain.

Nutrition and hydration

- Water and hot drinks were available for patients in the waiting room. Patients were given a hot drink and biscuit following their surgery.

Patient outcomes

- The treatment outcomes for the surgeons who worked at the Newton Abbot clinic were within the expected range. Treatment outcomes were monitored against the Optimax standard. The target for patient outcomes was to reach driving standard or better on discharge. Treatment outcomes were measured in terms of the surgeon's success rate and the patient satisfaction with their treatment journey. The treatment outcomes for all

surgeons working for Optimax were monitored. This data was used to conduct a yearly audit of the individual surgeon's outcomes which was made available to the registered manager.

- Optimax provided a touch screen system for all patients to complete a patient satisfaction survey at each aftercare appointment to the point of discharge. This survey comprised of twenty questions and enabled the company to evaluate individual clinic and overall company performance of patient satisfaction throughout the patient journey. If required, these results could be analysed on a day by day basis.
- There were reliable systems to ensure that complications following surgery were investigated and any trends monitored. If the optometrist identified any complications at the aftercare appointment, they assessed the patient thoroughly and booked them for a surgeon review. The Optimax electronic dashboard system automatically alerted the compliance team who investigated if the complications were abnormal and the reasons for their occurrence. Incidences of diffuse lamellar keratitis were monitored and grade one and above were monitored by the compliance team.
- During the 12 months preceding our inspection, two patients had unexpectedly been required to return to the clinic for further surgery. These patients had undergone toric lens implant surgery and required follow up surgery in order for the lens to be repositioned to address the degree of remaining astigmatism that had not been fully resolved during the initial surgery.

Competent staff

- Staff had the right qualifications, skills, knowledge and experience to do their job. Surgeons held the Royal College of Ophthalmology certificate in laser refractive surgery. Both surgeons also worked for the NHS in acute hospitals. All staff were trained in basic life support and two members of staff per shift were trained in advanced life support.
- There were reliable systems to ensure that staff had up to date knowledge of laser protection. At the time of our inspection, all staff apart from one patient advisor had attended the core of knowledge one day training course. The remaining member of staff was due to complete this within two months. Staff attended refreshers of this training every two years. Staff were invited to a laser protection study day every year. The laser protection supervisor (LPS) was the clinic registered manager. A laser protection supervisor was always present on treatment day. There was a corporate laser protection lead nurse available for advice. All staff read and signed the local laser rules and risk assessment prior to working in the laser controlled area.
- Patient advisors participated in induction training and completed competency training and assessments during their probationary period. More experienced members of staff acted as mentors for new staff. Staff competencies were reviewed on an adhoc basis by the registered manager.
- There was not adequate assurance regarding the competency of staff that were dispensing medicines. Nurses and patient advisors did not have specific training to dispense medicines and their competency in this task was not evaluated or monitored.
- There were arrangements for supporting staff employed by the clinic. All nursing staff and patient advisors participated in one to one supervision with the registered manager every two months. This provided an opportunity for reflect upon their practice. Managers used a range of strategies to support staff returning to work following a period of absence. Staff were given extra support to meet their required competencies.
- Nurses were invited to attend a study day once per year. Qualified nurses had received additional development opportunities such as attendance at the national aseptic non-touch technique conference, and completion of a module for adverse drug reactions
- Surgeons and optometrists working at Optimax were granted practising privileges by the medical advisory board that included surgeons, head optometrist and managers. Staff working under practising privileges signed a formal agreement that placed responsibility on them to provide the registered manager with evidence of their competence and scope of practise.
- All staff employed at the clinic had completed an appraisal in the 12 months preceding our inspection. However, not all staff working under practising privileges had evidence of a current appraisal in their staff file.

Multidisciplinary working

- Multidisciplinary working outside of the team was limited and dependent upon patient choice. Patients chose whether to give permission for the team to share

information with their GP. Following surgery all patients were given a letter to take to their GP detailing the procedure they had undergone and post-operative medication.

- Staff within the team worked together for the benefit of the patient. During our inspection the optometrist and the surgeon consulted one another regarding the presentation of a patient who had returned for follow up post-surgery. In theatre, we saw that surgeons and nurses communicated effectively and worked seamlessly as a team, providing constant reassurance to the patients throughout procedures.

Access to Information

- All patient information was accessible to the relevant staff. Each patient had an electronic patient record which could be accessed at any clinic location via a bespoke computer system. There were also paper copies of patient information. For example, information from the electronic record such as the health assessment questionnaire was printed off and handed to optometrists for ease of reference during their consultation. Printed consent forms were signed on paper by patients and then scanned onto the electronic record. On the day of surgery, a paper record of the patients journey followed the patient though the clinic and was later scanned into their electronic record.
- Patients were given clear verbal and written instructions regarding necessary precautions before and after surgery. Surgeons gave clear predictions to patients regarding what vision they would be likely to achieve following their surgery and explained how long they would need to wait before their vision would reach this level.

Consent and the Mental Capacity Act 2005

- The service ensured that patients gave informed consent before they underwent treatment. Staff gave detailed verbal and written information about all risks, benefits, realistic outcomes and costs of treatments. Consent was checked at all stages of the assessment and treatment process. Patients were offered a range of alternative options. Potential patients were given a 'cooling off' period of at least one week between agreeing to go ahead with the procedure and surgery being performed. There were no time limited deals offered.
- All staff were clear that patients would only be accepted if they were able to fully consent to the procedure. This was checked by the patient advisor, the optometrist, and the surgeon at different stages prior to surgery. The clinic had never treated any patient who was subject to the Mental Health Act 2005 and did not treat any person who was unable to give informed consent for a procedure. Best interest decisions were not made because the surgery was elective and required patients to be fully compliant during the surgery and with precautions during the post-operative period.
- Mitomycin-C is a medicine that is used in refractive eye surgery although it is not licensed for this purpose. The printed consent form clearly explained the risks of using this medicine in refractive eye surgery.

Are refractive eye surgery caring?

Compassionate Care

- Staff took time to interact with patients in a respectful, considerate and therapeutic manner. Surgeons maintained a reassuring dialogue with patients during surgery, talking to patients and explaining when they were likely to experience sensations such as pressure in the eye, a burning smell or fluid running over the eye. This complied with the Royal College of Ophthalmology professional standards for refractive surgery.
- Staff respected the identity and dignity of patients. All staff at every stage of the treatment journey introduced themselves to the patient. Staff used eye contact when speaking to patients and shook their hands in greeting. Patients wore their own clothes throughout their treatment.
- Staff supported patients to understand relevant treatment options including benefits, risks and potential consequences. 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, patients were given transparent and accurate information about all costs of potential treatment.

Understanding and involvement of patients and those close to them

- Patients were seen as partners in the treatment plan. We observed consultations and saw that surgeons and optometrists engaged with patients and involved them in decisions regarding their care. Clinicians gave thorough explanations and encouraged patients to ask questions.
- Patients were empowered and supported to manage their own health. Patients were given a choice of clinics to return to for their aftercare, and were given the option of seeing their own optometrist close to home for their annual checks.
- Patients were encouraged to be actively involved in all aspects of their treatment journey. Prior to surgery this included those patients considering monovision surgery having a trial of only wearing one contact lens. During surgery, patients were expected to stay very still. After surgery, patients were made aware of the importance of adhering to the precautions for their type of surgery in order to achieve the best possible outcome for their vision.

Emotional Support

- When patients were anxious, staff were sensitive to their needs for reassurance. Prior to the surgery, carers were invited to attend consultations with patients to help alleviate the anxiety of either party. When patients indicated on the health questionnaire that they felt anxious regarding the surgery, optometrists took time to show them the theatre environment and the equipment used, explaining exactly what would be involved in the procedure. A staff member was allocated to sit with the patient during surgery to hold the patient's hand if the patient requested this.
- Staff got to know patients during the appointments prior to 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 offered flexibility regarding the choice of dates for pre-operative appointment and for surgery. Refractive eye surgery was offered on one day per calendar month, intraocular lens surgery was offered on two days per calendar month. Patients could choose which month but the date was limited to the designated surgery day.
- The team tried wherever possible to provide continuity of care. For example, a patient would be seen by the same surgeon, the same optometrist and the same patient advisor throughout their patient journey.
- Where patient's needs were not being met, the company identified and used this to plan and develop new services. At the time of our inspection, a new clinic was preparing to open in Cardiff, which would meet the needs of patients in Wales who were required to travel to the Newton Abbot site for treatment.
- The facilities and premises met the needs of the service that was delivered. Waiting areas and treatment rooms were spacious and well maintained. The clinic was easily accessible from the town centre.
- The surgeon checked the patient's eyes before they left the clinic on the day of their surgery. The surgeon delegated the first post-operative review appointment to the optometrist. Optometrists followed protocols to ensure this review met standards set by the Royal College of Ophthalmology.

Access and flow

- Patients followed a surgical pathway. At their initial consultation, patients were seen by a patient advisor and an optometrist. The patient advisor performed topography and biometry scans. The optometrist examined the patient's eyes and assessed their vision and determined what surgical procedure to recommend to the patient, pending surgeon's approval. The patient advisor then talked to the patient about the costs of the recommended treatment and finance options and also explained what to expect during and after surgery. At this stage, patients were given a consent form to take away and read. At the next appointment, the patients saw the surgeon during a face to face consultation. At this appointment, the surgeon confirmed the recommended treatment option and went through the consent process with the patient. The patient advisor booked the patient in for their surgery. The next

appointment was the day of treatment. Patients were then seen by the optometrist one or two days following surgery for a review. Repeat aftercare appointments were then determined by the optometrist.

- Care and treatment was cancelled only when absolutely necessary and when this did occur, care was taken to maintain continuity of care. Where possible, patients were offered treatment at a different location on the same day. For example, if the laser machines did not calibrate effectively, the whole team moved to an alternative Optimax clinic and patients were offered their surgery at the alternative location. There had been two cancellations of surgery for non-clinical reasons during the 12 months preceding our inspection.
- The team took action to minimise the time that patients spent in clinic on their day of treatment. Patient arrival times were staggered to coincide with their allotted surgery time. This meant there was less time spent waiting in the clinic. During our inspection, clinics ran on time. Patients were informed prior to their surgery date that they may be in the clinic for up to four hours.
- As far as possible, the service offered appointments to patients to suit their needs. If the surgery dates at the Newton Abbot clinic were not convenient, dates at other clinics nationwide could be offered if the patient was prepared to travel.
- The service was responsive to the needs of patients beyond the immediate post-surgical period. Patients were offered follow up care as part of the original cost of treatment, until the point of discharge, usually approximately six months after surgery.

Meeting peoples individual needs

- The team considered the individual needs of every patient as a priority. Interpreters could be accessed when required and carers could attend appointments.
- All surgery was planned. Patients with complex needs or multi-pathologies were not accepted for surgery because the service was not equipped to meet their needs.
- Actions were taken to remove barriers for patients who found it hard to access services. For patients who travelled long distances to attend the clinic, appointments were made for later in the day.
- Reasonable adjustments were made so that patients with disabilities could use the service on an equal basis to others. Facilities were arranged on two floors. Ground floor facilities are accessed from the high street via an intercom door release system. There was a disabled toilet on each floor; there was a stair lift to facilitate access to the first floor. A raised toilet seat and sliding board were available for patients with impaired mobility and staff were trained to use these and practised this regularly. Patients were given a choice of clinic locations to meet their accessibility needs.
- Staff were available to assist patients with visual impairment to access the clinic. For patients with hearing impairment, written information was provided for all clients prior to attendance for consultation and during the consultation process, which reinforced all verbal information discussed face to face. A hearing loop was installed and turned on.
- Pre-treatment information included a clear explanation of what to expect during surgery with instructions about how the patient can help the procedure, as recommended in the Royal College of Ophthalmology standards for refractive eye surgery.
- Prior to booking treatment, patients were given an individual patient results forecast which detailed the likeliness of treatment outcomes based on their prescription and their age. This forecast included prospective vision without glasses and the probable refraction remaining after treatment. The forecast included a summary of the doctor's experience in terms of how many treatments they had completed within the six months preceding the patient's consultation and the total number of these procedures completed by the surgeon at the Optimax facility. The forecast included the contact details of a sample of patients who had given permission for other patients to contact them regarding their experience and treatment outcomes.

Learning from complaints and concerns

- Staff asked all patients to complete surveys at each visit in order to gauge their satisfaction with the service they received. The latest annual survey was displayed in the clinic patient's guidebook, for all visitors to see. Certain negative words were triggers on the electronic system that alerted the central compliance team to a patient's dissatisfaction. Managers accessed their ongoing data to enable them to discuss this with their teams during meetings and to take prompt action if required. When patients were not satisfied with the service, for example

if they spent longer than they expected in the clinic on the day of their surgery, the manager addressed this promptly which meant that few progressed to the stage of a formal complaint.

- The team had changed their protocols in response to negative feedback from this survey. For example, several patients had commented that the cost of a certain treatment was not "small" as stated in the consent form. The consent form was amended and clinic staff ensured they verbally informed the patient of this possible added cost for the future.
- Teams learned from complaints and shared this learning with other Optimax teams. For example, a patient had complained because their lens was not ready on the day of this planned surgery. Staff had been notified by email that the lens was not available but the patient's appointment had not been cancelled and rebooked. The investigation of the complaint concluded that emails should not contain multiple threads and this action was discussed and agreed in the national compliance teleconference.
- The service had not made use of all opportunities to explain the formal complaints procedure to patients. The patient guide did not include this information. However, there were suggestions and complaints forms available to patients on the front reception.

Are refractive eye surgery well-led?

Leadership and culture of service

- At location level, the service was led by the registered manager who was responsible for a team of four Optimax employees. Surgeons and optometrists were under 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 Newton Abbot location.
- The registered manager was supported in the governance of the location by the compliance manager and the director of operations at corporate level. All strategic and policy decisions were made at corporate level. The registered manager had the skills, knowledge, experience and integrity to lead the service with support from the central governance team. The manager worked in a clinical capacity as a theatre scrub nurse. The registered manager role included non-clinical hours, which provided capacity to oversee the operational management of the team.
- The registered manager was visible and approachable for staff and patients. We saw that all grades of staff were encouraged to voice their concerns and the registered manager responded positively. Staff told us they felt supported in their roles and valued for the work they did.
- The registered manager was able to give examples of the challenges to providing good quality care at this location. Primarily, challenges were due to patients having unrealistic expectations of their vision following surgery. We saw that all staff understood this challenge and were committed to addressing this by clearly outlining the possible limitations of proposed surgery at all stages of the patient journey.
- All marketing campaigns were directed by the central corporate team. At the Newton Abbot location, there was a culture of honesty regarding costs of treatment and conditions of the service provided. Optometrists and surgeons gave advice to patients regarding their best course of treatment, and this was not influenced by profit to the company. We saw that clinicians advised patients to choose less expensive treatment options when this was indicated. At the initial consultation, patients were provided with written statements detailing the terms and conditions of the service being provided and amount and method of payment of fees.

Vision and strategy

- The strategic vision and forward vision of the service was determined at a corporate level, the registered manager had opportunity to contribute toward this corporate vision via the monthly compliance teleconference and felt comfortable to raise concerns when they felt that the forward vision might compromise patient care. The company did not have a core set of values.

Governance Risk Management and quality measurement

- The monthly compliance teleconference was attended by the compliance manager, the director of operations, the diary team, the lens surgery lead and registered managers of clinics across the country. We checked minutes of these meetings and saw that risks were

discussed and mitigating actions put in place. For example, the compliance team clarified the procedure for responding to Medicines and Healthcare products Regulatory Agency (MHRA) alerts.

- The team identified, investigated and mitigated most risks effectively. Risks were identified as a result of incidents reported or audits completed. All incidents were reviewed and investigated by the registered manager. Similarly, all audits were reviewed by the registered manager in conjunction with the compliance manager. Alerts received from the Medical Device Agency (MDA) or Health and Safety Executive (HSE) were screened as relevant by the compliance manager and cascaded to the service. However, the processes in place to identify and monitor current risks were not comprehensive. We saw on inspection that some risks had not been addressed, such as the low compliance with 'introduction to safeguarding adults and children' training and the lack of assurance around the competencies of staff dispensing medicines.
- Where a risk was identified, the registered manager generated a risk assessment that was approved by the compliance manager. The compliance manager was responsible for ensuring that corporate policies reflected the mitigating actions identified in the risk assessments.
- We saw that this process of risk management worked at a local level. For example, during a routine audit, the registered manager discovered that the temperature of the hot water had been persistently lower then recommended. This meant there was a risk of legionella infection for staff and for patients. The manager reported this as an incident and immediate action was taken to test water safety. The subsequent investigation of that incident discovered there was a fault with the boiler and that staff had not informed the registered manager of the lower than expected recordings. This was discussed with the compliance manager, who completed a risk assessment. The risk assessment drew attention to the requirement to flush the water system at regular intervals. Detailed instructions for staff were included in the legionella policy. The policy was used by staff as operational guidance at location level. Water flushing was undertaken by staff as part of a series of weekly checks. Recordings of these checks were then included in the regular auditing process which ensured continued managerial oversight of this change to protocol.
- There was no centralised document providing oversight of the risks and mitigation processes company-wide. The processes of assurance around risk were not documented in a comprehensive risk register. A risk register had been produced for our inspection, but this did not contain details of mitigating actions or persons responsible for ensuring action plans for mitigation were completed.
- The process to provide assurance that external staff were competent and qualified to fulfil their role was not entirely robust. Not all surgeons and optometrists supplied the relevant documentation to support their practising privileges as identified in the company practising privileges policy. We reviewed the staff files of four staff working under practising privileges. Random omissions were evident such as evidence of mandatory training in one file, evidence of most recent professional registration certificate in one file.

Public and staff engagement

- The service proactively sought and acted upon the views and experiences of patients. A patient satisfaction survey of 205 patients was undertaken from January to December 2016. This concluded an overall patient satisfaction rate of 96.6%. Results of this survey were available to the registered manager to view on an ongoing basis, and a negative response indicating dissatisfaction with the service triggered an alert to the patient compliance team.
- The team communicated well with one another and were engaged in the running of the clinic at a local level. Staff were encouraged to speak up during team meetings that were held every week and leaders understood the value of staff raising concerns regarding the quality of the service provided. For example, staff highlighted that patients frequently expressed disappointment regarding the length of time they spent at the clinic on the day of surgery. This resulted in a change of protocol. During their initial consultation patient advisors warned patients to expect their visit to be between three and six hours on the day of surgery. This initiative was shared company-wide via the compliance teleconference.
- Staff engagement was not formalised. The team meetings were not recorded which meant that actions

completed as a result of staff concerns could not be tracked. At a corporate level, there had been no staff survey undertaken during the12 months preceding our inspection

Innovation,improvement and sustainability

- Leaders responded positively to opportunities for learning. For example, in response to concern raised by the inspection process, the registered manager immediately began discussions with their peers about how to improve the company protocol regarding the dispensing of medicines.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that medicines are managed in a safe way. There must be reliable systems and processes to provide assurance of the clinical based competency required for staff to dispense medicines safely and effectively. The provider must ensure that their policies and procedures for the dispensing of medicines and the training of staff reflect the increased risk associated with staff working outside of the remit of their professional registration. The provider must ensure that risks of error during surgical procedures are minimised as far as possible. Policies and procedures for surgery must reflect the guidelines published by the World Health Organisation in relation to the safe and effective use of the National Patient Safety Agency adapted Surgical Safety Checklist for Cataract Surgery
- The provider must ensure that systems and processes give clear oversight of patient care and treatment. This includes processes of assurance regarding the completion of patient records during the pre-surgery assessment stage, robust protocols for ensuring that the competencies of staff employed via practising privileges are up to date, processes to ensure that staff have completed mandatory training in line with the provider standard and use of a comprehensive risk register or equivalent tool to inform and monitor the management of risk to the service.

Action the provider SHOULD take to improve

- The provider should monitor future compliance with the duty of candour regulation. There should be reliable systems and processes to ensure that the planned introduction of duty of candour training for staff results in the embedding of this learning within everyday practice.
- The provider must ensure that where minimum and maximum medicine fridge temperatures are outside of range, staff are aware of protocols to address the risk to the medicines stored within the fridges.

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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for service users; ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely Medicines were dispensed by nurses and patient advisors (unregistered technicians). This was acknowledged by the registered manager as the standard practise at the clinic. These staff had not undertaken training specific to the role of dispensing medicines. The competency of these staff to undertake the role of dispensing medicines was not assured. The policy and protocols regarding the dispensing of medicines were not sufficiently detailed to provide adequate guidance to the staff dispensing medicines. Regulation 12 (1)(2)(c) Care and treatment must be provided in a safe way for service users; doing all that is reasonably practicable to mitigate any (such) risks For patients undergoing intraocular lens implant surgery, the system of checks used in the operating theatre to minimise the chances of surgeon error were not robust. Staff followed an Optimax protocol which did not reflect the World Health Organisation guidelines for minimising risk to patients who were undergoing intraocular lens implant surgery. In particular the National Patient Safety Agency Surgical Safety Checklist for Cataract Surgery (adapted from the World Health Organisation Surgical Safety Checklist) was not used in its entirety and was not read aloud as guidelines recommend. Regulation 12(1)(2)(b)

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Systems or processes must be established and operated effectively to ensure compliance with the requirements of this part. Systems and processes must enable the registered person to:** • assess monitor and mitigate the risks relating to health, safety and welfare of service users and others • maintain securely an accurate, complete and contemporaneous record in respect of each service user • maintain securely such other records as are necessary to be kept in relation to i)persons employed in the carrying on of the regulated activity ii) the management of the regulated activity **There were gaps in the oversight of patient care and treatment. Not all staff had completed mandatory introductory training in safeguarding adults and children. In four of the eight patient records we checked, there were omissions in the records of surgeon examinations. Team meeting minutes were not recorded. There was a lack of assurance regarding the competencies of staff dispensing medicines. The processes of assurance around risk were not documented in a comprehensive risk register.** Regulation 17(1)(2)(b)(c)(d)