Optimax Laser Eye Clinics - Bristol

Quality Report

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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

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

All patient activity is part of a surgery pathway, several elements of which occur prior to the day of surgery. This includes 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 by the optometrist for a post-operative check. The patient advisor explains to patients about their take home medication and repeats their topography and biometry tests. One to four 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 was completed, approximately six months post-surgery.

Patients self-refer for treatment. 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 April 2016 to March 2017, there were a total of 508 surgical operations, and 1459 aftercare appointments.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 30 November and 01 December 2017. There was no unannounced visit.

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:

- Staff knew how to raise concerns and report incidents. Incidents were investigated and action was taken to mitigate risks identified through incident reporting. Staff understood the key concepts of duty of candour.
- Staff were up to date with most mandatory training. Relevant staff required to complete laser core of knowledge training had done this within the 12 months preceding our inspection.
- Staff followed protocols to prevent and protect patients from health-care associated infections. There had been no infections reported during the 12 months preceding our inspection.
- Protocols for safe use of lasers were consistently followed by staff
- Records were complete and contemporaneous and stored securely.
- Staff followed safe systems for the management of medicines including the use of cytotoxic medicines.
- Patients underwent thorough assessment prior to the surgeon's decision to treat. Patients were carefully monitored post-surgery and had access to expert advice outside of working hours.
- 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.

Summary of findings

- Staff had adequate awareness of laser protection protocols. Staff employed at the clinic were supported to meet their competencies and received a yearly appraisal.
- The processes for seeking patient consent were followed in line with best practice and legislation.
- Patients told us they felt comfortable with staff. Feedback from patients was positive about the way staff cared for them.
- Patients were encouraged to ask questions. 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.
- 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.
- The registered manager understood the challenges to good quality care at this location. The leaders of the service discussed quality at local and corporate level.
- Staff felt able to raise concerns and these concerns were taken seriously.
- Audits were regularly undertaken and action plans were completed. Identified risks were investigated and mitigated.
- The registered manager was visible and approachable for staff and for patients. Staff told us they enjoyed their work and felt valued in their role.

We found the following areas that the provider needed to improve:

- There was a risk of cross infection because some equipment and facilities were not designed to minimise the risk of infection.
- Staff compliance for training in safeguarding adults level two was low at 50%
- The clinic did not contribute data to the Private Healthcare Information Network (PHIN).
- The premises and facilities did not always meet the needs of the service being delivered. Patients were required to ascend and descend stairs immediately post-surgery. The waiting area did not protect the privacy and confidentiality of patients.
- Patients who required sign language or foreign language interpreters were required to pay for this themselves.
- There was no documented strategy for the Bristol location.
- There had been no staff survey in the 12 months preceding our inspection. Team meetings were recorded but did not show a clear and complete record of discussions, outstanding actions from previous meetings were not reviewed.

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 one requirement notice that affected Optimax Laser Eye Clinic –Bristol. Details are at the end of the report.

Amanda Stanford
Deputy Inspector of Hospitals

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

Contents

Optimax Laser Eye Clinics – Bristol

Services we looked at
Refractive eye surgery;

Summary of this inspection

Background to Optimax Laser Eye Clinics - Bristol

Optimax Laser Eye Clinics – Bristol (hereafter known as 'the clinic') was operated by Optimax Clinics Limited. The service opened in 1993 as a private clinic operating in Bristol. The clinic primarily served the communities of the South West. It also accepted patient referrals from outside this area.

The service had been inspected previously in October 2013, the service was found to have met the core standards that were inspected. These included: respecting and involving people who use services; care and welfare of people who use services; consent to care and treatment; assessing and monitoring the quality of the service provision; requirements relating to workers.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a nurse specialist advisor. The inspection team was overseen by Amanda Williams, Inspection Manager and Mary Cridge, Head of Hospital Inspection.

Information about Optimax Laser Eye Clinics - Bristol

Optimax Laser Eye Clinic Bristol 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 1993. Patients are aged18 and over. The regulated activities at this location are diagnostic and screening procedures; and treatment of disease, disorder or injury and surgical procedures.

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 one 'tell us about your care' comment card which a patient had completed prior to our inspection. During our inspection, we reviewed seven sets of patient records.

There were no external reviews, 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 twice; 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 the 12 months preceding our inspection, the team had carried out 508 surgical operations, using laser equipment. No patients stayed overnight at the facility.

There have been no never events or serious incident reported in the preceding 12 months. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers.

There were no incidences of hospital acquired infection such as methicillin-resistant Staphylococcus aureus (MRSA), methicillin-sensitive Staphylococcus aureus (MSSA), the 12 months prior to the inspection.

In the preceding 12 months, there were 13 complaints; all of these 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

- Staff knew how to raise concerns and report incidents. Incidents were investigated and action was taken to mitigate risks identified through incident reporting. Staff understood the key concepts of duty of candour.
- Staff were up to date with most of their mandatory training. Those staff required to complete laser core of knowledge training had done this within the 12 months preceding our inspection.
- Staff followed protocols to prevent and protect patients from health-care associated infections. These included use of hand hygiene, personal protective equipment, cleaning of equipment and facilities. The most recent hand hygiene audit in October 2017 did not highlight any concerns. There had been no infections reported during the 12 months preceding our inspection.
- Protocols for safe use of lasers were consistently followed by staff
- Records were complete and contemporaneous and stored securely.
- Staff followed safe systems for the management of medicines including the use of cytotoxic medicines.
- Patients underwent thorough assessment prior to the surgeon's decision to treat. Patients were carefully monitored post-surgery and had access to expert advice outside of working hours.

However,

- There was a risk of cross infection because some equipment and facilities were not designed to minimise the risk of infection.
- Staff compliance for training in adult safeguarding level two was low at 50%

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.

Summary of this inspection

- 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.
- The 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.

However,

- The clinic did not contribute data to the Private Healthcare Information Network (PHIN).

Are services caring?

We found that

- Patients told us they felt comfortable and safe with staff. Feedback from patients was positive about the way staff cared for them.
- Staff built effective relationships with patients. 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 encouraged to ask questions. 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 did not always meet the needs of the service being delivered. Patients were required to ascend and descend stairs immediately post-surgery.
- The waiting area did not protect the privacy and confidentiality of patients.
- Patient information leaflets were not readily available in large print.
- Patients were required to pay the cost of sign language or foreign language interpreters.

However

Summary of this inspection

- 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.

Are services well-led?

We found that

- The registered manager understood the challenges to good quality care at this location. The leaders of the service discussed quality at local and corporate level.
- Staff felt able to raise concerns and these concerns were taken seriously. Audits were regularly undertaken and action plans were completed. Identified risks were investigated and mitigated.
- The registered manager was visible and approachable for staff and for patients. Staff told us they enjoyed their work and felt valued in their role.

However

- There was no documented strategy for the Bristol location.
- There had been no staff survey. Team meetings were recorded but did not show a clear and complete record of discussions, outstanding actions from previous meetings were not reviewed.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The team used an electronic incident reporting system and regular audits to highlight risks to safety in the service. In total there had been 13 incidents reported. During the reporting period December 2016 to November 2017 there had been no incidences of infection and no serious incidents. Audits identified that staff had followed incident reporting protocols and there had been no significant defects in environment or equipment.
- A never event is a serious incident which is wholly preventable as guidance and safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. There had been no never events at the clinic during the twelve month preceding our inspection.
- Staff understood their responsibilities to raise concerns and knew how to record safety incidents. Of the 13 incidents reported all were investigated and all categorised as low harm. Prompt actions were taken as a result of these investigations and learning was shared amongst the team. One incident related to a patient fainting when leaving the theatre. As a result of this incident, a risk assessment was completed and all staff were reminded to check patients appeared well before asking them to leave the theatre. We saw on our inspection that patients were escorted by staff when leaving the theatre.
- Managers looked for trends within incident reports and found that some of the incidents were related. The team had detected folds in the corneal flap created during surgery in two patients. This was an uncommon but unavoidable complication following laser surgery. This was included in the possible post-operative complications that patients were informed about as part of the consent process.
- Six incidents were related to pigeons outside the clinic causing offensive smells; this was resolved when the pigeons were removed. 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 Bristol clinic.
- When things went wrong, investigations were carried out and lessons were learned. Action was taken to mitigate risks identified through incident reporting. During our inspection, an incident occurred when information regarding a patient's latex allergy had not been communicated to the theatre team. This was reported as an incident by the registered manager and the patient checklist was amended to include a prompt to communicate allergies to the nurse setting up the theatre on the morning of surgery. Following our inspection this incident was discussed during the monthly governance meeting and a latex policy was written.
- Medicines and Healthcare Products Regulatory Agency (MHRA) alerts were checked by the central compliance team and forwarded to the clinic locations as appropriate. There had been no relevant alerts during the twelve months preceding our inspection.
- 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. All staff had completed training regarding this regulation and demonstrated a reasonable

understanding of the key concepts. There had been no incidents that were moderately serious or above during the 12 months preceding our inspection that required this duty of candour to be applied.

Mandatory Training

- Not all staff were up to date with mandatory training in systems and practices designed to keep patients safe. All staff were up to date with 100% compliance in their training for: introduction to safeguarding children, introduction to safeguarding adults, introduction to equality and diversity, data protection, infection control, medicines, 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.
- Staff were not fully compliant in their training for safeguarding children level two, manual handling, and first aid and automated external defibrillator and basic life support which were all at 75% compliance. Training in adult safeguarding level two was 50% compliant.
- Staff who were not compliant included a member of staff who had not worked at the clinic for several months over the summer and had missed opportunities for training completion. The registered manager was aware of the gaps in compliance and was in the process of booking staff members onto available training. The registered nurse, the registered manager, the patient advisor/laser technician, and the two surgeons had all completed additional mandatory training in laser safety. The registered manager also completed fire risk assessment training.
- There was a system for providing assurance that staff engaged via practising privileges had knowledge of safe systems and processes. We checked the staff records of two staff employed via practising privileges and saw that all mandatory training had been completed.

Safeguarding

- All staff we spoke with understood their responsibility to recognise and report safeguarding concerns. All staff had completed introduction to safeguarding children training. The registered manager was the safeguarding lead and demonstrated knowledge of local systems for reporting safeguarding concerns. There was a safeguarding information folder that staff could refer to and all staff knew where to go for further advice if needed.
- The registered manager had completed safeguarding children level three training and safeguarding adults level three training. However, only 75% of required staff had completed safeguarding children level two training and 50% of required staff had completed safeguarding adults level two training.
- No patients under the age of 18 were treated at the clinic and staff advised patients not to bring children to the clinic.

Cleanliness, infection control and hygiene

- There were reliable systems to prevent and protect patients from healthcare-associated infections. Standards of cleanliness in the laser treatment room and other patient areas were maintained. The cleaning schedule reflected the standards and guidance from the Royal College of Ophthalmologists. 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 and independent cleaners. All furniture was made from wipe clean fabric. Checklists were completed to evidence that cleaning was completed regularly and consistently. All surgical instruments were single use.
- Staff adhered to the uniform policy. Staff consistently wore appropriate personal protective equipment such as gloves and facemask. Staff wore freshly laundered scrubs whilst in theatre and their hair was tied back and covered. No jewellery was visible.
- Staff used effective hand hygiene techniques and were bare below the elbows during our inspection. We observed laser refractive surgery and saw that the staff washed their hands thoroughly in accordance with National Institute for Health and Care Excellence (NICE) quality standard QS61 Infection Prevention and Control. We saw that staff in the waiting area used antibacterial gel prior to performing scans.
- There was a risk of cross infection from some of the equipment and facilities used in the theatre. This included missing trunk cabling on the theatre wall, the flooring in the staff changing rooms was carpeted and the scrubbing brushes used in theatre were re-usable. There was an abrasive floor surface in the theatre that retained fibres from the mop when cleaned. There was one door into and out of the theatre, all equipment

(clean and dirty) and all patients and staff used this door to enter and to exit the theatre. The scrubbing brush used in theatre to scrub staff hands and fingernails was reusable.

- The registered manager had taken action to mitigate some of these risks of infection. The registered manager conducted an environmental audit every six months and actions arising from this audit addressed defects identified such as bubbling paintwork or stained carpets. The team now used a vacuum cleaner to remove mop fibres retained on the rough floor surface of the theatre. The re-usable scrubbing brushes were replaced with disposable scrubbing brushes when this risk was highlighted to the registered manager during our inspection process. However, no action had been taken to address the risks associated with use of one door into and out of the theatre. This risk did not appear on the clinics risk register.
- The air flow system of the theatre was designed to minimise the risk of infection in line with the Royal College of Ophthalmologists Ophthalmic Services Guidance 2013- Theatres. Laser refractive surgery was performed in a non-laminar air flow theatre. Temperature and humidity conditions were maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used. 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. The theatre was only used for eye surgery.
- There were systems to identify and prevent legionella infection. Records showed that water outlets were flushed weekly and tested annually. All staff completed training regarding water safety and legionella awareness.
- Not all staff had participated in training to recognise and take timely action for sepsis. Sepsis is a life-threatening illness caused by the body's response to an infection. The registered manager was not aware of any specific protocol that gave assurance of the clinic compliance with National Institute for Health and Care Excellence (NICE) guideline NG51:Sepsis: Recognition, diagnosis and early management. However, 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 96 hours after surgery. Following our inspection, the clinic instigated plans to introduce online sepsis training for all staff.

Environment and equipment

- All surgical instruments could be traced. Theatre staff attached unique identification stickers from every surgical instrument to the patient record.
- Equipment was maintained in order to keep patients safe. All surgical equipment had been serviced and checked for electrical safety within the twelve months preceding our inspection.
- Staff knew how to operate equipment in order to keep patients safe. There were systems to ensure that the risks associated with the use of laser equipment were minimised. These included a set of 'local rules'. Staff knew where to find these and were aware of 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 was present on site during treatment days. The team could access advice from a laser protection advisor and a corporate laser protection lead via telephone if needed.
- 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.
- 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.
- There were systems in place to ensure that surgery was performed using calibrated laser equipment. We observed staff completing the pre-surgery calibration process. The laser was calibrated according to the manufacturer's recommendations. Where calibration data for the laser 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 date.

- The arrangements for managing waste and clinical specimens kept people safe. There were safe facilities for the disposal of sharps, medicines, infected waste and cytotoxic waste. There were two bio-hazard waste kits available for cytotoxic waste spillages. Staff used these facilities in accordance with the Optimax protocol.
- Medical gases were not always stored safely. The emergency oxygen cylinder was stored in a sealed grab bag propped against the wall behind the reception desk, close to electrical sockets and the computer printer. Oxygen cylinders should be stored in a well ventilated, covered area on a level, well drained surface in a vertical and secured position. When this risk was highlighted during our inspection, the registered manager ordered a stand for this cylinder.

Medicines

- Medicines were stored securely and in accordance with manufacturer's instructions. Cytotoxic medicines (medicines that contain chemicals which are toxic to cells) were stored in a locked container inside a locked cupboard. We checked a sample of the medicines and intravenous fluids held in stock and these were within their use-by date.
- 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), they could amend medicines already prescribed following set protocol for diffuse lamellar keratitis management. DLK is a sterile inflammation of the cornea which may occur after refractive surgery. Optometrists administered some medicines such as eye drops in order to complete their examinations. 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 prescribing surgeon was responsible for the dispensing of the medicines as stated in the medicines policy. At the time of our inspection, medicines for patients to take home were dispensed by the surgeon.

Records

- Records were stored securely. Electronic records were password protected and paper records were stored in a cupboard in a locked room. We saw that no paper records or computers were left unattended at the time of our inspection.
- Leaders were assured of staff compliance with record keeping protocols. 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 a recording of the patient's blood pressure on the health assessment questionnaire and complete the data protection consent form.
- Individual patient records were completed. We looked at the records of seven patients who had undergone refractive eye surgery and all relevant stages of the patient pathway were documented clearly. We saw that staff inputted a contemporaneous record of laser operations for every patient.

Assessing and responding to patient risk

- The team mitigated risks to patient's safety by ensuring that only patients well enough to undergo surgery were recommended for treatment. Prior to the decision to treat, clinicians used the patient admission criteria to ensure that only patients well enough to undergo an operation were accepted for refractive eye surgery. The criteria included refractive parameters, such as the thickness of the eye cornea and the curvature of the anterior surface of the cornea; (particularly for assessing the extent and axis of astigmatism). Other contraindications included medications such as warfarin, ocular conditions such as previous retinal detachment and systemic contraindications such as pregnancy. Patients with high blood pressure were referred to their GP for further treatment before surgery was agreed.
- On the day of surgery, the surgeon reviewed the patient prior to surgery. In this review the surgeon checked that patients were still suited to the surgery previously

selected, confirmed the type and location of surgery to be completed, reviewed the risks associated with the surgery and reminded the patient of the aftercare regime.

- For refractive eye surgery, the surgical team completed the verbal checks stated in the Royal College of Ophthalmology standards for refractive eye surgery and recorded these in a surgical pause checklist that was signed and witnessed. This checklist included patients name, postcode, date of birth, medications, allergies, and which eye was to be treated.
- There was a risk that not all staff were fully aware of patients needs because there was no team briefing at the start of the day of surgery. On the day we inspected, a patient's allergy to latex had not been communicated to the surgery nurse prior to the patient commencing the surgical pause checklist in theatre. There was a risk that staff missed opportunities for learning and reflection because they did not participate in a debriefing on the day of surgery.
- There were suitably qualified staff available for the care of patients in the 24 hours following surgery. The optometrist reviewed the patient prior to them leaving the clinic and if necessary the surgeon could be asked to check the patient. The optometrist reviewed patients one or two days after their surgery depending upon the type of laser surgery the patients had. During clinic opening times patients were encouraged to call the clinic direct for advice if they had any concerns. If necessary patients returned to the clinic for review with either the optometrist or treating surgeon. Patients were given the mobile telephone number of the surgeon who could be contacted between 6pm and 8am on the night of treatment. One of the surgeons told patients he was happy for them to contact him at any time.
- 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.
- Staff did not use a recognised system for monitoring the deteriorating patient. Staff knew what to do if a patient required emergency assistance. The protocol was to call for an ambulance. There was no service level agreement in place to authorise transfer to an acute hospital in the event of a patient becoming seriously unwell during eye surgery. All staff were trained in basic life support.
- Adequate equipment was available to enable staff to administer first aid whilst awaiting assistance from the emergency services. There was one emergency equipment kit, containing an automated external defibrillator, emergency treatment for anaphylaxis resuscitation and a manual suction machine. Oxygen and oxygen mask were available in the waiting area and first aid kit was available in the theatre. We saw that all emergency equipment was regularly checked. Staff were trained to use this equipment in their annual mandatory training and participated in emergency drills every three months when they practised their response to emergency scenarios.

Nursing and medical staffing

- There were adequate numbers of suitably trained staff on duty on surgery days. Staffing numbers and skill mix complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres. The registered manager was in the process of recruiting for a full time patient advisor which when recruited would result in the service being fully staffed.
- Staffing included two full time patient advisors plus one full time nurse, and the registered manager. At the time of our inspection there was one vacancy. There had been no staff sickness at the clinic during the three months preceding our inspection. Optometrists and surgeons were self-employed.
- 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. Many staff were trained in multiple competencies, for example the registered nurse was trained in pre-operative assessment, post-operative care and 'runner' duties. The laser technician was also trained as a patient advisor. There had been no use of bank or agency staff.
- Surgeons held the Royal College of Ophthalmology certificate in laser refractive surgery. Both surgeons carried out the same surgery in NHS acute hospitals. The surgeon we observed on the day of our inspection had completed over 32,000 eye operations to date.

Major incident awareness and training

Refractive eye surgery

- Laser treatment was not compromised if power failed mid-treatment. There were back-up generators in theatres for the laser equipment and these were checked daily.
- The team were well equipped and trained to keep patients safe in the event of a fire. Staff participated in fire evacuation drills. All the 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 services 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. This was in line with the 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.
- Clinical protocols were discussed by the medical advisory board and amendments to current practices were made in line with evidence-based practice. For example, members of the committee agreed a standard protocol regarding the removal of contact lens prior to treatment or consultation. 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, the owner of the company, the chair of the board and the medical compliance manager. At this forum, clinical staff had opportunity to discuss complex cases. Information from the medical advisory board was shared such as changes to protocols or the introduction of new treatments and technologies.
- Technology and equipment were used to enhance the delivery of effective care and treatment. The laser software at Bristol was equipped with a function to evaluate the shape of the cornea in relation to the suitability for treatment.
- The service ensured that patients who were requesting laser refractive surgery received in-depth pre-operative assessment and 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. The most recent audit in September 2017 highlighted some areas of non-compliance which were collated on an action plan for the location. For example, to ensure that learning was shared from audits, the registered manager needed to ensure that all staff signed to say they had read the results of the patient notes audit. This had been completed at the time of our inspection. The registered manager also completed spot-checks of patient consultations with patient advisors.

Pain relief

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

Nutrition and hydration

- Cooled water and hot drinks were available free of charge for patients to drink in the waiting room. Patients were given a hot drink and biscuit following their surgery.

Patient outcomes

- Optimax reviewed patient outcomes for each surgeon to identify any anomalies and/or reduction in effectiveness. This data was used to conduct a yearly audit of the individual surgeon's outcomes which was

made available to the registered manager. Treatment outcomes were measured using the surgeon's success rate and the patient satisfaction with their treatment journey. The target for patient outcomes was to reach driving standard or better on discharge. The treatment outcomes for the surgeons working at the Bristol clinic were within the expected range set by Optimax. However, Optimax did not submit data to the Private Healthcare Information Network (PHIN).

- 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. The results of the survey showed that patients described the level of service provided and satisfaction received as excellent (60.6%), and good (35.5%). A small percentage of the patients surveyed (2.78%) identified that their experience 'could have been better'. The overall patient's satisfaction rate at Bristol was 96.4%; this was less than the overall Optimax satisfaction score of 96.6% nationwide.
- In the patient comments book, outcomes were described by patients as: "the best feeling in the world" and "made my dreams come true".
- 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 by the compliance team.
- At a corporate level, this system had been recently reviewed and changes were being made to the way that complications were reported in order for Optimax to have a clearer picture of the rate of different types of complications across locations.
- There had been one case of diffuse lamellar keratitis in the twelve months preceding our inspection. Three other patients returned to the clinic for further treatment relating to wrinkling of the corneal flap following laser surgery. There were 59 patients who had further treatments post-surgery, out of a total of 508 treatments. 25 of these were laser top-ups following lens surgery which is a predicted aftercare treatment. This resulted in a further 34 patients (7% of total patients) having re-treatments. Comparative data was not available.
- The percentage of patients that needed further surgery after their initial surgery was 7%, which is less than (better) than the Royal College of Ophthalmology standard. During the 12 months preceding our inspection, 34 patients (7%) out of a total of 508 patients returned for further treatment following their initial refractive eye surgery.

Competent staff

- Staff had the right qualifications, skills, knowledge and experience to do their job. All staff were trained in basic life support and two members of staff per shift were trained in advanced life support.
- There was a system to provide assurance of the competence of staff employed via practising privileges. 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. Optometrists were required to complete continuing education as a condition of their professional registration.
- There were reliable systems to ensure that staff had up to date knowledge of laser protection. At the time of our inspection, four staff members had attended the core of knowledge one day training course during the 24 months preceding our inspection. Staff attended refreshers of this training every two years. 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.
- There were arrangements for supporting staff employed by the clinic. Patient advisors participated in induction training and completed competency training and

assessments during their probationary period. Staff competencies were reviewed on an adhoc basis by the registered manager. All nursing staff and patient advisors participated in one to one supervision with the registered manager every three months. This provided an opportunity to reflect upon their practice. Similarly, surgeons attended one to one meetings with the clinical director once per year.

- Staff were offered professional development. Nurses were invited to attend a study day once per year where they heard presentations from in-house speakers and external equipment manufacturers. Optometrists told us that all their training needs were met.
- Five of the six staff employed at the clinic had completed an appraisal in the 12 months preceding our inspection. The exception was a member of staff employed on a zero hour's contract who had not worked at the clinic during the summer. All staff working under practising privileges had evidence of a current appraisal in their staff file. Surgeons also attended a face to face meeting with the clinical director once a year.

Multidisciplinary working

- 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. 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 password protected computer system. Printed consent forms were signed on paper by patients and then scanned onto the electronic record.
- Patients chose whether to give permission for the team to share their information with the GP.

Consent and the Mental Capacity Act 2005

- The service ensured that patients gave informed written consent before they underwent treatment. All staff understood the consent procedure. Staff gave detailed verbal and written information about all risks, benefits, realistic outcomes and costs of treatments. The surgeon gave detailed explanations to patients of all risks and the likelihood of adverse effects of specific surgery. The surgeon completed the consent process at their first face to face meeting with the patient. The optometrists and surgeons checked consent at all stages of the assessment and treatment process. The optometrists asked the patient eight key questions that ensured all aspects of consent were thoroughly discussed.
- Patients were offered a range of alternative treatment 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 as recommended in guidelines published by the Royal College of Ophthalmology. There were no time limited deals offered.
- 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.
- The printed consent form clearly explained the risks of using Mitomycin-C . This medicine is used in refractive eye surgery although it is not licensed for this purpose

Are refractive eye surgery services caring?

Compassionate Care

- Staff took time to interact with patients in a respectful, considerate and therapeutic manner. Nurses and surgeons took care to ensure that patients were comfortable before surgery commenced. Surgeons talked to the patients during surgery, explained 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 used eye contact when speaking to patients and shook their hands in greeting. At every stage of the treatment journey, staff introduced themselves to the patient. Patients told us they never felt rushed.
- Where possible, staff maintained patient privacy by closing doors to their consulting rooms during patient appointments.

- In the patient comments book, staff were described by patients as "so amazingly kind and helpful".
- Staff supported patients to understand relevant treatment options including benefits, risks and potential consequences. During face-to-face consultations, patient advisors gave patients information about costs of treatment and what to expect from laser surgery. Patients were given ample time to ask questions.

Understanding and involvement of patients and those close to them

- Surgeons and optometrists encouraged patients to ask questions and involved them in decisions regarding their care. Staff explained procedures clearly and without the need for unnecessary jargon, using demonstrations and models to assist understanding. Patient advisors gave detailed information about costs of treatment at the patient's first appointment. We saw that the surgeon took time to show patients what their vision would be like post-surgery, and in this way helped patients to manage their expectations of what the surgery would achieve.
- 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. One of the surgeons gave patients their mobile telephone number at their first surgeon consultation. This surgeon advised patients they could be contacted at any time before or after surgery with questions or concerns. We heard examples of when patients had used this option. For example, a patient telephoned the surgeon late at night to tell them she was pregnant and the surgeon explained that she would not be able to proceed with surgery as planned.
- Patients were encouraged to take responsibility for their aftercare. Staff encouraged patients to use effective hand hygiene when administering eye drops. The surgeon explained the importance of allowing the eye to heal effectively and the importance of following the 'do's' and 'don'ts' post-surgery in order to achieve the best possible outcome for their vision. This included avoiding shampoo, water or cosmetics entering the eye and avoiding contact sports for a defined period.

Emotional Support

- When patients were anxious, staff were sensitive to their need for reassurance. When patients indicated on the health questionnaire that they felt anxious regarding the surgery, optometrists took time to show them the theatre environment, the equipment used, and explained exactly what would be involved in the procedure. Prior to the surgery, carers were invited to attend consultations with patients to help alleviate anxiety. During surgery, a staff member would sit with the patient to hold their hand if the patient requested.
- Staff were friendly and approachable. All patients we spoke with agreed that staff made them feel comfortable and safe.

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

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 two days per calendar month. Patients could choose which month but the date was limited to the designated surgery day. Surgery was scheduled for Thursday, Friday or Saturday to minimise the time that patients would need to be absent from their work.
- The team provided continuity of care to patients. For example, a patient would be seen by the same surgeon, the same optometrist and the same patient advisor throughout their patient journey. When an optometrist recorded a patient as a complex case, the registered manager followed the patient journey to ensure that all appointments were arranged and clinical decisions were followed up as necessary. These complex cases were also monitored by the head office.
- Optometrists followed protocols to ensure the first post-operative review appointment met standards set by the Royal College of Ophthalmology. The surgeon delegated this review to the optometrist who checked the patient's eyes before they left the clinic on the day of their surgery.
- In some instances where patient's needs were not being met, the company identified and used this to plan and develop the service. More optometrist hours had been made available at the clinic on a Friday and Saturday as these were the most popular appointment choices for patients. Patients who required intraocular lens surgery were required to travel to Newton Abbot, Devon; Cardiff

or Birmingham for this type of surgery. To minimise this inconvenience, the Bristol clinic held an evening clinic once a month to facilitate pre-surgery consultations for this group of patients.

- However, the company response to unmet need was not consistent. The premises were located in a listed building. The layout did not meet the needs of the service that was delivered and this was not adequately addressed at the time of our inspection. The clinic was arranged over three floors. Patients were required to negotiate the stairs to access the surgeon's consultation room prior to surgery. Patients were required to negotiate additional stairs to the optometrist's consultation room immediately after surgery. A risk assessment had been completed. In order to reduce the risk to patients, staff offered patients a drink and asked patients if they felt well enough to ascend the stairs prior to doing so. Patients were advised of these access restrictions at their initial consultation. Patients with mobility impairment were advised to travel to an alternative clinic and the travel costs were reimbursed by the company.
- The arrangement of the waiting area did not protect the privacy and confidentiality of patients. The main waiting area was used for multiple purposes. In one corner, shoulder height panels screened an area where patient advisors completed tests to check patients vision prescription and eye pressures. Next to this, patients filled in their health questionnaire at a computer terminal. Adjacent to this, patients sat at the reception desk to discuss the aftercare medication regime with the patient advisor. Beside the reception desk, patients completed the patient satisfaction questionnaire on a computer terminal. Both computer screens faced the main waiting area and were visible to patients waiting at reception. When patients booked in for their treatment at the reception desk they could be overheard by other patients in the waiting area.

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 the 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 immediately after their surgery and then one or two days following surgery for a review. Repeat aftercare appointments were then determined by the optometrist.
- Patients requiring urgent treatment post-surgery were offered immediate appointments. During our inspection an optometrist identified that a patient may be presenting with diffuse laminar keratitis. The surgeon examined the patient the same morning and arranged to come to Bristol the next day (a Saturday) for an unscheduled appointment to review the patient. The patient advisor also volunteered to come to work to facilitate the appointment for this patient.
- Care and treatment was cancelled only when absolutely necessary and when this did occur, staff tried 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. During the period 01 May 2017 to 30 November 2017, the rate of cancellations with seven days' notice was 6.8% of consultations, 3.7% of treatments and 5% of aftercare appointments. The rate of cancellations with three days' notice was 5.1% of consultations, 1.4% of treatments and 3.5% of aftercare appointments. The number of patients who did not attend their first consultation appointment was high at 18.7%.
- Patients were not delayed once they arrived at clinic on surgery day. The registered manager monitored the length of time that patients spent in the clinic. Staff informed patients prior to their surgery date that they may be in the clinic for up to four hours. During our inspection, clinics ran on time and patients were in the clinic for an average of 2.5 hours. As far as possible, the

service offered appointments to patients to suit their needs. If the surgery dates at the Bristol 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. The cost of surgery included a lifetime guarantee. This meant that if patients required further refractive eye surgery, the cost was covered by the guarantee, so long as the patient had attended regular eye check-ups since their surgery.

Meeting peoples individual needs

- Staff went the extra mile to respond to the individual circumstances of each patient. The surgeon stayed late in clinic to accommodate an appointment for a patient who was getting married in two weeks and wanted the surgery to take place before her wedding.
- Patient's additional needs were flagged when they completed the health assessment questionnaire. These were discussed further during the first appointment with the patient advisor and optometrist during the first appointment and any additional information was added to the patient's electronic record for future reference.
- Some reasonable adjustments were made so that patients with disabilities could use the service on an equal basis to others. However, the extent of these adjustments was limited. For patients with mobility impairment who were unable to access both flights of stairs, Optimax reimbursed the costs of travel to an alternative clinic location. Patients with complex needs or multi-pathologies were not accepted for surgery because the service was not equipped to meet their needs.
- For patients with visual impairment, staff were available to assist patients to access the clinic. For patients with hearing impairment, written information was provided prior to the pre-operative consultation and during the consultation process, which reinforced all verbal information discussed face to face. A hearing loop was installed and turned on. However, if the patient needed the use of a sign language interpreter, the patient was required to pay the cost of this resource.
- For patients whose first language was not English, staff could arrange an interpreter, however, the cost of this resource was met by the patient. Patients were given the option of using clinical staff as interpreters where appropriate and only if that member of staff was able to understand the terminology of the consultation. For example, a lens surgeon from a different clinic attended the Bristol clinic to translate for a patient whose first language was Farsi.
- Pre-treatment information included a clear explanation of what to expect during surgery with instructions about how the patient could help the procedure, as recommended in the Royal College of Ophthalmology standards for refractive eye surgery.
- Staff gave patients individualised information that was specific to their treatment plan. 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 surgeon'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. Optometrists gave patients a copy of their discharge summary when their aftercare was completed. This was available as paper or electronic format.
- Patients were encouraged to communicate their individual needs and staff responded positively to their requirements For example, a patient who was a fireman requested advice regarding the impact of wearing a gas mask. The optometrist agreed to find out this information and call the patient the next day to advice.

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. Certain negative words were triggers on the electronic system that alerted the central compliance team to a patient's dissatisfaction. Managers could access this on-going data at any time. At the Bristol clinic, there had been no feedback that had required action to be taken. The registered manager was aware of learning from complaints at other locations. For

example, the cost of non-invasive laser treatment following intra-ocular lens surgery was not clearly explained in the consent form. The consent form was amended to make this clearer.

- Managers tried where possible to resolve any complaints as soon as they occurred. There had been 13 formal complaints in the 12 months preceding our inspection. All of these had been investigated at the time of our inspection.
- The service had not made use of all opportunities to explain the formal complaints procedure to patients. The patient information booklet did not include this information. However, there were suggestions and complaints forms available to patients on the front reception.

Are refractive eye surgery services 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 Bristol location.
- The registered manager had the skills, knowledge, experience and integrity to lead the service with support from the central governance team. 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 role included non-clinical hours, which provided capacity to oversee the operational management of the team.
- The manager was visible and approachable. Staff told us they felt supported in their roles and valued for the work they did. Staff were proud to work for Optimax and described their colleagues “like family”. Staff were grateful for the flexibility and the opportunities to work extra hours at different clinics.
- All grades of staff said they felt comfortable raising concerns and were confident that the registered manager would listen to them. For example, staff had raised concerns regarding the use of space in the clinic. As a result the team had trialled different ways of organising the use of space in the clinic. The registered manager identified the lack of space as the main challenge to providing good quality care at this location. The restrictions regarding space limited the scope for development of the service.
- All marketing campaigns were directed by the central corporate team. At the Bristol location, there was a culture of honesty regarding costs of treatment and conditions of the service provided. At the initial consultation, patients were provided with written statements which detailed the terms and conditions of the service being provided and amount and method of payment of fees. Patients told us they did not feel under any pressure when making their decisions regarding surgery.
- Optometrists and surgeons gave advice to patients regarding their best course of treatment. This was not influenced by profit to the company as we saw how clinicians advised patients to choose less expensive treatment options when indicated.

Vision and strategy

- The strategic vision and forward vision of the service was determined at 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 the forward vision might compromise patient care.
- There was no documented strategy for the Bristol location. The company had identified a core set of values but these were not known to the staff we spoke with during the inspection.

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 central compliance team screened all alerts received from the Medical Device Agency (MDA) or Health and Safety Executive (HSE) and cascaded to the service. There had been no relevant alerts during the 12 months preceding our inspection.
- The team identified, investigated and mitigated most risks effectively. Risks were identified as a result of incidents reported or audits completed and were reviewed and investigated by the registered manager in conjunction with the compliance manager. We saw that action was taken as a result of risks being identified through the audit process. For example at the monthly compliance audit undertaken by the compliance manager, several action points were identified that had all been completed by the time of our inspection. These included among others, a review of the human resources files, the documentation of a control of hazardous substances (COSSH) risk assessment for the cytotoxic medicines and the acquisition of privacy screens for the scanning area in the waiting room.
- 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 did not always take place when a risk was identified. For example, there was no risk assessment regarding the risk to infection control from the singular entrance and exit to theatre, there was no risk assessment for the risk to patient privacy from the layout of the waiting area.
- There was a risk register. This was up to date and contained details of live risks pertinent to the Bristol clinic including actions taken to mitigate these risks. Optimax had introduced the local risk registers in September 2017 and going forward, the plan was for each team to review their risk register during the compliance telephone call once every three months.
- There was a process to provide assurance that external staff were competent and qualified to fulfil their role. All surgeons and optometrists supplied the relevant documentation to support their practising privileges as identified in the company practising privileges policy, including evidence of their indemnity insurance. We reviewed the staff files of three staff working under practising privileges. No omissions were evident.

Public and staff engagement

- The service proactively sought and acted upon the views and experiences of patients. A total of 3,559 patients were surveyed during the period 1st January 2016 to 31st December 2016. Results of this survey were available to the registered manager to view on an on-going basis, and a negative response which indicated dissatisfaction with the service triggered an alert to the patient compliance team.
- There was a patient experience book available for visitors to write in and read in the waiting area.
- Action had been taken as a result of patient engagement. The Bristol clinic now offered consultation appointments for intraocular lens surgery patients in order to eliminate the need for these patients to travel to the clinic where the surgery was performed, which for some patients was a distance of over 100 miles.
- The team communicated well with one another. Concerns raised by staff were discussed at team meetings. However, actions taken as a result of these concerns were not adequately recorded; minutes did not include a clear and complete record of discussions, and matters arising from the previous meeting were not recorded or taken forward to the next meeting. 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 arranged a meeting with the director to review the layout of the clinic in relation to patient privacy and confidentiality.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that the environment of the clinic is planned in such a way that patient privacy and confidentiality is maintained at all times during consultations and treatment.

Action the provider SHOULD take to improve

- Ensure that all staff have completed all aspects of their mandatory training, specifically safeguarding training
- Contribute data to the Private Healthcare Information Network.
- Review the layout and facilities of the theatre environment to ensure that all risks of cross infection are minimised and mitigated where possible.
- Review the layout of the clinic to minimise risk to patient safety and where possible ensure that patients are not required to ascend and descend stairs immediately post-surgery.

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 10 HSCA (RA) Regulations 2014 Dignity and respect Service users must be treated with dignity and respect. 2)a) ensuring the privacy of the service user The layout of the waiting area did not protect the privacy and confidentiality of patients. Regulation 10(1)(2)(a)