Optimax Laser Eye Clinics - London

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optimax Laser Eye Clinics - London is operated by Optimax Clinics Limited. The clinic operates from the first two floors of a three storey building.

The ground floor has a reception area, main waiting room, topography room, YAG laser room and two consultation rooms. On the first floor there is a staff changing room, reception waiting area, managers', office, storeroom, laser preparation and treatment room, recovery room, doctor's consultation room and counselling room.

On the second floor of the building is Optimax's head office.

The service provides refractive eye surgery only. If patients required further care or surgery using anaesthesia or sedation, as an example, lens replacement surgery, patients are referred for private surgery to another Optimax branch. If patients have lens surgery in another branch the London location provided pre and post-operative care. We inspected refractive eye surgery.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 19 December 2017.

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

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

Services we do not rate

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

We found the following areas of good practice:

- We observed that all areas we looked at were clean and tidy. Records confirmed that equipment was suitably maintained and monitored in order to provide a safe environment for patients.
- The service collected information about the outcomes of patients' care and treatment. This was audited annually and reviewed across the service to ensure patients received quality care and effective outcomes.
- Patients we spoke with reported that all staff members were kind, caring and respectful. Results from the patient feedback survey undertaken by the service indicated patients were satisfied with the care they received.
- There was a clear leadership structure from service level to senior management level. All staff we spoke with reported they had good relationships with local and corporate management.

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

- The arrangements for dispensing medicines were not sufficient to provide safe management of medicines. Not all staff had received the appropriate competency training for staff to ensure that they had the correct skills to carry out their role.
- The service lacked an effective competency assessment process to ensure staff had the adequate skills and knowledge to care for patients. Non-medical staff performed extended roles without evidence of appropriate supervision or competency assessment.

Summary of findings

- Not all staff had completed the required mandatory training. Training information was not available for employed staff and those working with practicing privileges. Specific training information was not available in all personnel files.
- The service had a local surgery checklist in place however, this was not fit for purpose and staff did not understand the purpose of the process.
- Some of the organisation's policies, including the organisation's safeguarding policy, were not up to date with current legislation or guidelines.
- We were not assured that processes to ensure informed consent was obtained from patients were effective. Not all patients were given the recommended seven-days cooling off period.
- There was a lack of oversight of the recruitment and practicing privileges processes. Practicing privileges files for surgeons did not include any evidence on training and it was not clear how oversight of the practicing privileges process was maintained.
- Systems to identify, record and control risks were not well embedded. It was not clear how oversight of risks was being maintained as there was limited evidence of discussion on risk taking place at governance meetings. We were not assured that risks were always identified and addressed in a timely way.

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 four requirement notice for breaches of regulations 11, 12, 17 and 18 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). Details are at the end of the report.

Amanda Stanford

Interim Deputy Chief Inspector of Hospitals London

Summary of findings

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Services we looked at:
Refractive eye surgery.

Summary of this inspection

Background to Optimax Laser Eye Clinics - London

Optimax Laser Eye Clinics - London is operated by Optimax Clinics Limited. The service was established in 1991. It is an independent private service in the borough of Camden, London. The service provides refractive (laser) eye surgery for patients over the age of 18. The service receives patients from London and surrounding areas and is part of Optimax Clinics. It also accepts patient referrals from outside this area.

A registered manager has been in post since July 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and two specialist advisors with expertise in refractive eye surgery. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection

Information about Optimax Laser Eye Clinics - London

All patients are privately funded, referring and paying for their refractive (laser) eye surgery themselves. Surgery days are variable and are booked according to demand. There are no overnight facilities with opening times from 8am until 6pm Monday to Saturday.

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

During our inspection, we reviewed five sets of patient electronic records. We spoke with four patients in total who were attending for pre and post-operative assessments and laser surgery. Additionally we spoke with eight members of staff about their views and experiences.

We also received 14 'tell us about your care' comment cards, which patients had completed prior to our inspection. During our inspection, we reviewed 10 sets of paper patient records.

In the last 12 months the service performed 1,833 refractive eye surgery procedures.

The service has not been subject of any external review or investigation by the CQC at any time during the 12 months before the inspection.

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

Clinical incidents

There were no incidents of hospital acquired infection such as Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), E-Coli or Clostridium difficile (C.diff) in the last 12 months.

In the preceding 12 months there were 32 complaints, nine of which were upheld.

The service had been last been inspected in August 2013 where we found that Optimax Laser Eye Clinics - London had appropriate arrangements in place to ensure that patients received treatment that reflected their needs. Patients had been given relevant information to make informed decisions about their treatment.

Summary of this inspection

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Interpreting services
- Laser protection service
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

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

- The service had a local surgery checklist in place however; this was not fit for purpose. Checks were carried by staff that did not understand the purpose of the process and thought they were ID checks.
- Staff had received a medicines training course as part of their induction. However, there was no information on whether staff had been trained in dispensing medicines that patients took home (TTOs). Staff told us they had not received training that covered dispensing of medicines, and had not been assessed for competency to do this safely.
- Staff on probation were providing care and treatment for patients on a daily basis. However, they were unable to access all relevant training, including safeguarding level two training until they had passed probation, and this left gaps in staff skills.
- Not all staff were up to date with safeguarding adults and safeguarding children training. Only 40% of permanent staff who worked at the location were trained to safeguarding Level 2.
- The manager was not aware what training self-employed clinical professionals had. None of the consultants recorded as having practicing privileges at the service had any mandatory training information in their file. There was no information available to confirm whether they had completed the mandatory training set out in the company training and development policy.
- Some staff had limited awareness of the duty of candour process. Managers correctly explained that patients should be informed an incident had occurred, informed of the investigation and given an apology.

We also found the following areas of good practice:

- We observed that all areas we looked at were clean and tidy. Records confirmed that equipment was suitably maintained and monitored in order to provide a safe environment for patients.

Summary of this inspection

- The majority of staff understood their responsibilities to raise concerns and knew the process of reporting and investigating incidents.
- Patients told us that that risks and benefits were discussed with them prior to surgery and that they received good discharge and aftercare information.
- Laser safety measures were in place and were monitored in line with national standards.

Are services effective?

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

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

- We were not assured that processes to ensure informed consent was obtained from patients were effective. Not all patients were given the recommended seven-days cooling off period.
- We found that processes in place to review staff competencies were ineffective in ensuring staff worked within the scope of their qualifications and competence.
- Non-medical staff performed extended roles without evidence of appropriate supervision or competency assessment.
- We reviewed the provider's policies and found that several, including the organisation's safeguarding policy, were not up to date with current legislation or guidelines.

We also found the following areas of good practice:

- Patients were screened before treatment to ensure the most appropriate laser treatment was provided.
- The service collected information about the outcomes of patients' care and treatment. This was audited annually and reviewed across the service to ensure patients received quality care and effective outcomes.

Are services caring?

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

We found the following areas of good practice:

- Patients we spoke with reported that all staff members were kind, caring and respectful.

Summary of this inspection

- Results from the patient feedback survey undertaken by the service indicated patients were satisfied with the care they received.
- We saw staff treated patients with dignity and care.

Are services responsive?

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

We found the following areas of good practice:

- There had been no instances of unplanned transfer of a patient to another health care provider in the last 12 months. This meant that the service was able to recognise and address any potential complications to maintain quality of care to patients.
- We saw that patients were given written information on post-operative care and the 24 hour contact telephone number of the treating surgeon should they have concerns following discharge.
- The service had a complaints policy and system for handling complaints and concerns that followed the organisation's corporate complaints policy. This provided a structured process for staff to follow when dealing with complaints. There was evidence of learning from the complaints received from patients and patient feedback was positive.
- Services were organised in a way that met patient's needs. The service provided pre-planned services only. The service proactively planned surgical and clinic sessions and used data to identify number of patients and staffing requirements.

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

- Patient information leaflets were not available in other formats, such as large font or braille, and other languages.

Are services well-led?

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

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

- The service lacked an effective competency assessment process to ensure staff had the adequate skills and knowledge to care for patients.

Summary of this inspection

- Some of the organisation's policies, including the organisation's safeguarding policy, were not up to date with current legislation or guidelines.
- Systems to identify, record and control risks were not well embedded. It was not clear how oversight of risks was being maintained as there was limited evidence of discussion on risk taking place at governance meetings. We were not assured that risks were always identified and addressed in a timely way.
- Although a local risk register was in place, it was based on a standard list of risk assessments relating to refractive surgery and did not reflect local risk issues or related to local incidents. Senior staff informed us that there was no national risk register.
- There was a lack of oversight of the recruitment and practicing privileges processes. Practicing privileges files for surgeons did not include any evidence on training and it was not clear how oversight of the practicing privileges process was maintained

We also found the following areas of good practice:

- There was a clear leadership structure from service level to senior management level.
- All staff we spoke with reported they had good relationships with local and corporate management.
- Results from the patient feedback survey undertaken by service indicated patients were satisfied with the care they received.
- Information available for prospective patients was clearly written, honest and responsible and complied with guidance from the Committee of Advertising.
- Patients received a statement that included, terms and conditions of the service being provided, the cost, and method of payment for the laser eye surgery.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The service had reported no never events in the 12 months prior to our inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- The service used a paper based process for reporting incidents for adverse events and near misses. Staff we spoke with told us if they felt they needed to raise an incident, they would speak with their manager first.
- The service had a process in place to ensure they responded to patient safety alerts sent out from the NHS. They provide guidance on preventing potential incidents that may lead to harm or death.
- A duty of candour policy was available; a review of records and information supplied prior to the inspection showed that the service had no duty of candour concerns. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.
- Some staff had limited awareness of the duty of candour process. Discussions with the managers showed that they were aware of their responsibilities to act on any duty of candour concerns.

Mandatory training

- The service had a training and development policy and mandatory training information was also available in the service's staff handbook. Records we viewed confirmed that some specific mandatory training was undertaken by staff in order to develop and maintain staff skills. The training included areas such as fire training, data protection, health and safety, introduction to safeguarding level 1, personal safety and infection control.
- The service had a number of employees on probation at the time of the inspection. Staff had to complete an induction framework that was composed of a number of modules, including meeting sales targets before being signed off probation. Staff on probation were unable to access additional training including safeguarding level two training until they had passed probation and this left gaps in staff skills.
- Staff on probation provided care and treatment for patients on a daily basis. These staff were responsible for taking basic observations of patients, such as blood pressure and responsible for putting eye drops in patient's eyes and supporting patients to complete pre-assessment health questionnaires. They were also responsible for post operation care and providing discharge medication as stated on the patient's prescription. All staff, including those on probation had undertaken a medicine training (Optrainer) e-learning course.
- There was no information available to confirm whether self-employed clinical professionals had completed the mandatory training set out in the company training and development policy. The policy stated it applied to all "permanent, temporary, short-term, full-time or part-time employees of the Company including all self-employed clinical professionals including Optometrists, Surgeons and nurses". This meant they could not be assured self-employed professionals had met the mandatory training levels as set out in the company policy.

Safeguarding

Refractive eye surgery

- We were provided with a copy of the services safeguarding policy prior to the inspection. Although this had been reviewed in September 2017 it was not up to date. It referenced old legislation and did not give clear guidance to staff on their roles and responsibilities in safeguarding adults and children.
- The service did not treat patients under the age of 18 years old. The manager told us that all staff were provided with a basic introduction to safeguarding training for both adults and children. However, training records did not demonstrate that all staff had completed basic training. Four staff on probation either had not applicable or post probation recorded alongside their names which meant they had not completed any training. Only 40% of the staff who worked at the location were trained to safeguarding level 2; which was lower than the provider's standard of 95%.
- None of the consultants recorded as having practicing privileges at the service had any training information in their files, including whether they had completed safeguarding adults and safeguarding children training. The manager told us several of the consultants worked exclusively in private practice and all HR issues were dealt with at a corporate level. We asked for further information to be provided however this was not received. This means we were unable to confirm that staff with practicing privileges had completed mandatory training in safeguarding as stated in the provider's policy.
- The service had not reported any safeguarding concerns since its opening in 1991 and there were no safeguarding issues logged with CQC. The manager confirmed that there had never been a safeguarding concern in the service. Staff knew who their safeguarding lead was if they had any concerns and there was a national corporate safeguarding lead available to provide advice and oversight.

Cleanliness, infection control and hygiene

- The service maintained standards of cleanliness and hygiene and we observed all areas of the service to be clean and tidy.
- The service did not have a process in place to complete regular hand hygiene audits. The manager told us they had completed a one off audit earlier in the year however this was of poor quality.
- The service carried out regular audits to ensure the recommended standards of cleanliness in the laser/ clinical treatments rooms and theatre environment were maintained in line with the Royal College of Ophthalmologist (RCOphth) professional standards and guidance.
- Laser refractive surgery was performed in a minimal access intervention operating environment. A log was kept of temperature and humidity conditions demonstrating that equipment was being maintained consistently and safely.
- The service had an infection control policy in place however this had not been updated to reflect current legislation and guidance. There had been no instances of healthcare acquired infection in the last 12 months.
- Clinical areas we visited were visibly clean, tidy, well organised and mostly clutter free. We observed staff washing their hands, using hand gel between patients. Personal protective equipment, such as gloves and hand-washing facilities were available. We observed staff using personal protective equipment appropriately, and in line with the Health and Safety Executive (2013) personal protective equipment (PPE): A brief guide. INDG174 (Rev2). London: HSE.
- We observed sharps boxes were appropriately used for the safe disposal of items such as used needles. The service had a contract with an external organisation for the removal and replacement of sharps boxes in order to maintain safety
- The manager told us all staff completed mandatory training in infection prevention and control training on induction. Training records verified that staff were up to date.
- The majority of equipment used for surgery was "single" usage surgical equipment. We observed these were appropriately disposed of following surgery.

Environment and equipment

- We looked at the fire safety procedures for the building. Fire exits were clearly marked but not always free from obstructions. For example, the external evacuation route from the ground floor staff room was partially blocked by wooden planks and the quick-release exit bar was broken with part of the device detached from the door. This meant in an emergency there could be barriers to a quick evacuation. However, the fire policy was up to date and there was evidence the senior team reviewed this regularly.

Refractive eye surgery

- A fire marshal was always on duty whenever the building was open and these individuals undertook training to support an evacuation. We spoke with one fire marshal who had initiated simulated fire drills in November 2017 and told us these demonstrated an overall good awareness of fire safety. We looked at the records of fire drills and found an improvement in standards. For example, in August 2017 a drill highlighted that visiting staff from head office evacuated to an incorrect assembly point. The manager improved information available to visitors and in December 2017 a fire drill demonstrated an overall evacuation time of two minutes.
- The service maintained a register of persons responsible or competent for the management of fire precautions, which met the requirements of the Regulatory Reform (Fire Safety) Order 2005. The fire marshal also told us weekly fire alarm tests always took place. However documentation held on site indicated between April 2017 and December 2017 only 20 weekly fire alarm tests took place. In addition a fire safety risk assessment in July 2017 found emergency lighting checks were inconsistent although there was no audit or checking system in place to ensure this had improved.
- We found evidence of significant delays in repairing emergency equipment. For example staff noted a malfunctioning emergency light in August 2017 and maintenance records indicated this was not repaired until December 2017. Staff had not documented reasons for the delay or how any additional risks had been mitigated. We saw the senior team were not always consistent in response to recommendations from environmental risk assessments. For example in July 2017 a fire safety risk assessment found inconsistent fire safety signage. The manager rectified this in August 2017. However the same risk assessment found concerns with fire doors in the reception area and topography rooms and there was no documented resolution to this.
- Appropriate operating room and monitoring equipment was in place. We observed equipment stock in the storage areas was CE marked. For example, protective eyewear, needles and other surgery devices. This ensured that all equipment was approved and compliant with relevant safety standards.
- Theatre practices met the Association for Perioperative Practice (AfPP) guidelines. Humidity and temperatures in theatre and treatment areas were monitored and the records kept were accurate and up to date. All the equipment we saw was clean and well maintained.
- The service used single-use, sterile instruments as appropriate. The single use instruments we saw were within their expiry dates. The service was contracted out and monitored through a service level agreement with external provider.
- Laser warning signs were used to clearly identify controlled areas where lasers were in use and we saw that these automatically switched-on when the door to the controlled area was closed.
- There was a laser safety management file held in the manager's office which included the laser protection advisor's (LPA's) contact information should it be required. The folder was updated every three years by the LPA, or more frequently if there were changes to staffing or types of laser used. Local rules' were read and signed as understood by all relevant staff.
- We saw records and spoke with staff regarding their training in laser safety. Training was available and supported by a Laser Protection Supervisor (LPS) within Optimax Clinics Limited and a Laser Protection Advisor LPA who was part of an external company. Staff confirmed they knew who to contact if they had any concerns about the safety of the laser equipment.
- We saw evidence that the service followed guidance from the provider's laser radiation advisor. Controlled arears were clearly defined and relevant risk assessments in place
- We looked at clinical areas including examination rooms, consultation rooms and the laser room. Clinical areas were observed to contain equipment that was suitable to the diagnosis, laser surgery and recovery of patients.
- The service had a regular maintenance schedule in place. Any equipment or areas of the environment that needed repair or replacement were actioned rapidly in order to maintain the safety of patients.
- In the reception/waiting areas, we saw that there were "easy clean" chairs for patients to use whilst waiting for laser surgery. There were also magazines and a hot drinks machine available.
- We looked at emergency equipment including emergency medicines. These were checked by the manager weekly, all were in date, and all equipment

was in working order. Staff members spoken with were aware of the emergency equipment and how to use it. There have not been any occasions in the last 12 months in which the emergency equipment had been required.

Medicines

- The service has a prescribing, dispensing, administering medication policy. It described the competency and training of company medical and clinical staff. The manager told us that prior to surgery a clinic staff member would go through the medications that will be prescribed by the surgeon as take-home (TTO) medications. They will also provide the patient with the appropriate medication safety sheet and an instruction for use leaflet. Patients could raise questions at any time and have these answered by the surgeon.
- Post-surgery prior to the patient leaving the clinic a staff member would reiterate to the patient the take-home medications prescribed and the regime for them. This information was recorded on their electronic patient record.
- Records showed that staff had completed a medicines training course as part of their induction. However, this did not detail if reception staff had been trained in dispensing medicines that patients took home (TTOs). Staff told us they had not received training that covered dispensing of medicines. They had been told what process to follow but had not been assessed for competency to do this safely.
- Reception staff were responsible for recording with a "stamp system" medicines they had given patients to take home. This recorded a single entry of medicines given. Information on what medicines had been discussed by reception staff, or what instructions staff had given regarding the medicines was not recorded. The provider told us the information staff tell the patient is what is on the doctors take home medication sheet. Senior managers informed us they were reviewing this system in order to make a sure that a full record of medicines and any advice given was made.
- The service had a policy regarding the use of cytotoxic medicines, which included the management of risk. These are medicines that contain chemicals which are toxic to cells, preventing their replication or growth. The clinic had not used this treatment for any patients between January and December 2017. Managers told us the optometrist would discuss potential benefits and risks and this would be discussed again when the patients saw the consultant. All discussion would be recorded on the patient's records.
- There were appropriate risk assessments, policies and protocol associated with the handling of the cytotoxic medicines. We saw that saw that medicines were stored safely, within lockable cupboards.
- Patient records we viewed detailed current medicines, any allergies and a medical history in order to make sure that any medicines prescribed by the consultants were safe to be given.
- The service had an emergency medicines box containing non-controlled drugs for use in an emergency. The register manager told us there was a list on the outside of the box that alerted staff to check expiry dates, however these were not recorded so we were unable to confirm they had taken place.

Records

- We saw that there were appropriate records maintained each time a laser was operated and that each patient's pre-operative assessment was recorded.
- Records we reviewed contained copies of any referral letters and clinic letters that would be needed for any consultation. Additionally there were copies of post-treatment letters that were sent on behalf of patients to other relevant medical professionals where patients had given consent. Patients could choose what information was shared with their GP or other healthcare professionals. Copies of post laser surgery letters were given to all patients when discharged.
- An electronic medical record system was in place. This contained all the patients' personal infromation including assessments, medicines and details of the patients surgery. Electronic records were only accessible to authorised people. Computers and computer systems used by staff were password protected.
- Records were audited externally to the service, by a representative of the Optimax Clinics Limited. However these audits were not robust and had not noted the lack of recording for dose of medicines.
- Following surgery all patients are given a letter detailing the procedure they have undergone and post-operative medication regime to take to their GP.

Assessing and responding to patient risk

Refractive eye surgery

- Pre-assessment checks were carried out by untrained, non-clinical staff and we were told that blood pressure checks were not always completed for patients prior to surgery. The manager told us there were no competencies in place that assessed whether staff were competent to carry out these checks.
- Staff did not always adhere to World Health Organisation (WHO) best practice guidance surgical checklist for intraocular surgery. Managers told us the service had a local surgery checklist in place however this was not fit for purpose. This was because checks were carried by staff who did not understand the purpose of the process. A surgical safety checklist is designed to reduce the number of errors and complications resulting from surgical procedures by improving team communication and by verifying and checking essential care interventions. The service had plans to introduce the WHO checklist, however this was not yet in place and no date had been set for the process to start.
- The provider had exclusion criteria which they applied to all referrals to ensure they risk assessed patients prior to accepting the referral and offering appropriate treatment. The hospital had criteria for refusing patients with certain health conditions and this was checked with the patient at their initial appointment.
- Patients completed a basic pre- appointment medical questionnaire ensuring the clinic had the relevant health information needed to contribute to the assessment and suitability for treatment.
- All necessary diagnostic tests were completed on the first appointment along with an assessment with the consultant. If deemed suitable, patients were offered surgery.
- Patients went home when they felt well enough to go home. As the surgery did not involve general anaesthesia, patients did not require any observations post operatively. However, a staff member explained that they were aware of what actions to take if a patient became unwell. We saw several incidents where patients had fainted. Staff described how they would address this, and if necessary, they would call an ambulance for the patient.
- All patients were provided with an emergency card for their surgeon so they can contact them directly overnight in case of any queries or concerns.
- Patients told us they could contact the clinic direct during opening times if they had any concerns. However, they were advised to seek emergency medical assistance for more serious matters following discharge.
- The hospital had an anaphylaxis policy in place with a standard operating procedure of what should be done in the event of an incident; this was readily accessible to and familiar staff. Staff were advised to ring 999 in the event of an emergency.
- There had been no incidence of unplanned transfer of care within the last 12 months. If medical input was required staff were told to contact the emergency services.

Nursing and medical staffing

- The service was not following the Royal College of Ophthalmology (RCOG) guidance on staffing in ophthalmic theatres. The RCOG Roles within Refractive Surgery guidance states, "…nurses with an operating theatre background work closely with eye surgeons ensuring that all the correct checks are performed prior your surgery, maintaining a clean and safe surgical environment, and assisting during surgery". There was a lack of consistency with registered nurse provision on surgical treatment days and a lack of risk assessment documentation, specific to this risk. There was no permanent registered nurse and the most recent post holder had left in August 2017. When available, cover was provided by registered nurses working in other Optimax clinics. When this was not available a member of staff who was not a registered nurse and had not yet been signed off as competent assisted the surgeon.
- Staff told us that there was not always a registered nurse present in theatre during treatment and that the laser room technician was in the process of undertaking extended-role training to allow them to provide cover for the registered nurse role. However, this individual was still on probation and we did not see evidence that they were appropriately supervised. It was unclear how they were supported during their probation and training period as the supervisor was off-site.
- We saw that the provider had checks in place to ensure any new surgeon employed or granted practising privileges at the clinic, held the required level of professional training and experience to allow them to perform refractive eye procedures. All surgeons who performed refractive eye surgery were required to either hold a certificate in laser and refractive surgery

(CertLRS) or be on the GMCSpecialist Register in Ophthalmology, and hold evidence in their last revalidation cycle of an established refractive surgery practice.

- A review of staff files showed that all staff had received a DBS (Disclosure Barring Service) check. The manager told us they did not review these checks once done and we saw that several consultants with practicing privileges had not had checks re-done since 2003 and 2007. Whilst it is not compulsory to redo checks many organisation including the NHS do so on a regular basis.
- We saw a policy on the process to recruit doctors that supported safe recruitment. We were informed that this was undertaken at the Medical Advisory Board (MAB). However, there was no information available on the most recent MAB minutes of approval for a new consultant appointed in August 2017.
- We reviewed the files for practicing privileges for the ophthalmologists and optometrists. We were unable to locate any training records for staff. The manager told us they did not keep a local record training for staff not permanently employed by Optimax. They said this was held corporately. We asked for training information to be sent to us however none was received.
- We reviewed recruitment files for other staff. All but one of the staff working at the time of the inspection had worked in the service for less than a year.
- Senior managers told us the ophthalmologists and ophthalmologist consultants were employed under the practising privileges scheme. The medical director was also an ophthalmologist consultant employed under the practicing privileges scheme and worked across a number of Optimax clinics.
- Medical oversight was maintained by the Optimax national medical director from whom advice could be sought on corporate medical matters. Local medical supervision was available from the MAB chair who through the committee reviewed and monitored clinical practices across the service.
- A laser protection supervisor (LPS) was not always on site whenever laser procedures took place. However staff told us they were easily accessible via the telephone should they need to speak to them. The LPS help to ensure risks are managed and that best practices in laser safety are maintained.

Major incident awareness and training

- Up to date fire safety training rates for staff were at 31% of the team. A further 13% were due to expire in less than one month. The provider had three types of fire training available. This included basic fire safety, fire risk assessments and fire safety awareness. No staff had completed fire risk assessment or fire safety awareness training and it was noted ophthalmologists were exempt from this training. However, we spoke with the fire marshal who told us all staff had up to date fire training. We could not establish why this did not reflect training records on site.
- The clinic had a business continuity plan for major incidents such as power failure or building damage. The plan included emergency contact numbers for staff.
- Emergency backup generators were available and regularly serviced to ensure that treatments would not be compromised in the event of a power failure. Staff carried out daily checks to ensure they were working when the clinic was open. We saw records that confirmed this.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Patient procedures and care pathways we reviewed cited and included relevant best practice guidance such as National Institute for Health and Care Excellence (NICE) guidance for the treatment of macular diseases and The Royal College of Ophthalmologist (2017 RcOph) guidance. The Optimax Medical Advisory Board (MAB), set standards based on this guidance for all surgeons and optometrists across the service to work to.
- Minutes of these meetings showed that clinical protocols were discussed and amendments to current practices made to be in line with evidence-based practice.
- Staff were kept up to date with changes in practice and used this information to deliver care and treatment, which met patient's needs. For example, staff received National Patient Safety Alerts and alerts from the Medicines and Healthcare products Regulatory Authority. This meant they had accurate and up to date information confirming that best practice guidance was used to improve care and treatment and patient's outcomes.

Refractive eye surgery

Pain relief

- Where appropriate staff administered anaesthetic eye drops prior to surgery or procedures. Patients were asked about pain levels during and after procedures.
- Patients were asked post treatment how they felt and if they have any discomfort. If needed, extra time was provided for the patient in the recovery room where their pain was assessed and pain relief offered.
- Patients were advised on pain relief during discharge discussions and told that if the pain was severe they should go to their local accident and emergency department. Patients we spoke with stated they had very little pain and their pain levels were monitored by staff appropriately.

Patient outcomes

- Managers told us that Optimax Clinics Limited corporate clinical services team reviewed and audited all incidents, outcomes and complications by each individual ophthalmologist. Audits on patient experience showed that over 98% of patients reported they had a good experience with a good result.
- Staff assessed patient's needs and delivered care in line with current evidence based guidance and national guidance for best practice**.** The service audited the outcomes of every patient who had surgery at the service. .They used the data to more accurately predict successful outcomes from the surgery. We saw copies of patients' individual predicted outcomes and how this was used to monitor their individual outcome from the surgery.
- The provider assessed its own services against each individual clinic in order to measure the quality and increase performance. Individual Ophthalmologists results were assessed quarterly against the predicated outcomes of individual patients in order to make sure that the expected results were achieved Significant deviations would be recorded and investigated. If results outside the predicated range were identified this was discussed at the Ophthalmologists appraisal. Significant deviation would be logged and investigated.
- Managers told us quarterly audits were discussed at the Medical Advisory Board (MAB). However, we were unable to confirm this as the meeting minutes for May and October 2016 and March 2017 did not record any information on the outcome of audits.
- Senior managers told us they collated all the information nationally to provide patients with a realistic prediction of the outcomes for specific treatments before surgery. We were shown copies of patients' individual predicted outcomes and how this was used to monitor their individual outcome from the surgery. Any recommendations for changes were reviewed by senior managers via the national MAB and communicated to all staff in the organisation. This meant the service continuously reviewed the results that patients achieved and could quickly identify any areas where improvement was needed.
- The service had three patients unplanned returned to theatre after eye surgery in the last 12 months. Fifty-six patients had experienced complications within the last 12 months. Of these patients the majority (51) had minor or moderate complications including dry eye and under correction. Complication rates were less than 7% for all patients.

Competent staff

- All surgeons had the Royal College of Ophthalmology Certificate in Laser Eye Surgery. This ensured surgeons only carried out procedures that they are trained, skilled and experienced in.
- The manager was unable to provide evidence of appropriate training for all staff including self-employed staff. We found that not all staff was appropriately supervised when learning new skills prior to achieving full competence. For example, we saw evidence that personal assistants/reception staff were dispensing medication, and were carrying out additional tasks such blood pressure checks as part of the pre-assessment for surgery for which there were no competency information available to confirm they were suitably trained or supervised.
- The service had a vacancy for a registered nurse who had left in August 2017. Surgical operations were covered by Optimax nursing staff from other clinics when they were available. However, when there was no nurse available, the extended role treatment assistant who had not completed her competency training assisted the surgeon.
- The provider's policy stated that the role of the extended role treatment assistant is to oversee the general running of the treatment room in the absence of a registered nurse, and, along with the surgeon, ensure

that all practices were safe. During the laser treatments, the extended role treatment assistant assisted the surgeon, preparing and handing over the appropriate instrumentation, drops, swabs etc., and made sure that all equipment used during the surgical procedure was fit for purpose, maintained and safe for use. There was no registered nurse in post and the extended role assistant had not been signed off as competent to fulfil this role when registered nurses were unavailable. Staff told us they had covered surgical operations several times between August and December 2017. The manager told us this had only happened once however further evidence to support this information was not provided.

- We were not assured systems to monitor staff training were effective. Only two of the eight staff were recorded as completing fire safety awareness and none of the three optometrists on the training matrix had received fire training.
- The service had a mandatory training policy and staff were required to have annual refresher courses for basic life support, manual handling, fire awareness, infection control amongst others. It was the responsibility of the registered manager to ensure staff training was up to date. Most permanent staff had completed basic life support training, and the manager had completed intermediate life support training.
- All the company laser surgeons were required to attend the British Laser Medical Association "Laser Core of Knowledge" training every three years to ensure the surgeons' knowledge in the use of laser equipment was up to date. Managers told us evidence of attendance certificate was filed in the surgeons personnel file at head office and the clinic.

Multidisciplinary working

- The service did not provide an emergency eye surgery service. They provided for elective and pre-planned procedures only. Any emergency cases were referred to the appropriate emergency eye care services.
- Patient specific input could be sought through from consultants who were available by telephone. Where the patient's own consultant was not available, cover was provided by another consultant with the same clinical speciality.
- Although the service did not accept emergencies, a consultant or doctor was available during usual opening hours to review patients who might be experiencing difficulties post-operatively.

Access to information

- Medical records generated by medical staff working under practising privileges were available to staff or other providers, if necessary; care summaries and/or discharge information was communicated to GP where necessary if patients had given permission.
- Records showed that information was given to patients to provide to any external professionals that they wished to be informed about their surgery. Not all patients wanted their GP to have this information.
- Patient files were electronic, and were easily accessible for each appointment during laser eye surgery, and for staff to monitor patients after their laser surgery.

Consent and Mental Capacity Act

- The provider did not adhere to best practice guidance in relation to a 'cooling off' period between the consultation and the date of the procedure. This was because the provider's consent process offered patients as little as 24 hours cooling off, which did not meet the seven days recommended by the Royal College of Ophthalmology professional standards for refractive surgery. Although the consent declaration included the date of the surgeon's signature, it did not include the date of each patient's signature. This meant it was not possible to accurately identify when patients signed their consent form or whether the service had ensured an appropriate cooling off process.
- Consent procedures must make sure that people are not pressured into giving consent and, where possible, plans must be made well in advance to allow time to respond to people's questions and provide adequate information. Policies and procedures for obtaining consent to care and treatment must reflect current legislation and guidance and staff must follow them at all times
- It is good practice to ensure that consent is agreed and secured well in advance, so that patients have plenty of time to obtain information about the procedure and ask questions. A corporate consent policy was in place at

the service. The policy set out staff responsibilities for seeking and obtaining informed consent, including the type of consent (verbal or written) needed for different procedures undertaken at the hospital.

Are refractive eye surgery services caring?

Compassionate care

- We observed staff were friendly, warm and welcoming. Patients commented on the helpfulness of staff. Staff members were patient and kind towards patients, putting their minds at ease.
- Patients spoken with told us that staff were polite and they were treated with dignity and respect.
- Some patients returned frequently to the service for aftercare appointments. Patients could return for as many aftercare appointments as they needed without additional cost. Patients commented that staff were, "friendly and attentive" and, "kind and understanding"."
- The service was proactive in gaining feedback for patients. Patients were encouraged to give feedback and responses were reviewed and shared with managers. We were shown a copy of the latest results.

Understanding and involvement of patients and those close to them

- Staff told us that private patients received written information prior to surgery to ensure they felt supported and prepared for surgical procedures. We saw evidence in patient records of realistic outcomes following surgery being discussed.
- However, not all private patients were offered a seven-day 'cooling off' period to ensure that they had time to fully understand and consider all the information available.
- During the pre-assessment procedures, we observed staff explaining to patients what would happen during each stage of the procedure.
- Several patients we spoke with said they were aware of their surgical procedure and that it had been explained to them thoroughly and clearly. Patients told us they had been given time to ask questions to ensure understanding.
- Patients told us that staff kept them informed about the waiting times and how many patients were ahead of them on the theatre schedule.
- The service provided clear information on pricing for different surgeries. Following surgery, refractive eye patients were provided with written information explaining their follow-up care.

Emotional support

- We observed that staff respected patient confidentiality and ensured personal discussions took place in private rooms.
- Staff ensured that patients had the support they needed following a procedure and involved those close to patients to ensure they were supported when they returned home.
- After surgery all patients were given contact details of who to call if they had any concerns.

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

Service planning and delivery to meet the needs of local people

- The service provided laser surgery for the local population and across the London area. Staff informed us that any patient could attend any of the Optimax Clinics Limited services nationwide as the service could access electronic patient records from any clinic nationwide.
- Managers told us that all appointments were planned in advance. Optimax Clinics Ltd used a central booking system for all its services. This team responds to calls from prospective patients who want an appointment to assess if they were suitable for surgery. Patients were then booked a pre-assessment slot at the clinic of their choice.
- Managers told us the majority of patients had an appointment with the refractive surgeon prior to the day of surgery.

Access and flow

- Patients did not need a GP or optician's referral and could self refer directly with the clinic.
- Patients were able to access the service via a range of means. Including booking directly online with the clinic, via the customer service telephone number, calling the clinic direct or attending the clinic in person.
- All patients were treated as a day case under a local anaesthetic or sedation.

- The manager confirmed that the service did not monitor waiting times for surgery. Patients were generally allocated on to the next available surgical list once pre assessment checks had taken place.
- Waiting times to see the optometrist and ophthalmologist were not monitored by the service. Several patients we spoke with said they were booked in for pre assessment check quickly once they had contacted the service. The manager told us patients were booked for surgery fairly quickly after their pre assessment visit. This was confirmed by patients we spoke with.
- There had been 12 occasions in the last 12 months when refractive eye surgery procedures were cancelled for non-clinical reasons. The majority of these were due to staff sickness or not enough appropriately qualified staff available to staff the theatre.
- Staff and patients confirmed that where patients missed any appointments the service contacted them within 48hrs to follow up and rearrange an appointment as needed.
- There were no audits of arrangements in place to monitor the amount or frequency of aftercare that was needed. Staff told us this was dependent on the individuals needs and patients could have as long as was needed until they were satisfied with their treatment.
- There had been no incidences of unplanned transfer of a patient to another health care provider in the last 12 months. This meant that the service was able to recognise and address any potential complications to maintain quality of care to patients.
- A copy of the discharge letter was given to patients on leaving the hospital. Copies were also sent to the patient GP if the patient had given permission.

Meeting people's individual needs

- Staff were available to escort patients where they needed to go throughout the building and to support them with any needs they might have.
- The service provided a range of patient information leaflets, explaining the various conditions and laser surgeries it offered, including pre and post care instructions. However, all patient leaflets and documents, including consent forms, were in English.
- The manager and staff confirmed that the service only undertook laser surgery on patients aged 18 and above. Information sent to us prior to the inspection recorded that 26 patients aged 18 to 21 years had undergone laser surgery during the last 12 months. There was a policy in place for this age group which clearly stated the process to be followed before treatment.
- Staff confirmed that younger patients were advised that further laser surgery may need to be repeated at some stage in the future due to changes in eyesight commonly experienced with age. The suitability and laser surgery criteria protocol was the same for patients of all ages.
- We saw that patients were given written information on post-operative care and the 24 hour contact telephone number of the treating surgeon should they have concerns following discharge.
- The service did not provide an emergency eye surgery service. They provided elective and pre-planned procedures only. Any emergency cases were referred to the appropriate emergency eye care services.
- The waiting area was spacious with separate private rooms available if patients wanted to discuss their treatment in private.
- Staff informed us that patients with communication difficulties such as hearing impairments or literacy issues were advised to bring someone with them for every appointment.
- The manager told us that interpreting services were available for patients who required this service. However, the manager was unaware of whether the patient had to pay for this service and they were unable to tell us when this service had last been requested. Staff said that patients who did not speak English were advised to bring a friend or relative to translate, however this is not recommended best practice.
- Hearing loops were available for patients with hearing impairment if required.
- Patients had access to tea and coffee making facilities and water was available at all times.

Learning from complaints and concerns

- The service had a complaints policy and system for handling complaints and concerns that followed the organisation's corporate complaints policy. This provided a structured process for staff to follow when dealing with complaints.
- We reviewed the policy and found it had recently been reviewed and incorrectly stated that complaints could be directed to CQC if patients were not happy with the providers response. Whilst CQC will take information they do not investigate individual complaints.

- The service had received 32 formal written compliments in the last 12 months. Of these, nine were upheld. We were told that all complaints were acted upon and managers proactively aimed to resolve as many as possible informally. If the issue remained unresolved then the complainant was invited to follow the formal complaint procedure.
- The complaints procedure was included within the 'patient guide' which was available in the reception area and made available as part of the discharge information given to patients. This outlined how to make a complaint and included a copy of the patient survey to give feedback.
- Any concerns raised in patient surveys were logged and addressed as a complaint. On receiving the information the manager contacted the individual to determine the nature and scope of the complaint. A copy of any complaints and the actions the manager had taken to investigate and resolve the complaint was available in the service and the outcomes discussed in order to improve the service.
- Complaints were discussed at senior management meetings and if necessary the information was also referred to the Medical Advisory Board (MAB).

Are refractive eye surgery services well-led?

Leadership and culture of service

- Optimax Clinics Limited UK was established in 1991 and was still owned by the same individual. All staff knew who they reported to and the management structure of the service. Staff told us that management were accessible and they were confident they could approach their direct manager with any concerns.
- The registered manager had been in post since July 2017.
- A corporate compliance manager visited six monthly to review the quality of the service and make sure that staff working in the service were supported.
- Information available for prospective patients was clearly written and honest, responsible and complied with guidance from the Committee of Advertising. Patients received a statement that included terms and conditions of the service being provided, the cost, and method of payment for the laser eye surgery.

Vision and strategy

- The strategic vision of the service was determined at corporate level. There was a corporate core business plan for 2017, which set out the company's purpose, vision and values.
- The corporate vision was to be the UK's first choice for laser and lens surgery procedures and to provide high quality state of the art clinics and working conditions.
- Most staff were unable to tell us what the service vision or strategy was.

Governance, risk management and quality measurement

- There was a lack of effective systems and processes and we were not assured that there was an appropriate level of local oversight of risk.
- Systems or processes in place to identify new risks or monitor and review current risks were not effective. We identified several risks during the inspection that were not reflected on the provider's risk register. This included policies, and processes for reviewing policies, that were not fit for purpose. Various policies including vulnerable adults, had been updated in September 2017 however referred to out of date guidance and legislation. The infection control policy reviewed in August 2017 did not refer to all the latest regulations. Staff including the registered manager, had not received any training in risk management.
- Managers told us all changes to policies were reviewed by a panel of senior managers however this had not been picked up and managers were not aware of this until pointed out by the inspector on the day of the inspection.
- Medical professionals such as the optometrist and surgeons were employed under practising privileges. Practising privileges are where medical staff are not directly employed by the service but who have permission to practise there. All medical practitioners working under practising privileges received an annual appraisal and had professional indemnity insurance. This information was recorded in their individual files.
- There was a lack of oversight of the recruitment and practicing privileges processes. Practicing privileges files for surgeons did not include any evidence on training and it was not clear how oversight of the practicing privileges process was maintained. Minutes of medical

advisory board (MAB) meetings we reviewed did not show any evidence of discussion on surgeon recruitment. There was no process in place to regularly review disclosure and barring service (DBS) checks for staff including surgeons.

- The clinical governance policy stated the MAB were required to meet four times a year; however this had not been followed. Managers told us quarterly audits were discussed at the MAB to determine the results for patients' of the laser surgeries provided and safety. However we were unable to confirm this as the meeting minutes for MAB that had taken place in May and October 2016 and March 2017 did not record any information on the outcome of audits. The Royal College of Ophthalmologists standards for laser surgery states, "reports on clinical incidents should be discussed regularly at the Medical Advisory Committee or an equivalent clinical management group".
- Senior managers told us they were aware of the problems and plans were in progress to formalise the agenda for MAB meetings and ensure they took place quarterly however this was not yet in place and there was no planned start date.
- Reviewing minutes of MAB meetings it was not evident patient records relating to consent were always updated as a result of decisions made by the senior team. For example, in October 2015 and March 2017 MAB meeting minutes indicated clinical staff were involved in developing clinical trials and research and the provider's consent forms needed updating as a result. However, we saw on some consent forms in use at the time of the inspection that permission for staff to use patient outcomes in research studies was not routinely documented.
- In addition, consent forms did not include documented evidence from patients that they may receive contact lenses that were supplied as part of a clinical trial. This did not apply to YAG laser surgery and we saw patients were consented for participation in clinical trials for this type of procedure.
- There were no formal processes in place to link the MAB with the local management. However managers informed us informal conversations took place on an occasional basis.
- Phone conference team meetings with the manager and compliance manager occur once a month. Areas that are covered during these meetings include complaints, audits and incident and near miss reports.
- Infection control unannounced inspections were carried out annually by the organisation's infection control nurses. If a clinic under achieved, they would receive another visit within 12 months to ensure actions were completed.
- All clinical practitioners working under practising privileges had professional indemnity insurance and this was evidenced in their personal file.

Public and staff engagement

- The service had a website where information could be obtained about the types of treatment available for patients. This included information about costs and finance. It also outlined the suitability criteria, and explained the laser eye surgery. The website also included information regarding a free consultation and lifetime after care as needed.
- The service was proactive in obtaining patient feedback following their treatments. The feedback viewed was positive with patients recommending the service and describing positive results.
- The service had a high patient satisfaction rate of 98%, no serious incidents and no reported cases of infection. The compliance manager for the organisation audited these and other results in the service at quarterly intervals. The results of these were shared with local managers in order to monitor the quality of the service provided.
- Staff were actively encouraged to develop their skills and expertise. The registered manager told us the service did not undertake staff surveys. As a small team, staff told us they had good communication with managers and worked well as a team. The majority of staff were new to the service and were still getting to know one another.

Innovation, improvement and sustainability

- Staff informed us of the corporate plans to improve the services they offered.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to address concerns identified during the inspection in relation to governance of the service.
- The provider must ensure it implements and monitors a surgery safety checklist that is fit for purpose.
- The provider must ensure they have robust systems in place to monitor the administration, management and dispensing of medicines to provide safe care and treatment to patients.
- The provider must ensure that all policies and guidance are up to date with current professional standards and legislation.
- The provider must ensure that all staff, including clinical staff with practising privileges, have completed mandatory training.
- The provider must ensure that there are sufficient numbers of staff with the right competencies, knowledge and qualifications to meet the needs of patients.
- The provider must ensure consent forms include documented evidence from patients that they are aware they may receive contact lenses that were supplied as part of a clinical trial.
- The provider must ensure all staff and clinicians with practising privileges have the relevant training to ensure they have the required skills and knowledge to deliver effective care and treatment.

Action the provider SHOULD take to improve

- The provider should ensure they consider individual patients' needs, including patients with complex needs and cultural and religious requirements.
- The provider should ensure all patients have the minimum recommended cooling off period before surgery.
- The provider should ensure that patient leaflets are available in other formats, such as large font or braille, and other languages.

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 11 HSCA (RA) Regulations 2014 Need for consent Consent procedures must make sure that people are not pressured into giving consent and, where possible, plans must be made well in advance to allow time to respond to people's questions and provide adequate information. Policies and procedures for obtaining consent to care and treatment must reflect current legislation and guidance and staff must follow them at all times.

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 The provider must ensure that care and treatment is provided in a safe way for service users. The provider must ensure that medicines are managed and dispensed in a safe way. The provider must ensure staff have completed relevant competency assessments to ensure staff have the adequate skills and knowledge to care to carry out their role for patients

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance

This section is primarily information for the provider

Requirement notices

The provider must ensure that systems and processes are established and operated to assess, monitor and improve the quality and safety of the services.

The provider must ensure that they evaluate and improve their practice with regards to policies and procedures, guidance to staff in order to manage and reduce risks.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing Sufficient numbers of suitably qualified, competent skilled and experienced persons must be deployed. They must receive such appropriate support, training, professional development, supervision and appraisal as necessary to enable them to carry out the duties they are employed to perform.