Optegra Eye Hospital London

Quality Report

25 Queen Anne Street
Marylebone
London
W1G 9HT
Tel: 0808 273 2271
Website: www.optegra.com

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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

Optegra Eye Hospital London is an eye hospital located in Marylebone, Central London. Optegra Eye Hospital London is part of a nationwide company, Optegra UK Limited, which has seven hospitals and three outpatient clinics in the UK. The hospital provides services to adults over the age of 18 only.

The hospital opened in January 2016. The premises are two former Georgian and Victorian residential properties which have been refurbished to create an ophthalmic hospital.

The hospital is set over six-floors and has six consulting rooms, a reception area, five diagnostic rooms, three operating theatres including one used for minor laser procedures, a treatment room, four patient liaison rooms and pre and post-operative areas.

The hospital provides surgery; outpatients and diagnostic imaging. Services provided include refractive eye surgery, ocular plastic, retinal diagnostic, general surgical services and ophthalmic disease management.

We inspected this service using our comprehensive inspection methodology. Because refractive eye surgery accounts for the majority of services provided by the hospital, we have reported our inspection findings against the refractive eye surgery core service. We carried out the announced part of the inspection on 17 and 18 October 2017, along with an unannounced visit to the hospital on the 27 October 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 refractive eye surgery service as in the case of Optegra Eye Hospital, London. 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 report incidents, what incidents to report and were informed of incidents through staff meetings and emails.
- 100% of staff had completed their mandatory training.
- Staff had a good understanding on information governance.
- The hospital was visibly clean and tidy and there was no incidence of a hospital acquired infection in the reporting time period.
- Theatre practices met the Association for Perioperative Practice (AFPP) guidelines.
- All the equipment used in the hospital was recorded in the medical devices database, which was in line with best practice.
- The theatre department used three different types of laser machines and protective eye goggles that were colour coded to identify which machine these were to be used for**.**

Summary of findings

- We saw that implants bar codes with unique traceable reference numbers were recorded in patients' medical records, through the use of stickers.
- Controlled drugs (CD) were stored correctly within the hospital. All CDs we looked at were in date.
- A room where patient records were held had restricted access and was only accessible via key card entry.
- The hospital adhered to the World Health Organisations (WHO) Surgical checklist which was audited monthly for compliance.
- Staff had access to the laser protection advisor.
- The system that held the disclosure barring checks (DBS) records was able to identify, and highlight in red out of date DBS checks.
- The hospital was up to date in staff appraisals.
- Optegra used an electronic based system for storing clinical records. This was accessible to other Optegra hospitals should the need arise for patients to be seen at another site.
- We observed compassionate care and very positive interactions by all staff.
- Staff treated patients, and those close to them, with respect and dignity.
- The hospital arranged open days to give information to patients about different procedures and to answer their questions about treatment.
- The entrance of the building had been adapted to accommodate wheelchair users. Each floor within the building was accessible via a lift and set of stairs.
- Staff told us they all worked well together as a team. We saw teamwork was particularly good within theatres with each staff member having a voice and an equal place within the team.

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

- There was one never events in the last 12 months.
- There was one serious incident reported in the last 12 months.
- Staff had a poor understanding of the meaning of safeguarding.
- There was no policy on the treatment of sepsis.
- We found that registered nurses did not have the appropriate training to dispense medications, such as artificial tears, anti-inflammatories and antibiotics.
- The resuscitation trolley in the ward did not comply with national guidelines.
- Unique patient identification stickers were not used on all pages of patients notes.
- No member of staff was currently trained in advanced life-support training or equivalent.
- The hospital did not participate in any national audits.
- There was no service level agreement with another provider for emergency transfer of patients should there be an emergency at the hospital.
- There was some confusion amongst staff about the precise roles and responsibilities of some individual staff members.

Summary of findings

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

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		Surgery was the main activity of the hospital. Where our findings on surgery also apply to other services, we do not repeat the information but cross-refer to the surgery section.

Summary of findings

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Optegra Eye Hospital London

Services we looked at:

Refractive Eye Surgery

Summary of this inspection

Background to Optegra Eye Hospital London

Optegra Eye Hospital is operated by Optegra. The hospital opened in January 2016. It is a private hospital in Central London. Optegra Central London provides the end to end of Ophthalmology services to a wide geography of individuals and businesses. They see patients from all ethnicities with the majority of patients living or working within a 45 minute travel time from the Hospital. Optegra Central London is part of the Harley Street community of hospitals which attracts many overseas patients. None of the surgical procedures provided were NHS funded.

The hospital has had a registered manager in post since 21 October 2016.

The hospital covers a complete patient pathway, from ophthalmic consultations and diagnostics through to disease management or treatment including day surgery for adults over the age of 18 years. These include refractive, ocular plastic and retinal diagnostic and surgical services and ophthalmic disease management.

During the 12 months prior to our inspection, the hospital recorded 1,488 surgical procedures. Of these 54% were for refractive eye surgery and 46% were for non-refractive surgery. More specifically, of the total number of surgeries, 35% were for cataract surgery, 22% for refractive lens exchange, 27% for laser, and a small number (approx. 16%) of other procedures including implantable contact lens procedures, vitrectomy and blepharoplasty (eyelid surgery for non-cosmetic reasons).

During the 12 months prior to our inspection the hospital recorded 4,356 outpatients' appointments, which included initial appointments, consultations and follow ups. 63% of patients were seen for refractive outpatient appointments and 37% were seen for medical outpatient appointments.

The hospital is registered for the following registered activities:

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

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector, an assistant inspector and a specialist advisor whose background is as a theatre nurse. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Information about Optegra Eye Hospital London

During the inspection, we visited the theatres, diagnostic floor and the pre and post-surgical ward. We spoke with 20 staff including; registered nurses, health care technicians, reception staff, medical staff, operating department practitioners, and senior managers. We spoke with five patients and one patient's relative. During our inspection, we reviewed 38 sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the hospital's first inspection since registration with CQC.

Activity (2016 to 2017)

- In the reporting period 1 October 2016 to 30 September 2017 there were 1,488 surgical procedures recorded at the hospital.

Summary of this inspection

- The most common procedures were cataract procedures, with 514 privately funded cataract procedures recorded during the reporting period.
- During the same period, there were 736 refractive eye surgeries and 238 other procedures including implantable contact lens procedures, vitrectomy and blepharoplasty.
- All procedures were undertaken during the day and there were no inpatient beds for overnight stay.
- There were 4356 outpatient attendances in the reporting period; of this zero were NHS funded.

There were 44 ophthalmologists and 13 anaesthetists with practising privileges. Five out of 12 nurses were full time and the other seven nurses were on a zero hours contract. There were three optometrists, two out of the three were permanent members of staff. There were seven health care technicians (HCTs) altogether; five out of the seven were permanent. There were three receptionists, and the hospital also used bank staff when required.

The accountable officer for controlled drugs (CDs) was the clinical services manager.

Between October 2016 and September 2017 the hospital reported:

- There was one never event where the wrong lens was implanted during surgery; the mistake was picked up mid procedure and corrected.
- 33 clinical incidents including: 23 no harm, eight low harm, two moderate harm, zero severe harm, no deaths.
- There was one serious incident, where a patient was found to have an unexpected refractive error where the lens had flipped over. This was found during a routine post–operative appointment.
- There were no incidents of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (C.Difficile) or hospital acquired E-Coli.
- There were 24 complaints between October 2016 and September 2017.

Services accredited by a national body:

N/A

Services provided at the hospital under service level agreement:

- Interpreting services
- Grounds maintenance
- Laser protection service
- Laundry
- 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 areas of good practice:

- Staff knew how to report incidents, what incidents to report and were informed of incidents through staff meetings and emails.
- 100% of staff had completed their mandatory training.
- Staff had a good understanding on information governance.
- The hospital was visibly clean and tidy and there was no incidence of a hospital acquired infection in the reporting time period.
- Theatre practices met the Association for Perioperative Practice (AFPP) guidelines.
- All the equipment used in the hospital was recorded in the medical devices database, which was in line with best practice.
- The theatre department used three different types of laser machines and protective eye goggles that were colour coded to identify which machine these were to be used for.
- We saw that implant bar codes with unique traceable reference numbers were recorded in patients' medical records, through the use of stickers.
- Controlled drugs (CD) were stored correctly within the hospital. All CDs we looked at were in date.
- The hospital had a Home Office Controlled Drugs Licence which was recently renewed on the 14 June 2017.
- A room where patient records were held had restricted access and was only accessible via key card entry.
- The hospital adhered to the World Health Organisations (WHO) Five Steps to Safer Surgery Surgical checklist which was audited monthly for compliance.
- All staff had access to the laser protection advisor contact details.
- The system that held the DBS records was able to identify, and highlight in red out of date DBS checks.

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

- There was one never event in the last 12 months.
- There was one serious incident reported in the last 12 months.
- Staff had a poor understanding of the meaning of safeguarding.

Summary of this inspection

- There was no policy on the treatment of sepsis.
- We found that registered nurses did not have the appropriate training to dispense medications, such as artificial tears, anti-inflammatories and antibiotics.
- The resuscitation trolley in the ward did not comply with national guidelines.
- Unique patient identification stickers were not used on all pages of patients notes.
- For the eye drops listed on the pre-printed prescription forms, the instructions on how to take the medication were not clear.

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 areas of good practice

- The hospital recorded that there had been two occurrences of posterior capsule rupture out of 775 intraocular lens procedures over the last 12 months prior to our inspection which was a rate of 0.26% and below the national average.
- Pain relief medication was clearly documented in patient notes.
- The hospital was benchmarked against industry standards, and the outcomes often exceeded the benchmark standard.
- The hospital was up to date in staff appraisals.
- During our inspection, we saw good multidisciplinary teamwork between disciplines within the hospital.
- Optegra used an electronic based system for storing clinical records. This was accessible to other Optegra hospitals should the need arise for patients to be seen at another site.

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

- We reviewed 16 patient records and found that there was no indication of the 'seven day cooling off period' (a chance for the patient to reflect on their decision) within the patients record.
- No member of staff was currently trained in advanced life-support training or equivalent.
- The hospital did not participate in any national audits.
- Monthly hospital audits were undertaken for example the WHO 'five steps to safer surgery'. Although, we did not see learning shared from audits or recommended actions to be taken for improvement in writing. However, we did see recommended actions on the hospitals clinical governance meeting minutes that was attended by the CSM and clinical team members, where learning was shared.

Summary of this inspection

- During our unannounced inspection we looked at 18 consultant records and found little evidence to show suitable training to level two certification in safeguarding adults.
- Staff were not competent in their role to dispense medication.
- Key staff were not aware of who the laser protection advisor was.
- Staff we spoke with said that 'over the phone pre-assessments' were not adequate in identifying a patient's mental health status.

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

- We observed compassionate care and very positive interactions by all staff.
- Staff treated patients, and those close to them, with respect and dignity.
- We observed all staff, including reception staff and non-clinical staff, were kind and respectful to patients who used the service.
- Patients were provided with brochures and other patient information literature such as treatment side effects. Information was also available on the provider's website.
- Family members were allowed to come into the consultations with the patient, with the patient's permission.
- Staff ensured people's privacy and dignity were respected throughout the duration of the patient pathway.

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

- The hospital was easily accessible and well serviced by public transport.
- The hospital provided a 24 hour helpline for advice to patients outside of normal working hours.
- Consultants were available during normal working hours to review patients if necessary.
- The hospital arranged open days to give information to patients about different procedures and to answer their questions about treatment.

Summary of this inspection

- The entrance of the building had been adapted to accommodate wheelchair users. Each floor within the building was accessible via a lift and set of stairs.
- Optegra's policies and procedures and local policies were in place regarding complaints, reporting of incidents and near misses. These were discussed at governance meetings to review continuous improvement and learnings were shared with staff.
- The hospital had made several changes and improvements as a direct result of the views and experiences of people using the service.

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

- There was no service level agreement with another provider for emergency transfer of patients should there be an emergency at the hospital. However, the provider subsequently told us that unplanned transfers due to medical emergencies were taken to the nearest NHS provider with access to a high dependency unit and an intensive care unit.

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 areas of good practice

- Staff told us they all worked well together as a team. We saw teamwork was particularly good within theatres with each staff member having a voice and an equal place within the team.
- Staff we spoke to had a good understanding and knowledge of the hospitals four core values.
- The hospitals strategy was safety first, the hospital had conducted a review against the care quality commission and made a '121 point' improvement plan.
- The hospital director maintained a close link with the head of clinical governance and risk and the UK clinical lead to ensure compliance across the different areas of the service.
- Throughout the inspection, staff were welcoming and willing to speak with us.
- Staff spoke positively about the service they provided for patients.
- The service had a user friendly website which listed and explained the different types of treatments available for patients.

Summary of this inspection

- The patient liaison services manager (PLS) told us that as a team they have social evenings after work.
- Optegra had a new electronic governance reporting system, which incorporated incident reporting, auditing, competency trackers, complaints and risk registers.

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

- There was some confusion amongst staff about the precise roles and responsibilities of some individual staff members.
- The risk register did not identify that some staff did not have their disclosure and baring service (DBS) checks done or that registered nurses were not competent in dispensing medication.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Incidents and safety monitoring

- Staff we spoke with knew the types of incidents to report and could demonstrate how they would report incidents and escalate them to their managers. They gave us examples, that included a patient fall. Staff reported incidents on an electronic form and also verbally notified managers.
- The Clinical Services Manager shared learning from incidents with staff within team governance meetings that were cascaded to other members of staff through meeting minutes and by emails.
- Staff we spoke with were familiar with the duty of candour, and were aware of this duty when reporting an incident. The duty of candour is a regulatory duty that requires providers of health and social care services to disclose details to patients (or other relevant persons) of notifiable safety incidents as defined in the regulation. This includes giving patients details of the enquires made, as well as offering an apology. We saw that duty of candour was referred to in the incident policy. We also saw that the provider had a separate policy on being open and duty of candour, in line with Regulation 20 of the Health and Social Care Act 2008 (regulated activities) regulations 2014.
- To ensure that there was always a culture of transparency and in raising patient awareness of any incident, the hospital routinely referenced duty of candour within every incident form. The form also captured whether or not the patient had been made aware of the incident and surrounding circumstances.
- There were no formal notifications as per Optegra's duty of candour policy in the last 12 months. This was because no incidents of moderate or severe harm occurred during this period. The hospital ensured that the patients involved in the serious incident and never event were informed of the occurrence, cause and outcome by the consultant involved. This was captured within the patient notes. We looked at the formal root cause analysis investigation on the never event that was conducted by the hospital's governance team to ensure that learning was achieved. We saw that learning was included within the hospital's continuous improvement plan to ensure that the risks for recurrence were minimised.
- The never event reported in the last 12 months were reported as a low harm incident. The never event occurred in surgery There was also one serious incident reported in the last 12 months, this was also reported as low harm.
- 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.
- We saw that incidents, near misses, accidents, serious incidents, never event and duty of candour reports were discussed at the quarterly medical advisory committee (MAC) meetings and the monthly governance meetings.

- The Corporate Governance Team cascaded patient safety alerts. If a medicines incident occurred, staff were aware that this must be reported. There was an internal investigation process to do this.

Mandatory training

- We looked at the training matrix for the optometrists, clinical services manager, lead theatre nurse, registered nurses and healthcare technicians. All staff had 100% mandatory training compliance, which was above the 95% target compliance rate. This training included health and safety, fire safety, infection control, information governance, safeguarding, conflict resolution and basic and intermediate life support.
- We looked at the training for non-clinical staff and saw that there was a 100% compliance, which was above the 95% target compliance rate. Mandatory training included office health and safety, basic life support, equality, diversity and human rights, safeguarding, information governance and display screen equipment.
- Information governance training was completed and staff we spoke to had a clear understanding of the importance of how long they could retain patient information.

Safeguarding

- The service did not provide treatments for anyone under the age of 18.
- 100% of staff had completed safeguarding training to the appropriate level, of level two for adults. This training had been completed online and the course content for this training covered topics such as: 'how to keep people safe and how to respond to safeguarding alerts/referrals', and 'how to identify and reduce potential and actual risks after disclosure'. However, when staff were questioned on their competency of safeguarding, it was evident that there was a lack of understanding in this area. For example, one member of staff thought that safeguarding patients was to ensure that patients "did not slip on the floor", and another member of staff thought that safeguarding meant that it was important for patients to "leave with a smile on their face". This meant that the training in safeguarding was not adequate enough for staff, as information from this training could not be retained. We spoke to 16 members of staff and found that 12 members of staff showed a lack of competence in the understanding of safeguarding.
- We did not see any contact information or procedures for reporting allegations of abuse displayed anywhere within the hospital.
- The clinical services manager (CSM) was the safeguarding lead for this hospital and was trained to a level three in safeguarding adults. This was in accordance to the safeguarding policy, which stated that hospital safeguarding leads should be trained to level three. However, staff we spoke to were not able to identify the CSM as the safeguarding lead. The hospital director did not hold the relevant safeguarding level for safeguarding, which should be at level three. However when we informed the hospital of our findings we were given an action plan to ensure that the correct training levels would be achieved.. We were told that the hospital director would complete his training by a certain date, however annual leave commitments meant that this training was postponed and set at a different date.
- The corporate safeguarding adults policy did not have a review or issue date. The policy needed revising, as it did not make reference to the CQC when making safeguarding referrals.
- The local policy did not mention who the local safeguarding lead was, nor did the policy have the contact number of the local authority or where this information might be displayed within the hospital. The policy was last issued 16 October 2017 and was valid for three years. The policy also failed to highlight the importance of raising safeguarding concerns to the local authority. The policy was not clearly written and referred to an appendix three, for safeguarding supervision for all adults involved in safeguarding cases referred to the local authority. However we could not find this appendix. We raised this with the clinical services manager.
- Following our initial inspection, staff attended a workshop to refresh their knowledge on safeguarding.
- Also during our unannounced inspection we looked at a further 18 consultant records and found little to no

evidence to show suitable training in level two safeguarding adults that should have been attained from their respective NHS hospitals in which they worked at.

Cleanliness, infection control and hygiene

- The theatres, environment and equipment were visibly clean.
- The hospital was clean, tidy and clutter free. Housekeeping cleaning schedules were in place for the day-to-day cleaning, which domestic staff signed twice a day. The hospital manual cleaning policy stated that the manual cleaning of equipment was colour coded in accordance to the area in which that equipment was used. For example, the patient areas and treatment room equipment were colour coded yellow and the bathroom and washroom equipment was colour coded red.
- We looked at the morning and evening cleaning schedules which listed the areas that required cleaning. For example, the morning schedule included; the cleaning and restocking of the beverages station, in the reception and cleaning of the wash basin and mirrors on the clinical floors. The evening schedule included the vacuuming of the carpets and the cleaning of chairs in the reception and other waiting areas.
- The patients' chairs were covered in a fabric material which had anti-microbial and anti–fungal properties, also suitable for cleaning with disinfectant wipes.
- Staff we spoke with told us that the cleaners left green 'I am clean stickers' on everything that was cleaned after the evening shift. We saw these stickers on the morning of the second day of inspection. The stickers were placed on all of the clinical equipment and devices. However no stickers were placed on patient chairs within treatment rooms. This meant that we could not be sure if these chairs were cleaned on a daily basis. However, we were told that staff cleaned these chairs after every patient with an anti-bacterial wipe.
- During the inspection, we saw that clinical waste bins were available on all of the appropriate floors. There was always two bins available by the handwashing sinks, some with black bin liners and some with orange bin liners. However, the bins were not labelled and there were no signs to differentiate which bin was for clinical waste. Inside patient rooms there was a bin which was labelled 'domestic waste'.
- We saw that hand hygiene and decontamination audits were completed once a month. We looked at the results of these audits and found that there was 100% compliance with hand hygiene and decontamination.
- We saw that staff followed the National Institute for Health and Care Excellence (NICE) guidelines and adhered to the practice of bare below the elbows at all times whilst discharging their clinical duties. Staff also used appropriate personal protective equipment whilst in clinical areas. This meant that staff were aware of and followed the appropriate infection control procedures for appropriate dress and clothing.
- There was no incidence of a hospital acquired infection in the reporting time period. The service screened for methicillin-resistant Staphylococcus aureus (MRSA), herpes, human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS) during the surgical pre-assessment questionnaire.
- There was no separate policy for the treatment of sepsis and it was not included in any other policy. We were told that the corporate governance team were going to incorporate the management of sepsis in the policy for managing medical emergencies. NICE guidelines state that all healthcare staff involved in triage or early management are given regular appropriate training in identifying, assessing and managing sepsis. This should include local protocols for early treatments.
- The hospital adhered to the Control of Substance Hazardous to Health Regulations 2002 concerning the risk from exposure to Legionella.The hospital ensured that water could not stagnant anywhere in the system and ensured the release of water spray was properly controlled.

Environment and equipment

- The theatres, environment and equipment were well maintained.

Refractive eye surgery

- We saw that the facilities were spacious and fit for purpose. Staff and patients were positive about the environment.
- We saw controlled areas, where staff operated the machines were clearly defined and warning lights were turned on when lasers were in use.
- The provider used equipment that was specific to refractive eye surgery, and also that required a service in line with the manufacturer's guidelines and in accordance with Medicines and Healthcare Products Regulatory Agency (MHRA).
- There is a requirement to ensure that all medical devices are serviced. Best practice is that this information is contained on an asset register. This would enable the service to identify previous and upcoming service records and also when an asset was purchased. Best practice is to have this information available in a spreadsheet format or in a database that can be readily searched and identify items due for a service. We saw the medical equipment asset register for the hospital captured on an electronic spread sheet, which was organised and was easy to use. The database allowed information to be sorted and the database was also able to highlight equipment that was due for a service. The information stored included the serial numbers of the equipment, which made equipment easy to find on the database.
- All the equipment used in the hospital was recorded in the medical devices database, which was in line with best practice. Maintenance records were stored centrally and electronically on the intranet, which was monitored closely by the facilities manager, hospital director and clinical services manager.
- There was a planned preventative maintenance schedule that ensured all clinical medical devices were checked regularly according to manufacturer guidelines.We looked at the equipment used in theatres and checked their servicing dates which were all up to date. This corresponded with the medical devices database.
- We were shown evidence on a spreadsheet that all Portable Appliance Testing was up to date, and a retest was due for the 6 February 2018.
- We spoke to the laser protection supervisor (LPS) who showed us the theatre control panels, which remained active all of the time. The panel was made of stainless steel to reduce the possibility of hospital acquired infection. This control panel controlled the air flow, the humidity, medical gases, and 'room in use' lights and had other clinically based functions.
- In accordance with Optegra local rules and policies, the LPS routinely conducted safety checks on all laser equipment.
- The theatre department used three different types of laser machines and protective eye goggles that were colour coded to identify which machine these were to be used for.
- We saw local rules were in place to cover the use of the lasers located in the hospital. Local rules were kept in the laser safety book which was kept in theatre two.
- There were safe practices in place for the traceability of implants used in surgical procedures. We saw that implant bar codes with unique traceable reference numbers were recorded in patients' medical records, through the use of stickers.
- All patient bays had direct access to oxygen in the form of oxygen tubes and suction units which were mounted to the wall. All bays had a blood pressure machine and the equipment to measure oxygen in the blood.
- We saw a resuscitation trolley on all clinical floors, totalling five resuscitation trolleys. However, the resuscitation trolley on the ward did not comply to national guidelines. We looked at the resuscitation trolley on the ward, the checklist that accompanied the trolley reflected what was in the trolley. This however did not comply with the hospital's own resuscitation policy description of what should be in the emergency trolley.
- The only medication in the resuscitation trolley was one bag of IV normal Saline, and in the emergency pack there was a 1: 10000 Adrenaline and Amiodone 300 in 10 mls ampoule. There was no Dextrose or sodium lactate solution as per the resuscitation policy, nor other emergency drugs. We also saw two laminated posters with the initial management of

in-hospital cardiac arrest and the content of the resuscitation trolley. There was no algorithm of cardiopulmonary resuscitation (CPR) displayed anywhere.

- Staff had access to resuscitation trolleys across the hospital which contained emergency medicines and equipment for immediate life support. The resuscitation trolleys were being updated to include more medicines for use in medical emergencies. As a result, some resuscitation trolleys did not have the full complement of medicines required as per the resuscitation trolley checklist, however this was being dealt with as a matter of urgency.
- The resuscitation trolleys were readily accessible to staff in all clinical areas and were tamper evident. All resuscitation trolleys had oxygen cylinders. We saw that all of the oxygen cylinders were full and in date. Staff checked this equipment thoroughly on a weekly basis, and did a visual check of part of the trolley on a daily basis. The contents on the resuscitation trolley were decided by senior staff within Optegra.
- Single use instruments were disposed of safely by the use of a sharps bin; which was removed from the hospital on a weekly basis.

Medicines

- Medicines management policies were in place and we saw that 100% of staff had completed medicine management training.
- There was a service level agreement (SLA) for the supply of pharmaceutical products and clinical pharmacy services with a pharmacy service at a nearby hospital.The SLA also included the provision of medicines management audits to ensure the hospital complied with all regulations and best practice guidelines. We looked at the results for the medicine management audit which included checking the fridge temperatures, checking dates of medications, and looking at ordering and receipt of medications. The audit identified areas of compliance, concern and areas that required attention. The last audit conducted showed that the hospital required attention in three out of nine areas audited and that there was a 66% compliance rate with all other audited areas. These were removing expired stock, compliance with the type of controlled drugs the hospital was licenced for, and expiration of the T28 authorisation form (which allows the hospital to comply with the requirements of the Misuse of Drugs Regulations 2001 by making controlled drugs unsuitable for consumption).
- Areas of non-compliance were immediately flagged to the clinical services manager and the hospital director via a monthly report. The Head of Clinical Governance and Risk received a group report which highlighted any areas of concern. Medicines management was a standing agenda item on all corporate and hospital governance and risk meetings.
- There were controlled drugs (CD) stored and administered at this hospital such as Diazepam. We looked at the CD's which were all in date. Controlled drugs were kept in a secure cabinet by the nurses station. The key was kept in a coded locked box and only the staff nurses had access to this code. We looked at the CD register which was completed correctly. We spoke to the pharmacist who told us that the hospital was provided with denaturing kits to destroy out of date CDs. This was also a part of the medicine management audit and we saw that the hospital was compliant in this area.
- In addition, the SLA provided annual training to all relevant clinical staff at the hospital. We saw that the last training was held 15 August 2017.
- The hospital had a Home Office Controlled Drugs Licence which was renewed on 14 June 2017.
- The hospital had recently stopped the use of all cytotoxic medications and removed all traces of the drug from the premises.
- We found that the clinical rooms and fridge temperatures (where medicines were stored) were checked regularly. Whilst the temperatures were usually within the required range to ensure stability of medicines, there were some out of range temperatures seen. It was not clear from the records whether any actions had been taken by staff. We identified one room where medicines were being stored but the temperatures were not being recorded. We advised staff to keep records of temperatures in this room.

- We saw that pharmaceutical waste was handled appropriately throughout the hospital. However, the hospital did not have a valid T28 exemption certificate at the time of this inspection. The hospital director told us after the inspection they have now applied for the certificate.
- We found that registered nurses did not have the appropriate training to dispense medication. Consultants gave instructions to nurses on how a particular medicine should be taken, and then the nurse would dispense this medicine on the basis of that the consultant had instructed. However, we saw evidence that a competency assessment has been developed recently and was yet to be implemented. This meant that patient safety could be at risk if a patient was told to administer a medication at home incorrectly. We did not see this on this risk register. The provider informed us that patients were given verbal and written instructions by the discharging nurse on their take home medications which included type of eye drops, purpose, frequency and length of usage. However, if patients forgot or developed any other questions regarding their medications, there was an on-call number to ring to clarify any confusion. The CSM informed us that the patients would sometimes call the on call nurse confused about how to self-medicate.
- We looked at patient records and found that they all included patient demographics, medical history and information about allergies. The medicines required pre-operatively and for discharge were printed on pro-formas individual to each type of surgical procedure. If a consultant wanted a patient to have a particular medicine, they were supposed to sign that entry on the pre-printed form to validate the prescription. However, we saw an example where the consultant had not signed the prescription, but nursing staff had administered the drugs.
- We saw another example where a pre-printed prescription was signed to show that the medicine was given once before theatre. The nurse in theatre also gave a dose. However there was no record of a valid prescription to cover the dose given in theatre or a record made of what was administered. There was no associated incident form for this incident.
- We spoke to a staff nurse who told us that there were 40 different types of eye drops that could be given to the patient after surgery. We were told that different consultants had different preferences on which eye drops they wanted their patient to use, and the hospital accommodated this. These eye drops were either: artificial tears, anti-inflammatories or antibiotics. These were initially prescribed by the consultant but dispensed by staff nurses.
- For the eye drops listed on the pre-printed prescription forms, the instructions were not clear. For example we were told that two of the eye drops were administered three times before theatre. One member of staff told us that the three doses were given in 10 minute intervals, whilst the other member of staff told us that it was in five minute intervals. There was no clarity on what staff should be doing. In addition to this, one member of staff put two different eye drops in straight after each other, whilst another member of staff left a two minute interval between each eye drop preparation.
- The advice from the British National Formulary (BNF) is as follows: when two different eye-drop preparations are used at the same time of day, dilution and overflow may occur when one immediately follows the other. The patient should therefore leave an interval of at least five minutes between the two; the interval should be extended when eye drops with a prolonged contact time, such as gels and suspensions, are used.
- We asked nursing staff if they knew what some of the newly stocked emergency medicines were for. They did not know what all the emergency medicines were indicated for. However, there would always be doctors on site who would be able to deal with medical emergencies. In addition, nursing staff were awaiting training with regards to the management of medical emergencies.

Records

- Optegra Central London used both electronic and paper documentation which were updated during each episode of patient care and made available for all appointments and surgeries. We looked at the record store which had restricted access and was only accessible via key card entry.

- All patients had a unique ID number logged on both electronic and paper records. This unique ID number was found on the folder of each patient record. However, the ID number was not always printed on each separate page of the record, even though at the back of the patient record there were numerous pages of patient ID stickers available. This meant that there was a risk that patient notes could get mixed up.
- There was a records management policy in place if patients wished to have access to their records.
- We saw that the electronic software was integrated to the diagnostic equipment within the hospital which meant that patient records of scans and investigations were readily uploaded into the electronic patient record.
- Correspondence was sent from the consultant to the patient's GP. Unless the patient had stated that they wished otherwise when they completed and signed their registration form, it was also sent to the referring optometrist as appropriate. A copy was sent to the patient, providing information relevant to the patient's condition and treatment. Correspondence letters included suitable treatment recommendations, justifications for treatment, and the risks and benefits.
- We looked at 10 patient records and found that the registration form was sometimes left incomplete. We also saw that there was an inconsistency with the format and it was not clear what should be included within the patient record. Some consultants would use their own personal forms within the patient record to record patient information. However, the consultants had discussed and agreed to a standardised form during the hospital's quarterly refractive working group meeting. The organisation had also appointed a new refractive consultant clinical lead to support consultants.
- We saw that theatre batch numbers of equipment were recorded clearly in patient notes through the use of stickers.
- Relevant staff had access to details held on the electronic patient record and paper notes. These included pre-assessments information on patient's medical history, medications, allergies, referral letters, consent information and pre- surgery notes, and any consultants' operation notes.
- Paper records were archived to an external storage facility once the patient was discharged. Documents could be recalled should they be needed after being archived.
- Paper records were archived internally for one year. The patient services team also archived all discharged patient notes into an electronic system routinely. Optegra Central London also had a SLA with an external records management facility which could be utilised on choice. This records management facility was registered under the Data Protection Act and audited to ISO 9001;2000 every six months. Records were kept in this facility for up to 10 years.
- All members of staff had completed their mandatory training on information governance.
- During our inspection we noted that all patient information was secured and stored safely, and computers and laptops were locked and password protected.The hospital kept patient information for one year on site, and then this information was archived externally for a maximum of 10 years. We saw that particular floors within the hospital used shredders to appropriately dispose of confidential documentation.

Assessing and responding to patient risk

- The service did not routinely weigh patients and so did not calculate body mass index (BMI). This therefore meant that the hospital did not use BMI as criteria to determine treatment. As they did not weigh patients, they could not determine if maximum weight restriction for certain pieces of equipment were being observed. The hospital only weighed patients if they were undergoing general anaesthetic.
- The service had a surgical pre-assessment questionnaire that recorded known patient allergies, current medications, and existing medical conditions. This information was kept in the patients' records.
- The hospital adhered to the World Health Organisations (WHO) Surgical safety checklist for cataract surgery which was audited monthly for compliance. The WHO checklist formed part of every patient treatment pathway and was audited monthly by the clinical services manager (CSM) through a documentation audit. An audit of ten sets of patient

notes selected at random from the current month was carried out by the CSM. This included checks on compliance to the WHO checklist and if the WHO checklist was completed accurately. The audit included the signing in and out time of surgery, and whether the correct eye was marked by the surgeon.

- We reviewed the results of the WHO surgical safety checklist audit which demonstrated 100% compliance. The patient records we looked at showed that the WHO surgical safety checklist had been completed correctly on the day of the surgery.
- We looked at all the audits conducted in the hospital. We saw audits on documentation, venous thromboembolism (VTE) risk assessments, hand hygiene and the consent processes. However we found that even though audits were repeated monthly the data used for the audit were not representative. For example, the hand hygiene audit for September 2017 looked at six observation areas and four different staff members across one day. We saw all of the audits in a raw data format, the information recorded per audit was minimal, and repeated audits could not be ascertained from the information logged. The outcomes of the audits showed positive results, most receiving 100% compliance from staff. However the audits did not list or address areas for recommendations or improvements. The consent audit showed 90% compliance but no actions were suggested from this result. We found that this was the case for most of the audits conducted.
- 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. There was no formal service level agreement (SLA) with a local NHS provider for emergency transfer of patients. However, the provider subsequently told us that unplanned transfers due to medical emergencies were taken to the nearest NHS provider with access to a high dependency unit and an intensive care unit.
- The organisation's resuscitation policy did not refer to the latest resuscitation guidance. The registered manager told us that no member of staff was currently trained in advanced life-support training or equivalent. This did not meet the standards recommended by The Royal College of Anaesthetists as set out within the 'Provision of Ophthalmic Anaesthesia Services, 2017' that states that staff should be trained in basic life support and there should be at least one person with advanced life-support training or equivalent.
- There was a laser safety management file held in the management office which all staff had access to. This had the contact information for the Laser Protection Advisor (LPA) should it be required. There was also a LPA backup contact number and an emergency out of hours assistance contact information. Contact details were also included in the local rules which was kept in theatre two. The LPA was supplied from Public Health England.
- We reviewed the laser safety management folder which had not been updated since there was a change in the hospital director and the CSM. Nine clinical team members had laser safety awareness training which ensured that they were competent in laser safety. This was conducted on the 18 November 2015. The same nine staff members had undergone laser core of knowledge training on the same date which was valid for five years.
- The LPA reviews the file during each audit or when a change happens. Laser Protection Supervisors will liaise with the LPA should any change occur during the year to ensure all information is up to date
- There were four main contacts at the hospital for any concerns regarding laser safety. Which were the three LPS's and the clinical services manager.
- The hospital also had access to any LPS at other Optegra hospitals. The regional facilities manager was also a trained LPS.

Nursing and medical staffing

- There were 44 ophthalmologists and 13 anaesthetists with practising privileges. There were five full time nurses and seven nurses on a zero hours contract. There were three optometrists and seven health care technicians (HCTs). There were three receptionists, and the hospital also used bank staff if required. During the unannounced and announced inspection we were also introduced to new members of staff.On observation the hospital had enough staff for all the procedures that were taking place.

- The registered manager, who was the hospital director informed us that staffing levels were above the number of staff required. This was due to the fact that the hospital was preparing for a quick increase in activity and did not want to have the incorrect staffing numbers.
- The hospital's safe staffing policy was in line with Association for Perioperative Practice (AFPP) guidelines, to ensure safe, appropriate experienced and qualified staff were available to meet the demands of the patients attending the hospital. Thesafe staffing policy was followed and supported by local operating procedures.
- Regular bank staff were used to backfill planned or unplanned absences and to supplement current establishment vacancies.
- The patient services manager and clinical services manager were responsible for creating and overseeing weekly staff rotas. This ensured safe staffing and the appropriate skill mix was in accordance with the procedures scheduled, and the number of patients.
- Weekly planning meetings were held to plan for the following weeks activity to ensure operational readiness including strategies for managing unplanned occurrences.
- In the last 12 months, the organisation did not use locum or agency anaesthetists or ophthalmologists. However, agency nursing and operating department practitioner staff were used to backfill planned or unplanned absences and to supplement established vacancies.

Major incident awareness and training

- The provider had a clear business continuity plan for all major incidents such as power failure, building damage and bomb threats. The plan was detailed and included the utility shut down locations of the water, electric, medical gases, and clinical waste. The persons responsible for these tasks were also listed. The plan also highlighted the emergency contact numbers for staff or where to find these.
- All staff had attended annual fire training and the manager explained the evacuation procedure for the outpatient's clinics.
- Uninterruptible power supplies (UPS) were available for lasers to ensure treatment was not compromised if power failed mid-treatment. We asked the laser protection supervisor if the UPS was ever tested, but they were not sure. There had been a power failure in August where the UPS engaged after a few seconds. This was recorded as an incident. We looked at the incident form and saw that there was no documentation of UPS engagement. The form was not signed or dated on completion nor had the incident tracking number been recorded.

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

Evidence-based care and treatment

- Theatre practices met the Association for Perioperative Practice (AFPP) guidelines.
- We reviewed policies and found that many, including the organisation's resuscitation policy, infection prevention, and safeguarding adults, were not up to date with current legislation or guidelines. This demonstrated a lack of a robust systems to review policies and processes to ensure they remained fit for purpose.
- We were told that the hospital used guidance from CQC, Royal College of Ophthalmology, MHRA, NICE quality and standards, Mental Health Act and Health and Social Care Act 2008. However we did not see evidence in the clinical service manager (CSM) meetings minutes of how the hospital kept up to date with changes in guidelines. This meeting was attended by all the Opetgra CSM's. When we asked a staff member what guidelines the hospital followed specifically relating to their line of work the nurse could not list any of the above guidelines.
- Patients were consulted, assessed and a care pathway treatment was planned, discussed and agreed for positive outcomes, including informed consent.
- We were told that staff attended regular hospital wide team meetings and took part in the appraisal process.
- Good practice was audited via the introduction of the balance score card and hospital visit reports, as well as the daily care, responsive, effective, well-led, safe

(CREWS) audit. This was a daily audit that measures the service against CQC's key lines of enquires. However, there was no direct actions made for improvement other than in the hospitals 121 point plan.

- Monthly hospital audits were undertaken for example the WHO 'five steps to safer surgery'. Although, we did not see learning shared from audits or recommended actions to be taken for improvement in writing. However, we did see recommended actions on the hospitals clinical governance meeting minutes that was attended by the CSM and clinical team members, where learning was shared
- The pharmacist completed a monthly medicines management audit which highlighted areas for improvement.

Pain relief

- Pain relief medication was clearly document in patient notes. We looked at the preparation and aftercare booklets found in 14 patient notes. The patients medication sheet within the booklet had a list of medicines that could be used before and after the surgery. The sets of drugs used for pre and post-surgery were captured in two separate lists and there was a space provided in each list if the surgeon used a different medication.
- Staff we spoke to told us that patients were advised on pain relief during discharge discussions. Patients were told that if the pain was severe they should go to their local accident and emergency department.
- We looked at the patients' medical records and saw that pain relief was prescribed to patients, the drugs and the dosage was clearly listed. However, there was no written documentation in the patients notes to detail what was discussed with the patients or what the patient should do if they were not able to manage their pain.
- Staff could access medicines for pain relief. We saw stock of paracetamol, co-codamol, ibuprofen, as well as local anaesthetic eye drops. Patients were given medicines for pain relief on discharge from the hospital. Patients could contact a nurse both during the day and out of hours for medical advice. The on call nurse could contact a consultant out of hours for further medical advice if necessary.
- Staff did not use a pain score to assess patients pain.

Patient outcomes

- We saw that the hospital had an Eye Sciences division employed by the provider. The main role of this division was to collect and report on clinical data to provide clinical outcomes for the hospital. The data covered clinical complications, visual and refractive outcomes for laser, lens replacement and cataract patients, to an agreed protocol.
- National clinical audit plans were in place and were tracked for compliance against schedule and this was facilitated by the Optegra Eye Sciences Division.
- The hospital was benchmarked against industry standards by the eye sciences division, and the outcomes often exceeded the benchmark standard. For example patient outcomes for refractive lens exchange surgery for April to June 2017 was at 98%, against the benchmark standard of 96%.
- The data was captured by using an electronic patient record (EPR) system. The data was reported quarterly at meetings of the Optegra UK board, Medical Advisory Committees and corporate governance committees.
- Patient reported outcomes (PROMS) were also measured following the discharge of patients via a tablet device which fed into the outcome report. Information such as overall satisfaction rate was collected. Between June 2017 and October 2017, 89% of patients were extremely satisfied and only 1% was unsatisfied. 91% of patients were also extremely satisfied with their consultant and no patient was unsatisfied.
- The hospital did not provide data toward the National Ophthalmic Database Audit (NODA). The purpose of NODA is to collate anonymised data collected as a by-product of routine clinical care using electronic medical record (EMR) systems for the purposes of national audit, research and establishing meaningful measures for revalidation. The CSM and Eye Sciences were quite specific that Optegra Central London does not participate in the NODA as this audit applied only

to NHS patients. However, the CSM and Eye Sciences stated that the hospital will participate in gathering data for NODA in the new year as and when plans to treat NHS patients commence.

- Although the hospital did not participate in any national audits, the provider had started communications with Private Healthcare Information Network (PHIN) about providing them with national audit information, so that the service could publish the audit within the public domain. All providers of private healthcare in the UK, including most NHS hospitals, are required by law to submit data to PHIN.
- Posterior capsule rupture (PCR) is a recognised complication of cataract surgery, occurring in around 1 in 50 patients (just less than 2%). Rates are higher in those with known risk factors, e.g. a dense cataract. The hospital recorded that there had been two occurrences of PCR out of 775 intraocular lens procedures over the last 12 months prior to our inspection which was a rate of 0.26% and below the national average.
- The hospital reported two unplanned returns to theatre following refractive eye surgery in the reporting period.
- The hospital reported two incidences of unplanned treatment enhancement following refractive eye surgery in the reporting period.
- The hospital reported one patient experiencing complications following refractive eye surgery in the reporting period.

Competent staff

- We saw that staff received regular training as appropriate including mandatory training. We looked at staff competencies and certificates which were up to date and kept in the clinical services manager (CSM) office.
- External courses were regularly considered through the annual appraisal process. Also additional clinical professional development training had been provided externally for employees including sessions at the London Vision Clinic to learn about new procedures and techniques.
- All consultant applications for practising privileges were signed off via the medical advisory committee (MAC) following the review of required documentation. This was a standard item discussed at the MAC meetings. We saw that practising privileges applications were sometimes rejected or declined in the last 12 months, due to a lack of substantial NHS work.
- The CSM told us that no member of staff was currently trained in advanced life-support (ALS) training or equivalent. This did not meet the standards recommended by The Royal College of Anaesthetists as set out within the 'Provision of Ophthalmic Anaesthesia Services, 2017' that states that staff should be trained in basic life support and there should be at least one person with advanced life-support (ALS) training or equivalent. We were told that ALS training was booked in early November 2017 for two members of staff.
- We looked at the human resources (HR) documentation of six members of staff picked at random, an optometrist, a receptionist, two bank staff, a health care technician and a nurse. The HR documentation was accessed via the intranet and each staff member had a profile holding all the relevant documentation. This included the staff disclosure barring checks (DBS), right to work, curriculum vitae (CV), qualifications, references and certificates.
- We found that five members of staffwere awaiting their DBS checks. These staff members had applied for the DBS checks but were still awaiting their forms. The hospital conducted their own risk assessment on these staff members and these staff members were chaperoned by other staff whilst they were working. This was not seen in the hospitals risk register.
- The system that held the DBS records was able to identify, and highlight in red out of date DBS checks.
- The hospital was up to date in staff appraisals, however bank staff members did not have appraisals.
- We looked at 14 consultant and anaesthetists files which all showed relevant DBS checks, in-date appraisals, training certificates and practising privileges.

Refractive eye surgery

- The hospital reported to have 29% of surgeons that held the Royal College of Ophthalmology Certificate in Laser Refractive Surgery.The remaining five surgeons were accredited with a different body. We also looked at 11 consultant records and saw that all 11 had in date indemnity insurances.
- The laser protection supervisors (LPS) attended laser safety training. They were supported by Public Health England (PHE) which was the hospital's external laser protection advisor.
- PHE reviewed competencies, provided training and carried out annual audit of the LPS competence. This included a review of the local rules. The LPS training was repeated every three years unless there was a change in regulation and reviewed and audited via the training tracker mechanism. This training was last completed on the 9 October 2017.
- We spoke to members of LPS staff in the hospital. We were not assured that they were fully competent in their role. This is because both did not know who the LPA was and thought that this was the clinical services manager. Also the LPS's had not signed the local rules at the time of the inspection. During our unannounced inspection we saw that the local rules had been signed by two members of staff; one LPS and one healthcare technician. All staff that are involved in any aspect of the laser machines are required to sign the local rules. During the unannounced inspection we re-tested the knowledge of the LPS which had improved, for example the LPS knew who the LPA was.
- Core of knowledge training is the official and essential training for professional users of laser and light treatments in the medical aesthetics industry. It is the basic legal requirement for all technicians to achieve this certification referred to in the medicines and healthcare products regulatory agency (MHRA) guidelines. It is good practice for individuals to re-attend Core of Knowledge courses every five years. However, when we spoke to the LPS's about Core of Knowledge, one LPS did not know what this was. We then asked how often this training should be repeated and one LPS stated that it was once a year or every six months. The CSM told us that both LPSs had attended this training but were awaiting certificates.
- On the hospital's register of authorised users to operate laser equipment were consultants who operated the equipment and clinical team members who assisted with the procedure. This consisted of only eight consultants and the three laser protection supervisors. All staff that can operate the laser equipment were required to sign this.
- We saw that all consultants and clinical team members had training appropriate to their role. When new refractive lasers were introduced, the hospital carried out training alongside the manufacturer.This training was also arranged for any new consultant or member of the clinical team who assisted in the procedure.
- We saw that consultants and staff assisting with the refractive lasers: and the equipment had signed off certificates of competency. These lasers were used frequently and ensured ongoing competence.

Multidisciplinary working

- During our inspection, we saw good multidisciplinary teamwork between disciplines within the hospital. There was respect and recognition of the value and input of all team members.
- Most staff worked across surgery and outpatients departments. Staff explained that they worked together as a team and knew about each other's roles and responsibilities in the hospital.
- Within theatres staff stated that teams worked well together and all members of the team had a voice. Staff said that all grades of staff were able to have their opinions heard.
- Staff we spoke to told us that optometrists and ophthalmic consultants worked well together.
- We saw a good level of multidisciplinary team working within the theatres, and staff worked well together.

Access to information

- Optegra used an electronic based system for storing clinical records. This was accessible to other Optegra hospitals should the need arise for patients to be seen at another site. Should another hospital require paper records, these could be scanned into the patient administration system for quick and easy viewing. This

meant that if a patient required a follow up appointment at a different location to where their refractive eye surgery was originally performed, medical information would be easily accessible.

- Staff we spoke to told us that it could not be guaranteed that patients received their information pack prior to a telephone consultation from a nurse. This information was either sent via email or by post but there was no tracking system in place to monitor if patients had received this information. This information pack included information on whether or not patients could leave the hospital unaccompanied. Optegra had an unaccompanied disclaimer policy in place to be used if a patient decided to leave the hospital unaccompanied against the advice of the hospital.

Consent and Mental Capacity Act

- The Professional Standards for Refractive Surgery (April 2017) states that the service should ensure "informed consent is given by explaining/giving written information about all risks, benefits, realistic outcomes and costs." The service should then ensurepeople are given a 'period of reflection'/'cooling off' (at least one week) between agreeing to go ahead with procedure and surgery being performed.
- We reviewed 16 patient records and found that there was no indication of the 'seven day cooling off period' within the patients record. We looked at the consent forms and saw that the date on the consent form was the same date as the surgery. However when we spoke to senior members of staff we saw that the evidence of the '7 day cooling off period' was recorded in the electronic patient records. We looked at 12 electronic records that proved this.
- This meant that consultants or surgeons would need to refer to the electronic patient record to ensure that the '7 day cooling off period' was adhered to. We asked a consultant how he would ensure that his patients had their cooling off period and he told us that all surgeries were always booked after seven days or more from the initial consent period. The consultant also ensured that a consent form was completed on the day of surgery as well.
- The patient liaison services manager told us that the consent process was moving towards a two-step process. The first step of the consent process was to highlight the risks involved in the treatment and the form required the patient and the consultant's signature. The second consent form was completed in surgery seven days after the initial consent.
- Interpreters were also available during the consent process if a patient wished.
- We looked at the medical questionnaire for patients which asks numerous questions relating to the patients' health and well-being. However we did not see questions relating to dementia or learning difficulties. Staff we spoke to said that the over the phone pre-assessments were not great at assessing patients mental health status.
- We looked at the hospitals cardiopulmonary resuscitation (CPR) policy, which refers to do not resuscitate (DNR) and does not comply with the latest national guidelines on DNACPR and does not contain the new DNACPR form referring to mental capacity assessment despite being reviewed. We asked the clinical service manager about this, they did not know about DNACPR and the clinic did not have any DNACPR forms available. The policy was in date and had been reviewed this year.

Are refractive eye surgery caring?

Compassionate care

- We observed compassionate care and very positive interactions by all staff.
- Staff treated patients, and those close to them, with respect and dignity. They were aware of patients care needs and communicated in an appropriate and professional manner.
- The hospital encouraged patient-centred care and involvement of the patient at all stages of the decision making process.
- Patients we spoke with were positive about the care they had received and told us nurses and doctors were

kind and compassionate. Patients told us they had been put at ease by staff with one patient commenting that the "staff were fabulous" and had explained their procedure in a way they could understand.

- All staff we observed during pre-assessment appointments and during the checking in process were kind and respectful towards patients, taking their time to ensure they answered questions and concerns in full.
- We observed all staff, including reception staff and non-clinical staff were kind and respectful to patients who used the service.
- Staff ensured people's privacy and dignity were respected throughout the patient pathway.

Understanding and involvement of patients and those close to them

- The hospital promoted patient rights and choices, and were open and transparent on pricing and what the patient could expect to experience throughout the patient journey. We saw that prices were also clearly stated on the hospital's website.
- Family were allowed to come into the consultations with the patient, with the patients permission.
- During the surgical procedures, we observed staff explain what was happening during each stage of the procedure and checked on the patient's welfare.
- 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.
- Patients were provided with brochure and other patient information literature. Information was also available on the provider's website.

Emotional support

- All consultations and care-related conversations took place in private rooms where discussions could not be overheard.
- After surgery all patients were given contact details of who to call if they had any concerns.
- Patients we spoke to told us that they did not feel pressured into going ahead with surgery.
- Patients diagnosed with macular degeneration (a medical condition which may result in blurred or no vision in the centre of the visual field) received ongoing support and treatment from the same consultant. Patients were referred to psychological provisions by their consultant if this was deemed necessary.

Are refractive eye surgery responsive to people's needs?
(for example, to feedback?)

Service planning and delivery to meet the needs of local people

- The clinic provided a range of eye treatments including, refractive eye surgery.
- The hospital was easily accessible and well serviced by public transport, and directions to the hospital were listed on their website.
- The hospital provided a 24 hour helpline for advice to patients outside of normal working hours. Consultants were available during normal working hours to review patients if necessary.
- When a patient made an initial telephone enquiry about the hospital's service, there was a routine set of lifestyle questions that needed to be completed. The data captured included the motivation for wanting vision correction, if enquires had been made to other providers, and any previous eye surgeries that had happened.

Access and flow

- The hospital was open from Monday to Saturday including evenings, and a variety of appointment times and options were available. The service operated from 8am to 8pm. There was an emergency on-call service available on a Sunday but only the CSM and one registered nurse had completed training to perform the emergency on-call service. However as newly inducted staff completed their probationary period, more nurses were trained and available to participate in the emergency on call service. Surgeons were accessible on this day for advice if required.

Refractive eye surgery

- Patients could be referred by their GP, optometrist or through consultant referrals. There was also a patient services team based in Guildford that fielded calls from prospective patients wishing to access the hospitals services.
- A face to face 30 minute diagnostic test and a 30 minutes appointment with an optometrist took place after a patient completed a questionnaire. This was to identify which treatment was the most suitable for the patient by using specific criteria parameters. The form that stated these parameters was out of date and was last reviewed in September 2017.
- Some nurses told us of some difficulties carrying out a pre-assessment over the telephone. One nurse said it was difficult to judge, over the telephone, how far a patient could walk, or make assessments on a patient's mental health status. Nurses also mentioned that seeing a patient face to face before the procedure ensured that the patient could be taught how to use eye drops correctly before their procedure.
- The hospital used a pre-admission checklist to identify patients who may have had a previous heart attack or stroke, or who may require help with moving around. This was used to plan their treatment on the day and ensure there consultation was with the most appropriate health care professional.
- Patients were kept informed of the list order and how many patients were in front of them for treatment. We saw that appointments ran on time and we were informed that when delays occur patients arekept well informed and updated regularly by a member of the patient liaison team.
- An electronic patient booking systems were used to plan clinics and minimise waiting times. The provider was able to use this system to plan additional walk-in patients and take last minute bookings on the same day for patients with urgent needs.
- We saw that patients could access initial assessments, diagnosis and urgent treatment all in one day. This was often the case for many patients. Treatments were offered to patients at a time and day that suited the patients availability.
- We looked at the patient administration system which was straight forward and easy to use which was web based and could be accessed remotely by approved users.
- We saw that the cancellation rates were extremely low and cancellations were largely patient initiated.

Meeting people's individual needs

- The entrance of the building had an automatic front door. The steps to the door were adaptable and could accommodate wheelchair users. Each floor within the building was accessible via a lift and set of stairs.
- In the waiting area on the ground floor we saw that there was an information leaflet for an interpreter which could be made available over the phone. Interpreters were available to patients at no additional costs, either over the phone or in person. We also saw a poster for a chaperone which was available upon request and we saw signs in reception to encourage this. These two items of information were also printed in Arabic, Russian and Polish. There was also a hearing loop installed for patients, and signed which gave instructions on how to access this.
- Television and free Wi-Fi facilities were available and refreshments were also available in the waiting area.
- We saw respect for patient dignity and confidentiality, as patients were seen individually, in a consultation room and not in an open area. Discussions around care pathways could be addressed in private and where patients did not wish for their GP to be informed this was respected.
- The service provided was consultant led and patients saw the same consultant for their treatment throughout to ensure quality and continuity of care.
- We found that information leaflets given to patients after surgery were in small print. We looked at the medication given to patients and saw that the information provided with the medication was in small print. We also looked at the Optegra refractive lens exchange preparation and aftercare booklet and also found that this was in small print.
- The Optegra refractive lens exchange preparation and aftercare booklet did not mention that patients should call the emergency services in the event of an eye

related emergency. The information that was provided was informative but used medical jargon that may be confusing for some patients such as 'floaters and residual myopia'.

- The service had a Freephone contact centre which was operational from 8am to 8pm, Monday to Thursday, and 8am to 6pm on Fridays. This service also operated between 8am to 4pm on a Saturday. These times were displayed clearly on the provider's website. However, opening hours of the service was not displayed on their website.
- We saw an equality and diversity policy in place which was last reviewed 27 July 2017.

Learning from complaints and concerns

- There were 24 complaints recorded in the last 12 months. Complaints data captured the classification of the complaint, which was categorised as informal or formal, the severity of the issue, the type of complaint, patient ID and the consultant of that patient. 'Medical outcomes' as a category of complaint received the highest numbers of complaints in the last 12 months; this was followed by 'post-operative care' and then 'delays'.
- Optegra's policies and procedures and local policies were in place regarding complaints, reporting of incidents and near misses.These were discussed at governance meetings to review continuous improvement and learning was shared with staff.
- The hospital requested and acted upon feedback. Patients were encouraged to provide feedback and comments and told us they felt empowered to do so. In addition, we saw the hospital provided patient feedback forms, for compliments and complaints, and there was a comments book in waiting areas. This ensured that the hospital could learn from any communications made from patients.
- Formal complaints were required in writing. The hospital director or senior member of staff acting on behalf of the director offered support to any patient, patient's carer or family member in using the complaints procedures. Appropriate actions and feedback to patients were required when standards were not met. Optegra had three stages when dealing with complaints: local resolution, internal appeal, and an independent external review. The service had an SLA with the Independent Sector Complaints Adjudication Service (ISCAS) for complaints that required independent external reviews. ISCAS was used when patients were not satisfied with the internal complaints process. This service had not been used in the last 12 months.
- The hospital carried out electronic and paper based patient surveys, this included the friends and family test. Patients were asked to complete feedback on-line. We saw that the Friends and Family feedback survey was available at reception.
- Patients were able to provide verbal feedback which was shared via email to the relevant teams.
- The complaints policy stated that the hospital had 20 days for the complaint to be investigated and resolved. Within two days of receiving the complaint, a letter of acknowledgement was sent to the complainant. This was usually written by the hospital director. We looked at the spread sheet that captured all the complaints within the last 12 months and saw that four complaints out of 24 were not dealt with within the 20 days stated in the policy. The hospital purposely did not close a complaint made on December 16 2016 as the complaint had gone to the litigation register with no apparent progress from both sides. The other three complaints were medical outcome complaints; which the hospital did not want to close until the patients had undergone the necessary care and treatment that will help the patients come to terms with their complaints. We did however see that most complaints were dealt with on the same day the complaint was received or one day after.
- The hospital had made several changes and improvements as a direct result of the views and experiences of people using the service. For example there was a complaint regarding the information booklets provided to patients which was not user friendly and deemed confusing. Therefore, the hospital looked into these comments regarding the changes and had the booklets re-printed professionally.
- Furthermore, it was found that the quality of the refreshment provision for patients undergoing

procedures under general anaesthetic or sedation who fasted was poor. Therefore, the hospital set up a SLA with the local café to provide a selection of sandwiches and a breakfast menu to cater to patients. This had received praise and compliments from patients and their careers.

- There were three complaints regarding delays of surgery. Therefore the hospital conducted an audit on outpatient delays as well as delayed surgery lists. As a result, a new theatre timetable was developed with more efficiencies around session times, surgery duration times and the expectation to complete surgery within the set times amongst consultants.
- Staff we spoke to were made aware of these complaints and made sure that patients were kept well informed of potential delays and where they sat queuing to be seen.

Are refractive eye surgery well-led?

Leadership and culture of service

- The service was led by the hospital director who was in addition the hospital's registered manager. The hospital director reported to the chief executive of Optegra UK.
- The hospital had a patient services manager and clinical services manager who were responsible for managing front-line staff and reported directly to the hospital director and they made up the senior management team at the hospital. We saw a strong positive rapport between the senior management team. Staff told us that local leadership was good and managers were approachable and supportive.
- There were lines of management responsibility and accountability within service. Staff would often call upon the CSM who was their line manager for concerns or queries. However, staff were under the presumption that the CSM took on other roles such as the laser protection advisor, which was not the case. The CSM took on a lot of responsibilities and did not seem to delegate tasks to other members of staff within the hospital.
- Staff told us they all worked well together as a team. We saw teamwork was particularly good within theatres with each staff member having a voice and an equal place within the team. Staff told us that executive staff were visible and approachable and understood good quality care.
- Throughout the inspection, staff were welcoming and willing to speak with us. Staff spoke positively about the service they provided for patients. They were proud of their customer service and the way they worked as a team.
- There was an equality, inclusion and human rights policy in place. The policy described that every manager employed by Optegra was responsible for promoting equality inclusion and human rights in their sphere of management and for preventing undue discrimination in practice. The policy included clear aims and objectives.

Vision and strategy

- Optegra's vision was to be the world's most trusted eye healthcare provider.
- Optegra had four core values: passion and commitment, integrity and trust, professionalism and expertise and personal connection and care. We did not see these values displayed anywhere within the hospital. However the values were covered during staff inductions and staff we spoke to had a good understanding and knowledge of these values.
- The hospitals main objective was safety first. The hospital had conducted a review against the Care Quality Commission's key lines of enquires and made a '121 point' improvement plan. The hospital aimed to put their staff first in terms of their training and development. The hospital was working on improving HR documentation and to improve policy compliance.
- The refurbished hospital was fairly recent and a lot of capital had been invested therefore the hospital was working on plans to become busier.

Governance, risk management and quality measurement

- The hospital director was the location lead for quality monitoring at the hospital. The hospital director maintained a close link with the head of clinical governance and risk and the UK clinical lead to ensure compliance across the different areas of the service.

The hospital director was supported by the clinical services manager. This was achieved by ensuring that processes and procedures were monitored and audited through monthly key performance indicator reports and quarterly clinical quality reports. The hospital looked at the five main domains set out by the CQC and reported on safe, effective, caring, responsive and well-led, daily. This was known as a CREWS audit which measured the readiness of the hospital to receive patients against the key lines of enquiries set out by the CQC.

- Infection prevention control formed part of Optegra Central London's integrated governance meetings, quarterly clinical quality reports and monthly KPI's.Audits were shared at the Medical Advisory Committee (MAC) meetings.
- Clinical quality reports were discussed at the hospital governance committee and hospital MAC meetings. The agenda covered areas such as incidents, never events, SUIs, returns to theatre, and unplanned outpatients and transfers.
- Weekly operational review calls and monthly operations meetings were held with hospital directors across Optegra's seven hospitals to share insight and benchmark across other hospitals and clinics.
- Practising privilege compliance was regularly monitored and reviewed at weekly senior management team meetings.
- The clinical service manager attended a group CSM quarterly meeting, which was attended by the UK clinical lead and head of clinical governance and risk, together with other clinical service managers (CSMs) from all Optegra Hospitals nationwide. Key areas discussed were: medicine management, infection control, safeguarding, clinical incidents and health and safety. Incidents were shared between Optegra Hospitals for learning. The CSM meetings ensured uniformity across the hospitals in areas such as: shared pathways and, documentation. We reviewed the minutes of these meetings and saw evidence of shared learning.
- We looked at Optegra wide governance meeting minutes from October 2016 to September 2017. These meetings were held every three months. These meetings were held at this hospital and staff from all seven Optegra hospitals across England were invited. Attendance rates at these meetings varied from seven to four employees. We saw that the London hospital director had maintained good attendance at both the quarterly integrated governance meetings and the quarterly Medical Advisory Committee meetings (MAC). We saw issues discussed at the MAC meetings that included: adverse incidents, complaints, infections, and safety issues, and learning was identified for discussion from adverse incidents and events.
- There was an operational risk register detailing all the risk assessments and their risk scores after mitigation. We looked at the risk register and saw that all actions and monitoring was in place for each risk. For example the service highlighted the medical emergency process in and out of hours as a risk to patient safety if the processes were not fully in place and tested. There was no service level agreement with another provider if there was an emergency at the hospital. However, the provider subsequently told us that unplanned transfers due to medical emergencies were taken to the nearest NHS provider with access to a high dependency unit and an intensive care unit.
- The risk register did not include that registered nurses did not have the appropriate training to dispense medication. Or that that five members of staff were awaiting their DBS checks.
- The only audit we found that had areas of improvements and recommendations was an audit conducted by Public Health England (PHE) on laser safety. All eight areas of improvement recommended by PHE were completed. There was no report to state that the actions were addressed, but we saw the improvements within the hospital. There was no direct actions made for improvement other than in the hospitals 121 point plan. We did not see learning shared from audits or recommended actions to be taken for improvement.
- The hospital had recently started to record the number of patients that did not attend their appointment, rescheduled appointments and cancellations.
- We were told that the hospital used guidance from CQC, Royal College of Ophthalmology, MHRA, NICE

quality and standards, Mental Health Act and Health and Social Care Act 2008. However we did not see evidence in the clinical service manager (CSM) meetings minutes of how the hospital kept up to date with changes in guidelines. Staff we spoke with were not clear on what guidelines the hospital followed specifically relating to their line of work.

Public and staff engagement

- The service had a user friendly website which listed and explained the different types of treatments available for patients. Other information on the website included laser eye surgery costs and payment plans.
- The hospital had set up open days where patients could be given information about different procedures and have the chance to ask personal questions.
- The Patient Liaison Service manager told us of a variety of social events for staff throughout the year to allow staff to better integrate with each other.
- The hospital held a team wide meeting every other month to promote inter-departmental engagement and interaction.
- In the last 12 months the hospital held three staff engagement events outside of the hospital setting to focus on training and development, communication and to celebrate areas of successes.
- 'Colleague recognition' was how the hospital rewarded employees for delivering above and beyond expectation. Employees were encouraged to complete 'colleague recognition' forms and submit them to the central HR team. Every quarter one employee from each hospital was selected by a member of the senior management team to win a red letter day voucher.
- The hospital had arranged external customer service training for all employees; this was due to start soon.
- Employee benefits included private medical insurance, discounted eye healthcare, company matched pension scheme, life assurance and discounted gym membership.

Innovation improvement and sustainability

- The patient pathway for refractive eye surgery was newly implemented in June 2017. The changes had been introduced at this hospital and it was being rolled out to all other Optegra hospital in the UK. The pathway was developed with the help of consultants, patient liaison staff, management and feedback from staff. With the new pathway the patient was able to have 30 minutes of diagnostic testing, 30 minutes with the optometrist and 30 minutes with the consultant all in one day, to test suitability for surgery. Patients had previously stated that they did not want to come back and see the consultant on a different day to be told that they were not suitable candidates for surgery. This pathway was an improvement from the previous patient pathway and it was considered more flexible to fit around the patients' availability.

Outstanding practice and areas for improvement

Outstanding practice

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to ensure that staff are trained in dispensing medication to patients and maintain competency in this.
- The provider must ensure that protocols are in place and actions are taken when temperatures of refrigerators, that store medication, fall out of appropriate ranges.

Action the provider SHOULD take to improve

- The provider should develop their governance procedures further to strengthen their processes.
- The provider should show learning and improvements from audits.
- The provider should adhere to law and submit data to PHIN.
- The provider should ensure that all staff are competent in their roles and know their own responsibilities.
- The provider should ensure that all appropriate staff members read and adhere to the local rules.
- The provider should ensure that process are in place to ensure that staff are kept up to date with national guidelines.
- The provider should ensure that patient notes have the appropriate identification numbers on each page to ensure safe storage of notes.
- The provider must ensure that the resuscitation trolley complies with national guidelines.
- The provider must ensure that at least one staff member is trained in advanced life support.
- The provider must take prompt action to address concerns identified during the inspection in relation to safeguarding, ensuring that all staff have the appropriate training.

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
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment There were a number of medicine management issues within the hospital:- Records of temperatures where medicines were stored were not always being kept and where they were, we found that no evidence that temperatures that had been recorded as out of range were not being addressed. Nurses were not trained in dispensing medicines and found that different nurses were dispensing eye drops at intervals they felt were appropriate. Nurses also not been trained to know what newly stocked medicines within the resuscitation trollies were and how they would be used in the case of a medical emergency. The provider must take action to: • Ensure that records of temperature readings are kept for all rooms and fridges where medicines are stored and refrigerated and action is taken when temperatures fall out of appropriate ranges. Reg 12(1)(2) (g); • Ensure that nurses have the appropriate training to dispense medications. Reg 12(1)(2) (c); • Ensure that there is clear guidance available to staff on the administration of medicines and eye drops. Reg 12(1)(2) (g).

This section is primarily information for the provider

Enforcement actions

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.