Optical Express - Reading (Queens Road) Clinic

Quality Report

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

Ratings

Overall rating for this location

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

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

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

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

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optical Express Reading is operated by Optical Express Limited ,which is a nationwide company offering general optometric services. The clinic provides laser vision correction procedures for adults aged 18 years and above.

The clinic is situated in the basement floor with a passenger lift and level access from the small car park for people with limited mobility and wheelchair users. The clinic had a laser treatment room, surgeon's examination room, two screening rooms and two post care/discharge rooms.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 27 November 2017 and an unannounced visit to the service on 5 December 2017.

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

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

Services we do not rate

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

We found the following areas of good practice:

- The service had a process to review incidents, and investigations were shared with staff to assist learning and improve patients' care.
- Patients received care in visibly clean and suitably maintained premises, and their care was supported with the right equipment.
- The staffing levels and skills mix was sufficient to meet patients' needs and staff appropriately assessed and responded to patients' risks.
- Patients' records were detailed with clear plans of the patients' pathway of care.
- Patient consent was obtained prior to commencing treatment. Patients were provided with information to enable them to make an informed decision.
- All staff their mandatory training and annual appraisals. Care and treatment was provided by suitably trained staff, who worked well as part of a multidisciplinary team.
- There was clear visible leadership within the services. Staff were positive about the culture within the service and the level of support they received.
- There was appropriate management of quality and governance and managers were aware of the risks and challenges they needed to address.

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

- The consent policy did not reflect the Royal College of Ophthalmologists 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The process for the administration of a cytotoxic drug did not meet with current guidelines and practices. Staff did not follow single use policy for Mitomycin.

Summary of findings

- There was inconsistency about the interpretation and management of the checklist for laser surgery.
- Patient information leaflets, documents, and consent forms were only available in English.
- There was no interpreter service available for patients. Patients were advised to bring their own interpreter to the clinic, or use a family member.
- There was no staff's survey to gain staff's feedback regarding the service in order to make improvements as necessary.

Following this inspection, we told the provider that it must take action to meet the requirement. We have told the provider they should make improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report

Amanda Stanford

Interim Deputy Chief Inspector of Hospitals

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

Summary of findings

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Summary of this inspection

Background to Optical Express - Reading (Queens Road) Clinic

Optical Express Reading is operated by Optical Express Limited ,which is a nationwide company offering general optometric services. The clinic provides laser vision correction procedures for adults aged 18 years and above. The service has a registered manager who has been in post since 2013.

The clinic is situated in the basement floor with a passenger lift and level access from the small car park for people with limited mobility and wheelchair users. The clinic had a laser treatment room, surgeon's examination room, two screening rooms and two post care/discharge rooms.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and another CQC inspector.

The responsible head of inspection: Mary Cridge

Why we carried out this inspection

We inspected this service using our comprehensive inspection methodology.

How we carried out this inspection

We carried out the announced part of the inspection on 27 November 2017 and an unannounced visit to the service on 5 December 2017.

Information about Optical Express - Reading (Queens Road) Clinic

Optical Express, Reading is operated by Optical Express Limited. The clinic opened in December 2008. The service primarily serves the communities of the Reading and Berkshire area. It also accepts patients' referrals from outside this area.

The service accepted patients through direct referrals and patients were self-funded. Following a consultation with an optometrist, the patients were seen and assessed for their suitability for laser surgery by the surgeon and treatment was discussed and consent information was shared with them

Optical Express, Reading is registered with the Care Quality Commission to provide the following regulated activities:

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

Summary of this inspection

What people who use the service say

People we spoke with were complimentary about the care and treatment they had received. They told us they had adequate information to make an informed decision about their treatment. The risks and benefits of treatment were clearly explained to them . Staff treated them with care and respect.

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.

We found the following areas of good practice:

- There were appropriate policies and procedures to support the reporting of incidents and staff knew how to report these.
- There were robust processes and local rules that staff followed in order to manage the safety of lasers.
- Medicines were ordered and stored securely.
- Staff followed infection control procedures and the clinic was visibly clean.
- All staff had completed mandatory safety training.
- Equipment was serviced regularly and all electrical tests had been completed and were in date.
- There were adequately trained staff to manage patient's care and treatment.
- Equipment was well maintained, sufficient and available to the staff.
- However:
- We also found the following issues that the service provider needs to improve upon:
- Staff did not follow the guidance and procedures for the safe administration of Mitomycin.
- There was inconsistency about the interpretation and management of the checklist for laser surgery.
- The laser risk assessment had expired and no action was taken to resolve this.

Are services effective?

We found the following areas of good practice:

- Patients received care according to national guidelines and standards.
- Staff followed guidance in managing patients' consent to care.
- There was effective multi-disciplinary working. The clinic had adequately trained staff and in sufficient numbers to deliver patients' care.
- Surgeons' outcomes were measured and monitored on an annual basis.
- There was regular audits and actions were taken to make improvements.
- Additional training was provided to staff using laser equipment, which ensured patients' procedures were carried out safely.

Summary of this inspection

Are services caring?

- Staff were caring and treated patients with compassion, dignity and respect**.**
- Patients were involved in the planning and delivery of their treatment and care.
- Patients were positive about their experience of care and treatment.
- Patients received adequate information about the costs of treatment and procedures.
- Staff supported patients in a calm manner to relieve patients' anxiety during their care and treatment.

Are services responsive?

- Services were planned to meet the needs of patients, and took into account their choices.
- Patients were offered follow up appointments to ensure they continue to receive the right level of care.
- Complaints about the clinic were dealt with in a timely manner and information relating to complaints was shared with staff.

However:

- Patient's information leaflets were not available in different languages.
- There were no formal interpreting services available and patients were asked to bring a family member, or friend to their consultation to translate.

Are services well-led?

- There was effective teamwork and good leadership, which created a positive culture.
- There were clear organisational structures, roles, and responsibilities.
- There were good governance, risk and quality systems, and processes that staff understood.
- There was a good system in place for patients feedback. This enabled the service to benchmark against other clinics across the organisation.
- The organisation recognised staff through their staff reward scheme.

However:

- There was no organisation vision or strategy in place.
- Staff engagement in the form of surveys did not take place and the organisation told us this needed to be developed.

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
Overall	N/A	N/A	N/A	N/A	N/A	N/A

Notes

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

The clinic provides Laser vision correction procedures on average for two days a month and treatment was provided as a day care basis. The service had a small team which comprised of nurses, technicians and surgeons. They had one resident registered nurse and other staff worked as part of a regional team providing care and support in Reading, South East and London area.

Summary of findings

The service accepted patients through direct referrals and patients were self-funded . Following a consultation with an optometrist, the patients were seen and assessed for their suitability for laser surgery by the surgeon and treatment was discussed and consent information was shared with them

Optical Express, Reading is registered with the Care Quality Commission to provide the following regulated activities:

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

As part of the inspection, we reviewed eleven sets of patients' records and spoke with seven patients and relatives. We looked at the environment including the laser treatment room, the surgeon's examination room, post-operative rooms, discharge room, dirty utilities, and the reception area. We spoke with eight staff members including; registered nurses, doctors, laser technicians and senior managers. We also reviewed a number of policies, procedures and other records related to the running of the service.

There were no special reviews or investigations of the hospital on-going by the CQC at any time during the 12 months before this inspection.

In the reporting period October 2016 to September 2017, there were 761 day case episodes of care recorded at the service relating to refractive eye surgery.

Track record on safety

- No Never events

Refractive eye surgery

- No clinical incidents
- Two complaints

Services provided at the hospital under service level agreement:

- Medicines
- Cytotoxic drugs service from another provider
- Laser protection service
- Maintenance of medical equipment
- Clinical and or non-clinical waste removal

Are refractive eye surgery safe?

Incidents and safety monitoring

- Optical Express Reading had reported they had no never events in the reporting period October 2016 to September 2017. 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.
- There was a process that staff followed for reporting incidents, and this was supported by their internal policies and procedures. These were investigated and escalated to the corporate team as needed.
- There were two incidents and one near-miss which were clearly documented at the clinic and included actions taken. The near-miss related to a patient who did not declare that they were pregnant until the day of the procedure. Appropriate action was taken and the procedure was cancelled.
- The surgical manager and staff we spoke with said that incidents were discussed usually at the time and at staff's meetings. They said that sharing information was easy as they were a small team and this included lessons learnt.
- The duty of candour (DoC) is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff we spoke with were able to tell us about reporting and being open when things go wrong. Staff had not received any training relating to the DoC. Senior staff members were clear about their responsibilities in relation to DoC.
- We did not see evidence of the DoC having been initiated and staff confirmed that there had been no incident that required following this process.
- The surgical services manager had completed root cause analysis (RCA) training for serious incidents. RCA is a method of problem solving and identifying the root causes when things go wrong.

- We saw internal directives informing staff of changes in protocols, practices or policy. Each member of staff were required to sign to confirm they had read the information. These included compliance with team brief, using monovision indicator on treatment sheets and entering incorrect medications on the electronic medical records.

Cleanliness, infection control and hygiene

- At the time of the inspection, the reception area,laser treatment room, the surgeon's examination room, post-operative rooms, discharge room, dirty utilities were all visibly clean, tidy and in good decorative order.These were based on the Department of Health's code of practice on the prevention and control of infections, and included guidance on hand hygiene, use of personal protective equipment such as gloves and aprons, and management of the spillage of body fluids.
- We saw cleaning rotas in the operating theatres which were completed daily, and staff were clear about their roles and responsibilities regarding infection prevention and control. Infection control training was part of mandatory training for all staff. However we noted that staff went to the reception area and did not discard their gown when they left the treatment room.
- The treatment room was maintained in line with the Royal College of Ophthalmology guidelines.
- The clinic used all disposable instruments and the surgical packs were made up ready for the procedures. We observed staff observed aseptic techniques for the prevention of infection when preparing for tretament. The packs were disposed of safely and appropriately following each procedure.
- Staff followed best practice during laser surgery which included drapes around the surgical site and the use of sterile gowns and gloves. We observed three members of staff and saw they washed their hands in accordance with the World health Organisation (WHO) 'five moments for hand hygiene'. Posters were displayed at the clinic, which provided information on the 'five moments for hand hygiene' in line with WHO guidance.
- Although the nurses assisting during the laser treatment used sterile gowns, this was not consistent when we observed two different doctors who were providing similar type or same treatment to patients.
- We noted that sharps management complied with Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Staff followed guidance on sharps management which included no re-sheathing of needles. The sharp bins were clearly labelled and tagged to ensure appropriate disposal and to prevent risk of cross infection.
- There was adequate supply of personal protective equipment (PPE) such as gloves and aprons. We observed staff adhered to 'bare below the elbow' policy in clinical areas and used PPE as appropriate.
- Antibacterial hand gel dispensers were available at the entrance to the clinic and in the main reception area and in other clinical areas.
- Access to the operating theatre was appropriately restricted. There was a clean and dirty utility area to ensure that the risk of infection transmission was minimised.
- However one of the doors to the treatment room was faulty and this did not close fully during treatment. This may pose the risk of unauthorised access to the treatment room during procedures.We raised this with the staff who were aware of the door being faulty and told us this had been reported and had been faulty for a while.
- There were quarterly infection control audits which showed compliance levels between 83-100%. Areas audited included the environment, hand hygiene, cleaning and décor, sharps and waste disposal.We saw that action was taken following a recent audit that required staff to complete infection control training and for posters to be displayed in clinical areas.
- The clinic carried out an annual legionnaire test and we saw records which showed the necessary checks had been completed. Legionella is water borne bacteria that can be harmful to people's health. The clinic was compliant with water tests for Legionnaires disease with

- During the reporting period, there were no incidents of MRSA or MSSA and there were no cases of C.diff or E.coli infections.
- The clinic had spillage kit for the management of blood spillage and body fluids and Mytomycin.

Environment and equipment

- The environment was well maintained, bright, secure and welcoming and adequate seating was available in the two reception areas. Access to the service was monitored via an intercom system.
- There were systems in place to ensure that equipment used during surgery was calibrated and the surgeon was also responsible to ensure that checks were carried out.
- There was a process for the recording of implants and single use instrument kit where the unique identifying labels were attached to the patients' records for audits and traceability if required. The surgeon and scrub nurse completed a double check to ensure that the correct implant was used. This included size, type and make of implant which was recorded.
- There were accesses to the clinic through the front and back entrances. A passenger lift was in place to access the clinic in the basement area. There was a small car park at the back of the clinic providing access to people with limited mobility and wheelchair users as required.
- The service had a diagnostic test room, consulting rooms and a laser treatment room. All the rooms including the post procedure/recovery rooms were secure, and this ensured that patients had privacy during consultations and treatments.
- The clinic had two types of laser machines and these were kept in dedicated laser rooms. The clinic had a contract with an external provider for an annual service of the equipment. There were other regular checks and an emergency call out service.
- The laser treatment room complied with the safety requirements of the laser local rules, health, and safety at work requirements. The Laser treatment room was a controlled area with warning lights/signs to ensure safe practices.
- At the start of each laser treatment or procedure the laser technician performed safety and calibration checks. The machines also had safety warnings and failsafe cut outs built into the laser software. We saw that the checklists were completed and signed by staff.
- The clinic had contracted an external Laser Protection Advisor (LPA) who was responsible for undertaking risk assessments, providing advice, and training to staff on laser safety.
- The LPA was also responsible for provision of Local Rules and working practices. Local Rules contain guidance and instructions which are necessary to comply with the legislation, standards and management for the safe use of lasers.
- The Local rules were available and staff had signed the register to confirm they had read and understood the local rules.
- However we found that the Laser risk assessment had expired in June 2017. We raised this with the provider at the time of the inspection. They told us that the LPA had been busy and there was no action taken to remedy this. The lack of up to date document posed risks of staff following procedures that may be outdated. This had not been reviewed and updated in line with policy and practice guidance.
- There were no flammable liquids as recommended by the Medicines and Healthcare products Regulatory Agency (MHRA) guidance in the laser room.

Medicines

- The service had a service level agreement with an external provider and another hospital for the provision of patients' medicines.
- During the inspection we identified some concerns relating to the management of cytotoxic medication (Mitomycin).
- We noted staff had administered Mitomycin from a single bottle to three different patients between 27 November and 5 December 2017. We sought further advice from the manufacturer who advised the

prepared eye drop once opened, should be discarded within seven days. Staff did not adhere to the manufacturer's guideline for the use and disposal of this medicine.

- Staff were not adhering to Optical Express Mitomycin policy vol. 4/Jan 2017 which stated that Mitomycin should be ordered for a named patient, and staff had not adhered to this policy.
- We wrote to the provider as we were not assured that appropriate risk assessments had been carried out to identify and address risks posed to patients and staff associated with the management and administration of Mitomycin at this clinic.
- The provider responded within a short timeframe and confirmed that they would review their policy to ensure that Mitomycin was ordered centrally and the clinic receives one bottle for each patient's use. The policy would reflect single use of Mitomycin. A sealed bottle would be used for each patient and this would be discarded after each use.
- Other actions included further training for staff and a directive would be disseminated to advise staff of the changes and current procedures for the use of Mitomycin.
- The clinic held some emergency medicines such as adrenaline epipen for adverse reaction/anaphylaxis, GTN spray, Salbutamol and Glucagon hypokit for treatment of a variety of medical emergencies. These were checked regularly and were in date. These medicines were stored securely in a container, which was readily available in an emergency.
- The gas cylinders included those spare cylinders needed for re-fill of the main laser machines were stored separately in another room and were secure.
- The oxygen cylinders were stored in an upright position as recommended. A random check showed that these were within their expiry date.
- During the inspection we found all other medicines were stored safely and securely and processes were in place including an internal stock control checks.
- We carried out a random check of some medicines and found these were in date. A dedicated fridge was available for the storage of medicines at the clinic. The fridge temperature was monitored to ensure medicines were stored correctly as per recommendations.
- We saw that all drugs administered to patients were prescribed by the consultant and these included eye drops. The medicines administration charts were completed appropriately and included times and dates that eye drops were administered.
- We observed staff applying pre- printed labels to eye drops which were dispensed to patients as their take home medicines. Staff told us they had not completed additional training in dispensing medicines and there was no competency framework to support this practice. This was raised with the provider at the time of the inspection.
- Patients were given information about their eye drops following their treatment and this included written instructions. Feedback we received from three patients were that they were very happy and satisfied with the advice and instructions given regarding their eye drops.

Records

- There were two systems in place relating to patients' records. These included paper and an electronic medical record (EMR).
- Patients' records on the day of the surgery were in paper format which contained assessments, consent documents; prints of scans; instrument traceability labels; and medication prescriptions. There was a local protocol relating to records which staff followed.
- Following the patient's treatment the records were updated on the EMR record system which meant that records were available out of hours and could be accessed remotely by authorised personnel.
- We reviewed 11 sets of patients' personal records and saw these were detailed and included consent forms which provided patients with information relating to risks associated with the treatment or procedure.
- There were clear assessments recorded which included the patients' past medical history as appropriate.

- The records contained detailed information of care and treatment including consent and the type of lens. The serial numbers of the implants were recorded in patients' notes. Investigations and test results, care plans and records of care provided were available. Records followed the same formats which allowed for ease of access to all relevant information.
- We reviewed records of the World Health Organisation WHO five steps to safer surgery checklist which included, sign in, sign out and time out. The three members of staff present in the treatment room had signed the checklists.
- Records were stored securely and in line with the Data Protection Act 1998. The computers were password protected which minimised the risks of unauthorised access to patients' personal records.
- The surgical register in the operating theatre was completed. This recorded the procedures undertaken, names of surgeon and scrub nurse, the time each patient entered and left theatre, the patient's name and identifier.
- There were regular audits of patients' records. We saw the audit for August and September 2017 where 19 files were audited. This showed that staff complied with record keeping and the outcome of these was shared with the staff.

Safeguarding

- In the reporting period October 2016 to October 2017, there were no safeguarding concerns relating to this service reported to the Care Quality Commission (CQC).
- Staff confirmed they had completed Level 2 training for safeguarding adults; the clinic did not provide care and treatment to anyone under the age of 18.
- The clinic had policies and procedures including the PREVENT directive.
- Staff had clear understanding about what constituted abuse and the action they would take to report and record any allegations of abuse. Staff were aware of the escalation process including the contact details which we saw in a folder. Staff told us they would be supported to raise a safeguarding concern in order to protect people using the service.

Mandatory training

- There was a mandatory training programme which staff completed and this included updates on specified core subjects. The training included health and safety, safeguarding adults Level 2 , infection control, medicines management , moving and handling, basic life support, conflict resolution and fire safety.
- Staff also completed additional training which was specific to their role such as for laser equipment.
- All staff had completed annual basic life support training. The surgeons had basic and advanced life support. The policy at the clinic was for staff, in the event of patient collapse, to assess and if necessary administer basic life support and to call the emergency services for further management.
- Staff completed consent training which included the Mental Capacity Act 2015.

Assessing and responding to patient risk

- The service had clear admission criteria that the staff followed. All patients were assessed by an optometrist which included checks and an initial assessment for suitability of treatment and ensuring they met the criteria for laser eye treatment.
- After initial consultation, the patient was required to either attend a face to face appointment with the surgeon who would carry out the procedure, or have a telephone conversation with the surgeon. The patient was given the option and initial appointments were free of charge.
- Following consultation, patients were given clear information about the benefits and risks of treatment. Assessments also looked at previous health problem such as those who suffered from epilepsy had to confirm they had been seizure free for three months. They also provided a letter from their GP to confirm this.
- The assessments also took into account the psychological well -being of the patient. Patients with depressive disorders also required a letter from their GP supporting their treatment. . Other checks included infection including eye infections.

Refractive eye surgery

- Patients' suitability and treatment criteria were discussed at the annual International Advisory Medical Board (IAMB) meeting. This meeting comprised of refractive eye experts who were independent of Optical Express.
- Staff used an adapted "five steps to safer surgery" procedure. The World Health Organisation (WHO) guidelines (5 steps to safer surgery), the surgical safety checklist is guidance to promote safety of patients undergoing surgery. This sets out what should be done during every surgical procedure to reduce the risk of errors. The checklist must be read out loud, and must include all sections of the checklist including the 'sign in' before anaesthesia is commenced, the 'time out' before starting surgery, and the 'sign out' before any member of the team leave the operating theatre.
- We observed four patients undergoing laser treatment by two different consultants on two separate days. Although the checklist was completed, there was a discrepancy about the process that the staff followed. One surgeon was fully involved at all the stages and the checklist was completed. However on other occasion we found that the sign in was completed by the technician without the involvement of other team members. The preparation and the time out were completed by the nurse assisting in the procedure prior to the surgeon entering the room. There was a potential of risk and errors as guidance were not consistently adhered to.
- We observed handovers following laser treatment. Staff ensured information relating to the patients' care post- surgery was communicated clearly. Staff followed their internal process for monitoring patients post -treatment and ensured they were fully recovered before they were discharged.
- Patients were monitored in the recovery room by either a registered nurse or assistant. They were provided with written instructions for aftercare and follow up appointments. We observed a staff member providing aftercare instruction to a patient. The discussions were informative, clear and patients were given time to ask questions.
- The surgeon gave patients their mobile number and there was an out of hours telephone line available for them to use in case of an emergency or if they had any concerns. The line was managed by an ophthalmologist who had access to a surgeon and records of treatment.
- The surgeon remained on site while patients were recovering, and was available for advice.
- There had been no patients transferred out of the clinic to an NHS facility within the last 12 months. For medical emergencies, the clinic contacted emergency 999 services. They did not have a service level agreement with the local hospital and would initiate emergency call out instead.
- Traceability forms were completed which provided a tracking and tracing system of equipment and treatments used in case of any concerns arising post procedure.
- The clinic had an emergency support system for urgent cases such as patients' infection. They co-ordinated care between the surgeon and optometrist and external services such as referral to another Consultant externally or laboratory services.

Nursing and medical staffing

- Clinic opening times were dependent on patient's demand. Care was provided on average two days per month. The clinic had two surgeons who were part of the regional team including London and South East areas and a resident registered nurse.
- The organisations central scheduling team managed the staff rosters, which looked at the skill mix to ensure they had adequate, suitably qualified staff to cover clinic days. Rosters were allocated one to two months in advance. They looked at surgeon's availability first and other staff were rostered according to treatment at the clinic.
- During surgery, the team consisted of a surgeon, an aesthetic trained registered nurse, laser assistant, post-operative care staff and a co-ordinator.
- An external company provided the Laser Protection Adviser (LPA). Staff told us they were easy to access and the organisation had a good professional working relationship with them.
- The registered manager at the clinic was the named Laser Protection Supervisor (LPS).The registered

manager was away on leave.The surgical manager confirmed that other staff had completed the training to deputise as LPS when the manager was not present. The technicians worked in the laser treatment room, so this meant there was a LPS present during patient treatment. During the unannounced inspection, a senior staff from the London region was acting as the LPS for that day.

- Staff told us that there was always adequately skilled staff during treatment as they worked across different clinics to provide consistency in practice.

Major incident awareness and training

- The clinic carried out patients' simulated collapse exercises on a quarterly basis. We saw two reports of scenarios such as a choking incident in waiting room and patient collapse after getting up from treatment bed. Staff told us they found these exercises very useful.
- Fire escapes were marked throughout the clinic and easy to access. There was a process for checks of fire extinguishers at the clinic. Records showed that this had been completed by an external company.
- The clinic had an emergency lighting system and staff told us there was facility for uninterrupted power supply system. This gave a supply of power up to 30 minutes, which meant patient treatment could be completed. The system was checked at the beginning of the working day.

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

Evidence-based care and treatment

- The service provided care and treatment in line with national guidance and best practice such as the Royal College of Ophthalmologists (RCO) and National Institute for Health and Clinical Excellence (NICE).
- The service followed NICE IPG64 guidelines on photorefractive eye surgery. The surgeon carried out the tests and checks pre-treatment and ensured consent was obtained. Patients were supplied with information on the benefits and also the potential risks of the treatment.
- Pre-operative tests for elective surgery were in line with NICE guidelines NG45. The patient's medical history was discussed and appropriate tests and scans were taken to help determine an appropriate treatment.
- The service had policies and procedures and best practice guidance which staff had access to via their intranet and some were in paper form. These were reviewed and updated in order to reflect current best practice and evidence based guidance.
- Staff told us the International Medical Advisory Board (IAMB) reviewed guidance and treatment on an annual basis. The IAMB comprised of refractive eye experts who had no link to the company. Guidance and any recommended changes were discussed and reviewed internally via their Medical Advisory Board (MAB). Any changes in guidance or protocols were disseminated to staff.
- The medical director was a member of the Refractive Surgery Standards Working Group (Royal College of Ophthalmologists) and had recently published the latest guidance from the RCO 'Professional Standards in Refractive Surgery' April 2017. This work contributed to the guidance used for refractive eye surgery.

Pain relief

- Patients told us that their pain was well managed. They had the opportunity to ask questions pre-treatment and said they had felt reassured.
- We observed patients were prescribed local anaesthetic eye drops and these were instilled prior to treatment. Staff explained the usage of pre and post treatment eye drops to ensure people's pain was well managed. During treatment, staff ensured that patients were comfortable.
- Patients were prescribed anaesthetic eye drops post treatment. Patients were provided with verbal and written instructions and staff checked this was clearly understood prior to discharge.
- Patients were given a follow up appointment three days after their treatment and their pain was monitored.

- Patients were also given advice on pain control such as Paracetamol to help manage any pain or discomfort.
- Patients were administered local anaesthetic drops and advised to use sun glasses to reduce discomfort and glare and to rest the eyes post procedure.

Patient outcomes

- The patients were treated as day care and outpatients. Data we received from the service showed there was no unplanned re admission or unplanned /emergency transfer of patients to other hospitals in the last 12 months.
- In the reporting period for the past twelve months, there were no unplanned returns to theatre for refractive eye surgery.
- The clinic used the service of a bio-statistician who collated data for each surgeon's outcomes. The surgeon's individual outcomes were collected on an annual basis and were used as part of their appraisal.
- The data collected was used baseline analysis to monitor surgeon's performance such as to monitor vision comparisons pre operatively to post operatively.
- Collection of data also assisted them in looking at patients' demographic such as male to female ratio, age group; treatment type and safety data.
- The clinic expected to enhance approximately 5% of all treatments. Patients were advised of the need for enhancement at the start of their journey so they were not unexpected. The provider told us the enhancement data may also include patients who had treatment at other enhancements and 27 (eyes) enhancements. Eight patients had their primary treatment and enhancement within the last twelve months.
- The cancellation rate for the surgeon was collated along with enquiries to patient-derived regulated bodies such as the GMC to see if complaints and legal inquiries had been made. No complaints or inquiries had been reported.
- In the past 12 months, 113 patients experienced complications or side effects following refractive eye surgery. The majority of these related to dry eye (53), and haze or scar (10). The treatment plans included follow up appointments to increase lubrication for example. Others were referred back to referral back to the surgeon or were followed by the optometrist.

Competent staff

- There was a process in place where the laser protection supervisor (LPS) completed a week's course in the use of laser and associated equipment. This was followed by a competency assessment to ensure they had the necessary skills in the use of laser.
- The LPS were also subject to three yearly competency reviews to ensure their skills and knowledge remained current and competency in laser management was maintained. The clinic had Senior Refractive Trainers (SRT) and they carry out the laser competency assessments locally and support technicians and LPS to ensure they remained skilled.
- The registered manager was the nominated LPS. There were other staff who deputised in the registered manager's absence to ensure laser safety rules and guidance were followed.
- We viewed five staff records and saw that yearly appraisals were completed and took into account staff's clinical competency. There was an area for planning and development opportunities.
- The staff records showed appraisal was completed and included evidence of registration with the Nursing and Midwifery Council (NMC) and training competencies were complete. Competency checks included assessments for the scrub role.
- The medical director completed appraisals for surgeons and the surgery manager completed appraisals for local staff such as registered nurses and technicians.
- The Laser Protection Advisor (LPA) was available for advice and support and staff said they were able to contact them.
- The surgical services manager confirmed that there was always an authorised LPS on treatment days and staff had signed that they have read and understood the laser safety local rules.
- Information we received from the provider stated that the Ophthalmologist must undertake a number of

procedures under the supervision of the Medical Director or senior Ophthalmologist following their training before they gained certification. The surgeons once approved by the Medical Director were entered onto the list of authorised users.

Multidisciplinary working

- We observed effective multidisciplinary working between staff of all grades at the clinic. Staff told us they felt valued by all team members and worked cohesively.
- Staff worked across multiple sites in Optical Express, which meant there was consistency within the service.
- The service contacted GP's for relevant patients' information and with the patients' consent. Staff said that the GPs were responsive.
- We observed four patients' treatments, and noted that the consultants and other clinical staff treated each other with respect and there was good communication between the team including safety checks.
- There were regular team meetings, and staff said they were confident to raise issues including practices and these would be taken seriously.

Access to information

- The service held two systems for recording patients 'information such as EMR and in paper formats. Staff followed their internal process and we saw patients' records were ready for their appointments when they attended the service.
- All designated staff had access to patients' medical records which included assessments, tests results, current medicines, referral letters, consent forms, clinic notes, pre and post -operative records.
- Staff had access to a range of policies, procedures and guidance which was readily available on the service's electronic system.
- At the point of confirming their first appointment, patients were given written information of cost of care. All patients were offered a fixed package and costs varied according to the treatment they would receive.
- At the clinic there was information displayed, such as fire regulation guidelines and infection control procedures such as 'the five moments of hand washing'.
- There was a process to inform patients' GPs of treatment provided with the patients' consents.

Consent and Mental Capacity Act

- The service had policy and procedures for consent which were aligned to mental capacity act 2005 (MCA).
- Surgeons and the staff at the clinic had clear understanding of the consent to care and best interest process; they told us of the action they would take if someone lacked capacity. The capacity to consent was assessed as part of their pre-operative assessment.
- The consent policy did not reflect the Royal College of Ophthalmologists 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- At the first patient consultation, the optometrist provided an information folder to the patient, which contained a copy of the treatment consent form, and information about the risks and benefits associated with the treatment.
- Patients had a consultation with the surgeon which staff told us was was over the telephone or face to face as part of the assessment for treatment. Information was shared regarding the consent process, risks and benefits of procedure.
- As part of the consent process; patients had to agree to watch a video, which provided further information on the treatment, including potential risks associated with the treatment.
- We observed two consultations with the patients' agreement. The patient was fully engaged and the surgeon provided them with clear information and consent was signed on the day of treatment. Patients were given time to ask questions and the consultant also discussed the potential risks associated with treatment.
- We reviewed 12 sets of patients' notes and followed four patient's journeys through to surgery. We found that consent was discussed and recorded

appropriately which included on the day of their surgery. Patients told us they had discussed their surgery with the doctors, they were given clear verbal and written information. A patient commented that they were "very happy" and felt reassured about their proposed treatment.

- For patients whose first language was not English or have other communication problems; patients had to pay for a translation service as this facility was not available to them at the clinic. Staff told us that patients were asked to use a family member or friend to translate for them. They could not be assured that the correct information was shared.
- However in order for patients to make an informed choice and gain consent; it is best practice that there is an independent interpreter or advocate to ensure that medical information is explained correctly. This would also minimise the risks of coercion and is in the best interests of the patients.

Are refractive eye surgery caring?

Compassionate care

- We observed patients were treated with care, compassion, and respect by all staff they had contact with during their visit.
- There was information regarding the availability of a chaperone to all patients that requested this service. A chaperone is a person who serves as a witness for both patient and medical practitioner as a safeguard for both parties during a medical examination or procedure.
- We spoke with seven patients who were receiving care and their relatives at the time of the inspection. They were all positive about the care and treatment they had received. Patients told us their privacy and dignity was preserved when receiving care.
- We observed four treatment procedures. The surgeon explained the treatment and interacted with the patient ensuring they were comfortable.
- We observed nursing staff and the surgeons introducing themselves prior to consultation.
- We reviewed seven thank you cards which were on display in the waiting area at the clinic. The comments included the kind and caring attitudes of the staff and a patient said they were grateful.
- Patients were asked to complete an on-line survey at various points during their care. This included after the 24-hour post treatment.

Understanding and involvement of patients and those close to them

- Patients were involved in their care. Staff ensured they had adequate information to make an informed decision.
- We spoke with four patients who told us they were happy with the level of involvement and this was through the processes from consultation, investigation and treatment.
- We observed staff during treatment and discharge. Patients were kept informed about the procedure and shared relevant discharge information and gave them time to ask questions.
- There were leaflets available, which provided details of all the options available and the costs of treatment. Patients said they had accessed the organisation website and found it informative.

Emotional support

- Patients told us that they were fully involved in their care and treatment. They told us the staff had explained the procedure to them and their questions were answered in an unhurried manner, and they fully understood and considered the options available.
- Records seen and the patients we spoke with confirmed the provider followed due processes in terms of assessing and consulting the patients about their suitability for proposed treatment. This included pre-operative meeting, visits during admission and post operatively to provide support and information as needed.
- We observed four surgical procedures the surgeon and other staff involved the patient and explained what they were doing and ensuring the patient was involved as they chose.

Refractive eye surgery

- Staff provided patients with written and verbal information about their post- operative care and ensured that they had support at home if needed.
- We observed a patient who was anxious was given time to ask questions and staff continued to provide support and reassurance during the treatment.
- We observed staff in the discharge room supporting patients, treating patients in a calm manner and sharing information about after care information and allaying patients' concerns.

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

Service planning and delivery to meet the needs of local people

- There was a process that staff followed to ensure that care was planned to meet the needs of people using the service. Patients were referred to a surgeon of their choice where possible. The patient was seen by the same surgeon, who carried out the surgery or procedure and this was followed up throughout the patient's journey ensuring patients' continuity of care.
- Patients were offered flexibility in choosing their appointments and procedures were undertaken at a time that suited them. The provider offered their service on average two days a month and patients were aware of this.
- Patients accessed the service through self- referral process and information was available on line.
- All patients were privately funded, as the service did not undertake any NHS work and was planned around self-funded patients' demands.

Access and flow

- The clinic had 761 day care episodes in the reporting period from October 2016 to September 2017.
- The provider offered a day care service to patients and all care and treatment was planned around patients' needs
- Patients were self-referred and appointments were made to suit patient requirements. The clinic had the facility of treating patients in clinics in the surrounding areas which afforded patients choices for appointment and treatment.
- There was no arrangement for unplanned surgery as the service did not undertake emergency care. All patients were pre-booked.
- The average referral to treatment time was 10 days or sooner, and appointments were flexible and the service tried to fit these around patients' needs, choices and availability. All patients were triaged by clinicians at the initial appointments and patients informed early on of their treatment options.
- Within the last 12 months, there had been no cancelled refractive eye procedures due to non-clinical reasons.
- Patients who missed or did not attend (DNA) for treatment was followed up and clinic manager would make contact with the patients.

Meeting people's individual needs

- There was level access and adequate space for people with limited mobility and for wheelchair users.
- Patients' assessments were completed and this took into account any individual needs.
- There were facilities for patients to have hot and cold drinks in the reception area. Magazines and a television were available in the reception area.
- There was a variety of leaflets which was available to patients; other information such as post op care was only available in English. Staff told us that information in large prints would be available without delay. Information in audio formats and braille for example was available on request.
- The clinic did not treat patients with dementia, learning difficulty or patients with complex health conditions which staff said formed part of their initial assessments of patients.

Learning from complaints and concerns

- The service had a complaints policy, which provided guidance to staff on the processes they should follow in the event of a patient complaint.

Refractive eye surgery

- From October 2016 to September 2017, the service had received two complaints. We viewed the complaints summary and saw outcomes with actions taken were completed for each complaint. The complaints were related to booking errors and quality of vision and patients expectation. Against each complaint, we saw a response had been made to and learning outcomes were followed up required. These were managed by the clinical services team.
- Verbal complaints were dealt with by the surgery manager in an attempt to resolve the issue as quickly as possible with a satisfactory outcome for both parties. If the complaint escalated further, the clinical services department were then involved in the process. The organisation employed a solicitor assisted with the management of complaints.
- We observed a patient raising a complaint with a staff member during the inspection and this was dealt with in private by the business manager at the clinic.
- Written complaints were responded to by the clinical services team. The patient's electronic file was updated so the surgery manager could monitor the information regarding the complaint.

Are refractive eye surgery well-led?

Leadership and culture of service

- The corporate leadership arrangements consisted of the chief medical officer (CEO), optometry directors, operations director, and the clinical services team, which consisted of the refractive operation manager, surgical services manager, and location surgery managers.
- The service has a registered manager and the surgical manager who was both fully involved in the management of the service. Staff were complimentary about the management team and said they felt well supported.
- Staff who worked at the service told us they enjoyed working at the clinic, and everyone got on well with each other.
- Surgeons reported to the medical director and they told us they were happy with the service provision.
- Staff rotated to other clinics in the region and said they understood the reasons and they were part of the same South East team.
- Patients received the terms and conditions, which provided information on payment fees and details of the service provided. Patients told us they were happy with the information and were aware that the initial assessment did not omit then to receive treatment for example.

Vision and strategy

- The organisations vision and strategy , with reference to this local branch, was looking at possible equipment upgrade such as Intra ocular lens (IOL) implant theatre. Although there was currently no room at the Reading clinic for this.
- There was no facility in Reading clinic to compete for NHS work; and this did not form part of the current strategy.
- Staff were not aware of the organisations vision and strategy. However, they said they wanted to provide care in a compassionate way and ensuring the best outcomes for patients.
- We were told by the surgical manager that the service set up the first International Medical Advisory Board (IMAB). The board was made up world renowned refractive eye experts with no link to Optical Express. Optical Express finance the board and they meet annually to review the organisations data and clinical protocols.

Governance, risk management, and quality measurement

- There were policies in place to support the local governance of the organisation. These key policies provided staff with clear guidelines and processes to follow. Such key policies included risk management, incident reporting, information governance, medicine management and privacy, dignity, respect and human rights.
- The organisation held meetings through which governance issues were addressed. Meetings included the clinical committee meeting which was held on a

monthly basis. These meetings were attended by the clinical services director, medical director, surgical services manager, in house solicitor, and the responsible officer.

- We saw the meeting minutes of April 2017 and June 2017. Governance topics included the opening of new clinics, Royal College of Ophthalmologists guidelines, appraisals, mandatory training and other relevant topics related to the service. The minutes supplied actions taken and information sharing.
- The location had quality indicators, which covered, incidents, complaints and local audits. This local quality information was fed into the clinical governance committee, which met once a month, and in turn fed into the Medical Advisory Board (MAB). The CEO headed the MAB and all surgeons and heads of departments were members of the board. The MAB managed changing practices, either to treatment, surgery techniques or the introduction of new technology.
- Local monthly team meetings took place at the clinic and local topics were discussed including incidents and any changes to practice (which had been fed from the MAB). The meeting allowed time for staff to raise any concerns.
- There were risk assessments, which applied to the location. These risks were colour rated, red, amber or green (RAG), which meant the clinic were able to assess each risk's severity. We viewed the risks fire assessments. These were up to date, re-assessed, and kept for one year. As a single specialty service, the risks to patients were low and staff were trained and skilled to manage risks at the location.
- We were told by the surgery manager the top three risks of the clinic were needle stick injury, inflammatory response to treatment and an error of omission in the computer system. Staff we spoke with were aware of the risks and the steps they needed to take to reduce these risks.
- We saw evidence that checks for the surgeon's personnel file were completed and indemnity insurance was in place, an appraisal had been completed and clinical outcomes had been collected.
- The local surgery manager was able to manage performance and quality of the service through local auditing and was able to contribute feedback through their local meetings with the surgery services manager.
- The fit and proper person's checks were adopted for the company's director, nominated individual and registered manager.

Public and staff engagement

- There was a process for seeking patients' feedback and this was monitored. Patients were able to leave feedback online at the clinic or through the organisation's website. The result of this survey showed a high degree of customer satisfaction.
- The clinic had reviewed feedback from people using services across their locations and introduced changes had reviewed feedback from people across all their locations and introduced changes. These included a review of appointment scheduling for surgery in an attempt to reduce waiting times for patients in clinic. To relieve anxiety in waiting for scans and assessments, patients had been advised that although treatment itself took approximately 10-20 minutes in total, they would be in clinic for 2-3 hours for laser treatment.
- The organisation did not conduct staff surveys. The surgery services manager told us that the company was considering developing this.
- Staff were not aware of a Freedom to Speak Up Guardian in the organisation to enable them to raise any issues. The Freedom to Speak Guardian followed Sir Francis seminal inquiry report which exposed unacceptable patients' care and a culture which meant that staff did not report and raise their concerns. Although this was aimed at the NHS, it embodies a culture of openness across all sectors.
- There were regular team meetings and said they found them useful to share good practice and any concerns across the different teams and locations.

Outstanding practice and areas for improvement

Outstanding practice

The company developed the International Medical Advisory Board. The board was made up of specialists independent of Optical Express. They met annually to discuss outcome data and gave recommendations about any changes required.

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that Mitomycin is managed safely. Policies and procedures are developed for individual patient's use and discarded after each patient.

Action the provider SHOULD take to improve

- The consent policy should reflect the Royal College of Ophthalmologists' 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider should review the process for the WHO checklists regarding laser treatment in order to provide consistency in practices and safeguard patients.
- Staff should adhere to infection control procedures with regards to gowns used during surgery.
- Risk assessments and Local Rules should be reviewed and updated in order to provide current and up to date information to staff.
- The door to the surgical treatment room should be repaired to ensure that access is restricted when treatment is in progress.
- The staff should receive training regarding the application of Duty of Candour.
- The provider should offer patient information in the form of leaflets and documents in other languages other than in English.
- The provider should offer formal interpretation services for patients.
- The provider should consider developing a vision and strategy for the service.
- The provider should start staff engagement surveys.

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
	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Management of medicines- The provider is responsible for the proper and safe management of medicines. The policy, procedures and practices were not in line with guidelines. The management of Mitomycin was not safe and not single use as this was used for multiple patients which may put patients at risk of harm.

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.