Optical Express - Liverpool 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

Overall summary

Optical Express Liverpool is operated by Optical Express Limited. The clinic has pre-screening facilities, counselling rooms and a laser suite consisting of a small surgeon's treatment room, a larger surgery treatment room and utility rooms.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 11 July 2017, along with an unannounced visit to the clinic on 20 July 2017.

The service provides laser correction surgery for patients over the age of 18, and does not provide treatment for children.

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

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

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

- The service did not use a safer steps surgery checklist or equivalent before, during or after laser surgery treatments. The service had recently developed a surgery checklist, which was not embedded into practice yet.
- There was not always a registered nurse on duty during surgery days. There was no evidence that risk assessments were completed to access the impact of this on patient care and safety. However, on our unannounced visit, staff informed us that they had developed a risk assessment tool to monitor and access this impact. This needed to be embedded into practice.
- There was no evidence of regular local quality audits. The service undertook medicine and record audits and had recently introduced a monthly hand hygiene audit but this was not embedded into practice yet.

Summary of findings

- There was no evidence of local or regional learning, there were no regular team meetings, team briefs or shared learned forums. However, staff had recently introduced team brief meetings on surgery days.
- There was no evidence of a local, regional or national staff survey to assess staff motivation, experience and well-being.
- There was no formal system in place to record and document safe disposal of expired drugs at the clinic. However, on the unannounced visit, staff had developed a recording system to ensure dispose of drugs properly to help reduce harm from accidental exposure or intentional misuse.
- There was a lack of local oversight for training and competencies for all rotational staff attending the clinic.
- Patient information leaflets, documents and consent forms were only provided in English.
- There were no formal interpreter services available for patients. Patients were advised to bring their own interpreter in to the clinic with them or use a family member. Staff informed us that some staff were bi-lingual and were used to interpret information.
- Although a local risk register was in place, it was based on a standard list of complications relating to refractive surgery. It did not reflect local risk issues or risks related to local incidents. Senior staff informed us that there was no corporate risk register.
- The consent policy stated a "cooling off" period of three days prior to surgery procedure. Staff also undertook remote telephone patient consent. However, the new Professional Standards for Refractive surgery (April 2017) recommends a "cooling off" period of one week and consent should not be conducted by telephone.
- Clean sharps boxes were stored on shelving in the same room as gas cylinders and dirty waste. This was not following corporate policy on storage. However, on the unannounced visit, these had been removed to a more suitable utility room.

However, we found the following areas of good practice:

- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional.
- All areas of the clinic were tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff to move around freely.
- Information about the outcomes of patients' care and treatment was collected and audited annually by the corporate statistician to review quality care and patient outcomes. This process was completed through data imputed by the main surgeon at the clinic, in relation to patients who undertook surgery.
- Emergency equipment was checked on surgery days and staff documented all checks.
- We found that fridge temperatures, air humidly and room temperatures were recorded to ensure they were all within normal ranges.
- We observed that staff undertook appropriate Aseptic Non Touch Techniques (ANTT) to minimise the occurrence of infection during surgery.
- We looked at nine paper patient records and three electronic patient records (EMR) and found that all information was completed and information corresponded between the two versions of records. Every patient had consent forms, patient information leaflets and a health questionnaire completed in their paper records.
- The EMR system was accessible to all appropriate staff in all Optical Express clinics across the country.
- Mandatory training was made available to all staff to enable them to provide safe care and treatment to patients. Some of the training was completed through e learning, which staff could access at a time to best suit their needs.
- All patients we asked reported the staff were caring and respectful.
- Patients told us that that all risks and benefits were discussed thoroughly with them prior to surgery and that they all received good discharge and aftercare information. Patients also informed us that they received adequate time from their first consultation appointment, time of consent and day of surgery.

Following this inspection, we told the provider that it should make other improvements, to help the service improve. We also issued the provider with two requirement notices. Details are at the end of the report.

Ellen Armistead

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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Background to Optical Express - Liverpool Clinic

Optical Express Liverpool is a high street optical practice, part of a large shopping complex in Liverpool City centre. Optical Express offers patients laser eye surgery and has been opened since August 2008.

The clinic accommodates the treatment suite, and regulated activities on the first floor of the high street clinic. Pre-screening equipment and rooms are shared with the high street Optical Express shop on the ground floor. The first floor can be reached by passenger lift located at the back of the store.

Patients are self-referring and self-funded. The clinic provides laser vision correction procedures under topical anaesthetic using Class 4 and Class 3b lasers. Ophthalmologists carry out the treatments. The clinic provides laser surgery treatments approximately two days each month.

All patients self-referred into the service, they made enquires via the clinics website, in person, by telephone via the Optical Express central customer services or were existing optical practice patients.

Following an initial consultation appointment with an optical practice optometrist, patients book an appointment with the surgeon. The clinics surgical diary accommodates patients for treatment and surgeon appointments. As the service is not operational every day, the clinic has two resident team members, who form part of a regional surgery team covering the North West of England region.

The registered manager retired at the end of 2016. Optical Express has appointed a new surgery manager who is currently awaiting confirmation following submission of a CQC application to register.

Regulated Activities include:

- diagnostic and screening
- surgical procedures
- treatment of disease, disorder and injury.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and one other CQC inspector. The inspection team was overseen by Lorraine Bolam, Interim Head of Hospital Inspection.

Information about Optical Express - Liverpool Clinic

Optical Express Liverpool provides treatment and care to adults only and the service runs over seven days, Monday to Sunday. There are no overnight facilities. Opening times were flexible according to patient's treatments and appointments. Surgery days usually ran from 8 am to 5 p.m. There are no regular set day that surgery takes place. Surgery takes place about twice a month at the surgery. This meant there were days that the service did not open and staff were asked to work at another clinic across the North region on a rotational basis. .

The clinic has been operational since August 2008. The clinic has two floors.

On the ground floor, there are two screening rooms, which contain diagnostic equipment. The facility for treatment on the first floor consists of:

- One Laser treatment room. This contains an Excimer laser machine (Class 4); femtosecond laser machine (Class 3b). The laser room has three adjoining rooms: utility room, clean room and the surgeon's examination room.

Summary of this inspection

- One surgeon's examination room. This room was accessed by an external corridor and has direct access into the laser room.
- Two discharge rooms. These are small rooms where patients go immediately after their procedure and receive their aftercare advice and medication. It contains standard chairs only, with no recliner chairs available.
- One consultation room. This is a small room, used if patients need to discuss something private outside of the surgeon's room or treatment room.

The clinic undertakes refractive surgery (laser) on patients aged 18 and above. The clinic does not provide treatment and care for children and young people.

The service does not offer any other services other than refractive eye surgery that are within CQC scope of registration. If a patient required further care or services because of their treatment, for example, treatment for dry eye symptoms post treatment or treatment for an eye infection or inflammation, they would provide those types of activities as part of routine post-operative care but they do not provide other primary services.

As the service is not operational every day, the clinic have two resident team members only (the registered surgery manager and a surgery associate), who form part of a regional surgery team covering the North West area. Treatment days are staffed by the two-team members and supported by others within the regional team such as operating department practitioners and registered nurses. The clinic employed one full time ophthalmologist.

There are no current vacancies. In the last 12 month, one member of staff left the service and one joined the service.

We spoke with five patients on the day of their surgery and seven patients post-surgery on the telephone. We also spoke to four family members.

During our inspection, we reviewed nine sets of patient hard copy (paper) records and three electronic patient records.

We reviewed 18 corporate policies and 10 corporate clinical directives. All were available as paper copies with up to date review and version numbers.

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

The service was last inspected in September 2013, which found that the service was meeting all standards of quality and safety it was inspected against. This was the clinics first comprehensive inspection against the new methodology.

From May 2016 to June 2017, the clinic performed 304 surgery treatments.

All cases received topical anaesthesia.

No cases required anaesthetic blocks, intravenous sedation or general anaesthetic (GA).

All patients are self-referred and self-funded.

There were no Never Events reported between May 2016 and June 2017.

There were no Serious Incidents reported between May 2016 and June 2017.

There were no incidences of healthcare acquired Methicillin-resistant Staphylococcus aureus (MRSA),

There were no incidences of healthcare acquired Methicillin-sensitive staphylococcus aureus (MSSA).

There were no incidences of healthcare acquired Clostridium difficile (c.diff)

There were no incidences of healthcare acquired E-Coli

From May 2016 and June 2017, there were six complaints that were overseen by the senior team and Head office. Two remained unresolved at the time of inspection.

Services provided at the service under service level agreement:

- Clinical and or non-clinical waste removal
- Pharmacy
- Lift Maintenance
- Laser Maintenance service
- Uninterrupted Power Supply
- 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 services.

We found the following areas of good practice:

- All areas of the unit were tidy and visibly clean. It was free from clutter and provided a safe environment for patients, visitors and staff to move around freely.
- All paper patient records and electronic patient records (EMR) reviewed had information completed and information corresponded between the two versions of records.
- The EMR system was accessible to all appropriate staff in all Optical Express clinics across the country.
- We found that emergency equipment was checked on surgery days.
- We found that fridge temperatures, air humidly and room temperatures were recorded to ensure they were all within normal ranges.
- We observed that staff undertook appropriate aseptic non-touch techniques (ANTT) to minimise the occurrence of infection during surgery.
- Risks to patients were identified and managed.

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

- The service did not use a safer steps surgery checklist or equivalent before, during or after laser surgery treatments. The service had recently developed a surgery checklist, which was not embedded into practice yet.
- There was no evidence of learning from incidents within clinical practice.
- There was not always a registered nurse on duty during surgery days. There was no evidence that risk assessments were completed to access the impact of this on patient care and safety. However, on our unannounced visit, staff informed us that they had developed a risk assessment tool to monitor and access this impact. This needed to be embedded into practice.
- There was no formal system in place to record and document safe disposal of expired drugs at the clinic. However, on the unannounced visit, staff had developed a recording system to ensure dispose of drugs properly to help reduce harm from accidental exposure or intentional misuse.

Summary of this inspection

Are services effective?

We do not currently have a legal duty to rate refractive eye surgery services.

We found the following areas of good practice:

- There was an annual audit of the surgeon's patient outcomes.
- Multidisciplinary working was observed.
- Patients receiving care at the clinic were carefully screened and suitability accessed to ensure correct treatment was provided.
- Patients informed us that they received adequate time from their first consultation appointment, time of consent and day of surgery.

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

- The service did not follow the Professional Standards for Refractive surgery (April 2017) recommendations of a "cooling off" period of one week after obtaining consent from patients. However, patients informed us that they received adequate time between consenting to and the day of surgery and our review of patient records confirmed this.
- The clinic undertook patient consent by telephone. This did not follow the Professional Standards for Refractive surgery (April 2017) recommendations.
- There was no evidence of regular local quality audits undertaken. Medicine and record audits were completed and on the unannounced visit, staff informed us that they were introducing monthly hand hygiene audits. This was not embedded into practice yet.
- There was no evidence of local or regional learning. There were no regular team meetings, team briefs or shared learned forums. However, on the unannounced visit, staff had introduced team brief meetings on surgery days, which were recorded.
- We observed a lack of local oversight for training and competencies for all rotational staff attending the clinic. However, on our unannounced visit, staff were in the process of collecting this information.

Are services caring?

We do not currently have a legal duty to rate refractive eye surgery services.

We found the following areas of good practice:

- All patients we spoke with reported the staff were caring and respectful.

Summary of this inspection

- Patients told us that that all risks and benefits were discussed thoroughly with them prior to surgery and that they all received good discharge and aftercare information.
- All patients we spoke with were very happy with the care and treatment they had received.
- We observed good staff/patient interaction and communication.
- We observed that nurses had close working relationships with their patients. Interactions were positive, friendly and professional.

Are services responsive?

We do not currently have a legal duty to rate refractive eye surgery services.

We found the following areas of good practice:

- The service was planned and delivered to meet needs of local people.
- There were no waiting lists for clinic and surgery appointments. If patients wished to progress to treatment they were booked on lists at their convenience.
- We observed individualised care and treatment plans for patients.
- Hot and cold drinks were available to patients.

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

- There was no evidence of dissemination of learning to patients who made complaints.
- Patient information leaflets, documents and consent forms were only offered in English and not adapted for people with special needs.
- There were no formal interrupter services available to patients. Patients were advised to bring their own interpreter in to the clinic with them or use a family member. Staff informed us that some staff were bi-lingual and were used to interpreter.

Are services well-led?

We do not currently have a legal duty to rate refractive eye surgery services.

We found the following areas of good practice:

- There was a clear leadership structure from clinic level to senior management level.

Summary of this inspection

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

- There was no evidence of a local, regional or national staff survey to assess staff motivation, experience and well-being.
- There was no evidence of local or regional learning or sharing of experience. There were no regular team meetings or team briefs to reflect practice or enable staff to discuss their thoughts and consider ways to improve individual and team practice.
- Although a local risk register was in place, it was based on a standard list of complications relating to refractive surgery and did not reflect local risk issues or related to local incidents. Senior staff informed us that there was no national risk register.
- All polices and corporate documents were paper based and were not available electronically.

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?

Incidents

- The clinic had an up to date clinical incident reporting policy for staff to follow, which was in a hard copy version. The policy set out the accountability, responsibility and reporting arrangements for all staff in relation to incidents.
- We saw there was an electronic incident reporting system that captured details regarding clinical and non-clinical incidents.
- In the event of an incident, staff informed us that they were aware of their responsibilities in reporting through the on-line incident reporting system. However, staff could not give us examples of any lessons learnt from recent incidents.
- Between May 2016 and June 2017, the clinic had reported two incidents. One was a clinical incident and one was non-clinical. Both incidents were reviewed and investigated by the corporate clinical services manager and surgical services manager, according to policy. Feedback was received back to staff but no learning outcomes were identified on both incidents; therefore, no action plan was developed.
- When we asked to review incident reports, staff showed us paper-based copies from the electronic reporting system that were printed out and stored in a file in the staff office. However, management provided evidence following the inspection stating that the incident forms that we inspected were incident reporting forms: a record and notification of an incident, which was then sent to surgery service manager and the clinical services director for further investigatory work, analysis, leading to a root cause analysis (RCA) review if required.
- We saw evidence that written correspondence and communication were sent to patients from the corporate clinical services director according to the corporate duty of candour (DOC) policy. Staff informed us that they were aware of the DOC in general, in relation to care and treatment but were not directly involved with implementation when it was related to incidents. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.
- DOC was included in the annual mandatory training programme for staff.
- The corporate surgical services manager and clinical services director had oversight of any incidents that occurred within the service. They reviewed all incidents and emailed staff with all relevant feedback from any incidents.
- The service had reported no 'never events' from May 2016 to June 2017. 'Never events' are serious, largely preventable patient safety incidents, which should not occur if the available preventable measures have been implemented by healthcare providers.

Mandatory training

- Mandatory training, at a corporate level, was made available to all staff. Some of the training was completed through e learning which staff could access at a time to best suit their needs during the working week or at home. The corporate surgery services manager set training completion dates for staff and sent a weekly report on staff training to the medical director.
- Local training included training provided my laser machine and equipment manufacturers who visited the clinic and completion of competency assessments.
- Mandatory training included 14 modules such as fire training, moving and handling, safeguarding, duty of candour, infection prevention and control and consent.

- The training records spreadsheet showed that resident staff had completed their statutory mandatory training and their training records were up to date.
- Seven rotational staff were trained and up to date with basic life support (BLS). Five of the rotational staff were trained to immediate life support (ILS) level. No members of staff were trained to an advance life support (ALS) level. There was no evidence in the resident surgeons personnel file that any life support training was completed. This was highlighted to staff at the time of inspection and senior staff agreed that the surgeon was not up to date with life support training. No certificate of training was provided.

Safeguarding

- Data provided by the service showed that all staff had completed safeguarding adult's level two and children level one training.
- Safeguarding level two training was a 45-minute online teaching package. It consisted of aims and objectives of the training, Mental Capacity Act, restriction and restraints, ethical decision-making, patient case studies followed by interactive questionnaires. There were numerous links including best interests, presumption of capacity, which is responsible, alerting and referring, ethics, power, risk and your role. At the end of the training package, there were 15 links for further reading.
- The clinic did not provide services for patients under the age of 18 years and children were not permitted in the surgical departments.
- Staff we spoke with informed us that if they had any safeguarding concerns, they would escalate these to the national surgical services manager, who was based off site in another geographical region the country.
- Staff informed us that they reported any concerns to the local statutory authority or if in immediate danger, would call 999. This was in line with their safeguarding policy. Staff could not give us examples of any time this was implemented.
- Local authority contact details for adults and children's service were available in the front of the safeguarding folder in the staff office.

Cleanliness, infection control and hygiene.

- We saw that there was a corporate infection prevention and control (IPC) policy in place to maintain a safe environment for patients, visitors and staff. However, the policy did not state what specific audits needed to be undertaken, any timescales for completion of audits or named persons responsible for audits.
- The clinic did not complete observational hand hygiene audits on a regular basis. However, on the unannounced visit, staff informed us that they were introducing monthly hand hygiene audits. This was not embedded into practice yet. This required review and audit in the future.
- Results from the IPC review undertaken in July 2017 showed 100% compliance rates in environment, laundry, waste, hand hygiene, cleanliness and decontamination. This was an improvement from the May 2017 IPC review of 96% for hand hygiene, 92% for environment and 88% for cleaning and decontamination.
- Between May 2016 and May 2017, the service reported no cases of Methicillin-Resistant Staphylococcus Aureus (MRSA) and Methicillin-Sensitive Staphylococcus Aureus (MSSA). MRSA and MSSA are infections that have the capability of causing harm to patients. MRSA is a type of bacterial infection and is resistant to many antibiotics. MSSA is a type of bacteria in the same family as MRSA but is more easily treated.
- Staff informed us that there had been no reported infections or Diffuse lamellar keratitis (DLK: sterile inflammation of the cornea which may occur after surgery) incidents in 2016 or so far in 2017.
- We observed that staff undertook appropriate aseptic non-touch techniques (ANTT) to minimise the occurrence of infection during surgery. We observed that staff used appropriate personal protective equipment to minimise cross infection.
- All staff working in the surgery room wore disposal theatre clothes. Hand sanitising gel was available across the clinic.
- We observed that staff cleaned and disinfected each laser machine, chair/bed area between uses to ensure good standards of hygiene. This included all medical devices that were used.
- No external cleaning company were employed by Optical Express to clean the clinic. Staff informed us that they undertook all cleaning duties. Staff told us that surface cleaning undertaken on a daily basis or on

surgery days were not formally documented. However, the provider visit report and action plan, 9 July 2017, stated, "Daily hygiene sheets must be completed at the start of each session and retained".

- There were no cleaning schedules displayed in the clinic rooms. Staff undertook a monthly "deep clean" and this was recorded on a tick box paper spreadsheet. There were dedicated cleaning supplies for use in the surgery suite only. Staff wore non-sterile latex gloves for cleaning. All cleaning products were stored in lockable cupboards in the dirty utility room.
- Infection control checklists were completed twice a month. We observed checklists from May, June and July 2017. Items for review on the list were waiting rooms, toilets, treatment suite, uniform and cleanliness. There was a yes/no tick box to indicate compliance and a notes section. The surgery manager had responsibility for these checklists.
- From our observations, the clinic was well maintained and visibly clean.
- The scrub sink in the laser surgery room had wall mounted soap and alcohol gel dispensers.
- Clinical waste bins were foot operated and appeared clean.
- An external contracted company removed clinical waste from the clinic.
- Water temperatures were recorded monthly. Staff told us they ran the taps for at least three minutes if the water had not been in use for 48 hours or more. The service had a "maintenance of premises services and equipment" policy, which included a small section on Legionella prevention. The service undertook an annual test of their water outlet to ensure it was safe to use. The last test was in October 2016.
- Staff informed us that they shared a cold-water tank and that the building maintenance company managed the cleaning and chlorination.
- We saw evidence that all staff had completed training in infection control and prevention as part of their mandatory training.

Environment and equipment

- The refractive eye clinic, situated on the first floor, was a dual site location with a separately managed optometric practice on the ground floor.
- Patients were initially seen in two diagnostic and three consultation rooms on the ground floor. The waiting area adjoining these rooms was shared with patients attending the optometric practice on the ground floor.
- The first floor consisted of a staff office; staff break room, reception desk/waiting area, storerooms, consultation rooms, two discharge rooms with chairs, and a laser suite.
- The laser suite (surgery treatment area) consisted of a surgeon's room where patients were reviewed, pre-operative /discharge room, utility rooms, gas cylinder/clinical waste room and a large surgery room, containing a treatment bed and large laser equipment.
- Separate male, female and disabled toilets were available to patients.
- The patient records storeroom was also used as the staff changing room. The room was accessible by a key coded system. Records were kept in separate locked filing cabinets. Staff changed into clean disposable theatre clothes in this room on surgery days. This room was situated at the opposite side of the clinic corridor to the laser surgery room. Staff wore their own clothes on non-surgery days.
- All areas were tidy and well maintained; they were free from clutter and provided a safe environment for patients, visitors and staff to move around freely. All flooring was easy clean surfaces in case of spillages and appeared free of dirt and staining.
- All storage areas, including the dirty sluice room were well organised and tidy, however, clean and dirty utility rooms in the laser suite were not identified on the doors.
- All doors were unobstructed and fire escapes were clear. There were emergency exits on both the ground and first floors.
- There was an emergency call bell in the surgery room and the discharge room. This system was tested during the inspection and in working order.
- Access to the main clinic area was not controlled. Patients and visitors had free access from the street and shop on the ground floor via a staircase. However, access to the laser suite was by a security door keypad system.
- Stock in the store rooms were placed on shelving. However, we observed unused clean sharps bins stored

on shelves in the gas cylinder/dirty-waste storeroom. This was addressed with staff at the time of inspection and we saw these had been removed on the unannounced visit.

- We observed equipment stock in the storage areas was CE marked. For example, protective eyewear, needles and other surgery devices. This ensured that all equipment was approved and compliant with relevant safety standards.
- A hazardous waste disposal procedure poster was displayed in the laser suite to remind staff of the correct procedure.
- Sharps injury and safe sharps disposal posters were also displayed in the laser suite.
- We observed two spillage packs and saline eye washes for staff to use.
- We observed a maintenance folder with a spreadsheet at the front, listing the completed dates and due dates for maintenance for the laser equipment and machines. All maintenance was up to date.
- Technicians visited the clinic to carry out the maintenance. Staff we spoke with reported that technicians provided a good service and attended quickly if a fault developed.
- A contract was in place to service the treatment lasers every six months. The serial numbers on the service reports matched those on the laser machines.
- There was a calibration log for the excimer laser, which was completed on treatment days.
- Staff completed a competency assessment for all other medical devices. This was "signed off" by the surgery manager and updated by staff every three years.
- We saw evidence that electrical safety testing was being completed across the service. We reviewed six items of electrical equipment including fridges and scales that had been tested during 2017 and deemed safe for use.
- Emergency equipment was checked on surgery days, with items appropriately packaged, stored and ready for use. Emergency suction equipment was readily available in the surgery room. Staff checked this on each surgery day. The clinic did not have a defibrillator machine. Staff would ring 999 in an emergency.
- "Controlled Area" signs were clearly defined and in working order. Hazard warning lights boxes were switched on before use of the laser and treatment, which clearly defined the hazard zones.
- Wall mounted air conditioning and room temperature controls were displayed in the laser suite.
- A fire extinguisher was available in the laser suite.
- An electronic blood pressure machine, with a normal size arm cuff, was also available also and checked on surgery days. Staff informed us that they did not have a large arm cuff available for patients with a higher body mass index (BMI). Patients with high BMI were not specifically mentioned in the clinic's "assessing patient's needs" policy.
- The laser surgery room contained an operating couch. The bed rotated from left to right and there was a headrest facility that was adjustable for patient comfort. The room also contained two large laser machines.
- Air humidity and room temperature were monitored and recorded by staff on surgery days. Recordings we observed were within normal recommended limits. There was no specific standard operating procedure (SOP) or action plan for air humidity monitoring or issues. Air humidity monitoring was a small section of the corporate policy for maintenance of equipment and premises.
- All staff understood, signed and followed the "Local Rules" which contained copies of the laser protection advisor's (LPA) details, CV and certificate, MHRA bulletin (safe use of lasers, 2015) and authorised users list.
- There was an operation register book in the surgery room, which contained the details of each patient treated and details relating to the surgery. It also recorded the name of the surgeon and other surgery staff present during surgery. The laser serial numbers were recorded at the front of the register.
- The surgery manager was the designated laser protection supervisor (LPS) and in her absence, the technician was responsible for the safe management of the laser environment.
- The clinic did not have a formal optical radiation committee. The senior staff liaised with the LPA.
- The clinic had a named laser protection advisor (LPA) and a named laser protection supervisor (LPS).
- The LPA carried out a site visit and risk assessment every 3 years and re-issued or validated the existing Local Rules (summary of instructions intended to restrict exposure in radiation areas). The last revalidation took place in September 2014. All staff had signed the local rules to confirm they had read and understood them.
- In the event of any changes to the equipment (other than routine software upgrades) or any safety incidents, the LPA was notified and conducted a visit as necessary.

- On receipt of the Local Rules and LPA reports, these were assessed to identify any issues by senior management; however, staff informed us that there were no concerns raised for the Liverpool clinic.
- If issues were raised by the LPA concerning the application of the lasers, the national lead had responsibility in discussing these with the team (e.g. the laser manufacturers, in-house laser trainers and any other relevant party). Staff informed us that as the lasers did not emit harmful optical radiation, the clinic considered the above appropriate to the level of risk.

Medicines

- The service had a medicines management policy that was available to all staff. Staff were aware where to find it should they need guidance.
- Staff were trained and competency assessed by a registered nurse for ordering, receiving, recording, storing and disposal of drugs in the clinic as well as dispensing of take home medications for patients.
- Expired drugs were disposed of, on the premises, by staff. We found on the announced inspection, there was no system in place to record and document safe disposal of expired drugs at the clinic. However, on our unannounced visit, staff had developed a recording system to ensure drugs were disposed of properly, to help reduce harm from accidental exposure or intentional misuse.
- The service did not use any patient group directions (PGD's) and none of the nurses were trained in non-medical prescribing. The surgeon prescribed all medicines.
- Pre-operatively and during operations, eye drops were administrated by the registered nurse or registered operating department practitioner (ODP). Staff that had completed their competency assessment were able to dispense medications to patients to take home. These included antibiotic eye drops, anti-inflammation eye drops and lubricant eye drops. Staff did not supply oral painkillers to take home but recommended patients to buy them if required.
- The unit did not store or administer any controlled drugs. We saw that all medicines in the medicines cabinet were in date and records kept of expiry dates. We observed that the medicines cabinet was kept locked.
- The service monitored fridge and room temperatures to ensure all within normal ranges, which meant that medicines were stored at the correct temperature. All temperature logs we reviewed showed that medicines were stored within the correct temperature ranges.
- The registered manager was lead for the safe and secure handling of medicines at the clinic. The surgical services manager was lead at a national level, supported by the medical director.
- The clinic informed us that they rarely needed pharmacist support. They stored a small range of eye drops. However, the pharmacist who supplied their stock medication was always available in the event of a query.
- The surgery treatment room had a large emergency medicines box containing drugs for emergency situations. There was a list on the outside of the box to alert staff to expiry dates. All drugs were within their expiry dates. Drugs were checked and recorded on every surgery day. Restocking of drugs was through online ordering systems.
- The emergency medicines box was unsealed. The resuscitation council (2005) state that emergency medicines must be stored in a 'tamper evident' box. This means that it is clear when they have been opened, and staff can then take necessary steps to replace the used item(s) immediately. However, the location where the box was stored was only accessible by clinician.
- Portable oxygen cylinders, with bag, mask and tubing were ready available in the surgery room. There were securely stored in appropriate bags with secure straps.
- We reviewed the medicines audits from May and July 2017. These were a handwritten audit tool consisting of 14 statements and comment sections. Examples of the statements included "Medicines are not administered without a prescription and the administration of all medicines is recorded in the patient file" and "labelling of medicines is compliant". Of the 14, five statements were recorded as "none applicable". The audits stated no action plans needed. There was no evidence of lessons learnt, named responsible person or timelines on the audit tool.

Records

- The clinic used an electronic medical record system and a hard copy (paper) surgical record.

- Hard copies of patient records were stored in a room with keypad lock when not in use. Notes that were required on surgery days and consultation days were kept in the staff office, which also had a keypad lock.
- Patient's hard copy records contained pre-screening assessment, eye screening results, a health questionnaire, patient information pack, consent forms, traceability form and details of the surgery undertaken. This ensured the unit had the necessary information regarding the patient to ensure their needs could be met.
- All pre and post-surgery details and appointments were recorded on the electronic system.
- Record audits were undertaken every four months. We reviewed nine patient hard copy records and three electronic records. All records were completed, legible and up to date. These included patient information packs, consent forms and the risks and benefits of the surgery.
- We saw that every patient had an individualised "traceability sheet" completed in their paper records. This contained stickers, equipment packaging details and checks of disposal equipment and used during surgery. It also documented laser machine settings, room humidity and temperature settings.
- As the electronic system was used across the organisation, this enabled other Optical Express clinics to share information if a patient moved area to access treatment.
- Paper records were stored safely on the premises and were retrievable in a timely manner.
- The clinic had a full time archivist at an off-site facility, where hard copy file were stored as soon as possible after the patient was discharged.
- On the day of treatment, surgery information from the hard copy file was entered onto the electronic file. The electronic record was therefore integrated with the hard copy file.
- In the event of a patient request for a copy of their file, the patient was advised to contact the clinical services department and submit their request in writing. The file was provided free of charge, if copies of diagnostic scans and signed consent forms were requested, a small charge was required as an administration fee.

Assessing and monitoring risks to people who use services

- Prior to commencement of treatment, patients were assessed for their suitability for treatment at the clinic. We saw that pre assessment data included a health questionnaire and eye tests performed to access suitability.
- At an initial consultation, the patient was required to indicate on their health questionnaire whether they consented to the clinic contacting their GP and they were asked to provide their GP contact details. Pre assessment issues were highlighted to the surgeon who took the final decision about treatment the patient undertook. The optometrist could call or email the operating surgeon directly in the event of a query.
- Staff informed us that patient suitability guidance and treatment criteria were subject to critical review each year by the International Medical Advisory Board (IMAB). The IMAB are world renowned experts in the refractive surgery field and are independent from Optical Express.
- Staff informed us that they did not use a surgery checklist. A surgical safety checklist is designed to reduce the number of errors and complications resulting from surgical procedures by improving team communication and by verifying and checking essential care interventions. Therefore, there was no robust system in place to identify correct patient, assist team communication and have pre and post-operative oversight and assurance of equipment used such as gauze swabs, eye spears/sponges, Irrigation cannula, eye shield, lid specula, and disposable contact lenses.
- Staff informed us that they verbally checked the correct patient name, date of birth, allergies and correct procedure with the patient prior to surgery commencing. However, this was not documented in any patient records. This did not assure us that a standard process for checking the identity of a patient and matching that identity to a correct procedure was being assessed or monitored.
- With consent from patients and staff, we observed two surgery procedures. We observed during one procedure, when the surgeon entered the surgery room, staff did not confirm the patient details with the surgeon. Patients did not wear identity wristbands.
- We observed that the surgeon continuously talked to the patients to inform them what he was doing and what they needed to do. The technician called "Time Out", once the laser machine had started.

Refractive eye surgery

- We also did not observe staff identifying or marking the correct eye for surgery, however, staff did cover the eye that was not receiving treatment. We were informed that all the laser machines had an iris recognition (matching) system to detect the correct patient and correct eye for surgery.
- Staff informed us that patients with latex allergies were put first on the surgery list. We observed staff check allergies with all patients undergoing treatment in the theatre treatment room.
- Staff completed "traceability forms" to aid tracking and traceability of equipment and treatments used.
- On our unannounced visit, staff had developed a surgery checklist, which was not embedded into practice yet. This required review and audit in the future. The clinic had also developed a "surgical site marking and verification for correct site surgery" policy.
- Registered nurses (RN) were not always rostered to work on surgery days. Staff informed us that this was due to a small number of nurses on the regional rota and an increased demand for nurses on surgery days that clashed with other clinics surgery days. We were informed "operating department practitioner(OPD) staff or technicians were competent to assist the surgeon during the surgery and that the surgeon remained on site until the last patient was discharged home to ensure patient safety". However, we were not assured of patient safety, when a nurse was not on duty during surgery days.
- Staff informed us the role of the registered nurse was to observe and manage any medication reactions, review patients for any surgery contraindications, ensure medications were checked on the initial consultation appointments and that details are imputed on the patient record.
- There was no evidence that risk assessments were completed when no nurse was on duty during surgery days to access the impact on patient care and safety. However, on our unannounced visit, staff had developed a risk assessment to monitor and assess this impact.
- The clinic always has a designated laser protection supervisor (LPS) in the room whilst treatments were taking place.
- Staff informed us that patients stayed in the discharge room about five to ten minutes after their treatment. Once discharge and aftercare information had been discussed with patients and they were confirmed as visually well; they were free to go home. Staff told us that patients did not require post-operative observations such as blood pressure monitoring.
- We observed two discharge consultations between patients and the nurse on the unannounced visit. Information was clearly discussed and instructions about pain relief, administration of eye drops, wearing of eye goggles at night, returning to exercise and reducing the risk of contact with dust were all discussed. Emergency contact numbers were also given to the patient.
- Staff provided patients with an emergency telephone number for out of hours use. The information was written on the aftercare advice leaflets which staff discussed with patients prior to them leaving the clinic. Patients we spoke to said they received good aftercare advice.
- Staff informed us that they advised patients to call the clinic with general, non-urgent queries in working hours and the emergency number for out of hours use only. This number was not staffed during opening hours. Calls were routed to the on-call optometrist who provided support to the patient but also triaged the concern so that any emergencies were managed appropriately. Staff said that the optometrist might call the operating surgeon out of hours for advice if the situation appeared urgent. The out of hour's information was also available on the clinic website.
- In an emergency if a patient required immediate escalation, staff informed us that they could ring 999 for assistance.
- The clinic had a dedicated telephone line to their clinical services department at the corporate head office. The clinic had two centrally located office based optometrists who offered support and advice to optometrists (and surgery team) regarding pre and post-operative care as well as queries on process.
- The clinic had an emergency support system for urgent cases where the clinical services team co-ordinated care between the surgeon and optometrist in the event of for example, infection, and also co-ordinated external services such as external referral to another consultant or laboratory services.
- The clinic had an automated referral system for less urgent cases where the optometrist could refer the patient back to the surgeon for direct post-operative

care. The optometrist selected 'clinical review' at the end of their electronic examination record and the patient would receive an appointment with the operating surgeon.
- Staff informed us that the surgeon was the lead for post-operative care for patients and that he remained on-site until the last patient left the clinic on the day of treatment.

Nursing and medical staffing

- As the clinic was not operational every day, there were two resident staff members based at the clinic that was part of a larger regional team covering multiple clinics in the North West of England.
- We saw evidence that online duty rotas were completed four weeks in advance by the national surgery team scheduler based in Glasgow. The surgeon's availability and rota was completed first. Then other staff members rotas would be completed according to surgery and clinic demands.
- Monitoring of staffing levels was based upon the numbers of patients requiring refractive surgery across the region. Staff told us that they were often working across the North West region during the course of a week and that they could be given short notice if they had to work in another clinic in a different region.
- From duty rotas, we reviewed in May and June 2017, there were four to five staff allocated to each surgery day. The clinic always has a designated laser protection supervisor (LPS) in the room whilst treatments were taking place.
- The surgery manager reviewed skills mix to ensure that the teams had the correct level and skill mix of staffing for each surgery day.
- There were no current vacancies. In the last 12 month, one member of staff left the service and one joined the service. The service did not use agency staff.
- The clinic employed one full time resident surgeon, who undertook all the refractive eye surgery at the clinic over the last 12 months and was on the GMC Specialist Register in Ophthalmology.
- Staff informed us that they did work overtime often due to the amount of time spent travelling between the multiple clinics in the North West region and preparing for busy surgery days. However, they did get time back but sometimes felt overworked.

Major incident awareness and training

- Staff informed us that in the event of a major incident, they were reliant on the staff on the ground floor informing them. The large shopping complex also had a management team for support and guidance. Staff were unaware if there was a major incident policy in place.
- We observed a fire escape at the back of the clinic.
- We saw the clinic had fire extinguishers that were secured to the wall and were ready for use in the event of a fire. These were serviced and in date.
- The clinic had an uninterrupted power supply (UPS), which was last serviced in February 2017. The clinic also has an emergency lighting system, which was serviced in June 2017.
- We saw evidence of the lift maintenance; in-house engineers serviced this.
- The large shopping complex management team was responsible for the building and the staff were waiting on an update regarding any fire risks.

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

Evidence-based care and treatment

- Care and treatment was delivered to patients' in line with Optical Express corporate national guidelines, Royal College of Ophthalmology (RCO) Standards for Laser Refractive Surgery and NICE guidance.
- Staff informed us that their knowledge of technology and guidance was current by completing the "Scope of Knowledge" training every three years.
- Staff were aware of the new RCO Professional Standards for Refractive Surgery guidance (April 2017). However, staff informed us that they were not following the guidance relating to the "one week cooling off period between the procedure recommendation and surgery".
- Patients receiving care at the clinic were carefully screened and suitability accessed to ensure their needs could be met, and treatment was appropriate. This ensured that patient care needs were planned and delivered safely.

Pain relief

- Local anaesthetics, in the form of eye drops were administered to patients prior to surgery.

- Eye drops for dry eyes were prescribed as part of their take home prescription following surgery. Staff ensured patients had verbal and written instructions before they left the clinic. Patients were advised by staff to purchase their own oral pain relief such as paracetamol.

Patient outcomes

- Staff informed us that rather than examining clinical data by each individual clinic, which could result in inaccurate information, they reviewed and audited incidents, outcomes and complications by each operating surgeon. By involving the corporate clinical services team, the provider was assured that the patient received consistent continuous care, which was delivered at the time it was needed.
- The corporate service had full time biostatistician (based in the USA) who collected data, from patient electronic files, to correlate the surgeons' annual outcomes. Each year, the surgeon was presented with his clinical outcomes, which were discussed and evaluated as part of the surgeon's appraisal process.
- Data collected included total number of treatments, male to female ratio, analysis by age group, vision comparisons pre operatively to post operatively, safety and efficacy, enhancement rate (when additional surgery was needed) and complications. We were shown the results of the last surgeons' annual audit during the visit.
- This data assisted the International Medical Advisory Board (IMAB) assess the efficacy and safety of the treatments provided. In the event that recommendations for change were made, senior managers reviewed the recommendations internally via the national MAB and when changes were required; the information was disseminated to all parties involved in the treatment process.
- Between May 2016 and June 2017, there were two incidences of unplanned return of patients to theatre following refractive eye surgery.
- Data information provided by the clinic prior to the inspection showed that there were 23 enhancement procedures in the previous 12 months. Primary surgery had taken place between 2011 and 2016. The reasons for enhancement were due to quality of vision issues and desired outcome not achieved by the patient.
- Information provided by the service showed that 11 procedures were linked with Lasek treatments and 12 procedures were linked with lasik treatments. Staff informed us that patients were made aware of the potential need for enhancement at the start of their journey, so it was not unexpected. Some of the enhancements undertaken at the clinic were for patients who had treatment at another location and several years after the primary treatment.
- Staff informed us that seven patients experienced complications following refractive eye surgery in the last 12 months. These included a flap tear immediately post laser surgery (reported as an incident by the clinic) and a retained bandage left in place for eight days after surgery.
- There was no evidence of regular quality audits undertaken locally. The only main audit was completed annually by the statistician, which was related directly to the main surgeon's activities. Staff told us that the quality of the service was good; they received a high patient satisfaction, low complaints, no serious incidents and no infection rates. However, the provider visit report and action plan, 9 July 2017, stated, "Regular quality audit activity is the only way to identify potential areas for improvement". However, at the time of our inspection, there was no evidence that any audits had commenced.

Competent staff

- Staff attended the "core of knowledge" training with the LPA every 3 years. This was mandatory training for all staff present in the laser treatment room during surgery. It involved face-to-face training about laser hazards and safety. One resident staff had completed their training in May 2017; the other resident staff was due to attend training the week after our inspection. Resident staff were unaware when rotational staff had completed their training but they were assured that the corporate surgery services manager was aware who was trained and who was due training.
- Staff informed us and from duty rotas we observed, there was always at least one member of staff on duty during surgery days that were BLS (basic life support) trained. Some staff were ILS (immediate life support) trained, however there were no staff trained to an ALS (advanced life support) standard. Staff informed us that as a single speciality service, the risk to patients was low.

Refractive eye surgery

- All staff attended Core of Knowledge training which was provided by the LPA. The LPA was therefore known to the staff and accessible. During training, the LPA ensured that staff were aware they could contact them with any queries.
- The laser protection superior (LPS) was a certified laser technician, certified by the laser manufacturers following a week's course in the use of the lasers and associated equipment, followed by a period of competency assessment. They were subject to three yearly competency reviews to ensure their skills and knowledge remained current and competency is maintained.
- The service identified a number of laser technicians, who were funded to train with the laser manufacturers' clinical applications team in the USA. These were the senior refractive trainers (SRT) and they carried out the laser competency assessments locally and supported technicians and LPS to ensure they remained skilled.
- The surgery manager was the clinic's LPS, with overall responsibility for the safety and security of the lasers. As the manager was not generally in the treatment room during the procedure, the clinic ensured that all the certified laser technicians undertook the role of LPS on the day that they were allocated to the role of assisting the surgeon in the treatment room.
- The LPS were responsible for ensuring the lasers were calibrated, safety checks completed, the area was secure, lasers were closed down at the end of the day, all incidents were reported, laser performance issues communicated to the engineer, manager and head office and safe custody of the keys.
- We saw from staff files, that competency documents were in place for all laser equipment. Initial training, which included an exam, was provided by the refractive specialist trainer who had to "sign off" all staff to say they were competent. Three yearly updates were also mandatory for compliance.
- The ophthalmologist, who was directly employed by the clinic, had an appraisal and validation of professional registration completed for the last 12 months.
- The two resident staff were also up to date with completion of their annual appraisal; however, one senior manager completed their appraisal 14 months ago.
- All staff completed detailed competency assessments every three years. These included pre-screening, preparing and assisting in theatre, patient discharge and laser technician duties. Staff informed us that all staff competencies were reviewed and monitored by the national application trainer and the national training manager.
- We observed completed and up to date competencies for the two resident staff.
- However, there was a lack of local oversight and local management awareness for training and competencies for any rotational staff, from across the North West region that regularly attended the clinic, especially on surgery days. However, on the unannounced visit, staff were in the process of collecting this information, in order for it to be filed locally and assure resident staff that all staff attending the clinic were competent.
- The ophthalmologist surgeon completed three phases of training prior to working unsupervised. The ophthalmologist completed their induction programme with the medical director and clinical services director. The induction included detailed information about the procedures; clinical suitability guidance; policies and procedures; diary and patient management systems; protocols and pathways. They also shadowed the medical director or a senior ophthalmologist so that they could appreciate the running of a treatment diary, each staff member's role, become familiar with the general flow and records systems.
- When the surgeons' induction programme was completed, the medical director entered the surgeon onto the list of authorised users. This list was reviewed by the surgical services manager. The surgeon's performance in terms of outcome and complications was monitored centrally and informal feedback from the Surgery Manager. Clinical outcomes were subject to an annual audit by the statistical team who reviewed outcomes and flagged up any issues in between appraisal times.
- A medical personnel file, we reviewed, contained an up to date insurance indemnity certificate, identity passports, GMC number, qualifications and an up to date annual appraisal review but no life support training certificate.
- Personnel files for the resident staff we reviewed included identity passports, up to date mandatory training certificates, competency records and references. All new staff were given an induction pack

and general information handbook. Individualised plans were developed and competencies were signed off by the national surgery services manager. All staff had a probation period of six months.

Multidisciplinary working

- We observed good multidisciplinary working and communication between the team in the clinic on surgery day.
- Staff worked across the region in multiple Optical Express clinics, providing continuity for patients.
- Staff informed us that there were no regular forums for staff to communicate with each other. However, on the unannounced visit, we were informed that a team briefing session at the beginning of each surgical day had commenced, which included attendance from the surgeon, technicians, nurses, scanner and co-ordinator. This enabled sharing of information about patients, types and numbers of treatments and consents being carried out, specific patient needs, practice changes and any learning from the session.
- Staff informed us that local and regional team meetings were not held regularly. This did not assure us that sharing of information and lessons learnt were widely available and discussed at local level.

Access to information

- The clinic had two systems of recording patient information; an electronic medical record (EMR) and for the surgery day only, a hard copy paper file which contained signed documents, prints of scans and laser treatments, instrument traceability labels and medication prescriptions.
- Patient electronic records held details of a patient's past medical history, medications, allergies, consent information, clinic notes, pre-assessment notes, and surgeons' operation notes. This meant that information was readily available to all staff.
- On the same day as the patient's treatment, a staff member entered the treatment data on EMR. All information relating to the treatment was visible on the patients EMR including any specific instructions for the individual patient and any untoward or unexpected incidents, which occurred during the treatment.
- The EMR system was accessible in every Optical Express practice. It was password protected and different grades of staff could view, access and add records, which were appropriate to their role only.
- For patients' who had treatment in the Liverpool clinic and had their 24-hour post-operative examination in another location, the examining optometrist could access the file on the system in their examination room and could see all relevant information.
- Prior to leaving the clinic, patients were given verbal instructions, supported by a written leaflet, on when and how to take the prescribed eye drops, what to expect in the first 24 hours and personnel aftercare.
- All polices were up to date however, these were not stored online. All polices and non-clinical documents were paper versions. Polices were updated at the same time every three years by the corporate surgery services manager unless new guidance became available. A memo was sent to the manager with the amended policy or guidance, this would then printed for staff to read and then filed.
- If patients attended for post treatment care at another Optical Express location for a postoperative complication, the examining optometrist completed the patient's electronic file. The post-operative record had a mandatory field where the optometrist indicated whether the patient had a complication, the nature of the complication and whether the patient needed to be referred back to the surgeon or whether the patients file needed to be reviewed remotely (by the clinical services team in head office) for further advice.
- Staff informed us that if complications required urgent intervention, the examining optometrist was required to contact the clinical services team on their dedicated 'pre and post-operative advice' telephone line. The clinical services team co-ordinated and managed the patient's care. This would involve contact with the surgeon and liaison between the surgeon, optometrist and patient.
- Information about patient suitability for refractive surgery, clinical support and contact details, guide to patient documents were displayed in the staff office.
- Laser machines operational manuals were on display in the staff office. The treatment theatre also housed all documentation that related to each piece of equipment. This meant staff were able to immediately refer to them if they needed to

- Manual handling guidelines, how to report a RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulation) and fire guidelines were displayed in the staff break room.

Consent and Mental Capacity Act

- Information leaflets regarding refractive surgery and treatment options were available to patients prior to initial consultation.
- Patients attended an initial consultation with an Optical Express optometrist. The optometrist discussed information regarding treatment options and included information on costs and methods of payment.
- The optometrist completed an assessment of the patient's visual condition, taking into account the patient's medical history, views, experience and knowledge to identify which treatments are likely to result in overall benefit for the patient.
- The optometrist explained the treatment options to the patient and recommended a particular treatment option, setting out the potential benefits, risks, burdens and side effects of the treatment option or options, including the option to have no treatment.
- At the time of consultation, the patient received a 'patient information folder' which contained; a copy of the treatment consent form, the terms and conditions document, information on the procedures available including the associated risks and benefits as well as the associated advice sheets.
- During this appointment, the patient was also required to watch a video, which further explained the procedures and how they were carried out. The video detailed the potential risks and benefits of surgery. The patient was required to sign their medical record electronically at the end of the consultation to confirm that they had watched the video. They also confirmed that they had been provided with all the information they required, including the consent documents before proceeding to the next appointment.
- All discussions were recorded in the patient's electronic and paper records, which were then made available to the operating surgeon and surgery team.
- When patients wished to proceed to surgery, they attended a consent appointment with the proposed surgeon. Corporate policy and staff informed us that the consent process must take place three full days prior to any treatment. At this appointment, further diagnostic tests took place.
- Optical Express consent policy stated, "consent should not be undertaken on the same day as surgical treatments". It also stated, "Patients must attend a consent appointment with the operating surgeon at least 3 days prior to any primary surgical procedure. Sufficient time must be allowed to give the patient time to consider their treatment options (including the potential decision of not proceeding). Staff informed us that they did not consent patients on the same day of surgery.
- However, staff informed us that they did not follow the Professional Standards for Refractive Surgery guidance (April 2017) which recommends a "one week cooling off period between the procedure recommendation and surgery" and that if patients had travelled a very long distance, consent and surgery were performed on the same day, however, telephone conversations would have taken place prior to the day of surgery between staff and patients.
- Nine consent forms that we reviewed, all had patient consent forms signed and completed longer than three days before their surgery. However, information from staff did not assure us that all patients were given recommended time to reflect on their discussions with the surgeon due to the time period between consent for the procedure and actual treatment time for some patients.
- Staff also informed us that "remote" telephone consent was obtained from patients. Again, this practice did not follow the Professional Standards for Refractive Surgery guidance (April 2017) guidance that "telephone consents should be not conducted". This did not assure us that patients were fully informed, were aware of all the risk of surgery, had received information leaflets and had sufficient time to reflect on the procedure offered.
- Staff informed us that 53 telephone consents were undertaken at the Liverpool clinic within the last 12 months. Staff also told us that the option for patients to speak to the surgeon by phone rather than in person was introduced in December 2016. From June 2016 to December 2016, all consent appointments were face to face. On the unannounced visit, there were 12 telephone consent appointments booked for the afternoon.
- Of the nine patient consent forms we reviewed, six records had the surgery date manually crossed out and changed with a revised surgery date hand written. None

of these changes had been initialled or dated by the person who made the changes. Some signatures we observed on consent forms were illegible and did not have the surgeons GMC number recorded.

- Staff received annual mandatory training on consent that consisted of an online training package. This course looked at the key principles of consent from both adults who have capacity and those who do not. It contained several links to capacity, voluntarily given and sufficient information. It also contained case studies and interactive questions for staff to complete. There were also numerous links to further reading.
- Staff informed us that if they identified a patient that lacked capacity to consent, they would consult a family member and ultimately rely on the surgeon to make the final decision if the patient was suitable to consent and proceed with the surgery.
- If patients reported any mental health issues such as learning disabilities or autism, a GP letter was requested by the service and a declaration form was completed at the consultation appointment. Staff gave us an example of treating a patient with special needs. Detailed discussions took place with the patient and her mother to ensure they had a full understanding of the procedure being undertaken.
- The clinic had a policy incorporating advice about patients who were deemed unsuitable for treatment, equality and diversity, patients with physical disabilities, language difficulties, learning difficulties and visual, hearing and speech disabilities. This highlighted the need for multidisciplinary communication, reasonable local adjustments and sound objective reasoning to decline treatment.

Are refractive eye surgery caring?

Compassionate care

- All staff were compassionate and respectful to patients who used the service.
- Staff welcomed patients when they arrived on the ground floor premises. We observed that the staff were professional and friendly.
- We observed that staff introduced themselves to patients and were kind and compassionate in delivering care.
- Staff received positive comments from all the patients we spoke with. One patient told us they “would recommend the service to anybody”.
- Patient feedback obtained from the annual surgeons audit was positive.
- Staff informed us that patients were asked to complete an on-line survey at various points during their care. The surgery experience survey was completed at the 24-hour post-operative visit, if patients were willing to participate.
- Patient’s we spoke to told us that their expectations about the care they received "was exceeded" by the service.
- Staff informed us that a key part of the patient assessment was to deliver care in a patient centred way in order to protect and promote dignity, choice, and privacy. Discussions included the patient’s chaperone, which was supported by the service’s chaperone policy.
- We observed staff interacting with patients in the waiting rooms and in theatre. Staff treated all patients with respect and as individuals, taking into account their personal needs.
- The annual audit carried out on all procedures undertaken by the resident surgeon included patient satisfaction outcomes. Between October 2015 and September 2016, the patient response rate was 79% (Optical Express national range was between 77% and 80%). 83% of patients reported they were satisfied with care provide by the surgeon compared to an Optical Express average of 80%. 82% of patients were satisfied with answers provided by the surgeon to their questions compared to an Optical Express average of 78.2%. 95% of patients would recommend the surgeon to friends and family.
- All patients we spoke to were glad and happy with the treatment and care they received. All patients told us they were informed of all the risks and benefits and had plenty of time to reconsider their surgery.
- All patients we spoke with after surgery on the telephone told us that staff were caring and they were all recovering well. One patient told us that the care they received was “amazing from fantastic staff” and they “would recommend Optical Express to anyone”. Another patient told us that the staff were “friendly and nice”.

- Another patient was complimentary about the aftercare information as staff spent time discussing wearing safety glasses at work due to an increase in contact with dust.
- We observed nine patient testimonials displayed in the waiting area. These were dated between 2009 and 2017.

Understanding and involvement of patients and those close to them

- Patients we spoke to told us that they were given realistic expectations of the outcomes of their surgical procedure. We saw evidence in patient records of realistic outcomes following surgery being discussed.
- We observed the surgeon explaining the surgical procedure to patients and ensured they understood the information provided, by supporting verbal information with the use of diagrams and statistician rates.
- Patients informed us that they had sufficient time to consider the information provided about their proposed surgery, including any risks and benefits.
- Patient told us they "felt supported" and "fully informed" about their treatment.
- We observed staff taking time to clearly and carefully explain instructions to patients and to answer any questions patients had following surgery. This included how to insert eye-drops at home, cleaning around the eye to prevent infection and activities following surgery.
- Staff provided written information about aftercare and ensured that patients had the out of hours contact number if they had any questions or concerns following surgery.
- Patients told us that the staff were "brilliant" and they felt staff had "explained everything".

Emotional support

- We observed staff being supportive and making a patient in theatre feel relaxed.
- Patients told us that staff took time to discuss their worries and fears about possible treatments and staff put them at ease by explaining procedures thoroughly. They told us they felt confident and reassured by the support provided by staff.
- We observed staff speaking to patients in a sensitive and profession manner, we observed that patients were given time to ask any questions.
- All patients we spoke to told us that adequate time was given to consider treatments, to change their minds about surgery and discuss after care following surgery.

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's catchment area covered the immediate local population, patients from across the North West of England region and further such as Bournemouth and the Isle of Man. Staff informed us that any person could attend any Optical Express clinic nationwide as the service could access electronic patient records from every clinic.
- The service had direct access to patient electronic information in all Optical Express clinics. This meant that staff could access up-to-date information about patients, for example, details of their current treatment and follow up care.
- A patient lift was available for machine with mobility issues.
- Staff informed us that all patients were offered a follow up appointment 24 hours after surgery, one week, one month and three months post-surgery. These appointments were not routinely with the surgeon. These appointments involved after care advice and follow up, assessment for risk of infections or side effects and the possibility of the need for enhancement procedures to refine outcomes. One patient experienced a three-hour delay on the day of surgery. However, staff kept her updated and informed throughout the delay.
- The clinic was opened seven days per week. Surgery days were carried out approximately two to three times a month depending on treatment needed. This was dependent on patient demand and surgery days across the other regional clinic sites. The clinic would increase the number of days of treatment in the month if required.
- Additional surgical lists were added on Saturday mornings, if needed, to meet the demands of the service.

Refractive eye surgery

- During working hours, patients could contact the clinic if they had any additional questions or concerns. An out of hour contact number was available for patients to use after the service had closed.
- If the laser machine did not work on the day of surgery, patient treatments could not go ahead. Patients had the option to rebook their appointment for the next available time in any clinic location. On the day of our inspection, a patient was originally booked at another Optical Express clinic but due to equipment problems, was offered an appointment at the Liverpool clinic.

Access and flow

- Service users were self-referring. They made enquiries via the Optical Express website, in person at the clinic, or they may already have been an optical patient at the practice and have discussed laser vision correction during their routine eye test and health check.
- Currently the clinic was performing surgery two to three times per month at the Liverpool clinic. Appointments were also available pre-screening and consent.
- Patients entered from the main shopping mall directly outside the ground floor practice. Access to the second floor was by stairs or a patient lift.
- On surgery days, the clinic started between 8am and 8:30am. Patient's treatment appointments were approximately every 20 minutes. On the unannounced visit (a surgery day), there were 15 patients booked in the morning for surgery. In the afternoon, there were four patients booked for face-to-face consent appointments. After 4:30pm, there were 12 remote telephone consent appointments booked.
- All patients, who had surgery on their eyes a few months earlier, told us it was a "quick and efficient service". One patient informed us that the service were very accommodating, when he had to change his surgery date as he was going on holiday.
- Staff informed us that waiting times for clinic appointments were kept to a minimum and there was no waiting list for refractive eye surgery, however; they did not audit waiting times.
- Staff also told us that there were no refractive eye surgery procedures cancelled for non-clinical reasons between May 2016 and May 2017.
- Between June 2016 and May 2017, the clinic reported four days of surgery cancellations during the 12-month period, and none were related to inadequate equipment. Three of these were at the Liverpool clinic.
- The service scheduled additional clinics on Saturdays, when necessary, to meet demand.
- There were no incidences of unplanned transfer of a patient to another health care provider in the last 12 months.
- The service offered potential patients appointments from the patient advisors, whose role was to advise potential patients on the most suitable and appropriate solutions for their needs and explain and discuss cost and financial options. This enabled more time needed by other staff to discuss more clinical topics and treatment procedures.
- The clinic did not monitor or record "conversion rates" at the Liverpool clinic. Conversion means the ability to convert a patient's interest into a surgical procedure.

Meeting people's individual needs

- A hot drinks machine and cold water were available to patients. No food was provided by the clinic however, if required staff could go about to purchase snacks in the nearby shopping area.
- In the reception/waiting area, we saw that there were easy clean chairs for patients to use whilst waiting for treatment. There were also magazines, TV, tea, and coffee machine available. Posters displayed included patient satisfaction results and aftercare details.
- Staff informed us that patients with communication restrictions such as hearing, language or literacy issues were advised to bring someone with them for every appointment.
- The service had a range of patient information leaflets available, explaining the various conditions and treatments it offered, including pre and post care instructions. However, all patient leaflets and documents, including consent forms, were in English.
- Patients, whose first language was not English, were advised to book their own interpreters however, a staff member had been pro-active in translating when an interpreter was not available or pre-arranged by patients.

- Staff informed us that they did not supply written information in large print or require special signage in the clinic for patients with sight difficulties as patients who attended for laser correction surgery did not require these adjustments.
- With consent, we followed two patients on their day of surgery, including consultation reviews and surgery treatments on the unannounced visit. Patient details and procedure was confirmed verbally, drawings were used to illustrate the two types of surgery available, risks were explained, as well as vision post-surgery, dry eyes, the need for glasses in the future and infection and inflammation rates. Patients were given time to ask questions and the option to change their minds about going ahead with the surgery. Patients that were nervous were put at ease by staff.
- Surgeons advised patients dependent on their age, that the treatment may needed to be repeated at some stage in the future and that treatment was not permanent for them. The suitability and treatment criteria protocol was the same for patients of all ages.

Learning from complaints and concerns

- In the period May 2016 to June 2017, six complaints relating to the clinic were received and managed by the clinical services department team. At the time of inspection, three complaints had been closed and three were still ongoing.
- Complaints escalated to clinical services department tended to be based on patient dissatisfaction, visual outcome over time and terms and conditions once a 12-month plan finished.
- We reviewed all six complaints; actions following one complaint had the opportunity to improve practice, however staff informed us that it did not result in change in practice.
- We reviewed another complaint during the inspection and requested further information following the inspection from the provider. We saw evidence that negative feedback from a patient was escalated to a complaint level by the provider, which was then reviewed and investigated. We saw evidence of learning and of dissemination of information to staff. However, correspondence from the provider to the patient did not include these lessons learnt or how the provider was planning to implement improvements into practice.
- Patient electronic files were updated so that the information regarding the complaint was accessible to the surgery manager who was then able to monitor progress.
- Staff informed us that if a verbal complaint was made on the day of treatment, the surgery manager would try to resolve any issues and address the complaint directly with those involved.
- Staff told us that if the nature of the complaint was not resolved quickly and locally, the central clinical services department took over the management of the process. The clinical services department team had a resident solicitor who assisted in the management of complaints.
- Staff informed us that complaints were often hard to resolve locally as these were dealt with at a corporate level.
- We observed that patient's consent form and terms and conditions document contained information about how to make a complaint. We also saw a notice at reception with a summary of the process (who complaints should be raised with, addresses and information about how to contact the CQC in the event of a breach in regulation).
- Staff informed us that the company's customer services manager monitored patients on line feedback and where there was a negative comment, a response and assistance was provided in order to resolve issues.

Are refractive eye surgery well-led?

Leadership and culture of service

- The corporate management structure consisted of the Chief Medical Officer (CEO), optometry directors, managers and optometrists; operations director, managers and teams and the clinical services team, which consisted of the refractive operations manager, surgical services manager, location surgery managers and location surgery team.
- We observed that staff were clear about their reporting line within the management structure.
- Staff told us that local management were honest, proactive and they felt confident to approach their direct manager with any concerns. However, staff told us that they were not regularly praised or received positive feedback for senior management.

- Staff informed us that the corporate surgery service manager attended the Liverpool clinic approximately every 4-6 weeks. The clinic manager told us that she spoke to the corporate surgery services manager regularly on the telephone.
- The surgeon's accountability was to the medical director and in turn the CEO.
- There was one full time surgery manager based at the Optical Express clinic, Liverpool but also worked clinically at other regional Optical Express clinics.
- Staff informed us that because they had to rotate regularly to other clinics in the North West region, it was sometimes difficult to prioritise work and responsibilities. They told us that they often felt "stuck in the middle" between their day-to-day work, local managerial responsibilities and senior management involvement.
- Staff told us they felt supported and were able to raise any concerns with their line manager and senior managers. The staff member told us there was a good sense of teamwork on surgery days. However, some staff informed us that they felt restricted at times and would like more responsibility at a local level.
- We observed marketing to be honest, responsible and comply with guidance from Committee of Advertising. People received a statement that included terms and conditions of the service being provided and amount and method of payment of fees.
- Staff informed us that the surgeons and medical director were accessible and responsive for advice and support.
- The clinic had a regional clinical director whose role involved induction, training, development, support and appraise optometrists in the optical practices and a significant part of their role was training and developing optometrists to support the refractive surgery services which included the management of post-operative side-effects and complications.
- There was no robust system in place locally such as a training matrix or spreadsheet to monitor training and competencies for all rotational staff attending the clinic, especially on surgery days. Staff informed us that they relied on the national corporate team to oversee and monitor these issues but agreed that there was a lack of oversight locally to be assured that all staff were up to date and competent to carry out their duties. However, on the unannounced visit, staff were in the process of collecting this information, in order for it to be filed locally and assure resident staff that all staff attending the clinic were competent.

Vision and strategy

- Optical Express set up the first International Medical Advisory Board (for refractive surgery). The board was made up of refractive surgery experts with no link to Optical Express. Optical Express financed the board and they met annually to review data and clinical protocols. Outcomes were reviewed annually at the European and American Academy meetings.
- Staff informed us that the service had an international role, presenting data and research projects at the European Society of Cataract and Refractive Surgeons and the American Academy of Ophthalmology meetings.
- Senior staff told us that plans for the future included opening new locations, continuing to pioneer advancements in technology by sharing outcomes, maintaining and increasing the organisations profile by increasing influence in consultation processes and continuing to invest in electronic medical records system.
- Senior staff informed us "whilst it may be inappropriate and unrealistic to expect all staff who worked in the clinic to fully understand overall strategy, staff understood their role and how the quality of their work affected the overall patient experience in terms of satisfaction, safety and efficacy". This was confirmed when we interviewed staff.

Governance, risk management and quality measurement

- Staff informed us that quality and safety monitoring was conducted through the annual audits, incident reporting system, complaints, review of complications and patient feedback.
- Optical Express Ltd governance structure and members included the clinical governance group, National Medical Advisory Board (MAB), services director, medical director and chief executive officer (CEO).
- The company had an "open" MAB, headed by the CMO and managed by the MD and clinical services director. All surgeons and key heads of department were members of the board. From this meeting, the team managed the process of changing practice, changes to

treatment criteria, surgery techniques, management of conditions and complication and new introduction of technology. We were provided with meeting minutes from these meetings.

- The corporate clinical governance committee was headed by the clinical services director and included the MD, responsible officer, refractive operations manager and surgical services manager. Local surgery managers did not attend these meetings. The committee, by telephone, meet monthly to discuss general and local aspects of the service including trends and feedback. Staff informed us that feedback was from the surgical services manager.
- The provider visit report and action plan, dated 9 July 2017, recommended formal periodic meetings would be beneficial to discuss issues, review policies and practice. However, there was no evidence that further dates were arranged for such meetings.
- However, on the unannounced visit, staff had introduced team brief meetings on surgery days, which were recorded. Staff told us that this was a good platform to discuss immediate issues relating to the surgery day.
- Staff informed us that as a single speciality service, the risk to patients was low. Senior staff were assured that staff were well trained, skilled and experienced and that policies, procedures and practice risk assessments were up to date.
- A hard copy risk register was in place since 1 July 2017. The register was not available electronically. It was based on a standard list of complications relating to refractive surgery and did not reflect local risk issues or local incidents. 21 of the 25 risks listed were added in July 2017. These risks included needle stick injury, incorrect adjustment and eye complications such as monovision, payment not taken prior to treatment, wrong eye treated and gas leak.
- The "laser risk assessment" had been on the risk register since September 2014 and was rated "not applicable". Three other risks on the register were added in February 2017 and included fire (rated "low"), waiting room and reception environment (rated "low") and diagnostics machinery/room (rated "low").
- Risks were colour RAG rated according to severity, (a system to track, monitor and control risk) but appeared in black and white text on the hard copies (not colour coded red, amber, green) with current numerical controls in place to support the rating.
- All risks had an individual paper based risk assessment completed and were reviewed annually by the surgery services manager. However, there was no evidence on the risk assessments to highlight if the control ratings had increased or decreased since the previous review. These were stored in a "Practice Risk Assessment" folder in the staff office.
- However, following the inspection we were told that the laser practice risk assessments were only introduced to the clinic in July 2017. The review period was 12 months, and therefore the assessments would be reviewed in July 2018.
- Risk assessments included a "what needs to be done" and "agreed actions" column. On three of the four risk assessments, we reviewed; the agreed action column stated the same information. However following the inspection, the clinic informed us that the control measures ('what needs to be done (and by whom)') described in the risk assessments were the standard working practice in the clinic. Where the control measures were therefore the actions to be taken, it was appropriate to have this statement entered as the agreed actions. The "agreed actions" was blank on the fourth risk assessment.
- Each risk assessment contained a section for completion by the person who had reviewed the risk and a section to complete about incidents since date of initial assessment, changes in practice or equipment affecting risk and changes to rating or activity. This remained blank in all four assessments we reviewed. None of the assessments were signed or dated in person.
- As the risk register did not reflect local practice, did not include increasing or decreasing ratings and blank information sections, there was no evidence that the risk register was a dynamic, meaningful working document that related directly to the Liverpool clinic.
- The surgery manager of the location was the named person responsible for all risks and actions.
- Minutes from the clinical services and surgical services conference call meeting from April and June 2017 were provided. Five senior managers attended the call. Topics included surgeon recruitment update and appraisals, mandatory training, new clinics, regulators, new guidance and refractive eye surgery specific items. There were no specific actions or named responsible persons listed nor actions carried forward for review from previous meetings.

- Staff informed us that a regional "complex case" day was held monthly to discuss policies, procedures, resources and personnel required to provide definitive medical management to high levels of patient dissatisfaction with their visual outcome or care provided, through the complaints process.
- Staff informed us that the complex case day also enabled discussions for any adverse events or complications of surgery. Those attended included the surgeon, nurse, technician and surgery manager.
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- The complex case day also enabled discussion for any adverse events or complications of surgery. Those attended included the surgeon, nurse, technician and surgery manager.
- However, following the inspection, the provider informed us that complex case days were for patients to attend clinic who required non routine follow up care directly with the surgeon. This highlighted the inconsistency of knowledge among staff regarding the aim and objective of the complex case day.

Public and staff engagement

- There was no evidence of local or regional learning or sharing of experience. There were no regular team meetings or team briefs to reflect practice or enable staff to discuss their thoughts and consider ways to improve individual and team practice. Staff could only give us one example of a team meeting that had occurred in February 2017.
- Staff told us there was no formal regular clinic or regional team meetings to discuss complaints, incidents or share from other practitioners.
- The only current form of shared learning was by internal directive (in the form of emailed memos) which were received, read and signed by staff as evidence of continued learning from complaints and incidents.
- We were provided with minutes from the last two surgery team meeting in November 2016 (four staff attended) and February 2017 (six staff attended). The February 2017 meeting included the staff from the other regional clinics. Items on the agenda included staff training, incident reporting, stock management, health & safety, patient satisfaction, complaints, and managing patient flow. All items had an action plan section, a named lead member and a timeline for actions to be completed.
- There was no evidence of a local, regional or national staff survey. There was no anonymous forum for staff to report on fulfilment and contentment at work, support from managers and ability to access opportunities for personal development. Therefore, outcomes relating to staff motivation, enthusiasm and satisfaction were not available to senior managers to review and action to help achieve service objectives.
- Staff informed us and we observed that the main line of communication and feedback on equipment, training corporate changes and practice changes was via an internal directive surgical department hard copy memo, sent to a group email address from the surgery services manager. An example of a memo we reviewed related to incorrect discharge medications being entered onto the patients EMR. Staff were instructed, "to stop with immediate effect entering post-operative medications on to EMR, as they were entering incorrect information. Staff needed to stop practice immediately". These nonverbal, one-way communication tools appeared formal and did not encourage staff discussion or engagement.
- The service accepted public feedback through its website. Staff informed us that the volumes of responses were good in relation to the amount of activity and that satisfaction rates compared favourably with the company's averages.
- Patients completed short satisfaction surveys throughout their treatment period so the service could identify trends and dissatisfaction and strive for improvement. An example included dissatisfaction about waiting times in the clinic. Staff reviewed the appointment scheduling and informed all referring centres to advise patients that although treatment itself took approximately 10 minutes in total, patients would be in clinic for 2-3 hours. However, staff informed us that they do not undertake waiting time audits.
- Staff informed us that following patient feedback, the font size in the patient information pack was increased.
- Staff were unable to give us any examples of public engagement at the Liverpool clinic, however, a public promotion day was held recently in the large shopping centre in a neighbouring large city to promote the company.

- A "wonderful Wednesday" initiative had only just started nationally three weeks before the inspection and was not embedded at the time of the inspection. The scheme was to promote and acknowledge members of staff or staff groups work and achievement. Staff were asked to nominate each other in recognition of their work. Prizes included a restaurant voucher or spa day. So far, no staff at Liverpool clinic had been successful.

Innovation improvement and sustainability

- Staff also informed us that the service had several research studies published in professional press and that Optical Express data was used by manufacturers of diagnostic equipment and lasers to advance treatment and help drive new technology.
- Senior staff informed us that they would like to increase patient demand and numbers attending the Liverpool clinic for surgery but this was dependent on other resources. Staff told us about a new online social media programme to target bloggers and promote online marketing. We were informed that the vision and plan for the future was a list at the back of the provider visit report and action plan , dated 9 July 2017, this included "local improvements and aims for the year".
- Senior staff told us that local improvements for the clinic included improving the quality of mandatory training in order to increase staff knowledge and ensure training remained in line with legislation and standards. They also intended to increase the surgical services team, especially when new clinics open.
- Senior staff told us that additional resources would enable the team to undertake a number of new initiatives such as more frequent supervision, greater support for surgery managers, non-routine auditing and more team meetings within the regional teams.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The service must implement regular team meetings to establish shared learning locally and across the North West region.
- The service must ensure that systems and process are in place in order for the local risk register to reflect, identify, capture and mitigate local risks.
- The service must ensure that systems and processes are in place to provide robust feedback to staff following complaints and incidents.
- The service must embed and monitor robust local quality audit systems to monitor outcomes and make improvements.

Action the provider SHOULD take to improve

- The service should continue to correlate and increase local awareness of training and competencies of all rotational staff working at the Liverpool clinic.
- The service should follow the Royal College of Ophthalmologists recommendations relating to face-to-face (not conducted by telephone) consultation and consent process.
- The service should formalise, embed, monitor and audit their newly development surgery checklist.
- The service should follow the national recommendations for the cooling off period of one week following patient consent to date of surgery.
- The service should embed, monitor and audit their newly development risk assessments when no registered nurse are on duty and review the impact on patient care and treatment.
- The service should undertake regular staff surveys in order to collect staff views, measure performance and implement improvements.
- The service should establish a robust system to promote staff learning from incidents.
- The service should include examples of lessons learnt and improvement to practice into written correspondence with patients who have made a complaint.
- The service should establish a formal high quality interpreting and translation service to ensure accurate and effective communication is taking place.
- The service should ensure that all staff are up to date with life support 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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 (1) (2) (b) assess, monitor and mitigate the risks relating to the health and safety of the services provided in the carrying on of the regulated activity.** **How the regulation was not being met:** • The local risk register did not reflect, identify, capture and mitigate local risks. **Regulation 17 (1) (2) (e) seek and act on feedback from relevant persons and other persons on the services provided in the carrying on of the regulated activity, for the purposes of continually evaluating and improving such services.** **How the regulation was not being met:** • There were no regular team meetings and team briefs to establish shared learning locally and across the North West region. • There were no robust systems in place to provide feedback to staff following complaints and incidents. • There were no local regular quality audits in place to continually evaluate and improve local services.