Lancashire Eye Clinic

Quality Report

9 Lowther Terrace
Lytham St Anne's
Lancashire
FY8 5QG
Tel: 01253 730302
Website:www.lancashireeyeclinic.co.uk

Date of inspection visit: 19 September 2017
Date of publication: 30/01/2018

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

Ratings

Overall rating for this location	**Inadequate**
Are services safe?	**Inadequate**
Are services effective?	**Requires improvement**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Inadequate**

Overall summary

Lancashire Eye Clinic is operated by Lancashire Eye Clinic Limited. It is an independent ophthalmic clinic, located in Lytham St Anne's, Lancashire, providing treatment and care for various eye conditions. The clinic offers a range of treatments and surgery for conditions such as cataracts, diabetic retinopathy glaucoma, laser (non-refractive) and occulo-plastics (non-cosmetic).

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

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

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

Summary of findings

The clinic provided surgery and outpatients services. Where our findings on surgery for example, management and governance arrangements, also apply to other services, we do not repeat the information but cross-refer to the surgery core service.

We rated this Lancashire Eye Clinic as require improvement overall.

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

- Many of the policies were not evidence based according to the National Institute of Health and Care Excellence and the Royal College of Ophthalmologists. Polices were short and brief and did not provide staff with clear guidance, structures, processes and systems regarding service delivery.
- There was no local or external system to benchmark or peer review processes to assess and monitor outcomes and review practice.
- There was no formal governance framework to assess and monitor quality of care and mitigate risk.
- The clinic did not have a patient inclusion and exclusion policy. This was up to the discretion of the surgeon and individual staff.
- Staff at the clinic were not compliant with safeguarding training.
- Staff did not undertake routine annual appraisals or supervision.
- The clinic did not have a formal system to record and monitor training or highlight when staff were due training.
- Staff did not take part in a staff survey.
- There was no formal system in place to record and document safe disposal of expired drugs at the clinic.
- Staff did not sign the medicines checklist on the arrival of ordered drugs from the local pharmacy.
- Safeguarding systems and processes for vulnerable adults and children were not established effectively to investigate or protect patients from abuse and improper treatment.
- Training was not provided for staff on the Mental Capacity Act.
- Staff needed to increase their awareness and understanding of duty of candour.
- There were no regular staff meetings to review and disseminate information and patient related issues to staff.

We found good practice in relation to surgical care:

- The clinic was spacious, visibly clean and tidy. There had been no reported infections in the period April 2016 to March 2017.
- For the same time period, there were no complaints, reported incidents or never events.
- The clinic was well staffed. The clinic did not employ bank or agency staff. Theatre staff used at the clinic also held current posts at local acute trusts. All staff had worked at the clinic for many years.
- Staff worked well together and were happy working at the clinic.
- Access and flow of patients through clinic was good, there were no patients on a waiting list.
- There was access to the building for patients with mobility difficulties, which was clearly accessible and appropriately signed.
- Patient feedback was good.

We found good practice in relation to the outpatients and diagnostic service:

- The clinic was able to allocate patient appointments in a timely manner.
- We saw that patients were greeted by name on arrival at the clinic and patients were taken to the waiting areas by the staff.

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 (North Region)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	**Inadequate**	Surgery and outpatients services were the main activities of the clinic. Where our findings on surgery also apply to other services, we do not repeat the information but cross-refer to the surgery section. We rated this service as inadequate overall because: Not all polices were not evidence based according to the National Institute of Health and Care Excellence and the Royal College of Ophthalmologists. Polices were short and brief and did not provide staff with clear guidance, structures, processes and systems regarding service delivery. There was no local or external system to benchmark or peer review patient outcomes to assess and monitor outcomes and review practice. There was no formal governance framework to assess and monitor quality of care and mitigate risk. Staff were not compliant with safeguarding training. Staff did not undertake annual appraisals or supervision. Staff did not sign the medicines checklist on the arrival of ordered drugs from the local pharmacy. Safeguarding systems and processes for vulnerable adults and children were not established effectively to investigate or protect patients from abuse and improper treatment. Training was not provided for staff on the Mental Capacity Act. Staff needed to increase their awareness and understanding of duty of candour. Staffing was appropriate and there was no use of agency staff. Access and flow of patients through surgery was efficient.
Outpatients and diagnostic imaging	**Inadequate**	We rated this service as inadequate; please refer to comments in surgery. However: Patients were seen in a timely manner. Staff were very caring and patient feedback about the clinic was very positive.

Summary of findings

Contents

Inadequate

Lancashire Eye Clinic

Services we looked at

Surgery; Outpatients and diagnostic imaging

Summary of this inspection

Background to Lancashire Eye Clinic

Lancashire Eye Clinic is operated by Lancashire Eye Clinic Ltd. It provides consultation and ambulatory surgery to patients with various eye conditions such as cataracts, diabetic retinopathy glaucoma, age-related macular degeneration, laser (non-refractive) and occulo-plastics (non-cosmetic). The clinic is independently owned by the consultant ophthalmologist and practice manager who were both previously employed within the NHS but work only for the clinic now.

The clinic have no inpatient beds and provides all treatment on an outpatient basis.

The clinic first opened in 2001 and then moved to a larger building in 2011. The building is a large property on three floors in Lytham St Anne's.

The theatre suite is situated on the ground floor. Other treatment and consultation rooms and patient waiting rooms are found on all three floors. There is a lift access to all floors. There is also disability access situated at the rear of the property.

The clinic is open Monday to Friday, variable hours depending on patient demand. The clinic runs two to three outpatients clinics a week, one theatre session every two weeks and one laser clinic every two weeks.

The regulated activities provided by the clinic include

- surgical procedures
- treatment for disease, disorder or injury.

There is a registered manager who has been in post since April 2012.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and another CQC inspector. The inspection team was overseen by Nicholas Smith, Head of Hospital Inspection.

Information about Lancashire Eye Clinic

We inspected two core services at the clinic, which covered all the activity undertaken. These were surgery and outpatient and diagnostic services.

We carried out an announced visit on 19 September 2017. During the inspection we spoke with four staff including; consultant ophthalmologist, the registered manager, who also works as a specialist ophthalmic nurse at the clinic, one part time registered nurse and one part time administration staff.

We spoke with three patients. We also received seven 'tell us about your care' comment cards, which patients had completed. During our inspection, we reviewed 10 sets of patient records.

There were no special reviews or investigations of the clinic, ongoing by the CQC at any time during the 12 months before this inspection. The clinic was last inspected in August 2013, where all standards were met.

There were 335 outpatients attendances recorded at the clinic in the reporting period (April 2016 to March 2017); all patients were self- funded. Of these attendances, 202 patients had cataract surgery, 94 patients had intravitreal injections and 39 patients had oculoplastic (non-cosmetic).

The service was mainly for adults over 18 years of age. The clinic could provide consultation only for patients

Summary of this inspection

under 18 years of age in the outpatient clinic but this was a rare occurrence and there were no patients under 18 years seen in the period April 2016 to March 2017. There was no surgery offered for children and young people.

Track record on safety for the period (April 2016 to March 2017).

- No never events
- No clinical or non-clinical incidents.
- No serious injuries.
- No deaths.
- No safeguarding concerns reported to CQC.
- No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (C.diff)
- No incidences of hospital acquired Escherichia-Coli (e-coli)
- No complaints.
- No surgery related infections.

Services accredited by a national body:

- The clinic was not accredited to any national body.

Services provided at the clinic under service level agreement:

- Decontamination services
- Clinical waste

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?

Inadequate

We rated safe as inadequate because:

- The clinic did not have robust systems and processes in place to assess, monitor, and mitigate risks.
- There was no framework for safeguarding adults and children to ensure all staff were trained appropriately to assess, identify, monitor and respond to patients correctly.
- There was no evidence that any risk assessments had been completed regarding the possibility of the service providing care for children under 18 years old.
- Not all staff had completed mandatory training. There was no robust system in place to monitor and record staff training.
- Staff were not aware what the term “duty of candour” meant and were not aware of the associated requirements and responsibilities.
- There were no records to show that the laser machines were maintained annually.
- Staff did not sign the medicines order checklist on receipt of the items.
- There was no system in place to record and document safe disposal of expired drugs at the clinic.
- Patient hand written records were illegible, written in different coloured inks and were not always signed by staff.
- Staff were not bare below the elbow when working in outpatient areas.
- The clinic did not have “local rules” (summary of instructions intended to restrict exposure in radiation areas) guidance in place for the safe use of lasers in the clinic. We saw no evidence that any risk assessments were completed to ensure safe working practices were in place to minimise the risk of adverse health effects.

However:

- There were no incidents or never events reported at the clinic in the period April 2016 to March 2017.
- Access and security to the clinic was good.
- The clinic had no health care associated infections.
- All areas appeared visibly clean and tidy.
- Nurse and theatre staffing was appropriate for the needs of the service.
- All staff had basic life support training completed.
- Medicines were stored in locked cupboards.

Summary of this inspection

- As the building was over many floors, a specialist evacuation chair was available to ensure a smooth stairway descent during an emergency.

Are services effective?

Requires improvement

We rated effective as require improvement because:

- The clinic did not have a robust audit system in place to monitor non-surgical patient outcomes in order to evaluate and benchmark their practice.
- Polices did not reflect up to date current national guidance or refer to national bodies.
- Not all staff had completed an annual appraisal.
- Staff had not received specific Mental Capacity Act training and it was not part of a clinic policy. Patient capacity was dependent on individual staff interpretation.
- The clinic did not have an inclusion and exclusion criteria as per guidance from the Royal College of Surgeons. Patients were treated under the discretion of the surgeon and staff.

However:

- The consultant used a two-stage consent process. All consent forms we reviewed were complete.
- There were no cases of unplanned readmissions within 28 days of discharge or unplanned returns to theatre.
- The staff at the clinic worked well together as a team.

Are services caring?

Good

We rated caring as good because:

- Patients we spoke with were happy about their treatment and their care.
- Staff knew patients names when they arrived at the clinic reception and greeted them appropriately.
- Staff reassured patients throughout their treatments at the clinic and feedback from patients was very positive.

Are services responsive?

Good

We rated responsive as good because:

- There was no formal translator service used. Family members and staff were used to translate.
- Information leaflets were available in the clinic but they were not available in any other languages other than English.
- Family members and staff discretion was used to access mental capacity and patients with learning disabilities.

However:

Summary of this inspection

- There were no waiting times for treatment, patients were reviewed and treated promptly.
- There were no complaints reported in the period (April 2016 to March 2017).
- There were no surgery cancellations within the last 12 months.
- A ramp access and disabled toilets were available.
- Refreshments and magazines were available to patients in the waiting areas.

Are services well-led?

Inadequate

We rated well-led as inadequate because:

- There was no forum or team meetings to disseminate patient outcomes or discuss clinical or non-clinical issues. There was no clinical effectiveness processes or governance systems in place to monitor or assess individual clinical practice or patient outcomes.
- There was no evidence of formal staff and patient engagement.
- There was insufficient guidance in many polices, processes and standard operating procedures.
- Staff did not routinely identify, assess, monitor and mitigate risk to people who used the service. There was insufficient attention to the safeguarding of adults and children, completion and recording of staff training, accurate completion of patient hand written records, dispensing and disposal of medicines and accurate records for the maintenance of laser machines.
- There was little evidence of learning from events or actions taken to improve safety, as the reporting of incidents was limited. There were no incidents reported since 2011, therefore the measurement and monitoring of safety performance was restricted.

However:

- The clinic had a mission statement for the service, which was to provide a high quality service with exceptionally high standards of care where clients were happy to receive and staff were proud to provide.
- Many staff had worked at the clinic for a long time and staff we spoke with said that they liked working there.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inadequate	Requires improvement	Good	Good	Inadequate	Inadequate
Outpatients and diagnostic imaging	Inadequate	N/A	Good	Good	Inadequate	Inadequate
Overall	Inadequate	Requires improvement	Good	Good	Inadequate	Inadequate

Inadequate

Surgery

Safe	Inadequate
Effective	Requires improvement
Caring	Good
Responsive	Good
Well-led	Inadequate

Are surgery services safe?

Inadequate

The main service provided by this clinic was surgery. Where our findings on surgery for example, management and governance arrangements, also apply to other services, we do not repeat the information but cross-refer to the surgery section.

We rated safe as **inadequate.**

Incidents

- The incident reporting policy was short and brief and did not recognise or describe the approach to incident reporting, management and investigation. It did not define the types of incidents that may occur or describe the different incident grades.
- The incident reporting system was a paper based system. The last incident reported was in 2011. However, staff were able to tell us what would constitute an incident that needed reporting.
- There were no never events reported at the clinic in the period April 2016 to March 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- Staff informed us that they acted upon any issues that arose during daily activity by escalating to the practice manager or consultant ophthalmic surgeon as they had overall responsibility of activity in the clinic. There was no evidence to demonstrate that these issues were recorded formally, therefore there no evidence that incidents were investigated thoroughly or learning identified and shared with staff.
- Following the inspection, the clinic informed us that they had developed an "incident reporting policy". However, they stated that they had no accidents, incidents, never events or complaints to document or report.
- The duty of candour was not specifically identified in the incident policy. When asked, staff were not aware what the duty of candour was and were not aware of the requirements and responsibility of the duty of candour. However, following the inspection, the clinic informed us that a duty of candour policy was in place. We were also informed that relevant training has been given and staff fully understood the implications. This had yet to be embedded into practice.
- 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.

Cleanliness, infection control and hygiene

- There had been no reported incidents of acquired infections at the clinic in the period April 2016 to March 2017.
- There was a policy for infection control, this included sections on the purpose of infection control, general surveillance guidance and principles.

- The clinic had a separate hand washing policy however, the policy did not include an information or guidance on how to hand rub using gel and how to hand wash prior to surgery.
- The clinic did not have aseptic technique handwashing posters near the sink in the theatre room.
- E-learning mandatory training included infection control training however; we did not see evidence that all staff had completed this training. Following the inspection, the clinic informed us that all staff had completed e-learning mandatory training on both infection control and handwashing; however, no evidence of training completion was provided.
- There were cleaning schedules for the theatre areas and we saw that these had been completed before each surgery day. All areas were visibly clean and tidy and maintained to a high standard.
- We reviewed theatre environmental audits completed in July, August and September 2017. All audits scored 100%. These included hand hygiene, surgical trolleys and floors.
- The clinic employed an external cleaning company for general surfaces and worktops in theatre and throughout the clinic. Clinic staff undertook their own cleaning of larger devices as they were delicate and there was a risk of damage.
- Most individual pieces of equipment used were for single patient use. However, there was one piece of equipment that staff flushed and washed with water before sending to an external sterilization company. There was a dirty room adjacent to the theatre for staff to use but the infection control policy did not include guidance on decontamination of equipment. Following the inspection, the clinic informed us that guidance for flushing this piece of equipment was available in a policy under "theatre processes". This was not provided during or after the inspection to support the evidence.
- Staff wore disposable gowns during procedures in theatre. These were disposed of in yellow clinical waste bin bags after use.
- Sterilised and ready for use instruments were packed and stored ready for use on shelves in a clean storeroom adjacent to theatre.
- Patients were asked about any previous hospital acquired infection or risk in their admission for cataract surgery admission assessment. The clinic had a separate MRSA policy. However, the policy was very brief and did not include guidance and process for a patient with MRSA. Following the inspection, the clinic provided evidence that the MRSA policy had been updated.

Environment and equipment

- The main front and back doors were locked to ensure security and safety for patients and staff. Assess was by an intercom system.
- Resuscitation equipment was kept in the operating theatre room. We checked the contents of the equipment; everything was within the manufacturers' expiry dates apart from one instrument, which was highlighted to staff at the time. All equipment was checked before each theatre session.
- We saw that most equipment was serviced regularly and according to the manufacturers' specifications. However, we saw no records to show that the laser machines had been maintained annually. One laser machine record showed that it had not been checked since 2013. This was highlighted to staff at the time of inspection, who informed us that the machine had been regularly serviced but the clinic could not find the latest certificate of service.
- Following the inspection, the clinic provided evidence to suggest that both laser machines had been serviced since the inspection.
- There was appropriate signage on the doors for laser equipment and oxygen storage. There were lights to indicate that lasers were in use.
- Staff wore safety goggles when the laser machine was used.
- Staff informed us that they did not have "local rules" (summary of instructions intended to restrict exposure in radiation areas) guidance in place for the safe use of lasers in the clinic as the type of lasers used did not require this). We saw no evidence that any risk assessments were completed to ensure safe working practices were in place to minimise the risk of adverse health effects.

Medicines

- There was a medicines policy for the clinic, which was dated and had a review date.
- There was a patient group directive (PGD) in place for staff to give eye drops to patients in the clinic. Patient group directions allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription so that patients have safe and speedy access to the medicines they need. We saw that these had been signed and were up to date.
- All medicines were ordered on a Lancashire Eye Clinic pharmacy ordering form, which was signed by the consultant ophthalmologist. Staff took the form to a local pharmacy. A photocopy of the order form was kept at the clinic.
- The local pharmacy delivered the medicines to the clinic where they were checked by staff and stored as appropriate. We saw evidence of a checklist used by staff when drugs were delivered however, staff did not sign the checklist on receipt of the items.
- Expired medicines were disposed of safely, on the premises, by staff. However, we found on inspection, there was no system in place to record and document safe disposal of expired drugs at the clinic. After the inspection, the clinic provided evidence to suggest they had developed a new recording system. However, this needed to be embedded into practice. The clinic had also developed a new "receivership of medicines policy", which had yet to be embedded into practice.
- Medicines were stored appropriately in a locked cupboard in an adjacent room to the theatre. This included emergency drugs. All drugs we checked were in date.
- Eye drops were stored appropriately and fridge temperatures were monitored and recorded. Records showed that medicines had been stored at the correct temperature.
- One portable oxygen cylinder was available in theatre and the provider had a contract for the disposal and replenishment of the oxygen cylinder. The oxygen cylinder was checked as part of the resuscitation checklist for theatre prior to every surgery day. We saw evidence that this had been completed. However, the batch number and the expiry date of cylinder were not recorded on the checklist. Following the inspection, the clinic informed us that the batch number and expiry date of the oxygen cylinder in theatre had been added to the equipment checklist. However, no evidence was provided to support this.
- There were no controlled drugs stored in theatres or in the clinic.
- Staff informed us that all medications and doses e.g. eye drops, topical or local anaesthesia were prepared immediately before administration from single dose bottles.
- Any take home medications, mainly eye drops, were labelled with the patient's name and instructions for usage.
- Patients were given instructions about the administration of eye drops before they were discharged from the clinic
- The consultant ophthalmologist provided private prescriptions for patients that were dispensed at the patient's own pharmacy.

Records

- We looked at 10 sets of patient records during the inspection; these were paper-based records. Eye test screening outcomes were printed from the associated machine used.
- Hand written records were documented on small cards. Staff used different coloured ink to write with such as black, blue, red and purple which appeared untidy. Information was difficult to follow and flow of care hard to track. Documentation was often illegible and cards were not always signed by staff. No staff printed their names. This was highlighted to staff at the time of the inspection, who informed us that they were the only people to look at these notes and they could understand them.
- Following the inspection, the clinic informed us that a "record keeping and documentation" policy had been updated. This needed to be embedded into practice and documentation monitored and audited by the clinic in the future.
- We saw no evidence of risk assessments being completed for patients, in the records we reviewed.

- The theatre checklist was completed for every patient prior to surgery, which included details on procedure, blood pressure observations prior to treatment, eye drops used, allergies, consent form, name band and whether jewellery was taped. The theatre nurse signed these.
- We saw that every patient had an individualised "sterile pack" sheet completed that was used as a traceability tool. This contained stickers of drugs and equipment used on each patient.
- The theatre team also completed a register book with details of all patients and surgical treatments undertaken. This also included traceability stickers for drugs and instruments used. A similar register book was completed for patients receiving laser treatments.
- Staff informed us that patient records were never removed from the premises. Records were stored in a lockable filing cabinet in the staff office. However, during our inspection, we observed staff bringing patients into the staff office while the filing cabinet was unlocked and patient data was visible on the computer screen. We highlighted this to staff at the time of our inspection.
- An audit of care carried out in February 2017 found that on six occasions out of twenty, a theatre practitioner omitted to countersign a checklist for theatre and that follow up appointments were not always recorded. These were discussed and highlighted to staff following the audit. There was no evidence that a re-audit had been completed to access an improvement. However, following the inspection, the clinic informed us that a re-audit of care was to be carried out in February 2018.

Safeguarding

- The clinic did not have adequate policies for the safeguarding of children and adults who used the service. This meant that we were not assured that there were effective systems, processes and practices for investigating and protecting patients from abuse and improper treatment.
- However, following the inspection, the clinic provided evidence that new polices had been developed. This included "safeguarding of adults incorporating Mental Capacity Act" policy and "safeguarding Children" policy. These had yet to be embedded into practice.
- There were no safeguarding concerns reported to the Care Quality Commission (CQC) in the reporting period of April 2016 to March 2017.
- Not all staff at the clinic were compliant with safeguarding training. Theatre staff that also had posts in the NHS were up to date with safeguarding training, however there were not always compliance certificates filed in their personal files. They had just provided dates of completion to the clinic manager. Due to the lack of safeguarding training to help staff identify and respond to patients correctly, we were not assured that staff were able to identify and manage issues arising from patients with safeguarding concerns.
- Following the inspection, we were informed that staff participated in an approved on-line internet based programme which included numerous modules including safeguarding, which were all CPD certificated. However, evidence to support the completed training was not provided.
- There was also no evidence of domestic abuse guidance that described signs to be aware of and the effects of domestic abuse on individuals or how to raise a concern if staff suspected domestic abuse.

Mandatory training

- Staff used an online training system to complete training and senior staff told us that it was the individual staff member's responsibility to keep up to date.
- We reviewed the training records and personnel files for all the staff. We observed that staff had completed different training topics. The clinic did not have a compliance or completion target set. It was difficult to ascertain if all staff were compliant with their mandatory training requirements, as there was no formal process in place to check that mandatory training was completed or up to date.
- Following the inspection, the clinic informed us that all staff were now up to date with mandatory training, however no evidence was provided. The clinic also stated that, with the introduction of the new formal team meetings, staff needs would be identified formally, however, these meetings were not embedded into practice yet.

- All staff had up to date basic life support (BLS) training. Some staff had also completed "management of sudden cardiac, defibrillation and medical emergencies" training by a recognised body.
- Theatre staff that also worked in the NHS completed their mandatory training through their NHS post. The clinic had evidence of some of these training events but also stated that they had difficulty obtaining evidence of completion and relied on the honesty of staff to report when they had completed their training.

Assessing and responding to patient risk (theatres, pre and post-operative care)

- The clinic did not use an admission inclusion and exclusion criteria policy to access patients' suitability for surgery. Staff, based on their knowledge and skills, individually assessed patients.
- The consultant discussed the risks, benefits and method of anaesthesia with patients at their initial consultation. Patients were given information documents to take home to read, sign and date.
- A further pre-assessment appointment was provided prior to surgery, which included relevant tests, measurements and eye scan.
- The clinic had a pre-assessment policy however; it did not include pathways for staff to follow when there were abnormal results or observations.
- Patients completed an admission sheet for cataract surgery. This included personal details, past medical or surgical history, medications, allergies, MRSA risk and name of the surgical procedure to be undertaken.
- The admission sheet also included a "discharge after surgery" checklist for both eyes. This included details about eye drops, post-operative appointment and any special instructions.
- The clinic completed adapted World Health Organisation (WHO) safer steps to 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. Staff informed us the surgeon marked the eye for treatment prior to surgery commencing. However, this was left blank on all five checklists we reviewed. Otherwise, all other information was completed. This was highlighted to staff at the time of inspection. Following the inspection, the clinic provided evidence that this had been addressed with staff.
- Staff informed us that on arrival to the clinic, patients had their pupils dilated ready for surgery and the eye for treatment was marked. The nurse checked the patient's consent form.
- Patients in theatre had their blood pressure monitored before surgery. If a patient became unwell, the staff would ring 999 for an ambulance to attend.
- There was defibrillator and suction equipment for use in clinical emergencies. Emergency drugs and equipment was available in the theatre, these were checked on surgery days and were within the manufacturers' expiry dates.
- Following surgery, patients were taken to the waiting area to rest before being allowed home.
- For out of hour's emergency cover, patients were given the contact number of the practice manager, who was a specialist ophthalmic nurse within the clinic. There was no formal plan in place if the practice manager was unavailable for this on call service, which was provided 24 hours a day, every day of the week.
- The clinic had a "care of the patient in the daycare setting" policy and a safe post-operative care and discharge policy. These consisted of a step-by-step list of what patients should expect and what staff should do in the care setting. However, it did not include guidance or pathways when things went wrong.
- The premise was fitted with a nurse call bell system.

Nursing and support staffing

- Staffing levels consist of one consultant ophthalmic surgeon, one practice manager who was a registered nurse and ophthalmic trained, one part time nurse and two part time secretaries.
- On theatre days, every two weeks, the clinic employed four extra theatre nursing staff, who were also employed by the NHS and worked on a rotational basis at the clinic.

- Theatre nurses self-rostered for theatre sessions. Clinic staff informed us that they had never experienced a shortage of staff for theatre days.
- There was low staff turnover at the clinic and there were no vacancies at the time of the inspection.

Medical staffing

- There was one consultant ophthalmic surgeon working full time at the clinic, dividing his time between surgery and outpatient clinics.
- The surgeon provided out of hours support to patients in conjunction with the practice manager.

Emergency awareness and training

- The clinic did not have a major incident policy. Staff informed us that this was unnecessary, as it was such a small service.
- Staff received evacuation training twice per year and a means of escape checklist was completed by staff four to five times per month.
- Fire risk assessments were completed annually and this was in date at the time of inspection.
- Fire alarms were tested four times per month by staff.
- Emergency exits were well signed and there were fire extinguishers that were appropriate to the type of fire that could occur. These were all in date.
- On inspection, we found the lift was last serviced in January 2017. The lift is required to be serviced on a three monthly basis. There was no evidence from the records that this has been done since January. However, following the inspection, the clinic informed us that lift inspections were carried out three monthly. Evidence was not available at the time of the inspection due to the lift company changing their system of documentation. The clinic had discussed the situation with the lift company who have rectified the issue. Evidence was provided of regular checks in 2017.

Are surgery services effective?

Requires improvement

We rated effective as **requires improvement.**

Evidence-based care and treatment

- The clinic did not have accreditation with any national organisation. AccreditationStaff at the clinic informed us they worked to guidelines from the Royal College of Ophthalmologists (RCO) and NICE. However, many guidelines and polices we reviewed, such as clinical governance, quality assurance, work place risk assessment, reporting adverse incidences, out of hours cover, patient assessment and complaints were all brief with limited information or reference to national guidance or professional bodies. Patient information leaflets were also not referenced to a national body, apart from one.
- The clinic did not have the equivalent of a medical advisory committee (MAC) or hold formal team meetings. The surgeon told us that when new guidance came out from national bodies, he would have full responsibility to keep himself update, review any new information and implement changes into the clinical practice if appropriate.
- We were informed that the surgeon kept up to date with ophthalmic knowledge by reading journals and attending meetings whenever possible. We saw evidence that the surgeon had attended three national meetings in the last 12 months, North of England ophthalmology meeting, a roadshow and the RCO annual congress.
- It was the role of the consultant and practice manager to update the standard policies at the clinic following any new or revised guidance. However, we saw no evidence of references made in polices to reflect recent or new guidance.

Patient outcomes

- The clinic did not participate in any local or other audits. Patient reported outcomes are linked to clinical data allowing consultants to compare results to those of their colleagues. Surgical results can be audited and can be used to encourage surgeons to make adjustments to their techniques and to improve outcomes.
- Patient outcomes were monitored by inputting and collecting individual patient data after each patient

appointment. This was correlated and reviewed by the surgeon. There was no formal system or external review in place to look for any trends in events in order to make changes to standard operating procedures.

- We were informed that the surgeon monitored his own practice and due to the clinic having no recorded never events, wrong site surgery, complaints or recorded incident, the clinic did not need to complete any audits.
- Surgery outcomes were summarised in the surgeons' annual appraisal, which took place in September 2017. Outcomes showed that between 2016 and 2017, the surgeon performed 396 cataract operations. Standards such as monofocal implant, multifocal implant were better than RCO standards. The clinic did not have any capsule rupture intraoperatively or endo-ophthalmitis for over five years. The cystoid macular oedema rate was 1.2%. The RCO expectation rate was 1% to 2%.
- There were no cases of unplanned readmission within 28 days of discharge between April 2016 and March 2017.
- For the same period, there were no cases of unplanned returns to the operating theatre.

Competent staff

- The consultant file contained a copy of his recent appraisal. The Medical Director at a local NHS trust, who was not clinically involved in ophthalmology, validated this.
- Theatre staff employed by the clinic but who also worked in the NHS were required to have references from their employing trust, which were filed in their personnel files.
- Details of continuous professional development were variable in the personnel files we reviewed. We were informed that it was difficult for NHS staff to provide evidence of completion of training, as they were not always given certificates. This did not provide us with assurance that the practice manager had oversight that all necessary training was completed in the appropriate time.
- We saw no evidence of ophthalmic courses attended by staff in the last 12 months apart from the surgeon, who had attend the North of England ophthalmology society meeting in June 2017, a roadshow in March 2017 and the Royal College of Ophthalmology annual congress in May 2017.
- All of the nurses were up to date with NMC revalidation.
- The two core nursing staff in the clinic did not have an appraisal in the reporting period (April 2016 to March 2017). We were informed that they did not undertake formal appraisal or participate in any external supervision meetings. Communication and support was informal on a day-to-day basis. Staff told us that professional and personal development or concerns were discussed during the year by approaching the practice manager and surgeon in an informal manner.
- Following the inspection, the clinic informed us that the practice nurse and the practice manager had completed their annual appraisal. However, the clinic did not provide any evidence to support this.
- We saw no evidence of appraisals being completed by the staff that were also employed by the NHS in their clinic personnel files.
- Therefore, there waas no formal process in place to identify learning needs of staff or to manage poor or variable performance within the team.
- The manufacturers of the equipment used in theatre provided updates and training for staff.

Multidisciplinary working

- The clinic referred patients to a specialist eye hospital in the North West, if patient needed treatment that was out of the scope of practice for the surgeon. This decision was on an individual patient basis. There were no guidelines in place. The clinic did not keep a record of how many times this has occurred in the last 12 months but staff said it did not happen very often.
- Staff told us that all staff, including the theatre staff that periodically came to the clinic, all worked well together for the benefit of the patients.

Access to information

- All policies and standard operating procedures were available electronically in the clinic and we saw that there were computers for the use of staff.

- All patient records were available onsite; therefore, staff informed us that records and relevant information were always available on surgery and clinic days.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- There was a consent policy for the clinic. Consent was a two-stage process and consultant gained consent from patients during their outpatient appointment before treatment and on the day of the intended procedure.
- When attending the clinic on their surgery day, patients consent was also checked by staff as part of the admission process, WHO checklist and theatre checklist. We checked 10 consent forms in patient records and all were completed.
- The consultant consented the patients for treatment and was aware of the Mental Capacity Act (MCA, 2005) however, there was no criteria guidance for surgery, which would exclude some patients who did not have capacity to consent. Mental capacity assessment was up to the discretion of the surgeon and staff. Staff informed us that they had never refused any patient treatment and involved family members in the consent process if necessary.
- Staff told us that if they had patients with a learning disability or mental capacity issues, they would encourage a family member to attend the clinic with the patient. Staff would use their own skills to access a patient and deter if appropriate for treatment.
- When we discussed the Mental Capacity Act with staff, there was little awareness of how this was relevant to their service. Staff informed us that they did not receive Mental Capacity Act training and it was not part of any clinic policy. Therefore, due to the lack of specific awareness training to help staff identify and respond to patients with mental health issues, we were not assured that staff understood the Mental Health Act and were able to identify and manage issues arising from patients' mental health concerns.
- There was no evidence of patients' best interest meetings taking place to put arrangements in place for patients with mental health issues.
- There was no evidence that appropriate mental health risk assessments were completed and in place for those who needed them or plans and reviews being documented in clinical records.
- The clinic did not use an admission inclusion and exclusion criteria policy to access patients' suitability for surgery. Staff, based on their knowledge and skills, individually assessed patients.
- However, following the inspection, the clinic informed us that a mental capacity policy was incorporated within the new safeguarding of adults policy. This had yet to be embedded into practice.
- We were also informed that since the inspection, all staff have completed, whether it was in-house, on-line or within the NHS workshops, mental capacity training.

Are surgery services caring?

Good

We rated caring as **good.**

Compassionate care

- We saw that staff were caring and compassionate and that they treated patients with dignity and respect.
- We observed staff escorting patients to the appropriate clinic rooms and asking if they would prefer to take the lift or stairs.
- During the inspection, we saw patients were offered refreshments in the waiting area.
- Patient comments included, "staff were professional, friendly and caring" and "treated with dignity and respect". Other patient comments included they would highly recommend the clinic, all had been seen immediately from referral and the environment was safe and clean.

Understanding and involvement of patients and those close to them

- Family members and carers were encouraged to attend with patients and wait for them while they had their surgery.

Inadequate

Surgery

- We reviewed 10 patient satisfaction surveys for surgery patients and 100% rated the consultant as very good when asked how good their doctor was at involving them in decisions about their treatment.

Emotional support

- Staff informed us that patients were often nervous before surgery and staff reassured them all through the surgical pathway.
- Staff told us they knew their patients very well as many of them had been coming to the clinic for years. Therefore, they were able to discuss other sensitive issues, apart from their eye conditions, openly with them.

Are surgery services responsive?

Good

We rated responsive as **good.**

Service planning and delivery to meet the needs of local people

- The clinic was open Monday to Friday. The clinic ran two to three outpatients clinics a week, one theatre session every two weeks and one laser clinic every two weeks. These times were based on the patient demand.

Access and flow

- The clinic provided private consultant led ophthalmology treatment and care for various eye conditions. There were 335 outpatients attendances recorded at the clinic in the reporting period (April 2016 to March 2017); all patients were self- funded. Of these attendances, 202 patients had cataract surgery, 94 patients had intravitreal injections and 39 patients had oculoplastic (non-cosmetic).
- Staff informed us that the clinic usually undertook 11 cataract procedures in a theatre session, every two weeks. Approximately five to six patients received intravitreal injections and six to eight laser clinic patients were seen every two weeks.
- Staff informed us that there were no patients on a waiting list. All patients were seen within two weeks for consultation and surgery was organised to suit the patients, usually within one to three weeks. However, the clinic did not monitor waiting times.
- Patients were referred into the service by community orthoptists, GPs or self-referral. Following an initial assessment, patients were listed for surgery. The service was adept at scheduling patients promptly according to the patient's availability.
- Staff informed us that patients were given staggered times to arrive for surgery and following dilation of their pupils they were taken into appropriate rooms for topical or local anaesthesia and then surgery. Processes and procedures were efficient and there was excellent team working allowing effective access and flow for treatment.
- Clinic staff told us that there had no surgery cancellations within the last 12 months.

Meeting people's individual needs

- Information leaflets were available in the clinic but they were not available in any other languages other than English. Staff informed us that the black and ethnic minority population of the area was very low. However, staff did inform us that they did see patients from abroad.
- The clinic did not use a translator service to communicate with patients whose first language was not English. Patients were encouraged to bring a relative with them to appointments. A member of staff who spoke different languages was also used to interpret. Therefore, we could not be assured that accurate and effective communication was taking place.
- We reviewed all nine patients' information leaflets for major procedures undertaken at the clinic. The leaflets were informative but only one document had a reference to the Royal College of Ophthalmologists guideline 2012. There were no references mentioned in any of the other documents. All documents were within their review date.
- Patients were given an information document entitled "your surgery day", which gave them information prior to, during and following surgery.

Inadequate

Surgery

- Patients had access to on street parking at the front of the building. The main building was well signposted.
- There was ramp access to the building for patients who had mobility issues at the back of the clinic. Disabled toilets and a lift were also available in the building.
- Patient toilets were available on all levels of the building, these were clean and had handwashing facilities available.
- As the building was over many floors, a specialist evacuation chair was available to ensure a smooth stairway descent during an emergency.
- Refreshments and magazines were available to patients in the waiting areas.

Learning from complaints and concerns

- The clinic received no complaints in the reporting period April 2016 to March 2017. No complaints had been raised with CQC.

There was a complaints policy with appropriate periods for the initial response to the patient and then for the outcome of the complaint. A written acknowledgment was made within two working days of receipt of the complaint in the clinic. A full response was made within 20 working days of receipt of the complaint (unless an investigation was required and ibn progress). Complaints were the responsibility of the practice manager and staff would always try to address complaints locally and would apologise to the patient if something had gone wrong during their time at the clinic.

Are surgery services well-led?

Inadequate

We rated well-led as **inadequate**

Leadership / culture of service related to this core service

- The consultant surgeon and practice manager independently owned the practice. Both were involved with the day-to-day running of the practice as well as providing daily clinical care and treatment.
- The practice manager directly managed staff. However, the surgeon had ultimate surgical responsibility.
- Staff told us that they worked well together to form a strong team and that the surgeon and practice manager were very visible and supportive to patients, family members and to staff.
- Staff we spoke with on the inspection were very complimentary of the team. Staff felt valued, appreciated, and enjoyed working at the clinic.
- There was a raising concerns policy. Staff we spoke with said they would be happy to raise any concerns in their work.
- Staff told us that they had a good working relationship with the theatre staff, who came to the clinic on surgery days.

Vision and strategy for this core service

- The mission statement for the service was to provide a high quality service with exceptionally high standards of care where clients are happy to receive and staff are proud to provide.
- The vision was to be a centre of excellence and continue to provide high quality patient centred ophthalmic care and treatment in an environment.
- Staff informed us that the clinic was providing a good service with no rates of post-operative infection, no incidents or complaints and the vision was to continue to do the same.

Governance, risk management and quality

- The clinic had a clinical governance policy, which was brief and short. The policy did not include structures, processes and systems that an organisation needed in place to manage the quality of service provision.
- We reviewed 29 clinic policies. Many policies were short, brief and non-descriptive and did not provide a framework to capture key information regarding service delivery and service arrangements. Policies such as patient assessment, work place risk assessment, reporting adverse incidences, out of hours cover, child protection, clinical governance and quality assurance did not provide clear guidance and standards to advice and support staff and ensure safe care and treatment.

Inadequate

Surgery

- There was no robust audit system in place to review performance and implement changes in practice as a result. Staff informed us that because the clinic was small and had received no complaints or had reported no incidents, no regular audits were undertaken.
- There were no forum or team meetings to disseminate patient outcomes or discuss clinical or non-clinical issues, such as incidents or complaints. The clinic did not have the equivalent of a medical advisory committee (MAC) to identify record, manage and mitigate risks, discuss issues and monitor actions.
- However, following the inspection, the clinic informed us that they have instigated a monthly formal team meeting where issues and outcomes were discussed and documented. This was yet to be embedded into practice and no meeting minutes were provided.
- There were no clinical effectiveness systems or processes in place to monitor or assess individual clinical practice.
- Possible risks were not anticipated through clinical governance, education and training or clinical audit. Policies were not robust and informative and there was no platform to share good practice or otherwise to all staff. Potential clinical risks were not discussed at any forum or team meetings.
- There were no frameworks or processes in place to improve quality of care. The only system in place was a patient treatment information spreadsheet updated by the surgeon and reviewed only by the surgeon. There was no external peer review process in place.
- There was insufficient guidance in many polices, processes and standard operating procedures for staff to refer to or follow.
- Staff did not routinely identify, assess, monitor and mitigate risk to people who used the service. There was insufficient attention to the safeguarding of adults and children, completion and recording of staff training, accurate completion of patient hand written records, dispensing and disposal of medicines and accurate records for the maintenance of laser machines.
- There was little evidence of learning from events or actions taken to improve safety, as the reporting of incidents was limited. There were no incidents reported since 2011, therefore the measurement and monitoring of safety performance was restricted.
- Following the inspection, the clinic informed us that they had developed an “incident reporting policy”. They stated that they had no accidents, incidents, never events or complaints to document or report. However, if any such occasion did occur, it would be documented appropriately.
- Risks assessment forms were completed with rating scores and controls in place to reduce the risks. We reviewed 13 risk assessment forms and saw that all forms were issued in 2015 and all were due their next review in 2018. We observed that the further actions to control risk and target date were all blank. Following the inspection, the clinic provided evidence that they had developed a newrisk register document help monitor and review risks, however, this had yet to be embedded into practice. We observed some staff working in dual roles such management and clinical duties. We were told that balancing the volume and demands of clinic work and the pressures of organisational responsibilities was at times difficult. The clinic had no contingency plan when managers were away from work for significant periods.

Public and staff engagement

- There was no formal staff survey or engagement forums, therefore no formal system to gather views on staff experience and assess overall performance in order to help the clinic understand and compare performance.
- Staff informed us that they were responsive to their patient’s views, which were received by the clinic verbally or by patients completing satisfaction surveys but were unable to give us any examples when practice was changed because of these.

Innovation, improvement and sustainability

- Staff informed us that their focus was to continue on improving the service they provided, by keeping up to date with their knowledge and skills and by implementing any changes, which may be beneficial to their patients and their treatment.

Inadequate

Surgery

- Following the inspection, we were provided with evidence to suggest that staff had identified the need to have more audits and team meetings in place and aimed to achieve this within the next 12 months.

Inadequate

Outpatients and diagnostic imaging

Safe	Inadequate
Effective	
Caring	Good
Responsive	Good
Well-led	Inadequate

Are outpatients and diagnostic imaging services safe?

Inadequate

The main service provided by this clinic was surgery. Where our findings on surgery for example, management and governance arrangements, also apply to other services, we do not repeat the information but cross-refer to the surgery section.

We rated safe as **inadequate.**

Incidents

- There were no clinical or non-clinical incidents reported in outpatients in the reporting period April 2016 to March 2017.
- There were no never events in the reporting period April 2016 to March 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- Please refer to the surgery report.

Cleanliness, infection control and hygiene

- There had been no incidents of acquired infections at the clinic during the reporting period April 2016 to March 2017.
- We saw that clinical areas and patient waiting areas were visibly clean and tidy and that areas were maintained.
- We reviewed three months data from an internal environmental audit that showed hand hygiene was available 100% and that the blinds were free from stains, dust and cobwebs and that bins were emptied daily.
- Hand sanitizing gel was available for staff to use. Personal protective equipment, such as gloves and aprons, were available throughout the outpatients department. We saw that staff used them appropriately.
- However, we observed staff were not bare below the elbow when working in outpatient areas. Staff wore their own clothes. However, there was no written policy for work wear and uniform laundering available. The "health and well-being of staff" policy only stated that uniforms and other clothing should be changed regularly and that protective clothing must be worn for specific tasks. This did not assure us that clothing worn by staff helped to prevent and control infections.
- However, following the inspection, the clinic informed us that a new uniform policy was in place, which included that all clinical staff were encouraged to have bare arms below the elbow to reduce the risk of cross infection.
- On inspection, we were informed that when a patient was having a set of four eye drops the first would be administered in the consulting room and the following three would be administered in the patients lounge area. This area was not a clinical area and was also used for other patients waited for treatments therefore reducing an individual patient's privacy and dignity. The clinic felt this was in some ways beneficial to patients, particularly those with reduced mobility but that it would be assessed on a case by case basis.

- The clinic had a disposal of waste policy. All clinical waste was disposed of appropriately and appropriate colour coded bags. Sharps bins were available in clinic areas. An external company disposed of all clinical waste appropriately.
- We reviewed outpatients environmental audits completed in July, August and September 2017. Forty-four areas and items were reviewed. All audits scored 100%. These included storage of drugs, hand hygiene, area free from dust and stains and daily emptying of dustbins.

Environment and equipment

- There were two laser machines in use at the clinic and on the day of inspection, we found no evidence that either of these were up to date with being serviced. We found evidence that one was last serviced in August 2016 and the other in January 2013. We were advised that these had been serviced annually but that the documentation had been misplaced. Staff informed us that they did not routinely check or record the temperature or air humidity in the clinic room containing the laser equipment. Staff informed us that this was not required as they did not carry out refractive eye surgery but just performed laser treatments using class 4 laser machines. Following the inspection, the clinic provided evidence to suggest that both laser machines had been serviced since the inspection.
- On inspection, we found the lift was last serviced in January 2017. The lift is required to be serviced on a three monthly basis. There was no evidence from the records that this has been done since January.
- During the inspection, we observed equipment being cleaned prior to patient use.
- Emergency resuscitation equipment was available on site. This was stored in the theatre suite. The equipment was checked and recorded on theatre days but not on other days.
- There was a designated laser room in the clinic with restricted access. There were appropriate goggles in the room for the safety of staff. Appropriate warning signs were displayed outside the room. This was all in accordance with the clinic's health and safety policy.
- Staff informed us that they did not have "local rules" (summary of instructions intended to restrict exposure in radiation areas) guidance in place for the safe use of lasers in the clinic. We saw no evidence that any risk assessments were completed to ensure safe working practices were in place to minimise the risk of adverse health effects. However, the clinic provided staff with safety eye goggles, gloves, a designated treatment room with restricted access and warning signs were displayed outside the treatment room.
- Staff informed us that the clinic did not have a laser protection advisor (LPA). The laser protection supervisor (LPS) was the consultant ophthalmic surgeon. Staff informed us that an LPA was not required due to the type of laser machines used within the clinic. However, we observed in the surgeon appraisal documents, that the surgeon was the laser protection advisor for the clinic.
- However, following the inspection, the clinic informed us that they had recently appointed a new laser protection advisor.

Medicines

- There was a medicines policy for the clinic, which was dated and had a review date.
- A patient group directive (PGD) was in place for the use of eye drops in the outpatients department. PGDs are a written instruction for the supply and administration of a specified medicine. PGDs were seen to be signed and dated.
- The cupboard and fridge used for the storage of medicines was visibly clean. The fridge temperature was within the recommended range of two to eight degrees. There was an automated temperature gauge, which would alert staff if the temperature were to fall or increase out of the recommended range for medicines storage. We reviewed the temperature checklist for the last three months and found these were inconsistently filled out with one month the fridge being checked on four occasions. This was raised with the manager at the time of the inspection.
- The clinic did not dispense any medicines. Medicines were provided by a local pharmacy using an order form that was faxed from the clinic and then the pharmacy delivered the medicines to the clinic.
- The clinic did provide post-operative drops as part of the theatre procedure. A private prescription was

provided if deemed necessary. All GPs, with patients, permission, were informed by letter of current treatments and any changes of treatment on the day of the patient visit. A new policy was developed for the disposal of medicines.

- There was no robust system in place for signing in new medications received from the pharmacy or for the safe disposal of medicines that had expired. We highlighted this to staff at the time of inspection. Following the inspection, the clinic provided evidence that a new recording system was now in place but this had to be embedded into practice.
- All outpatient medications were stored in a locked medicines cupboard within a locked treatment room. The keys for this were stored in a secure location in the building. Access to the medicines was the responsibility of the practice manager and the registered nurse.
- Samples of medicines were checked during the inspection and all were found to be within the manufacturers' expiry dates.
- There were no controlled medicines kept onsite.
- The practice manager oversaw stock control and a minimum stock level was kept available.
- Patients were provided with information on how administer eye drops before discharge.

Records

- There was a policy for record keeping and documentation, which was dated and had a review date and the policy was in date.
- Patient records were paper based and were kept onsite in a secure cabinet within the office. Records were archived in another area of the building in locked cabinets and stored for 10 years. The clinic had a contract for the removal and disposal of records.
- We reviewed five sets of outpatient records. Patient records were paper based and staff documented care provided on small cards. Records we reviewed were illegible, written in several different ink colours, were not consistently dated and signed and had no printed name on them. There was no GMC number recorded on the notes.
- This was highlighted to staff at the time of the inspection, who informed us that they were the only people to look at these notes and they could understand them.
- Following the inspection, the clinic informed us that a "record keeping and documentation" policy had been updated. This needed to be embedded into practice and documentation monitored and audited by the clinic in the future.
- During the inspection, we observed a patient and relative invited into the clinic office by staff to discuss a query. At the time, there was patient identifiable information visible on the computer screen in the office and patient records were stored in this area. This was highlighted to staff at the time of inspection.

Safeguarding

- Staff informed us that they could see young children and babies for consultation only but could not remember when the last time this happened. The clinic did not keep an official record of the number of under 18 patients they reviewed but staff were sure it had not been for a few years. They told us that the last child they reviewed was a baby who required a prescription for sticky eyes.
- There was no evidence that any risk assessments had been completed regarding the possibility of the service providing care for children under 18 years old.
- Following the inspection, the provider informed us that in the previous 17 years, they had seen, for consultation only, five children and had never undertaken surgery on any person under the age of 18 years. Since the inspection, their policy had been updated and a decision was made by the provider that they would no longer be accepting children as patients.
- Not all staff had completed safeguarding training. Due to the lack of training to help staff identify and respond to patients correctly, we were not assured that staff were able to identify and manage issues arising from patients with safeguarding concerns.
- Please refer to the surgery report.

Mandatory training

- Please refer to the surgery report.

Inadequate

Outpatients and diagnostic imaging

Nursing staffing

- There was no use of bank or agency nurses or health care assistants in the outpatients department during the reporting period April 2016 to March 2017.
- There were two nursing staff members in the outpatients department. One full time specialist ophthalmic nurse who was also the practice manager and one part time nurse.
- There had been no sickness from outpatient staff in the reporting period April 2016 to March 2017. There were no vacancies at the time of the inspection.

Medical staffing

- One consultant ophthalmic surgeon worked in the outpatients department. This was the same surgeon who undertook the surgical treatments.

Emergency awareness and training

- Please refer to the surgery report.

Are outpatients and diagnostic imaging services effective?

We do not rate the effective domain in the outpatient core service.

Evidence-based care and treatment

- Please refer to surgery report.

Patient outcomes

- Please refer to surgery report.

Competent staff

- Please refer to surgery report.

Multidisciplinary working

- As the clinic was small, staff worked in both the outpatient department and the surgery service depending on the needs of the service.

Access to information

- All policies and standard operating procedures were available electronically in the clinic and we saw that there were computers for the use of staff.
- Clinic letters were dictated by the surgeon, typed by secretarial support on the day of clinic, and sent to the relevant GP practice. Referrals to other hospitals were faxed and a copy was stored on computer and within the patient's paper records.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff in the outpatients department understood the importance of patients giving consent prior to any interventions or assessments. We reviewed five sets of outpatient records and consent forms were signed and dated in all of them.
- Please refer to surgery report.

Are outpatients and diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- The clinic collected patient feedback for outpatients. We reviewed ten feedback questionnaires that showed 100% of patients rated their overall service as excellent. However, it was difficult to ascertain when the questionnaire were completed as there was no date documented.
- Patients we spoke with felt they were informed about their care and had sufficient time to read information provided before surgical treatments.
- We observed on inspection that a clinic room door was left open during appointments whilst patients were undergoing eye examinations. This did not assure us that privacy and dignity was maintained at all times.

Understanding and involvement of patients and those close to them

- We spoke to three patients who told us they were kept informed about their care and treatment during their patient journey. All the patients we spoke with were very positive about the service.

Inadequate

Outpatients and diagnostic imaging

- We reviewed 10 patient satisfaction surveys for clinic patients and 100% of these were rated excellent when asked how patients would rate opportunities to ask questions about their treatment.

Emotional support

- We observed staff greeting patients arriving for the outpatient's clinic by name. The staff and the environment of the clinic provided calming and supportive treatment for patients.

Are outpatients and diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service planning and delivery to meet the needs of local people

- Please refer to surgery report.

Access and flow

- There were 335 outpatient total attendances in the reporting period April 2016 to March 2017 all of which were self-funded.
- Outpatient clinics ran two to three days per week between 8.45am and 5pm depending on patient demand.
- There were no out of hours clinics or clinics at weekends. Appointments were flexible and days and times of appointments were changed to meet the patient's individual needs. Staff informed us that extra clinics could be added during the week to meet the demands where required.
- Staff informed us there were no waiting times or waiting lists. However, the clinic did not audit this. They informed us that they offered patients appointments promptly depending on the patient's availability.
- There were two part time secretaries who both worked together on one day a week for continuity of service and ensure access and flow was managed well.

Meeting people's individual needs

- There was no evidence that staff provided information or resources for people with dementia.
- Please refer to surgery report.

Learning from complaints and concerns

- Please refer to surgery report.

Are outpatients and diagnostic imaging services well-led?

Inadequate

We rated well-led as **requires improvement.**

Leadership and culture of service

- Please refer to the surgery report.

Vision and strategy for this core service

- Please refer to the surgery report.

Governance, risk management and quality measurement

- Please refer to the surgery report.

Public and staff engagement

- Please refer to the surgery report.

Innovation, improvement and sustainability

- Please refer to the surgery report.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Action the provider MUST take to improve:

- The service must have systems and processes in place to assess, monitor, and mitigate risks.
- The service must develop a robust audit system for non-surgical patient outcomes in order to evaluate practice.
- The service must develop and embed a framework for safeguarding adults and children and ensure all staff are trained appropriately to assess monitor and mitigate any risks.
- The service must ensure that robust, informative polices are in place that reflect up to date current national guidance and refer to national bodies.
- The service must ensure that risk assessments are completed to ensure safe working practices are in place to minimise the risk of adverse health effects when using laser machines.
- The service must ensure all staff are up to date with mandatory training and that competencies are recorded.
- The service must ensure all staff have completed annual appraisals.
- The service must ensure that accurate, completed and contemporaneous patient's records are maintained.
- The service must implement and embed regular staff meetings or an alternative forum to establish shared learning.
- The service must ensure that all equipment is properly maintained and up to date accurate records are retained.

Action the provider SHOULD take to improve

- The service should seek external review with regards to patient outcomes and clinical practice and act on feedback from relevant persons for the purpose of continuously evaluating and improving services.
- The service should embed, monitor and audit their newly developed risk register document to ensure risks are identified, assessed and monitored regularly in order to mitigate risks.
- The service should undertake regular staff surveys in order to collect staff views, measure performance and implement improvements.
- The service should establish a formal high quality interpreting and translation service to ensure accurate and effective communication is taking place.
- The service should embed, monitor, audit and review medicines management process especially around the delivery of stock and disposal of expired drugs.
- The service should monitor and embed staff awareness on the Duty of Candour.
- The service should ensure that all equipment and laser machines are properly maintained and up to date accurate records are retained.

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
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 (1) (2) (b) doing all that is reasonably practicable to mitigate any such risks: How the regulation was not being met: • Accurate, completed and contemporaneous patient's records were not maintained. Regulation 12 (1) (2) (c) ensuring that persons providing care or treatment to service users have the qualifications competence, skills and experience to do so safely. How the regulation was not being met: • Not all staff were up to date with mandatory training and not all competencies were recorded. • Some staff had not completed annual appraisals. • Not all staff had completed safeguarding training. Regulation 12 (1) (2) (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way. How the regulation was not being met: • There were no risk assessments completed to ensure safe working practices were in place to minimise the risk of adverse health effects when using laser machines.

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

This section is primarily information for the provider

Requirement notices

Regulation 17 HSCA 2008 (Regulated Activities) Regulation 2014 Good Governance.

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:

- There was no robust audit system for non-clinical outcomes, in order to evaluate practice.
- There was no framework for safeguarding adults and children.
- Policies were not robust or informative and did not reflect up to date current national guidance or make references to national bodies.

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 staff meetings and team briefs to establish shared learning