Advanced Visioncare Limited

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

Advanced Visioncare is operated by Advanced Visioncare Limited. The service provides refractive eye surgery for self-funded patients over 18 years old. Facilities include two surgical theatres, two assessment rooms, a consultation room, recovery room and diagnostic facilities.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 19 September 2017 along with an unannounced visit on 10 October 2017.

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

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

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

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

- Medicines were not stored safely and staff were not following the service's own policy on medicines management.
- The access to theatres was not secure; this could give access to unauthorised individuals and medication could be tampered with or stolen.
- Patient information leaflets, documents, and consent forms were only provided in English.
- There were no formal interpreting services available. Patients were advised to bring their own interpreter to the clinic, or use a family member.
- There was no organisational vision or strategy.
- The consent policy did not state a "cooling off" period prior to procedure. The new Professional Standards for Refractive surgery (April 2017) recommends a "cooling off" period of one week, less so in exceptional circumstances. However, the service provided patients with a terms and conditions document, which supplied information on the procedures available and the associated risks and benefits which patients took away with them. We also saw there was a period of a day between the confirmed consent with the surgeon and actual treatment.

However, we also found the following areas of good practice:

Summary of findings

- Patients received care in visibly clean and suitably maintained premises and their care was supported with the right equipment.
- The staffing levels and skills mix was sufficient to meet patients' needs and staff assessed and responded to patient risks.
- All staff had completed their mandatory training and annual appraisals. Care and treatment was provided by suitably trained, competent staff that worked well as part of a multidisciplinary team.
- There was clear visible leadership within the services. Staff were positive about the culture within the service and the level of support they received.

Following this inspection, we issued the provider with a Warning Notice for breaches of the Health and Social Care Act 2008 Regulations. We told the provider that it must take action to comply with the regulations by 1 December 2017.

We also told the provider that it should make other improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Following the Warning Notice, the provider submitted evidence of improvement to the CQC and we returned to review progress and found these improvements had been made.

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		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

Contents

Advanced Visioncare LTD

Services we looked at:
Refractive eye surgery

Summary of this inspection

Background to Advanced Visioncare Limited

Advanced Visioncare is operated by Advanced Visioncare Limited. The service opened in 2004. It is a private service in London. The service primarily serves the communities of London. It also accepts patient referrals from outside this area.

The location has had a registered manager in post since 2004.

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 Nicola Wise, Head of Hospital Inspection.

Information about Advanced Visioncare Limited

The location is registered to provide the following regulated activities:

• Surgical procedures

• Treatment of disease, disorder, and injury.

The service is based on the ground floor of a multi-occupied building. Patients are self-referring and self-funded. The service provides laser vision correction procedures using laser machines. Ophthalmologist surgeons carry out the treatment. The clinic is open Monday to Friday, 9am to 6pm, with one Saturday a month for consultation and treatment. Laser vision correction procedures are carried out twice a week. Following an initial consultation appointment with an optometrist, the patient then has a follow up consent appointment with the surgeon. Treatment is offered on a day care basis.

During the inspection, we visited the laser treatment room, main surgical theatre, pre and post-operative rooms, diagnostic area and examination rooms. We spoke with 10 staff including; registered nurses, reception staff, medical staff, consultants, and senior managers. We spoke with 4 patients and one relative. During our inspection, we reviewed 15 sets of patient records.

On our inspection day laser vision correction clinics and procedures were taking place. On our unannounced inspection day cataract operations were taking place.

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

The service had a focused inspection in May 2016 to check whether medicines were being managed safely. We found that the service was meeting all standards of quality and safety it was inspected against.

Activity (August 2016 to August 2017)

In the reporting period August 2016 to August 2017 there were 660 day case episodes of care recorded at the service.

Track record on safety

- No never events, clinical incidents or serious injuries reported
- No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA), Meticillin-sensitive staphylococcus aureus (MSSA). Clostridium difficile (c.diff) or E-Coli
- One formal complaint

Services provided at the hospital under service level agreement:

Summary of this inspection

- Clinical and or non-clinical waste removal
- Grounds Maintenance
- Electrical testing maintenance
- Laser protection service
- Maintenance of medical equipment
- Decontamination of sterile equipment.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

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

- Duty of candour requirements were not evident.
- Medicines were not stored safely and staff were not following the service's own policy on medicines management.
- The resuscitation trolley was unsecured and not tamper proof.
- Fridge temperatures were not being recorded daily in line with national guidelines.
- There were computer passwords displayed on stickers attached to monitors so records were not secure.
- Theatres were not secure and accessible to unauthorised persons.

However, we also found the following areas of good practice:

- There were policies and procedures to support the reporting of incidents and staff knew how to report incidents of all severities.
- Equipment was serviced regularly and all electrical tests had been completed and were in date.
- There were sufficient numbers of competent staff to deal with patients' care and treatment.
- Staff followed good infection control procedures and the service was visibly clean.
- Equipment was well maintained and available.

Are services effective?

Are services effective?

We found the following areas of good practice:

- Patients received care according to national guidelines and standards.
- There were thorough processes for pre-operative assessment.
- Suitably trained, competent staff that worked well as part of a multidisciplinary team provided care and treatment. All staff had completed their appraisals.
- Additional training was provided to staff using laser equipment, which ensured patient procedures were carried out safely.

Summary of this inspection

- The surgeon had adequate patient information to advise on the most suitable treatment

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.
- The service did not contribute outcome data to the national ophthalmic database.

Are services caring?

We found the following areas of good practice:

- Staff were caring and treated patients with dignity and respect.
- Patients were involved in the planning and delivery of their treatment and care.
- Feedback from patients was positive.
- Clear information was provided about the costs of treatment and procedures.
- Staff were able to recognise anxious patients and assist them during their treatment of care.

Are services responsive?

We found the following areas of good practice:

- Appointments for consultations were flexible and could be booked and changed easily. Additional consultations could be arranged if the patient needed further information.
- Reasonable adjustments were made for wheelchair users and people with restricted mobility.
- The complaints procedure was clear to patients and complaints were managed in line with the provider's policy by the service.

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

- Patient information on how to make a complaint did not include information about the Optical Complaints Consumer Service.
- Patient information leaflets were not available in different languages or formats.

Are services well-led?

We found the following areas of good practice:

- There was effective teamwork and good leadership, which created a positive culture.

Summary of this inspection

- There was a good system for patient feedback.
- Staff told us they were well supported and they were able to give feedback.

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

- There did not appear to be a vision or strategy.
- There were no staffsurveys, which meant the organisation could not monitor staff motivation and satisfaction.

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 services safe?

Incidents and safety monitoring

- Advanced Visioncare had not reported any never events in the last twelve months from August 2016 to August 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.
- The service had an "Incidents and Near Miss" policy dated February 2014 and due for review in March 2018. This provided staff with reporting, escalation, and investigation processes. Staff were expected to complete an incident report form and submit this to the theatre manager.
- There had been no incidents reported during the reporting period. The staff we spoke with were aware how to report an incident and could describe the process. They had a good understanding of what an incident was and the different types of classifications.
- We were told the theatre manager investigated incidents of a low level. Incidents that were more serious were overseen and investigated by the medical director. They were able to review all incidents and emailed staff with all relevant feedback from any incident. At the time of our inspection there had been no serious incidents reported for the past twelve months, so we were not able to see any examples of the investigatory processes and lessons learnt.
- The theatre manager had received root cause analysis (RCA) training for serious incidents. RCA are investigations to identify why and how safety incidents happen.
- The duty of candour (DoC) is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- We saw no evidence of a DoC policy. However, staff we spoke with were able to tell us elements of the process, in that it meant being truthful and open and transparent with the patient when things went wrong. We did not see evidence of the DoC having been put into use as the service had not needed to use the process.

Mandatory training

- We saw staff who worked at the service had completed mandatory training topics. This safety related training was renewed every three years and included core topics such as: information governance, conflict resolution, infection control prevention, fire safety, safeguarding children young people and adults, medicines management, health and safety, duty of care, consent, equality and diversity, and moving and handling. Consent training included the Mental Capacity Act 2005. Staff were given protected time to complete training at work or were paid time if they completed at home.
- The theatre manager had completed immediate life support training. All other staff had completed annual basic life support training. The majority of staff were not trained to an immediate or advanced level of life support, as the treatment provided at the service did not include the use of general anaesthetic. The service's policy was to provide basic life support until the emergency services arrived.
- In the event the laser machine was upgraded or in light of new improved ways of working the machine manufacturer had a dedicated team of trainers who delivered training to staff.

Safeguarding

Refractive eye surgery

- The service did not provide treatment to young people under the age of 18 and young children were not allowed in the treatment area.
- The service had a safeguarding policy, which described the types of abuse, and concerns staff should report. There were clear lines of escalation and contact details for the local authorities.
- No safeguarding concerns were reported to the CQC during the year up to our visit.
- Staff we spoke with had an understanding of safeguarding. Any safeguarding concerns were reported to the medical director, who escalated these to the necessary local borough safeguarding teams.
- The theatre manager was trained to level one and two safeguarding for children's and adults. On inspection we saw no evidence of any other staff members safeguarding training.

Cleanliness, infection control and hygiene

- All areas we inspected appeared visibly clean.
- The service had an Infection Prevention and Control (IPC) policy dated January 2017, which provided staff with guidance and IPC procedures they should follow to minimise the risk of infection. Staff completed IPC mandatory training, which they refreshed every year. All clinical staff had completed this training. The medical director was the IPC lead for the service and the theatre manager assisted with IPC issues and audits.
- We observed staff adhere to IPC policy during our inspection. Staff wore clean disposable scrub uniforms, closed toe shoes and their hair was tied back. During patient treatment, staff wore theatre caps, masks, and non-latex gloves and were bare below the elbows. This enabled good hand washing techniques and reduced the risk of cross infection, as long sleeves can interfere with this process. During treatment, patients were provided with a cap to cover their hair and shoe covers.
- We observed patients being told what to look out for after treatment such as signs of inflammation or infection.
- We observed three members of staff and saw they washed their hands in accordance with the World health Organisation (WHO) 'five moments for hand hygiene'. Posters were displayed throughout the service, which provided information on the 'five moments for hand hygiene' in line with WHO guidance.
- There was a clear written procedure for what staff should do in the event of blood or bodily fluid spillage.
- The service had a contract with an external cleaning company who cleaned the clinic. We saw completed and up to date cleaning schedules including a deep clean schedule.
- Sharps bins were in place, dated, signed and off the floor in all areas, we visited. This reflected best practice guidance outlined in the Health and Safety Executive (HSE) The Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. Sharps bins are used by clinical staff to safely dispose of used instruments such as, syringes, needles, and glass ampoules.
- Most instruments used for treatments were single use and could be disposed of after treatment. The small amount of equipment that was multi use was decontaminated and sterilised by an authorised local company.
- Legionella is a waterborne bacterium which causes legionnaires disease. We saw no evidence of an annual legionnaire test conducted. This was against Royal College of Ophthalmology guidance and other professional guidance on theatres, surgical site infection, timely identification and treatment of sepsis etc.
- During the reporting period, there were no incidents of MRSA or MSSA and there were no cases of C.diff or E.coli infections.

Environment and equipment

- The clinic and treatment areas were visibly clean, well maintained, and free from clutter. Patient waiting areas appeared comfortable with the provision of TV, magazines, hot and cold beverages.
- The service was positioned on the ground floor within a multi-purpose building that housed other health services. The public entered the building through the main door which on the day of inspection was unlocked. The public would then be greeted by a front of house staff member at the reception desk.
- On the day of inspection we found the main door unlocked and there was no member of staff at the reception desk. We were able to walk straight through to the waiting area and laser suite without being stopped. However, on an unannounced visit we found the main door closed and were greeted by a member of staff at the reception desk.

Refractive eye surgery

- Patients were seen in a consultation room for diagnostic tests. Their treatment was undertaken in a laser theatre or main surgical theatre for cataracts. Patients were taken to a separate room to recover. All rooms afforded patient privacy.
- Two types of laser machine were used at the location. The first was located in the dedicated laser room and was maintained under a contract, which provided for an annual service, a quarterly engineer's check and an emergency call out service. The Phaco laser was housed in the main surgical theatre and was maintained under the same contract
- The service met the standards recommended by the Royal College of Ophthalmologists (RCO) for a safe environment within the treatment room. There was minimal access for intervention, warning hazard signs were illuminated both internally, and externally to show treatment was underway. There was a glass wall and door separating the laser theatre and consulting area, this meant patients relatives could view the procedure as it occurred.
- The entrance to the laser theatre was only accessible directly from the communal patient waiting area. There was a small no entry sign on the door. However, on inspection we were able to access the laser theatre as the door was open and the theatre was unattended.
- The main surgical theatre was accessed through a door behind the reception area. On the days of inspection the door was unlocked and meant that public could have access to theatres.
- The dedicated laser room was visibly clean and suitable precautions had been taken to meet the requirements of the laser local rules, health, and safety at work requirements. The controlled area was clearly defined with warning signs displayed so staff and patients knew not to enter. Blackout blinds were fitted on the windows and other reflection hazards were minimised. We reviewed evidence of regular testing and servicing of the equipment and the availability of safety eyewear.
- The laser technician before each use performed safety and calibration checks. The machines had safety warnings and fail safe cut outs built into the laser software. We observed the checklist for the month of August 2017 had been completed and signed by staff.
- The service had a contract with an external Laser Protection Advisor (LPA) who was responsible for undertaking risk assessments, providing advice, and training on laser safety. They also drafted and issued suitable local rules and working practices and investigated adverse laser incidents. We noted the risk assessments and local rules were reviewed on a two yearly basis and the dates showed they were in order.
- We viewed the Local Rules for the laser machines. The rules contained information on the control of hazards, responsibilities, risk assessments, laser hazards, and gas hazards. Staff had signed the rules to show they had read and understood all the information.
- Staff attended core knowledge of training every three years with the LPA. We viewed staff records, which showed all staff had completed their training.
- The surgery manager at the location was the Laser Protection Supervisor (LPS) and directly supervised all optical radiation protection at the service in line with the Local Rules. The laser technicians were LPS trained and would assume the role when the LPS was not available.
- We observed electrical safety checking labels were attached to some electrical items showing they had been tested and were safe to use. The service had an external yearly contract with a company providing electrical safety checking. We were able to gain assurance of electrical safety of remaining devices from a hard copy of the contract.
- All flooring was easily cleanable and in accordance with Health Building Note (HTM) 00-10 part A: Flooring. All work surfaces appeared to be clean and were clutter free.
- Ophthalmic diagnostic equipment that was not in use had appropriate covering to keep the machines clean and dust free.
- On inspection we noted that some computers had login details and passwords printed onto labels and attached to the monitor. This was a security breech and could compromise patient details if stored electronically. We alerted the medical director and theatre manager and on the unannounced inspection we saw the stickers had been removed.

Medicines

- Pharmacy support was provided to the service by an external company. In addition to supplying medicines the company undertook quarterly medicines audits. We saw copies of the results of these audits for the last two quarters which indicated that the service was compliant in all areas reviewed.

Refractive eye surgery

- We saw that medicines were not stored securely and access was not appropriately restricted. We found multiple boxes of prescription only eye drops stored on open shelves in unlocked rooms, in both the laser theatre and the surgical theatre. This was against the services own medicines management policy which stated that 'all medicines kept in clinic must be stored in a locked cupboard which is secured to a wall'.
- In the laser theatre we also found the fridge containing multiple prescription only eye drops unlocked. Oral, inhaled and injectable medicines were all stored in a secure locked cupboard in line with the service's policy. The keys to the cupboard were held by the registered nurse.
- We checked all the oxygen cylinders and found they contained safe levels of oxygen and were all within their expiry date. All oxygen cylinders were stored safely.
- We saw and were told that staff were not following the service's policy for temperature monitoring. Policy stated that temperatures should be monitored daily however this was happening infrequently and at most twice a week. We saw that the medicines fridge in the laser theatre was regularly outside of the required temperature range and staff were not able to tell us what action they had taken to address this issue.
- The resuscitation trolley was kept in an unlocked corridor of the surgical theatres. Guidance from the Resuscitation Council (UK) was not being followed. We saw that medicines stored on the resuscitation trolley we not stored in tamper evident boxes. The resuscitation trolley stocks were checked monthly. The Resuscitation Council (UK) recommends that they should be checked daily. We saw no documentation or policies detailing how often the resuscitation trolley should be checked. First line emergency medicines kept on the trolley and other, second line, emergency medicines were stored in the locked medicines cupboard.
- None of the staff had received specific training on the use of medicines at the service. Staff told us that competency based training from their usual place of work was enough.
- We checked a sample of patient medical records and saw that medicines were prescribed by the doctor on pre-printed prescriptions. In each case the prescriptions for medicines were signed by the doctor, with signatures of the nursing staff who dispensed and checked them.
- Allergies were recorded in a specific section of the records. Eye drops supplied to patients were labelled with all the required information and an information sheet with details on how to use these drops was included.
- During some laser procedures the cytotoxic medicine Mitomycin was used. Mitomycin is a cytoxic drug used to decrease haze after surface abrasion procedures. This contains chemicals, which are toxic to cells. We saw that patients who received this drug had an additional consent form to complete, however this consent did not include details that the medicine was being used outside of its license.
- Staff told us that patients were not provided with any written information about Mitomycin before or after the procedure. A policy for the use of mitomycin was in place but had not been reviewed or updated since 2012. The policy did not include details of training requirements and staff told us there was no additional training for the use of mitomycin.
- We saw that an external pharmacy company had provided the theatres manager with details of how to reconstitute the mitomycin via email but this information was not included in the policy.
- The use of mitomycin was not consistently and accurately recorded in patient's notes. Unlike other medicines there was no pre-printed proforma for the doctor and nurse to sign to record administration. For one patient we saw that "MMC" was written in the comments section of the surgical notes but that no records of batch number, expiry, strength or number of sponges used or the time were made. For a second patient although the batch, expiry and strength were recorded, there was no record of the time administered or the number of sponges.
- Cytotoxic waste bins were available for the disposal of mitomycin and other materials. No cytotoxic spills kit was available and the directions in the mitomycin policy on managing a cytotoxic spill were inadequate. No Control of Substances Hazardous to Health (COSHH) risk assessment for the use of mitomycin had been undertaken.
- We observed a patients discharge with a technician. The patient was provided with clear, concise instructions on how to use and store the medicines. The patient was given opportunities to ask questions and the patient was not discharged until they confirmed they understood all the instructions.

Refractive eye surgery

Records

- The service used paper records. The paper notes were kept on-site for one year post procedure. All records containing patient information were stored securely.
- We saw prescription charts had been signed by the surgeon and registered nurse. Records included patients' medical history, eye tests, and scans taken. The examination records included psychological testing the patient's motivation for having treatment. At initial consultation, the patient was required to indicate on their health questionnaire whether they consented to the service contacting their GP and we noted patients who consented provided their GP's details.
- All files were of a standard format and were neat and clear for staff and patients to read.
- We reviewed records of the World Health Organisation WHO five steps to safer surgery checklist which included, sign in, sign out and time out. The three members of staff present in the treatment room had signed all checklists.
- There were no audits of records or WHO safety checklists completed. We were told that this would be commenced the following year.
- Each time the laser machine was used it was recorded in a log and in the patient's record, we observed this taking place.

Assessing and responding to patient risk

- Patients were assessed for their suitability for treatment at the clinic prior to treatment Suitability guidelines also included other heath associated issues. For example, patients with epilepsy had to confirm they had been seizure free for three months and had to have a letter from their GP to confirm this. Other checks included whether patients had rheumatoid arthritis, MRSA, whether patients had a pacemaker, and keratoconus, which is a non-inflammatory eye condition.
- Psychological issues were part of the assessment criteria. Patients with disorders such as depression also required a supportive letter from their GP.
- After an eye examination was conducted the patient was provided with information on likely outcomes, the surgeon would make the final decision of laser technique and discuss everything again and review examination results.
- The risks of treatment were explained to patients and we observed two consultations where health checks and eye tests were undertaken. Lifestyle questions were asked so the patient could make an informed decision about the different laser treatments. For example, patients who played rugby and martial arts were better suited to a certain laser treatment as, although a longer recovery, the treatment was more robust and less liable to cause issues for those patients who played contact sport.
- The laser treatment team consisted of a 'scanner'; a registered nurse, a laser technician, the surgeon and a discharger. The 'scanner' was responsible for checking the patient's identification, eye scans, and the results of other pre-assessment tests. The nurse would collect the patient and assist the surgeon during the operation. The nurse was also responsible for dispensing the medication for the patient to take home after the procedure. The technician was responsible for ensuring the laser was correctly calibrated and working within safe parameters. The surgeon performed the procedure and the discharger waited with the patient in the recovery area until they were able to leave.
- Staff used an adapted 'five steps to safer surgery' World Health Organisation (WHO) checklist to minimise errors in treatment, by carrying out a number of safety checks before, during, and after each procedure. During our inspection, we observed two patient procedures, where the WHO checklist was used correctly and saw other patient notes, which showed the WHO check had been completed fully.
- The service used an operating theatre register. These registers are used to provide an on-going record of patients that have undergone treatment at the service and included the following information: patient name, age, address, diagnosis, names of attending doctors and assistants, date and time of procedure and anaesthetic used.
- A laser protection supervisor was always present throughout the patient's treatment.
- Post-operative patients were assessed in the recovery room by either a registered nurse or technician. They were provided with written instructions for aftercare and follow up appointments. We observed a technician provide aftercare instruction to a patient. The discussions were informative, clear and provided useful information for after care instruction.

Refractive eye surgery

- The service did not provide treatment, which required general anaesthetic. However, patients were offered Diazepam an anti-anxiety medication which was taken 30 minutes before procedure. We saw these patients were closely monitored post procedure.
- Patients were given an out of hours telephone number to use if they had any concerns following treatment. They were also given detailed written instructions on aftercare and the time and date of their next appointment. The out of hours telephone was answered by an optometrist who had additional training in post-operative care complications. The optometrist had access to an on call ophthalmology surgeon.
- The surgeon was available in the 24 hour period following the procedure. Managers told us that there were back up surgeons available in the event that the operating surgeon was not available, for example to cover illness or annual leave.
- The need to transfer a patient to another health care provider had not occurred in the past 12 months. For medical emergencies, such as collapse, staff dialled the 999 emergency ambulance service. For optical emergencies there was a system to refer the patient to an emergency outpatient appointment with an ophthalmic specialist.

Nursing and medical staffing

- The service employed one permanent registered nurse who was the theatres manager. Other registered nurses were employed on locum contracts.
- Clinical staff rotas were dependent upon the number of surgical procedures booked for that day. During refractive laser surgery the staff consisted of one surgeon, one scrub nurse, one laser technician and one clinic technician. For non-laser refractive surgeries (for implantable contact lens and cataracts) the staff consisted of one surgeon, four to five nurses and two clinic technicians.
- The service employed six part time opthalmologists under practicing privileges and one full time directly employed ophthalmologist. There were five locum part time nurses as well as four locum optometrists employed.
- Of the six surgeons currently performing refractive eye surgery at the service, five held the Royal College of Ophthalmology Certificate in Laser Refractive Surgery.
- There were no staff vacancies at the time of our inspection and the service did not use agency staff.
- An external company provided the Laser Protection Adviser (LPA). Staff told us they were easy to access and the organisation had a good professional working relationship with them. We reviewed evidence of their input into training for core skills knowledge.
- The theatre manager was the service's named Laser Protection Supervisor (LPS). Surgical days were fixed on Tuesdays and Thursdays, we were told the theatre manager was always on site during those days.
- Patients were seen by the surgeon or optometrist post operatively and care pathways were in place for referral of the patient to specialist advice if required. The care pathways ranged from contacting the ophthalmic surgeon for advice to liaising with other consultants or laboratory services if required. The surgeon retained overall responsibility for the patient following their treatment.

Major incident awareness and training

- An effective uninterrupted power supply system was installed in the treatment rooms. It provided enough power for staff to complete a procedure. We saw the annual maintenance report.
- There was no business continuity plan for the service.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance. Policies and guidelines had been developed in line with the Royal College of Ophthalmology (RCO) Standards for laser refractive eye surgery and the National Institute for Health and Care Excellence (NICE) guidelines in relation to refractive eye surgery. Policies and procedures were in date and staff were able to access these online and in paper form.
- The service followed NICE IPG64 guidelines on photorefractive eye surgery. The surgeon made the appropriate tests and checks pre-treatment and ensured robust consent was obtained. Patients were supplied with information on the potential risks of the treatment.

Refractive eye surgery

- Pre-operative tests for elective surgery were in line with NICE guidelines NG45. Patient's medical history was discussed and appropriate tests and scans were taken to help determine treatment.
- We were told by staff that an infection control audit was undertaken twice a year, however, we did not review this. On inspection we saw results of an annual laser and health and safety risk audit in addition to a quarterly medicines management audit.

Pain relief

- Local anaesthetic eye drops were prescribed prior to treatment. Patients were asked if they were in any discomfort during surgery.
- Patients were prescribed anaesthetic eye drops post treatment. We saw staff made sure patients were provided with verbal and written instructions.
- A courtesy call was made by clinical staff member to all patients who had undergone a procedure at the end of every surgical day. This was to ensure that the patient was comfortable.
- Patients were told to purchase analgesic such as paracetamol to help manage any pain.
- Patients were asked about the monitoring of their pain within the patient questionnaire. However, we did not see any results for this part of the questionnaire.

Patient outcomes

- The provider did not contribute to the National Ophthalmic Database (NOD) Audit. This meant that current practice could not be compared against the national standard.
- In the past 12 months there were no unplanned returns of a patient to theatre following refractive eye surgery or following cataract surgery.
- There were no treatment enhancement procedures within the last 12 months.

Competent staff

- Staff we spoke with had the correct skills and competencies to carry out the duties required of them.
- All new staff undertook an induction programme. This included a familiarisation of policies and procedures. Staff working with lasers worked alongside more senior staff until they had completed the core knowledge training. Staff then had a week of observations from the patient journey to discharging and scanning.
- Medical staff also completed an induction programme and the core knowledge training. They shadowed the medical director and senior ophthalmologist during a period of supervised practice. If satisfactory, they were approved by the medical director and entered onto the list of authorised users.
- All competencies had been completed such as the checking of calibration of lasers and this had been certified by the laser manufacturers. Other competencies such as the reporting of incidents had been assessed and completed.
- We saw evidence that all staff who worked with lasers had completed core knowledge training as well as attending manufacturers training. This was refreshed every three years.
- The Laser Protection Advisor (LPA) was a certified member of the association of laser safety professionals. All staff knew who they were and had met them personally.
- Staff told us they attended an annual appraisal. We saw evidence of this in the staff records we reviewed. All staff had attended an appraisal meeting within the last 12 months.
- We viewed the theatre manager's record and identified the certificate obtained for the Laser Protection Supervisor role. All competencies and checks for this role were in place. They were subject to three yearly competency reviews to assess their skills and keep up to date with latest guidance.
- We reviewed the personnel file of the surgeon working on the day of our inspection. It contained the following: Royal College of Ophthalmology Certificate in Laser Eye Surgery, General Medical Council registration, professional indemnity insurance, Disclosure and Barring Service checks, references, curriculum vitae, evidence of continuing professional development and patient feedback exercise.

Multidisciplinary working

- We saw good multidisciplinary working between the team at the service. There was good communication and each staff member knew their role within the service.
- We observed the medical team working well together in the treatment room. The nurse anticipated instruments

to pass to the surgeon and the technician read out laser recordings to assist them with the procedure. Each staff member was calm, professional and treated each other with respect.
- Staff responsible for managing out of hours queries from patients were clearly identified and understood escalation processes for referring patients to a higher level of care.
- Communication with the patient GP was encouraged and GPs were able to access the service through the out of hours telephone number.

Access to information

- At initial consultation the patient was required to indicate on their health questionnaire whether they consented to communication with their GP.
- Any health issues reported by the patient during their initial consultation were reviewed by the surgeon. If they required any further medical information they would ask the patient for permission to contact their GP. If the patient did not give consent for the surgeon to contact their GP the surgeon would not agree to carry out the procedure unless they were fully confident to do so.
- If the patient had consented to information about their treatment being shared with their GP the service sent a copy of the discharge letter. The GP could access the patient's surgeon if necessary via the same contact telephone numbers as given to the patient.
- Organisation policies were accessible on the service's intranet and these included polices such as safeguarding and incident reporting. Updated guidelines were also available for staff to access.

Consent and Mental Capacity Act

- There was a consent policy dated February 2017 and this provided staff with guidelines on obtaining patient consent.
- From the 15 records we viewed, we saw consent was legible and risks associated with procedures had been explained to patients.
- Four out of 15 patient records reviewed showed there was insufficient time between the consent with surgeon and procedure to allow patients a time for reflection and to decide whether they wished to proceed with treatment. The time ranged from one day to three days. This was against the Royal College of Ophthalmologists recommendations relating to consent processes and the "cooling off" period between confirmed consent with the surgeon and surgery.
- At the initial patient consultation, the optometrist provided an information folder to the patient, which contained a copy of the treatment consent form, risks associated with the treatment and the benefits of the procedure.
- If patients wanted to proceed with treatment they had a consultation with the surgeon who would perform the treatment. The surgeon offered the same information on the benefits and risks associated with the procedure. Further diagnostic tests were also taken.
- The consent appointment was made at least three days before any treatment took place. We were told that the service did not consent patients on the same day as treatment. However, the new Professional Standards for Refractive surgery (April 2017) recommends a "cooling off" period of one week.
- We were told for those patients who did not speak English, they were asked to bring somebody with them who could translate information. This was usually a family member or friend. However, for consent procedures, it is best practice for an independent interpreter to explain treatment and assist with consent, to minimise the risk of coercion and to ensure medical information is translated correctly.
- It was the responsibility of the surgeon to assess capacity to consent. Any concerns would be raised with the patients GP, with the patients consent. However, the surgeon had the final decision as to whether the patient was suitable to proceed with treatment.

Are refractive eye surgery services caring?

Compassionate care

- We observed staff were caring and compassionate in interactions with patients. Staff treated patients with kindness, dignity, and respect. Staff interacted with patients in a positive, professional, and informative manner.
- We observed nursing staff collecting patients from the waiting room, shaking hands and introducing themselves prior to consultation.

Refractive eye surgery

- The four patients we spoke with said the staff were very friendly, kind, and considerate.
- Patients were asked to complete a patient feedback form after refractive surgery. The responses were collected, compiled and audited annually. Patients were also encouraged to leave feedback on the website.
- We reviewed patient feedback data for 2016. The feedback showed that scores for a rating of 'excellent' for initial contact, service, treatment option explanation, medication explanation and aftercare service were all above 90%.
- All comments and feedback from the patients were used to improve the service. We saw recommendations from feedback put into practice. For example, patient information pack content was updated and processed efficiently.
- We saw positive feedback cards from patients, one had written, "care and expertise has been life changing."
- There was no information on chaperones displayed. However, patients were able to involve relatives, friends, and chaperones in their discussions about treatment and care. This was with the patients consent

Understanding and involvement of patients and those close to them

- Staff involved patients in their care, and gave time to discuss procedures. We observed two surgery procedures. We saw informed discussions between the surgeon and patients were in-depth with discussed outcomes, expectations, risks, and recovery.
- We spoke to two patients who described the initial consultation, investigation, and treatment options. The patients said, staff encouraged them to think before making a decision about treatment.
- Patients we spoke with told us they were given full explanations of the treatment, expectations and post-operative care. This was backed up by patient information leaflets, contact phone numbers and an informative website. We observed patients being encouraged to ask questions.
- There were leaflets available, which provided details of all the options available and the costs of treatment. The organisations website was clear and easy to use and gave an informative description of each procedure as well as other patient stories.

Emotional support

- We observed two procedures in the laser treatment room and saw that the nurse who was present reassured the patients throughout the procedure. They provided support to an anxious patient and were able to allay their fears and concerns regarding treatment. They were kind, non-persuasive and made the patient feel relaxed.
- We spoke with four patients who told us the staff made them feel comfortable and relaxed and eased their fears for any concerns they had with their treatment. We observed a technician speaking kindly and supporting the patient with aftercare treatment. They spoke calmly, answered all the patients' questions, and asked how the patient was feeling. They told the patient what to anticipate in terms of post treatment discomfort and how to minimise their concerns.

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

Service planning and delivery to meet the needs of local people

- The service did not do any NHS work and did not receive referrals from the NHS. Patients could access the service through self-referral.
- The provider generally undertook refractive eye surgery as and when patient demand dictated. Operating sessions were arranged according to patient numbers.

Access and flow

- Pre-operative appointments began with an initial consultation with an optometrist and followed by a preoperative consent appointment with the surgeon. If necessary additional pre-operative consultations could be arranged if the patient needed more information prior to the procedure.
- Patients could access the service either through self-referral, word of mouth, through an internet search or in response to marketing. The service also accepted patients through an optometrist partner referral system. This would mean that when a patient attended their regular ocular examination and an enquiry was made about refractive surgery, the optometrist would ask if the patients contact details could be forwarded to the service.
- Appointments were made to suit patient requirements. Patient's appointments were flexible and they could be

seen at different clinics to suit their needs. Patients told us they were able to book and change appointments easily and had a good choice of treatment dates including the choice of Saturday operating days.
- Pre-operative appointments began with an initial consultation with an optometrist and followed by a preoperative consent appointment with the surgeon. If necessary additional pre-operative consultations could be arranged if the patient needed more information prior to the procedure. Patient's initial consultation appointments lasted approximately 20-30 minutes but the full patient journey for treatment lasted two to three hours.
- Patients were given a follow up appointment for the next day for LASIK procedures and for four days after LASEK procedures. All non-laser refractive procedures were seen the next day post operatively.
- Within the last 12 months, there had been no cancelled refractive eye procedures.

Meeting people's individual needs

- The service had a small lift to access the first floor where consultations and diagnostic tests took place. This lift was not adequate for a wheelchair. The service told us that wheelchair users could be seen in the ground floor consulting room within the laser theatre and diagnostic tests could be done there.
- Patients with wheelchairs were invited to access the service before their treatment day so their needs could be assessed and accommodated. For example, patients were shown the treatment room and how they could manoeuvre their wheelchair before receiving treatment.
- There were hot drinks and biscuits available in the reception area along with a cold-water dispenser.
- Magazines and a television were available in the reception area.
- There was a range of information leaflets available throughout the service. They provided information on treatments and various conditions; however, they were only available in English.
- There was no access to translation services or an interpreter. Patients were asked to bring a relative or friend to accommodate them.
- The service did not treat patients with, learning disabilities or patients with complex health conditions. Screening procedures at the start of the patient's journey ensured those patients who required additional support were referred to alternative services with the support of their GP.
- Patients were provided with information on aftercare and emergency contact numbers if they felt the need to contact the service with any concerns.

Learning from complaints and concerns

- The complaints policy described the process staff should follow in the event of a patient making a complaint. Staff told us they knew how to manage a complaint and that information about complaints was shared during team meetings.
- We saw notices in the clinic and information in patient leaflets describing how to make a complaint. Information about how to make a complaint was also available on the website. Patient information did not include information about the Optical Complaints Consumer Service.
- The theatre manager told us they would attempt to resolve verbal complaints on the day, more serious complaints were escalated to the medical director. Complaints could also be submitted via the website.
- The service received one complaint during the reporting period. We reviewed this complaint and saw that it had been managed according to the complaints policy. We saw evidence that learning had been identified and shared with staff.

Are refractive eye surgery services well-led?

Leadership and culture of service

- The theatre manager also acted as clinical manager. They were visible, part of the team and took part in the day to day running of the services as well as managing the staff.
- On the day of our inspection we saw the theatre manager coordinating the refractive eye surgery team effectively
- Staff we spoke with talked positively about the medical director. They said they were supportive, approachable and managed their concerns. There was clear leadership. Staff knew their reporting responsibilities and the role they played within the service.

Refractive eye surgery

- Staff were complimentary about their workplace and colleagues; we did not see and were not told of any conflict within the workplace however staff told us they were confident that the manager could help to resolve conflict should it occur. Surgeons were managed by the medical director.
- There was no whistle blowing policy but staff told us they would be able to raise any concerns freely.
- We observed marketing to be honest and complied with guidance from Committee of Advertising. Patients received a statement, which included terms and conditions, which provided information on payment fees and details of the service provided. Patients told us they did not feel pressurised to go ahead with treatment from staff working at the service.

Vision and strategy

- The provider did not have a clearly defined vision and strategy and therefore this was not evident. Staff were not aware of the organisation's values.
- Royal College of Ophthalmology standards were incorporated throughout policies and procedures.
- The medical director spoke with us about plans to expand to Devon but this was still work in progress.

Governance, risk management and quality measurement

- There were policies to support the governance of the organisation. These key policies provided staff with clear guidelines and processes to follow. Key policies included incident reporting, information governance, medicine management and privacy, dignity, respect and human rights.
- We reviewed the laser treatment risk register which identified potential risks, their severity and mitigating actions, risks identified were relevant to the environment and activity taking place. We also reviewed the LPA visit report June 2017, no concerns or actions had been identified.
- The service did not have an overall risk register. However, there were risk assessments, which applied to the location. We viewed the risks for laser risks and fire assessments. These were up to date, re-assessed, and kept for one year. As a single specialty service, the risks to patients were low and staff were trained and skilled to manage risks at the location.
- We reviewed the surgeon's personnel file and were satisfied that all employment checks were complete, indemnity insurance was in place, patient feedback exercise had been completed in August 2013, annual audit of performance had taken place, and appraisal meeting within the last 12 months.
- The fit and proper person's checks were adopted for the company's director, nominated individual and registered manager.

Public and staff engagement

- The organisation did not conduct staff surveys.
- Patients were able to leave feedback at the service or through the organisations website. We were told there was a good level of response. For the year 2016, the level of patient response was approximately 80%. The service regularly received scores of 80-100%.
- Information from patient surveys was collated annually and trends identified. For example, patients expressed concerns around the content and amount of information provided at the initial stage of consultation. In response the service updated the patient information pack and made sure that all content was up to date and processed efficiently.
- Patients highlighted time keeping as an issue during post-operative appointments which resulted in delays when seeing patients. The service found this was due to facilities constraints as there were two examination rooms only. In response the service expedited an additional examination room to reduce patient waiting times.
- There were regular team meetings where staff were encouraged to raise any concerns and staff we spoke with said they felt comfortable to do so. They told us they were happy to discuss issues with the surgery manager who had an open door policy.

Innovation improvement and sustainability

- The service was in the process of recruiting to an operational manager post.
- Advanced Visioncare were in the process of sharing audit and outcome data with laser manufacturers to contribute to the development and improvement of the technology.
- When speaking with the medical director we were told of plans to introduce corneal implants and also to open and expand the service into Devon.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to address concerns identified during the inspection in relation to medicine management and security.
- The provider must ensure they have robust systems to monitor the administration, management and dispensing of medicines to provide safe care and treatment to patients.
- The provider must ensure that all policies and guidance are up to date with current professional standards and legislation.
- The provider must take prompt action to address the security concerns identified in relation to access to the theatres and resuscitation trolley.

Action the provider SHOULD take to improve

- Duty of candour requirements should be fulfilled including staff training and revision of complaints and incident management policies.
- The provider should consider contributing outcome data to the national ophthalmic database.
- The provider should consider developing a corporate vision and strategy.
- The provider should consider how it collects and collates staff feedback.
- The service should follow the Royal College of Ophthalmologists recommendations relating to consent processes and the “cooling off” period between confirmed consent with the surgeon and surgery.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment Prior to the main receptionist arriving to the building at 9 AM, the front door of the building, and access doors to clinical areas, were not locked or secure on the days of our inspection. This meant that an intruder could enter the building easily and access clinical areas, including access to medication. Any person who has also gained access to the waiting area would be able to enter the laser theatre and surgery theatre without authorisation. This was concerning as medication areas were not currently secure which could result in the theft or tampering of medications. Regulation 15 – (1)(b

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent Some patients using cytotoxic medications were not provided with information about their treatment to understand the potential risks and complications and to make an informed decision. During some laser procedures the cytotoxic medicine Mitomycin was being used post-operatively. We saw that patients who received this drug had an additional consent form to

Enforcement actions

complete, however this consent did not include details that the medicine was being used outside of its license, and did not provide sufficient information on the potential risks of using cytotoxic medication.

Regulation 11 – (1)

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment 1. During our inspections on the 19 September and 10 October 2017, we reviewed how the service undertook the proper and safe management of medicines. We found that you were not managing medicines in order to provide safe care and treatment to patients. 2. A policy for the use of the cytotoxic medication Mitomycin was in place but had not been reviewed or updated since 2012. The policy did not include details of training requirements for staff, and staff told us there was no additional training required for the administration of mitomycin. We saw that an external pharmacy had provided the theatre manager with details of how to reconstitute the Mitomycin via email, but this information was not reflected in the service's policy. 3. The administration of Mitomycin was not consistently or accurately recorded in patient's notes. Unlike other medicines there was no pre-printed proforma for the doctor and nurse to sign to record administration. 4. Staff told us that patients were not provided with any written information about Mitomycin before or after the procedure, and we found no examples where additional information had been provided.

This section is primarily information for the provider

Enforcement actions

5. No cytotoxic spills kit was available and the directions in the Mitomycin policy on managing a cytotoxic spill were inadequate. No Control of Substances Hazardous to Health (COSHH) risk assessments for the administration of Mitomycin had been undertaken.

6. We saw that medicines were not stored securely and access was not appropriately restricted. We found multiple boxes of prescription only eye drops stored on open shelves in unlocked rooms, in both the laser theatre and the surgical theatre. This was against Advanced Visioncare's Medicines Management Policy which states that 'All medicines kept in clinic must be stored in a locked cupboard which is secured to a wall'. In the laser theatre we also found the fridge containing multiple prescription only eye drops unlocked.

7. We saw and we were told that staff were not following Advanced Visioncare's policy for temperature monitoring of medication refrigerators. The relevant policy stated that temperatures should be monitored daily however this was happening infrequently, often at most twice a week. We saw that the medicines fridge in the laser theatre was regularly outside of the required temperature range and staff were not able to tell us what action they had taken to address this issue.

8. The resuscitation trolley was kept in an unlocked corridor leading to the surgical theatre, and guidance from the Resuscitation Council (UK) regarding trollies was not being followed. We saw that medicines stored on the resuscitation trolley we not stored in tamper evident boxes. The resuscitation trolley stocks were checked monthly, the Resuscitation Council (UK) recommends that they should be checked daily. We saw no documentation or policies detailing how often the resuscitation trolley should be checked at Advanced Visioncare. Medicines kept on the trolley were amiodarone, adrenaline and oxygen.

This section is primarily information for the provider

Enforcement actions

9. None of the nursing staff had received specific training on the use of medicines at Advanced Visioncare. Staff told us that competency based training from their usual place of work was enough.

Regulation 12 – (1), (2)(a), (b), (c) and (g)