

Accuvision Laser Eye Clinics Solihull West Midlands

Quality Report

3 The Courtyard
707 Warwick Road
Solihull
West Midlands
B91 3DA

Tel: 0845 000 2020

Website: www.accuvision.co.uk

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

Ratings

Overall rating for this location

Are services safe?

Are services effective?

Are services well-led?

Summary of findings

Letter from the Chief Inspector of Hospitals

The inspection took place on 14 December 2015. This was an unannounced responsive inspection. We had received allegations to the effect there was a risk that staff were undertaking procedures for which they were not qualified.

We found no evidence that the allegations could be substantiated. We found that all the staff employed by the service were qualified, competent and skilled, the only exception being the cleaning contract staff who had not received any training in their role.

We inspected the following domains; safe, effective and well-led. These domains were identified as the most appropriate to help us to determine if the allegations were true and if any members of the public had been put and risk and continued to be so.

We have not rated this inspection as our policy does not allow for that until April 2016.

The provider has two other locations from which it conducts regulated activity. We attempted to inspect both of these on the same day. However only the London office was open. Please note the London location has a head office function, as well as undertaking the regulated activity.

Our key findings were as follows:

- Staff were suitably qualified competent and skilled to undertake their roles.
- On call and out of hours support was available for patients following their procedures.
- Equipment management and maintenance was well maintained.
- We saw that patients were seen promptly for their appointments.
- Although audit was limited, where it was undertaken we saw good learning, resulting in positive change for patients.

However, there were also areas of poor practice where the provider needs to make improvements.

- No accredited training had been offered to housekeeping personnel who had been employed for general cleaning duties. However we noted that the premises were visibly clean.
- The written infection control policy was not available for staff to refer to.
- We saw limited benchmarking data which compared patient outcomes in this service with those in similar services.
- The privacy of patients was compromised by their notes being stored on an open shelf in an office where patients were invited to on arrival to the clinic.
- Governance arrangements needed strengthening to identify more areas for improvement.

In addition the provider should:

- Establish a clear incident reporting mechanism that includes a trigger for the Duty of Candour requirement.
- Improve the arrangements for storing patients' records while they are in use, to protect them from casual view.
- Strengthen governance arrangements including internal audit, risk management and frequency of governance meetings/communications.

We will follow up with a full comprehensive inspection in line with our policy and risk.

Summary of findings

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating Summary of each main service

- Clinical staff discussed any incidents or near misses.
- Equipment was used safely. We found laser room protocols in place and health and safety processes and procedures were audited regularly
- The clinic was clean, tidy and uncluttered. There were some procedures in place for infection control but no written policy available to staff at the clinic.
- Good record keeping systems were in place and patients were assessed for any clinical risks or deterioration.
- There was an on call system for out-of-hours urgent contact and there were sufficient numbers of ophthalmologists, optometrists, technicians and nurses available to treat and support patients through consultations and procedures during their appointments.
- There were systems in place to check on the on-going competence of clinical and technical staff.
- Some clinical audit was undertaken and these demonstrated positive outcomes for patients.
- Information was made available to patients and prospective patients and the services were available on Saturdays.
- Leadership was visible and the culture was open. The Director of the provider company had regular contact with staff and patients at the clinic.

However;

- There was no clear incident reporting or learning mechanism in place. There was a risk that the Duty of Candour requirements could be overlooked.
- Some patients' records were incomplete some were not stored securely to protect patient confidentiality.
- Poor management of pain relief record had not been identified through audit.

Summary of findings

- Governance arrangements were not sufficiently effective and did not provide assurance of the quality and safety of the quality of the service and managing risk.
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Summary of findings

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Accuvision Laser Eye Clinics

Services we looked at

Surgery

Summary of this inspection

Background to Accuvision Laser Eye Clinics Solihull West Midlands

Accuvision laser eye surgery clinic in Solihull is one of three clinics nationwide run by an independent healthcare provider. It offers laser vision correction surgery and treatments for short-sightedness (myopia); long-sightedness (hyperopia); astigmatism; keratoconus treatment; age related long-sightedness (presbyopia) and access to non-laser cataract surgery through another provider.

This was an unannounced inspection in response to some specific concerns raised about the provider organisation. These related to claims that staff were undertaking procedures for which they were not qualified. We visited the clinic on Monday 14 December 2015, spoke with staff and looked at records.

Our inspection team

Our inspection team was led by:

Inspection Manager : Donna Sammons Hospitals
Birmingham

Our colleagues in London were inspecting the provider's other premises at the same time. We had access to a specialist ophthalmic surgeon for specialist advice during the inspection.

How we carried out this inspection

This was an unannounced inspection as a result of an allegation to the affect there was a patient safety concern. The publication of this report was in part delayed by CQC's quality assurance process.

We interviewed key members of staff, reviewed documents required and used for the running of the service. We reviewed 27 patient records. During the inspection a few patients attended the clinic for follow up post-surgery.

Information about Accuvision Laser Eye Clinics Solihull West Midlands

The service was registered with the CQC 07 December 2010

The regulated activities are diagnostics and screening, surgical procedures and treatment of disease disorder or injury.

The registered manager is Nick Dash.

Refractive eye surgery

Safe

Effective

Well-led

Summary of findings

- Clinical staff discussed any incidents or near misses.
- Equipment was used safely. We found laser room protocols in place and health and safety processes and procedures were audited regularly
- The clinic was clean, tidy and uncluttered. There were some procedures in place for infection control but no written policy available to staff at the clinic.
- Good record keeping systems were in place and patients were assessed for any clinical risks or deterioration.
- There was an on call system for out-of-hours urgent contact and there were sufficient numbers of ophthalmologists, optometrists, technicians and nurses available to treat and support patients through consultations and procedures during their appointments.
- There were systems in place to check on the on-going competence of clinical and technical staff.
- Some clinical audit was undertaken and these demonstrated positive outcomes for patients.
- Information was made available to patients and prospective patients and the services were available on Saturdays.
- Leadership was visible and the culture was open. The Director of the provider company had regular contact with staff and patients at the clinic.

However;

- There was no clear incident reporting or learning mechanism in place. There was a risk that the Duty of Candour requirements could be overlooked.
- Some patients' records were incomplete some were not stored securely to protect patient confidentiality.

- Poor management of pain relief record had not been identified through audit.
- Governance arrangements were not sufficiently effective and did not provide assurance of the quality and safety of the quality of the service and managing risk.

Refractive eye surgery

Are refractive eye surgery safe?

We found:

- There was no clear incident reporting or learning mechanism in place and a risk that the Duty of Candour requirement could be overlooked.
- Some patients' records were not stored securely to ensure patient privacy.
- Administration time of medications were not routinely recorded.

However, we also saw:

- Clinical staff discussed incidents and near misses.
- Staff used equipment safely.
- The clinic was clean, tidy and uncluttered and there were procedures in place for infection prevention and control.
- There were good record keeping systems in place for the vast majority of records we reviewed.
- Patients were assessed for any clinical risks or deterioration. There was an on call system for out-of-hours urgent contact.
- There were sufficient numbers of ophthalmologists, optometrists, technicians and nurses available to treat and support patients through consultations and procedures during their appointments.

Incidents

- The clinic did not have a clear mechanism in place for reporting and learning from incidents. However, staff we spoke with understood their responsibility to raise any concerns they had.
- There was no incident log at the clinic except for the statutory health and safety log books and record sheets. This meant clinical incidents were not put on record for reporting up through the organisation, investigation and learning.
- 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 relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to the person. We noted from minutes of the December 2014 clinical governance meeting that the Duty of Candour regulation was discussed and a new policy had been put in place for the clinic. We looked at 20 patients' files

and noted a record of one incident. This incident was about pain management during a procedure. There was a lack of record to demonstrate that Duty of Candour had been considered in this instance for example.

- Staff confirmed this was discussed and dealt with locally within the clinic team but was not recorded and reported as an incident. This meant opportunities for learning and improving practice and triggers for the Duty of Candour requirement may be missed.

Cleanliness, infection control and hygiene

- All areas of the clinic were clean, tidy, uncluttered and well organised. There was no surgery being undertaken on the day of our visit so we could not observe infection control and hygiene practices for surgery.
- We noted hand cleansing gels and personal protective equipment were available in clinic rooms.
- We asked to see the clinic's policy and procedure on hygiene and control of infection (IPC).
- The provider sent us a copy after our visit as staff told us it was not available for them to consult on the clinic on the day of our visit. We noted it was dated December 2015 with a review date of December 2016. The provider later sent us 'older versions' of the ICP policy and procedure dated June 2014 with a review date of June 2016, It does appear therefore that a policy was in place, although staff at Solihull could not direct us to it at the time of our visit and it was the June 2014 policy.
- We noted the policy and procedures were in line with National Institute of Clinical Excellence NICE 2014 infection prevention and control quality standard QS61 and the Health and Social Care Act code of practice 2015.
- We asked the cleaning staff about cleaning procedures and instructions and they told us they had only been instructed to use anti-bacterial spray and dispose of cloths after one use. They were not responsible for the cleaning of medical equipment or clinical areas.

Environment and equipment

- We noted there were 'local rules' for the safe use of the class of laser equipment used at the clinic. The Local rules define at a minimum, the possible hazards from the equipment, how these are controlled, including the specification for Personal Protective Equipment (PPE), where the Laser can be used, the laser controlled area, the personnel allowed to use the equipment and action to be taken in the event of an accident or incident.

Refractive eye surgery

- There was a system of statement of declaration signed by nominated users of the laser equipment, technicians and maintenance personnel. This was an audit trail of activities undertaken by staff members for each patient procedure. This was produced for every patient who underwent laser eye surgery.
- We saw a copy of a risk assessment report for the laser equipment, undertaken by a radiation consultancy service, dated in May 2015. The safety score was 100% compliant.
- We asked the provider to send us a copy of the risk assessment log for the Solihull clinic as it was not available on the day of our visit. They sent us a log which showed a system for addressing environmental, equipment and cleaning hazards. All hazards were scored as low risk, 'no action required'. It was dated January 2016, after our inspection visit. The provider subsequently told us the log was updated in January 2016 as planned to address the target date for meeting two improvement actions it had identified in September 2015.
- We found from records health and safety processes and procedures were audited regularly. There were some actions indicated to improve compliance with procedures.

Records

- The clinic had systems in place for record keeping including a standard patient file set up.
- We noted from minutes of the December 2014 governance meeting the provider identified improvements needed for data entry on pre operation forms.
- We looked at 27 sets of patient notes and saw risk assessments, pre-operative assessments and treatment records detailed on file for all of them.
- Records were up-to-date, kept in good order and most were legible. We noted one record of summary of discussion with the patient was illegible.
- Staff at the clinic did not use the 'WHO (World Health Organisation) 'five steps to safer surgery' standards safety checklist. The provider had adapted this checklist to the service it provided. .

- However, not all records were complete. For example, we noted contrary to Royal College of Anaesthetists and Royal College of Ophthalmologists (Royal colleges) 2012 guidelines there was no 'five steps to safer surgery' safety checklist in one file.
- Archived patient records were properly stored in a locked room.
- However, we observed current patients' notes were stored on an open shelf at the rear of the small reception room. Notes of patients attending that day were placed on a tray just inside the door. Patients were invited by signage to go to this room when they arrived to book in.
- Although we noted this room was not left unlocked when unattended by staff, we found we were able to read patients' names from file covers when we stood where patients stand to check in and arrange further appointments. This compromised patient's privacy..

Mandatory training

- Cleaning staff told us they had received no training in hygiene and infection prevention and control.
- We saw a basic life support training sign in sheet which all the operational staff had signed in 2015.

Assessing and responding to patient risk

- The provider undertook a pre surgical assessment which included medical history and discussion of patient's expectations of vision following surgery.
- When the laser was in use it generated a report of the surgery and who operated the equipment.
- Electronic diary records showed an optometrist remained free of appointments and available before a surgery list commenced in case they were needed for re assessments or repeat measurements.
- Staff were available post operatively to support patients out of hours. Staff were identified on a rota system. If the patient needed urgent attention and the clinic was not open the duty on call optometrist would advise them to attend their local emergency department
- Prescriptions for medicines pre-operative did not consistently contain the time of administration.

Surgical staffing

- Staffing levels were appropriate to meet the needs of patients. The rotas we reviewed demonstrated adequate staffing for both the days of surgery and post-surgery appointments.

Refractive eye surgery

- The service was staffed by surgeon, ophthalmologists and optometrists. We noted from scrutinising the theatre register, laser log and patient records of surgical procedures for 20 patients an ophthalmologist and laser technician was present during each surgical procedure.
- In order to verify their presence in the theatre we compared the signatures on these documents against a record of sample signatures for these staff.
- The clinic director, who was the provider company's Laser Protection Supervisor, was present during surgical procedures.
- The clinic had out-of-hours arrangements with an emergency on call system staffed by a duty optometrist. We noted the minutes of the December 2014 clinical governance meeting reported this arrangement was working well.
- The service employed one nurse part time.

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

We found:

- Laser room protocols were in place and health and safety processes and procedures were audited regularly.
- Some clinical audit was undertaken and results demonstrated very positive outcomes for patients.
- There were systems in place to check on the on-going competence of clinical and technical staff.
- Information was made available to patients and prospective patients.
- The services were available on Saturdays.

However we also saw:

- Poor management of a pain relief record was not picked up through audit.

Evidence-based care and treatment

- We looked at the policies file that was made available to us at the clinic. We saw some evidence of policies based on NICE or Royal College of Ophthalmologist's (RCO) guidelines at the time, for example in the Laser Protocol file and the RCO patient guidelines were available for patients to read We have been subsequently provided with a range of updated policies by the provider.

Pain relief

- We noted that patients were offered pain relief and the effectiveness of the pain relief was recorded.

Patient outcomes

- We noted from patient records that patient expectations were discussed during the pre-assessment in every case.
- There was clear information on the provider's website about intended and realistic outcomes for patients following procedures and treatments.
- The clinic audited some of its local activity such as the number of patients and types of procedures undertaken each year. We noted some evidence of ad hoc retrospective audit activity on patient notes with annotated comments, for example 'please check...not discussed'.
- The provider audited procedures undertaken across its services from December 2013 to December 2014 to assess visual quality and treatment outcomes. The audit reported:
 - 99.6% patients achieving best corrected visual acuity (BCVA) 6/6 (1) or better pre-treatment achieved uncorrected visual acuity (UCVA) of 6/6 (1) across all prescriptions.
 - all patients with an amblyopic eye where full correction was intended have achieved the same uncorrected visual acuity (UCVA) post op as the best corrected visual acuity (BCVA) they presented with pre-operatively.
 - the enhancement rate across all patients and all prescriptions was 1.07%
 - zero patients with unresolved post-operative complications
- There was no re-audit available for 2015. Post inspection the provider told us these would be routinely collected as the timeframe for assessing the outcome of a treatment progressed.
- The statistics reported were from across the full range of treatments offered by the clinic and demonstrated very positive outcomes for patients.
- We noted the clinical governance meeting minutes for December 2014 reported the number of patients who had re treatment 'was almost identical' to the previous year.

Multi disciplinary team working

Refractive eye surgery

- Patients received care from a multidisciplinary team which included surgeons, laser technicians, optometrists and a registered nurse.

Competent staff

- Staff were suitably trained or qualified for the clinical tasks they were undertaking, which was contrary to the information we had received that led to the inspection. Surgeons undertaking laser eye surgery at the clinic were registered with the GMC and had a broadly based knowledge of ophthalmology. However the recommendation from the Royal College of Ophthalmologists is that all surgeons undertaking this treatment should additionally hold the certificate Laser Refractive Surgery.
- The clinic gained additional assurance of the surgeon's ability to undertake their roles by relying on the revalidation process conducted within the NHS. Revalidation is the process by which licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise.
- Clinical staff told us they did not receive any formal regular professional supervision but they discussed issues among themselves on a regular basis. However the surgeons used also worked within the NHS and annually shared with the provider their training records and revalidation. The provider told us that as the staff numbers were small within the service they always worked together and got professional support from each other and the Director.
- We noted from a sample of one signed declaration, the provider had a system in place for continuing requirements for ophthalmologists/consultants that included an annual review of practising privileges. This was the contract of services the surgeons would offer and proof of their competence to do so.
- The clinic director, who we noted attended each surgery procedure for the 27 patients whose files we looked at, was the laser protection supervisor for the provider company. We saw this was confirmed by up to date certificates in training for the laser equipment used.
- We noted from a laser and diagnostic training log that clinical staff performing procedures at the clinic had updated training in February 2015.

Seven-day services

- We noted from patients records and the appointments diary for the clinic that surgery was undertaken on week days and on Saturdays.

Access to information

- Staff told us all information for patients about their procedures was available to them on the clinic's internet site. This was brought to their attention on their first visit for assessment.
- We noted information was available on line including what the service could not achieve for prospective patients.
- Staff had access to patient information via their records; we also saw that some of the information was transferred to electronic software which was accessible from all three clinics. The provider told us that all patient information was subsequently up loaded to an electronic record.
- Staff had access to policies and procedures kept on site.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- We saw consent was recorded on each set of patient notes. This was informed consent and a record of the discussion was present in the patient's records.
- Staff told us the clinic did not generally see vulnerable patients or children. However policies and procedures relating to this were available to staff.

Are refractive eye surgery well-led?

We found:

- Local leadership was visible and the culture was open, the director of the provider company had regular contact with staff and patients at the clinic.
- The provider company was closely involved with developing technology.
- Patients were encouraged to give feedback on their experience of the service.

However, we also saw:

- Governance arrangements were not sufficiently robust enough to be effective in measuring and monitoring the quality of the service and managing and mitigating risk.

Vision and strategy for this service

Refractive eye surgery

- The service was described on its website as ‘dedicated to its patients, their care and their future vision’. There was a commitment that the service and its practitioners were closely involved with developing technology.
- However, we noted no specific evidence of strategy for the service, or a set of values.

Governance, risk management and quality measurement

- The provider held six monthly governance meetings. These were planned six monthly but there had been a gap of 12 months during 2015, so none had occurred with minutes for 2015
- A governance meeting had taken place two days before our visit. The minutes of this meeting reported the 2015 clinical audits were still in progress. Post inspection the provider explained clinical outcomes required a time frame before they could be assessed. However this meant they may not be discussed for at least a further six months. We were concerned that the infrequency of meetings meant there was no assurance that managers used up to date and reliable information to assure themselves of patient safety and quality.
- We asked to see the risk register for the Solihull clinic and noted it was a log for identifying and monitoring health, safety and security risks. No clinical, operational or organisational risks were identified and it appeared the provider did not have systems in place for this type of risk management.
- Risks to patient privacy from the storage of patient files in the reception room had not been effectively managed.
- Some important policy and procedure documents such as incident reporting and infection control were not available for clinic staff to consult and staff did not refer us to on line copies when we asked for them. Post inspection the provider told us these documents were held on line for staff to access.
- There appeared to be some confusion about which version of the infection control policy was in place at the time of our visit
- Where incidents and near misses had occurred staff told us they discussed these locally. However, there was no formal mechanism in place for reporting these through the organisation and monitoring learning and improvement.

- We spoke with the director on 15 February 2016 and were given assurance that since our visit a formal mechanism had been put in place to record and monitor any incidents or near misses.

Leadership of service

- The provider organisation’s director frequently attended at the Solihull clinic, including on most occasions when surgery was undertaken. This was confirmed by staff and from the electronic diary records we saw. For example, we noted a record of an ‘unannounced visit’ to the clinic by the director in June 2015.

Culture within the service

- We noted the clinical governance meeting minutes for December 2014 reported all staff had been informed about the provider requirements related to Duty of Candour and a policy was in place.
- However, staff we spoke with although confirming their understanding of the Duty, did not describe any formal incident reporting mechanism they would use to accommodate it.
- Staff we spoke with told us the provider company had an open culture and they felt able to raise any concerns they had with the director.

Public engagement

- We saw a patient satisfaction report for February 2014 to May 2015. The questionnaire covered 15 areas of questions including a ‘Friends and Family’ question.
- We noted the majority of respondents indicated within the ‘Delighted’ category for most questions.
- Patients were asked what they did not like and for suggestions for improvements.
- There were four negative comments on the immediate post-surgery facilities for recovery. Patients said they felt vulnerable and exposed in the waiting areas. However, they did not identify which clinic it was relating to. Post inspection the provider told us the locations could be identified by interrogating the electronic records.

Staff engagement

- We did not see any evidence of specific staff engagement processes. Staff we spoke with were well motivated in their work with patients.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Strengthen governance arrangements including internal audit, risk identification and management and frequency of governance meetings/communications.

Action the provider SHOULD take to improve

- Establish an effective incident reporting system that includes a trigger for the Duty of Candour requirement.
- Surgeons carrying out laser surgery at the clinic should hold the Certificate in Laser Refractive Surgery as recommended by The Royal College of Ophthalmologists.
- Improve the arrangements for storing patient's records while they are in use to protect them from casual view.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Diagnostics and screening</p> <p>Surgical procedures</p> <p>Treatment of disease disorder or injury</p> <p>17 Good Governance</p> <p>You are failing to comply with Regulation 17 (1) (2) (a) (b) which states:</p> <p>(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.</p> <p>(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to –</p> <p>(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity</p> <p>(including the quality of the experience of service users in receiving those services);</p> <p>(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at</p> <p>risk which arise from the carrying on of the regulated activity;</p> <p>How the provider was not meeting this requirement:</p>

This section is primarily information for the provider

Requirement notices

There was no incident log at the clinic except for the statutory health and safety log books and record sheets.

There was no risk register for the clinic that identified, assessed and acted as a working tool to mitigate, monitor and manage any clinical risks

There was a lack of records to demonstrate that Duty of Candour had been considered.

Governance meetings were infrequent.

Some key policy and procedures were not easily available for staff to refer to.

Risks to patient privacy from the storage of patient files in the reception room had not been identified and managed.