Optyco Ltd

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optyco Limited is a high street optician providing refractive eye surgery. The service is delivered from premises in the centre of Leicester. The ground floor houses the opticians service and the first floor the refractive eye surgery services. We did not look at the optician's service as part of this inspection, as it does not fall within the scope of registration.

Refractive eye surgery facilities include one operating theatre and several consulting/treatment rooms. Optyco only routinely treats adults over the age of 21, however in exceptional circumstances would treat patients 18 years and over.

This inspection was a focussed inspection following our initial inspection on 11 and 13 June 2018 when we suspended services for three months. The inspection took place on 31 July 2018 and focussed on safety.

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.

We found the following areas of good practice:

- Staff had individual employment files and had attended the provider's mandatory training.
- All areas were visibly clean with cleaning schedules and colour coded cleaning equipment was used.
- Medicines were managed in line with the provider's policy and current best practice guidance and legal requirements. Emergency drugs including oxygen, were easily accessible.
- All sterile and non-sterile surgical equipment was stored correctly and was within expiry its date. There was a service level agreement with an external provider for the supply of sterile, single use surgical equipment.
- Products subject to Control of Substances Hazardous to Health legislation were stored correctly. Clinical and hazardous waste were disposed of safely. Electrical appliance testing had been carried out and there were maintenance schedules for specialist ophthalmic surgical equipment, we were unable to establish if these were followed as they have been newly implemented just prior to our re-inspection. The registered manager had oversight of this process.
- Information was shared with other medical staff such as GPs where patients gave their consent.
- Patient records and patient identifiable information was stored securely.

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

- Some documentation needed reviewing for clarity and completeness such as cleaning schedules, fridge temperature monitoring logs and hot water tap flushing.
- The drug fridge had a small amount of water in the bottom which could affect the integrity of the medicines packaging.
- The examination seat still needed recovering in order that it could be cleaned effectively according to infection prevention and control guidelines.
- There was broken glass in the vicinity of the fire exit which could present a hazard for staff and patients in the event of the fire escape being used.

Following this inspection, we 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.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		We did not rate this inspection as it was a focussed follow up inspection. At our previous inspection we did not have the legal power to rate this service. At our next inspection we will rate the service.

Summary of findings

Contents

Summary of this inspection

Background to Optyco Ltd

Optyco Limited has been operating from its clinic since May 2012 providing optician services. In March 2013 Optyco Limited began providing refractive eye surgery (otherwise known as laser eye surgery using a laser machine). It is a private clinic in Leicester, Leicestershire. The service primarily serves the communities of Leicestershire. It also accepts patient referrals from outside this area. The optical clinic is open 9am to 5pm seven days a week and refractive eye surgery is performed monthly. The service does not routinely treat anyone under the age of 21, however in exceptional circumstances accept patients over the age of 18.

The service has had a registered manager since March 2013 and provides the following regulated activity:

Treatment of disease, disorder or injury.

Surgical procedures.

Diagnostic and screening procedures.

We carried out an unannounced focussed inspection of the safe domain on 31 July 2018. This followed a comprehensive inspection on the 11 and 13 June 2018. At the comprehensive inspection we took action to suspend the registration of the service due to immediate safety concerns. We returned to review the actions the provider had told us they had carried out.

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 Simon Brown, Inspection Manager.

Why we carried out this inspection

This was a focused follow up inspection to check on progress on actions we told the provider to take following our previous inspection.

Information about Optyco Ltd

Optyco Limited refractive eye surgery services are provided from the first floor of a building of which Optyco rent the ground and first floors. The refractive eye surgery suite comprises: an operation theatre, two consulting rooms, a pre-screening room, recovery room, staff room, waiting area and toilets. We inspected all the rooms and spoke with the provider who was the registered manager. On the day of our inspection there were no patients undergoing refractive eye surgery and no patients attended for pre-screening or post-operative follow up. The service employed reception staff only. All other services were carried out by the registered manager with the exception of the laser eye surgery which was performed by a visiting consultant working under practicing privileges.

At the time of the inspection, registration as a service provider in respect of the above regulated activities had been suspended until 14 September 2018 under Section 31 of the Health and Social Care Act 2008.

Activity (April 2017 to March 2018)

- Fifty five refractive eye surgery operations.

Summary of this inspection

- One consultant ophthalmology surgeon worked at the clinic under practising privileges.

Track record on safety (April 2017 to March 2018)

No reported never events, clinical incidents, serious injuries, hospital acquired infections or formal complaints

Services provided at the clinic under service level agreement:

- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- Provision of sterile surgical supplies
- Laser protection service
- Laundry
- Maintenance of medical equipment

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

Are refractive eye surgery services safe?

Mandatory training

- Staff had completed mandatory training in line with the provider's policy. There were ten mandatory training topics including health and safety, infection control and information governance. All topics had been attended in the last twelve months and were refreshed annually.
- The visiting consultant performing the refractive eye surgery attended annual basic life support training and we saw this in appraisal documentation. We saw the registered manager also attended annual basic life support training.

Safeguarding

- We reviewed the safeguarding children and adults policies dated May 2018 and found them to be basic. However it was in line with national guidance. For example, it included referral contact information for local safeguarding services.
- Optyco did not usually treat people under the age of 21 years. However in exceptional circumstances Optyco would consider patients over the age of 18 years following full assessment by the consultant and providing their vision was stable.
- The provider was the safeguarding lead. The provider had attended both adult and children (level 2) safeguarding training in the past twelve months. We saw contact details for the local safeguarding teams displayed on documentation and at the reception desk. The provider told us if there were any concerns about safeguarding they would contact the local safeguarding team. There had been no cause to make any safeguarding referrals in the reporting period.
- Occasionally the receptionist assisted patients attending for refractive eye surgery. Most reception staff had attended safeguarding adults level two training and the remaining member of staff was planned to complete safeguarding children level one awareness training following our inspection.

Cleanliness, infection control and hygiene

- All the areas and equipment we inspected were visibly clean. There were cleaning schedules and cleaning equipment was colour coded. Colour coded equipment helps to eliminate the spread of germs and bacteria and increases hygiene by specifying use of the equipment for example a mop for the kitchen and one for the operating theatre. This meant that cleaning was taking place regularly and equipment used to clean domestic areas was not used to clean the clinical and operating areas. Cleaning schedules had been introduced following our last inspection but we were unable to comment on the effectiveness of these as the provider had not been operating since our last inspection. This was in line with the providers Infection Control Policy dated May 2018 and the Royal College of Ophthalmologists Ophthalmic services Guidance 2013. Logs for recording that cleaning had taken place needed reviewing and simplifying as it was difficult to see from the chart what had, or had not, been cleaned.
- All areas we inspected had been deep cleaned by a contracted cleaning company and the cleaning schedule indicated this deep clean took place once a fortnight. There was a detailed cleaning schedule for the laser room which included the procedure for preparing the room and the procedure for cleaning the room and equipment in-between patients, these had been newly implemented since our last inspection. The provider had not been delivering a service therefore we were unable to test the effectiveness of these schedules.
- Since our last inspection the provider had installed a hot water supply to all sinks and implemented a regular flushing procedure in order to reduce the risk of legionella bacteria multiplying in the hot water system. Legionella is a waterborne bacterium, which causes legionnaires disease. However, the flushing procedures were not recorded in a log so could not be verified.
- Personal protective clothing worn in the operating theatre was clean and packaged ready for use including operating theatre footwear. The provider had a process for the laundering of theatre clothing after use with an external provider.
- We saw that the temperature and humidity in the operating room was monitored by a hygrometer. Laser

machines require specific temperature and humidity levels to operate effectively. A Hygrometer/Humidity Meter is used to measure the amount of water vapour in the air

- Single use sterile surgical equipment used during refractive eye surgery was supplied by an external company. Individual packs were obtained for each patient and available on the day of surgery. A small stock of sterile and non-sterile single use consumables were kept in the operating rooms. All were within their expiry date.
- Seating in clinical areas had been replaced since our last visit with chairs that could be wiped clean. However, the examination chair seat still needed recovering, the provider had placed a temporary cover over the worn seat. There was a risk to cross contamination as the seat could not be effectively cleaned between patient use.
- Antiseptic wipes were available in all clinical rooms. This meant that equipment could be cleaned in-between patients.
- There was no records showing hand hygiene audits had taken place but the provider told us, and we saw a plan of how, they would be introduced.

Environment and equipment

- Since our last inspection the provider had taken measures which assured us that the maintenance of the facilities, equipment and premises kept people protected from avoidable harm. All rooms had been cleared of any unwanted, unused items and rubbish, and areas of disrepair had been repaired.
- All electrical equipment had been tested and we saw the stickers and certificates to confirm this. There were service schedules were for all specialist equipment used to deliver refractive eye surgery treatments and we saw that all equipment had been serviced in the last month.
- Clinical waste bins were clean and locked, sharps and cytotoxic waste boxes were empty, signed and dated. All waste bins had been replaced with stainless steel pedal bins. This meant that the provider was now compliant with health technical memorandum (HTM) 83, 07-01 safe management of healthcare waste.
- Reasonable adjustments had been made in accordance with the Equality Act 2010, a small lift gave access to the first floor of the building for patients with limited mobility. We saw the providers risk assessment for accessibility which identified that the service was not suitable for wheelchair bound patients.
- Two foam fire extinguishers had been obtained since our last inspection which were located in prominent positions and we saw valid certificates for both fire extinguishers. We did however find there was broken glass in the vicinity of the fire exit which could present a hazard for staff and patients in the event of the fire escape being used.
- All COSHH products were stored in a locked cupboard in a locked room. We saw that the procedure for the correct handling and disposal of Mitomycin C had been updated. There was a contract with a private contractor for the collection and disposal of hazardous substances.
- The provider had obtained a range of emergency medicines including those for treatment of anaphylactic shock, acute asthma and angina. The oxygen cylinder in the emergency oxygen kit had been replaced and was full and in date, however it was located in a room distant to the emergency medicines. This meant there could be a delay in accessing this in an emergency.
- The provider was compliant with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance on the safe use of lasers, intense light source systems and light-emitting diode (LED) in medical, surgical, dental and anaesthetic practices September 2015. The provider was the Laser Safety Supervisor and had access to a Laser Safety Advisor through a private company. We saw a copy of the Laser Safety Advisor Risk assessment and the local rules. The provider was the only authorised user of the laser machine and had signed to confirm they had read and understood the local rules. The provider also had a Laser Safety Policy dated May 2018 which made reference to relevant guidance.
- Staff and patients could not inadvertently enter the room during a laser session. The operation room had a key pad lock system and hazard warning signs which could be illuminated when the laser machine was in use.
- We saw that suitable protective eyewear was available in line with the laser machine manufacturer's recommendations.

Assessing and responding to patient risk

Refractive eye surgery

- At our last inspection we had concerns the provider was not using or monitoring the use of the WHO checklist. We were not able to re-inspect this aspect of the service but saw there were plans to introduce a system of audit going forward.
- There was no policy outlining agreed referral criteria detailing suitability of patients for refractive eye surgery. This was a concern we raised at the last inspection and we were not assured this had been addressed.
- The provider told us that all patients were seen back at the clinic within 24 hours of their refractive eye procedure and there was a 24-hour help line to support patients in the out of hours period. However, we were unable to verify this at our inspection as the service had not been operating.
- There was no formal transfer protocol with local acute hospitals in the event a patient needed a higher level of care either during or following their refractive eye surgery procedure. The provider told us that due to working at the local acute hospital he had a good relationship with consultant ophthalmologists and could ring them if he needed. In the event of a medical emergency the process was the provider would dial the emergency ambulance service.

Nursing and Medical staffing

- The provider did not employ nursing staff. However, the provider informed us that for future refractive eye surgery sessions he would procure the services of an agency nurse so a third person was present to monitor patients pre- and post-surgery and act as a runner for surgery staff. It is important for a nurse to support in this area to ensure there is sufficient continuity and oversight of patient care in addition to nursing support during procedures.
- The ophthalmology consultant worked under practising privileges and carried out one refractive eye surgery session per month at Optyco. We reviewed the practising privileges agreement and saw all required information was present, for example the consultant was on the General Medical Council, specialist register for Ophthalmology. His revalidation was not due until April 2020. Medical practitioners in the UK are subject to revalidation every five years to prove their skills are up-to-date and they remain fit to practise. We
- The provider undertook the role of Laser Protection Supervisor and had access to a Laser Protection Advisor for further advice and support if needed.

Records

- Patient records and identifiable information were filed and stored in a locked room in line with the provider's Information Security Policy dated May 2018.
- The clinic used paper and electronic records for documenting patient information. Information required to deliver care was available to staff. In the ten sets of patient records we reviewed we saw completed screening tests, health questionnaires and consent forms.
- Since our last inspection the provider had implemented a system so, with the patient's consent, clinical information could be shared with other healthcare professionals such as the patient's GP.
- The laser log was kept electronically and automatically populated each time the laser was used. We saw the laser log displayed on the laser machine computer screen and included calibration.

Medicines

- Medicines management had been changed in line with best practice guidance and the provider's own policy. The provider had systems for the procurement and disposal of medicines. All medicines we inspected were stored in a locked cupboard in a locked room. There was amedicines fridge and its temperature was monitored daily. We saw the daily log which was signed and up to date. However we did find the drug fridge had a small amount of water in the bottom which could affect the integrity of the medicines packaging. All medicines packets were intact at the time of our inspection.
- There was no system to monitor the temperature of the room where medicines were stored. This meant there may be a risk that medicines may be exposed to high or low temperatures and may not be fit for use.
- The provider did not have microbiology protocols for the safe use of antibiotics. Microbiology protocols make sure that antibiotics are only used when necessary and recommend the appropriate antibiotic at the right dose, frequency and duration to optimize outcomes while minimizing adverse effects.
- Patients had been asked about allergies and these had been recorded appropriately in the ten sets of patient records we reviewed.
- The consultant did treat some patients with Mitomycin C. We saw a Control of substances hazardous to health

(COSHH) risk assessment for the management of Mitomycin C which clearly described the precautions for handling and safe disposal of the drug. Mitomycin C is a cytotoxic drug which can be harmful to health. The consent process included information about the use of Mitomycin C and the patient signed to say they understood the information.

- Following surgery, patients were given aftercare advice sheets which clearly described the post-operative medication instructions including eye drops and analgesia.

Incidents

- There were no reported never events and no serious or other incidents in the reporting period.
- There was a system for reporting incidents we saw the report forms and policy. However in view of the number of unsafe areas we discovered, we were not assured the incident reporting procedure was understood or used by staff. For example, the two unplanned re-treatments had not been recorded as incidents.
- The provider received safety alerts through the College of Optometrists bulletins and we saw how he would action when they were appropriate to his service, such as following an alert around medicines.

Major Incident Awareness

- The provider had policies for business continuity in the event of water, power or information technology (IT) failure and a Fire Drill Policy. We saw records of a fire drill practice that had taken place in the last 12 months. We did however note there was rubbish located adjacent to the fire exit, this posed a risk to the evacuation of the building. We escalated this to the provider for action.
- There was an uninterrupted power supply which meant that if there was a power failure during refractive eye surgery the procedure could continue without disruption.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should ensure that all staff have safeguarding children level one training.
- The provider should ensure that all paper logs and records are reviewed and fit for purpose, in particular legionella flushing log, fridge temperature monitoring log and cleaning schedule checklists.
- The provider should consider replacing the drug fridge.
- The provider should ensure that hand hygiene and infection control audits are completed.
- The provider should ensure the seat on the examination couch is recovered without delay.
- The provider should ensure that all rubbish is removed from the area of the fire exit.
- The provider should consider locating the oxygen supply closer to the emergency medicines.
- The provider should have a system to monitor the temperature of the room housing the medicines store.
- The provider should ensure the correct number of staff with the right skills and experience are present at future refractive eye surgery sessions.