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.

Services we do not rate

We regulate refractive eye surgery services 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 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.

Summary of findings

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

Summary of findings

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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.

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.
- 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

Summary of this inspection

- Provision of sterile surgical supplies
- Laser protection service
- Laundry
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

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

Notes

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

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Mandatory training

- As the provider was an employee of a local acute hospital trust mandatory training was provided as part of this employment.
- We saw a copy of the providers mandatory training record. 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 consultant performing the refractive eye surgery attended annual basic life support training and we saw evidence of this in his appraisal documentation. We also saw evidence that the provider also attended annual basic life support training.
- We did not see any evidence of a training record for the receptionist.

Safeguarding

- We reviewed the safeguarding children and adults policies dated May 2018 and found them to be basic but did include referral contact information for local safeguarding services.
- Optyco did not treat people under the age of 21 years. However, 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.
- We saw in the appraisal document of the consultant performing refractive eye surgery that they had attended safeguarding training in February 2017. We did not see any evidence that they had attended a refresher session since then.
- The provider told us that occasionally the receptionist assisted patients attending for refractive eye surgery. The receptionist had not attended safeguarding training.

Cleanliness, infection control and hygiene

- In all the areas we inspected: waiting area, consultation room 1, consultation room 2, pre-screening room, staff room, pre- op room, toilet and operation theatre, we found cleanliness and hygiene were below standard and procedures not in line with the providers Infection Control Policy dated May 2018 or the Royal College of Ophthalmologists Ophthalmic services Guidance 2013.
- A refrigerator which had medicines stored within it was visibly dirty. There were medicines (eye drops) in the fridge during our inspection.
- Scrubs used during operative procedures were hanging in the staff room, these were visibly dirty. Furthermore, footwear used in the operating room had visible stains on them.
- Four vents in the operating room were covered with white tape – this posed a risk of contamination to the operating room as an appropriate ventilation system was not in place.

Refractive eye surgery

- We saw that the temperature and humidity in the operating room was monitored and controlled by a hygrometer and a de humidifying machine. Laser machines require specific temperature and humidity levels to operate effectively.
- We found an unpackaged scalpel blade on a shelf in the fridge in the staff room.
- There was no hot water available in any of the three sinks we checked (Consultation Room 1, Operation Theatre and toilet). The provider told us there was no hot water supply to these sinks apart from the sink in the toilet which had a small water heater. We ran the taps in the said toilet for seven minutes, however no hot water was available. This meant that correct hand hygiene procedures could not be carried out.
- There was no evidence that hand hygiene audits had taken place.
- We saw no evidence of a legionella risk assessment or water flushing procedures. Legionella is a waterborne bacterium, which causes legionnaires disease.
- Some surgical implements were packaged in self-sealing sterile pouches. One of the eight pouches we examined was not sterile as indicated by the pink indicator tab. Chemical indicators are visual aids that show if an item has been subjected to the sterilization process. Most of these indicators change colour when exposed to the high temperatures achieved in a sterilizer, or to a combination of temperature and time. The Pink indicator indicated that the instruments within the pouch had not been through the sterilization process. None of the pouches had an expiry date on them. There is a risk that a member of staff could use these instruments during a surgical procedure which may expose the patient to infection as the sterility cannot be guaranteed.
- We found there were a number of sterile consumables which had expired. These were present in the operating room and there was potential for these to be used during procedures. Consumables used by healthcare professionals are single use, sterile items and it is normal practice to check stock and replace as necessary. Where these items have expired their integrity and sterility can be compromised, posing an infection risk to patients.
- Some patient seating was unsuitable and worn. There were fabric covered chairs in clinical areas and the examination chair in Consultation Room 1 was so worn the internal filling could be seen. This means they could not be effectively cleaned and therefore posed a cross contamination risk.
- The seal on the work surface in the Operation Theatre was broken and visibly dirty underneath.
- Antiseptic wipes were not readily available in all areas to clean equipment between patients.
- Waste bins in consultation rooms were non-compliant with health technical memorandum (HTM) 83 as they were not fire retardant, were not enclosed and were not foot operated which are requirements under the larger waste management guidance document HTM 07-01 safe management of healthcare waste. Waste bins in consultation room were basic open basket style, some bins had a bin liner, others did not. The two bins in the staff room had between them approximately 20 discarded lumps of chewing gum in them. All the waste bins were visibly dirty.
- The large yellow clinical waste bin in the staff room was filled with cardboard boxes and not locked as per the providers own policy. Three small yellow sharps bins in the Operation Theatre were not dated or signed to verify who had assembled them. Two purple sharps bins used for the disposal of cytotoxic medicines were filled to above the recommended level, not sealed correctly and not signed or dated. We could not be assured of how long they had been in use.
- Cleaning equipment was not colour coded. Colour coded equipment helps to eliminate the spread of germs and bacteria and increases hygiene by specifying the use of different equipment for the kitchen and the washroom, for example. There were three mops in the staff room, two were not fit for purpose because they were visibly heavily soiled and stored in debris. One mop was stored in a damp bucket. This meant the mops could be harbouring bacteria. We did not see different coloured mops therefore there was a risk the same mop used to clean the toilet floor could be used to clean the operating room floor, this increased the risk of cross contamination of the operating room environment.

- We found a cleaning checklist in the operating room which contained date and a tick to indicate cleaning had taken place. There was no year identified on the checklist. We were not assured that cleaning had taken place prior to or following patients procedures. We asked the registered manager to provide cleaning schedules and were told that the operating room schedule applied to all rooms, however we saw no evidence of these during our inspection.
- The Infection Control Checklists supplied by the provider did not appear to relate to the environment and equipment at Optyco, for example there were references to a music system, equipment that was not present in the clinic, discarded anaesthetic cartridges, teeth and amalgam. We were not assured that this checklist was written for the Optyco clinic.
- There were no reported incidences of health care acquired infections in the reporting period.

Environment and equipment

- We were not assured that the design, maintenance, facilities and premises kept people safe.
- The maintenance of the building was poor and there were several areas of dis-repair. Several windows to the rear of the building (staff room, consultation room 2 and toilets) were broken. Some windows had been boarded, whilst others had not. Some had exposed broken glass, this posed a health and safety risk to people and staff using the service.
- The provider could not provide maintenance schedules for all the clinical equipment. The laser machine had only been installed in March, the provider told us a service schedule was in place for the machine to be serviced every three months however we did not see documentation to confirm this. The provider also told us the two slit lamps used for testing and pre-screening did not need servicing. A slit lampeye and requires an electrical connection, so therefore should at least be portable appliance tested annually.
- The staff room and Consultation Room 2 were extremely untidy with what appeared to be general rubbish, unwanted equipment, broken equipment, boxes of leaflets, paper towels and surplus equipment. This posed a fire risk.
- 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 in place dated May 2018 which made reference to the relevant guidance.
- The Operation Theatre (laser room) did not have an effective warning system in place such as an illuminated sign to indicate when a laser session was taking place, this was not in line with Medicines and Healthcare Products Regulatory Agency and Health and Safety (Safety Signs and Signals) Regulations 1996. The provider showed us a temporary 'stick on' light that was used during operation of the laser however, at the time of our inspection it was not working. Safety signs and lights should comply with the Health and Safety (Safety Signs and Signals) Regulations 1996. All safety signs must be properly maintained so that they are capable of performing the function for which they are intended. All safety signs should maintain their intrinsic features under power failure – either from emergency lighting or phosphorescent material – unless the hazard is itself eliminated by the power failure.
- The Operation Theatre (laser room) did not have a suitable locking system in place, normal practice would be to have a key pad access. The provider told us the door could be locked with a standard key and lock system but that it was broken. This meant that staff or patients could enter the room during a laser treatment, this posed a risk to inadvertent exposure to the laser. Medicines and Healthcare Products Regulatory Agency guidance suggest whatever mechanism is used to control access to the room while the laser is in use should be practical and realistic to the environment in which it is to be used. An unlockable room was not in line with this guidance.
- We saw that suitable protective eyewear was available in line with the laser machine manufacturers recommendations.
- Toilet facilities were poor. There was no hot water to the hand basin and the window had a large hole in it. There was exposed plaster on the ceiling.

Refractive eye surgery

- People with limited mobility were unable to easily access and enter the upstairs to the premises. There was no lift access and the clinic was on the first floor. No reasonable adjustments had been made in accordance with the Equality Act 2010.
- There was visibly exposed plaster in the corridor adjacent to the operating room.
- There were no functioning fire extinguishers on the premises apart from one foam extinguisher which had expired May 2017.
- There was no resuscitation or anaphylactic shock equipment on the premises apart from an oxygen kit. This was contrary to the providers Medicines Management Policy and Resuscitation Policy both dated May 2018. On examination the oxygen had expired December 2015. There was no compressed gas hazard sign on the door of the room where this oxygen was stored.
- We found substances regulated under the Control of Substances Hazardous to Health (COSHH) not stored correctly. For example, a bottle of bleach was stored on a shelf in the toilet, a tub of Chlor Clean tablets was stored in an unlocked cupboard in the Operation Theatre, a bottle of hand gel was stored in an unlocked cupboard in the Prescreening Room and a bottle of iodine stored on the work surface in the Operation Theatre. We did not see evidence of the correct disposal procedure for unused Mitomycin C. In the providers COSHH assessment form for Mitomycin C dated April 2018 section 13 disposal considerations (waste disposal method) states dispose in accordance with local, state, and federal regulations.
- All electrical equipment associated with the treatment of patients in all the rooms we inspected had not been portable appliance tested since March 2013. We asked the provider for a copy of the maintenance or service schedule for the Slit Lamps, and we were told this equipment did not require servicing. Slit lamps deliver a high intensity light source which shines a thin sheet of light into the eye to facilitate examination of the inner eye. We were not assured that equipment was therefore safe for use.

Assessing and responding to patient risk

- People were assessed in line with recommended guidance however they did not have their safety monitored throughout refractive eye surgery.
- We did not see a policy outlining agreed referral criteria detailing suitability of patients for refractive eye surgery. However, in all of the ten sets of patient records we reviewed patients had completed health questionnaires including past medical history and allergies.
- There was an adapted version of the World Health Organisation surgical safety checklist in each of the ten sets of patient records we reviewed but none of the ten had been completed fully or signed and dated.
- The provider told us that all patients were seen back at the clinic within 24 hours of their refractive eye procedure and that a 24-hour help line was in place to support patients in the out of hours period.
- There was no formal transfer protocol in place 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. There was a risk to patients as this had not be formally agreed.

Nurse staffing

- The provider did not employ any nursing staff. The provider told us that the consultant performing the refractive eye surgery was accompanied by a scrub nurse on the day of surgery. However, when we asked the provider if a scrub nurse was present at the refractive eye surgery session which took place in May 2018 we were told that only himself and the consultant were present for this session. Eight patients were treated at the RES session in May 2018. Therefore, we could not be assured that staff with the right skills were present during the May 2018 session.

Medical staffing

- The ophthalmology consultant worked under practising privileges and carried out one refractive eye surgery session per month at Optyco. We saw that the consultant was on the General Medical Council, specialist register for Ophthalmology. His revalidation was not due until April 2020.

- The provider undertook the role of Laser Protection Supervisor and had access to a Laser Protection Advisor for further advice and support if needed.
- Patients requiring advice following surgery could contact the clinic or the consultant by telephone.
- In the event of patients requiring emergency medical care the provider called the 999-emergency service and patients were transferred to the local acute hospital.

Records

- 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.
- The provider had an Information Security Policy dated May 2018 in place which referred to compliance with the general data protection regulations, however, patient records were not stored securely. We found an unlocked four drawer filing cabinet in the unlocked Consultation Room 2 which were full of patient records, these included patient identifiable information such as pre-operative assessment forms, health questionnaires, surgery details and consent forms. In addition, in the same room there was a box containing two lever arch files containing invoices with patient identifiable information on them. Furthermore, on 13 June 2018 we found an Operation Theatre log book left in an unsecure room containing patient identifiable information.
- Information was not routinely shared with the patients GP and the provider did not have an option for this to happen even if the patient was happy for their information to be shared.
- We did not see evidence of a laser use log. A log of each time the laser is used should be kept including after each patient during a refractive eye surgery session.

Medicines

- Although a Medicines Management Policy dated May 2018 was in place, the provider did not ensure the proper and safe use of medicines in line with this policy. Medicines were not procured appropriately or stored safely.
- For example, in the fridge in the staff room there were two boxes of chloramphenicol eye drops and one box of proxymetacaine eye drops. The fridge was not a designated drug storage fridge and we saw food items were also stored in this fridge. The temperature of the fridge was not monitored, therefore there was no guarantee the eye drops had been stored in line with manufacture guidance, and may not be suitable for use.
- In Consultation Room 1 we found a box of tropicamide minims on the work surface, one unpackaged minim of tropicamide, one unpackaged minim of fluorescein and a bottle of contact lens solution all of which had expired in February 2018.
- We found a box of co-codamol which had expired in November 2017. This was incorrectly stored in an unlocked, non-designated medicine cupboard in the pre-screening room. This medicine should not have been stored in this cupboard.
- We found a bottle of aspirin on the work surface in the Pre–op room. This should have been stored in a locked designated medicines cupboard in line with national guidance and the providers policy.
- We inspected the drug cupboard in the Operation Theatre. The cupboard was lockable however, the key was in the lock and the lock was broken and therefore could not be locked and was therefore easily accessible. We examined the contents of the cupboard and found:
- A tube of sterile eye gel which was open but had not been dated with an expiry date, so we could not be assured it was still sterile or fit for use.
- A box of seven single use ampoules of ethanol. One ampoule had been used and placed back in the box instead of being disposed of.
- A box of fourteen amoxycillin 250mg capsules which expired in July 2015,
- A box of seven voltoral eye drops which expired in October 2017.

Refractive eye surgery

- The provider did not have microbiology protocols in place 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.
- In the ten sets of patient records we reviewed we saw patients had been asked about allergies and these had been recorded appropriately.
- The consultant did treat some patients with Mitomycin C, we saw a COSHH risk assessment for the management of Mitomycin C but the risk assessment was not clear about the disposal of unused and unwanted Mitomycin C. Mitomycin C is a cytotoxic drug which can be harmful to health. The consent process included information about the use of Mytomycin 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 in place for reporting incidents we saw the report forms and policy, however in view of the number of unsafe areas we discovered we were not convinced the incident reporting procedure was understood or used by staff. For example the two unplanned re treatments had not been recorded as incidents.
- We saw one partially completed incident report form recording a lack of power to the service for approximately four hours. However, the date had not been completed fully so we could not be sure this was relevant to the reporting period.
- The provider received safety alerts through the College of Optometrists bulletins.

Major Incident Awareness

- The provider had policies in place for business continuity in the event of water, power or IT failure and a Fire Drill Policy. We saw evidence that a fire drill practice had taken place in the last 12 months.
- An uninterrupted power supply was in place which meant that if there was a power failure during refractive eye surgery the procedure could continue without disruption.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- We did not see any reference to the National Institute for Care Excellence clinical guidelines or the Royal College of Ophthalmology professional standards for refractive surgery April 2017 in the policies and procedures we reviewed although an adapted version of the World Health Organisation surgical safety checklist was used during refractive eye surgery procedures.
- In the ten sets of patient records we reviewed we saw comprehensive pre- assessment health questionnaires completed, including questions about the patients mental health, and pre-screening vision tests.
- The provider was aware of the Mental Capacity Act and had attended training in November 2017.
- Patients were given clear instructions about aftercare following their refractive eye surgery including what to do if they had any concerns including out of hours contact telephone numbers.

Nutrition and hydration

- Hot and cold drinks and biscuits were available in the waiting area.

Pain relief

- Patients were given aftercare advice sheets which described the medication that could be taken to relieve pain.
- We were not assured that pain was assessed and monitored during or after surgery as we saw no pain management documentation or tools in use.

- The provider told us he would purchase pain relieving medication from a local chemist if it was required. This was not satisfactory as anticipatory pain reliefand post operative pain relief should be available at the time of treatment to be most effective.

Patient outcomes

- We were not assured that information about the outcomes of peoples care and treatment was being routinely collected and monitored and therefore not contributing to quality improvement initiatives.
- Data was being routinely collected from the laser machine to measure patient outcomes. However, at the time of the inspection the new laser machine had only been used twice and there was not enough available data to produce meaningful results. The provider told us patient outcomes would be available for the refractive eye surgery after 12 months. We were shown a previous outcome report produced by the laser manufacturer which was mostly positive but this was not relevant to the current laser machine or the reporting period. Following our inspection, the provider submitted an audit of the visual acuity of ten patients before and after surgery which showed that the target had been achieved in all ten cases.
- Some audit had taken place in the past twelve months. We saw the treatment records audit report dated May 2018 which identified action to feedback to staff at the next staff meeting.
- The provider reported two incidences of unplanned re treatments in the past twelve months. The treatments were to enhance the outcome of the refractive eye surgery. There were no complications reported.

Competent staff

- The provider was an optometrist and the Laser Safety Supervisor. We saw evidence that they were a member of the Association of Optometrists. The provider had attended training on the new laser machine in March 2018. The provider was the only authorised user of the laser machine. We were not assured that the provider had attended core of knowledge training in the past three years. The 'Core of Knowledge' is a recommended course as per theMHRA guidance document: Lasers, intense light source systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices. September 2015.
- One consultant ophthalmology surgeon worked at the clinic under practising privileges. We saw a copy of his most recent appraisal dated September 2017 and that his revalidation was due in April 2020. The consultant held the College of Ophthalmology certificate in laser refractive eye surgery. The provider informed us that the consultant had attended training to safely handle and administer Mitomycin C although we did not see documentary evidence confirming this.

Multidisciplinary working

- We were unable to assess the effectiveness of multidisciplinary team working due to the low staff numbers and the fact that there was no surgery taking place on the day of our inspection.
- There was not an option for the provider to share treatment and discharge information with other health professionals such as the patients GP.

Seven-day services

- Although the optician service of the provider was open seven days a week the refractive eye surgery service only operated monthly. Patients were given out of hours emergency contact numbers in their aftercare information packs.
- There were no formal protocols in place for the transfer of patients to acute hospitals in the event they needed a higher level of care. The provider told us they would call emergency services if necessary but they had never needed to do this.

Health promotion

- A good range of health promotion leaflets were available in the waiting area including information on stroke, cancer and change 4 lives.

Consent and Mental Capacity Act

- We reviewed patient consent documentation. The consent form was detailed and described the risks and

benefits of the surgery clearly for the patient. In the ten sets of patient records we reviewed we saw that consent forms had been fully completed, signed and dated.

- We saw that in four of the ten sets of patient records we reviewed the cooling off period had been less than one week. This was not in line with The royal College of Surgeons guidance which recommendspatients having cosmetic procedures including refractive eye surgery are given at least one week to consider their options from the consent and information procedure.
- Consent documentation was reviewed as part of the treatment record audit. No issues had been identified with the consent process in the last audit.

Are refractive eye surgery services caring?

Compassionate care

- We were unable to assess how staff interacted with patients as there were no patient activity on the day of our inspection. In the 17, Care Quality Commission, 'Tell us about your care' cards patients described staff as kind and helpful, warm and welcoming, thoughtful and caring.

Emotional support

- We were unable to fully assess the emotional support offered to patients by the service as there was no patient activity on the day of our inspection. However, we saw that pre- assessment health questionnaire asked questions about mental health of the patient and one patient fed back that staff at the clinic made them feel comfortable and at ease throughout their care.

Understanding and involvement of patients and those close to them

- Patients were given an information pack prior to consenting for surgery which detailed the risks and benefits of the surgery and potential costs. In addition, we saw in the patient records we reviewed where a detailed description of the treatment and aftercare was given and signed by the patient throughout the document to say they understood the information.
- The provider told us that two days before the date of surgery the consultant rang the patient to check if they had any last-minute concerns or questions.
- We were not confident that patients could be assured that information about them was treated confidentially due to the insecure way that we found patient records were stored.

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

Service delivery to meet the needs of local people

- In the information brochure we saw that several treatment options were available to patients and each option was described in detail. The service offered flexible appointment slots to suit patients and advertised 'lifetime aftercare'.
- We found that facilities and premises were not appropriate for the service being delivered. In addition to concerns already raised in this report:
- The maintenance of the building was poor and there were several areas of dis-repair. Several windows to the rear of the building (staff room, consultation room 2 and toilets) were broken. Some windows had been boarded, whilst others had not. Some had exposed broken glass, this posed a health and safety risk to people and staff using the service.
- Toilet facilities were poor. There was no hot water to the hand basin and the window had a large hole in it. There was exposed plaster on the ceiling.
- There was exposed plaster in the corridor adjacent to the operating room.

Meeting people's individual needs

- The provider told us the service did not have any formal translation services in place but told us he spoke several different languages. Patients whose first language was not English were often accompanied by friends or relatives who could translate for them if necessary.This was not in line with best practice guidance.

Refractive eye surgery

- People with limited mobility were unable to easily access the first floor of the premises. There was no lift access and the refractive eye surgery clinic was on the first floor. No reasonable adjustments had been made in accordance with the Equality Act 2010.
- We saw that large print information leaflets were available for patients who had impaired vision.

Access and flow

- Generally, patients could access care and treatment in a timely way. New patient enquiries were first sent an information pack which was followed up by a telephone call a few days later to answer any questions and book a consultation if the patient wished to proceed. Patients told us that appointments were flexible and convenient in the 17 CQC comments cards we received.
- At the time of the inspection the provider reported nine patients on the waiting list and no cancellations.
- The date of surgery was less flexible as this only took place on one day per month.
- Patients returned to the clinic the day after surgery to be reviewed by the optometrist.

Learning from complaints and concerns

- Information about how to make a complaint was included in the information pack given to all prospective patients. This included the timescale in which a patient should expect a complaint to be dealt with and details of the Patients Association for patients who did not feel their complaint had been dealt with fairly.
- The provider had a complaints policy in place dated May 2018. The provider was responsible for investigating complaints. There were no complaints in the reporting period.

Are refractive eye surgery services well-led?

Leadership

- The provider was visible and approachable and we observed good interactions with the employee. However, we were not assured that the provider had the skills, knowledge or integrity to deliver high quality sustainable care. In our conversations with the provider they did not appear to understand the importance of many of the concerns we raised with them as a result of the inspection.

Vision and strategy

- The provider did not have a clear vision or set of values and we did not see evidence of a realistic strategy for delivering good quality care.

Culture

- We were unable to assess elements of this section as there were no staff to interview on the day of our inspection. However, we did see that human resource policies did include a whistle blowing policy and a harassment and bullying policy which indicated there was some understanding of openness and honesty.
- We saw that pricing was openly available to patients in the information pack with details of the terms and conditions.
- The provider had equality and duty of candour policies in place dated May 2018 but we did not see evidence that the provider had attended duty of candour training.

Governance

- The governance processes implemented by the provider were not robust, monitored or implemented. We saw in the policy and procedure folder a range of appropriate governance documents however it was clear the provider was not abiding by them or had not implemented them. For example, the quality management policy described an annual patient survey, regular staff meetings to discuss treatment techniques and outcomes, annual review of training logs, appraisal documentation and annual maintenance of equipment document. We did not see any documented evidence that these had taken place.
- There were no individual personal staff files for persons working at the clinic. This is not in line with Human Resource best practice and meant that we could not effectively inspect staff recruitment processes.

Refractive eye surgery

- The provider had a practicing privileges policy and register and we saw that the appropriate checks had been made for the one consultant practicing at the clinic and evidence of the consultant's indemnity insurance.
- The provider used third parties for the disposal of clinical waste and we saw the service level agreement in place for this but it did not mention the disposal of the cytotoxic waste bins.

Managing risks, issues and performance

- The provider did not identify, record or manage risks and did not maintain a risk register for the service. For example, there was no risk assessment for the fact there was no hot water, broken windows and no fire extinguishers.
- Clinical and internal audits were taking place and we saw evidence of visual acuity and records audits. No actions were identified in either of the audits.
- The laser machine had an emergency back up, uninterrupted power supply which meant that if power was lost there was enough emergency power to complete any laser session taking place.

Managing information

- We could not be assured that information was being effectively processed, challenged and acted on. For example, no incident reports had been completed for the broken windows, out of date drugs, out of date sterile supplies or the broken lock on the drug cupboard. Therefore, no incidents were investigated or plans put in place to rectify or learn from the incidents.
- GP's were not sent discharge information for patients who had refractive eye surgery and had consented to their details being shared with their doctor. So, they would be unaware of any contact details in the event that a patient presented to them with an eye problem.
- A records and information policy was in place but the provider was not compliant with this policy as records were not stored securely.

Engagement

- Patients were sent a satisfaction survey one month after their refractive eye surgery. The provider told us that the way aftercare was explained had been revised following patient feedback.

Learning, continuous improvement and innovation

- Systems and processes were not in place for learning continuous improvement and innovation

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must put systems in place to ensure that medicines and medicines related stationary are ordered, transported, stored and disposed of safely and securely including medical gases.
- The provider must ensure that products subject to the Control of Substances Hazardous to Health regulations are stored securely and that risk assessments have been completed for all products including uses and handling.
- The provider must ensure the Optyco Limited Records and Information Management Policy is fully implemented and that it follows the principles of the NHS Record Management Code of Practice.
- The provider must ensure that all equipment used in the delivery of refractive eye surgery services is fit for use, maintained and serviced in line with manufacturers and professional guidance.
- The provider must ensure that premises and equipment are cleaned in line with relevant standards and guidelines to prevent and protect patients from healthcare associated infection.
- The provider must put in place systems for delivering hot water to all sinks in all clinical areas to ensure that staff and patients can perform effective hand hygiene procedures.
- The provider must ensure the premises and equipment are fit for purpose and follow Health and Safety Executive guidance, RCOphth professional standards for refractive surgery and MHRA guidance on the safe use of lasers, intense light source systems and LED's in medical, surgical, dental and aesthetic practices.
- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to safeguarding, incident recording and reporting, and the governance of the service.

Action the provider SHOULD take to improve

- The provider should ensure that staff understand the importance of the surgical safety check list and that it is completed in full for all patients undergoing refractive eye surgery.
- The provider should attend the core of knowledge training recommended by the MHRA to ensure Laser Safety Supervisors have the relevant competencies and knowledge for the role.
- The provider should make all reasonable attempt to improve access to refractive eye surgery services for people with reduced mobility in accordance with the Equality Act 2010.
- The provider should implement systems for sharing patient information so patients have the option for refractive eye surgery information to be shared with their GP.

On the basis of this inspection, the Chief Inspector of Hospitals has recommended that the providers registration be suspended for a period of three months.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **(a) The provider must assess the risks to the health and safety of service users of receiving the care or treatment** **(b) The provider must do all that is reasonably practicable to mitigate any such risks.** **(c) The provider must ensure that persons providing care or treatment to service users have the qualifications,competence, skills and experience to do so safely;** **(d) The provider must ensure that the premises used by the service provider are safe to use for their intended** **purpose and are used in a safe way;** **(e) The provider must ensure that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way;** **(f) where equipment or medicines are supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and to meet their needs;** **(g) the proper and safe management of medicines;** **(h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated;**

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment

How the regulations were not being met:

The Health and Safety Policy was dated May 2013, therefore out of date and not reviewed in line with Health and Safety guidance.

There were no functioning fire extinguishers throughout the building. There was one carbon dioxide extinguisher in the staff room expired May 2017.

There was no hot water system and therefore no hot water to the sinks in the Operation Theatre, Staff Room, Toilet and Consultation Room 1. We confirmed this at our second visit by letting one of the hot taps run for 7 minutes and letting the electric water heater in the toilet area run for 4 minutes. There were no sinks in the pre-testing room or the post op room.

There was no evidence of water flushing or Legionella risk assessment.

The staff room and Consultation Room 2 were extremely untidy with what appeared to be general rubbish, unwanted equipment, broken equipment, boxes of leaflets, paper towels and surplus equipment presenting both IPC and fire risk.

We found substances regulated under the Control of Substances Hazardous to Health not stored correctly. For example, a bottle of bleach was stored on a shelf in the toilet, a tub of Chlor Clean tablets was stored in an unlocked cupboard in the Operation Room, a bottle of hand gel in an unlocked cupboard in the Prescreening Room. A bottle of iodine on the work surface in the Operation Room. We did not see evidence of the correct disposal procedure for unused Mitomycin C.

This section is primarily information for the provider

Requirement notices

We found an unpackaged scalpel blade on a shelf in the fridge in the Staff Room.

The Operation Room (laser room) did not have an effective warning system in place such as an illuminated sign to indicate when a laser session was taking place. You showed us a temporary 'stick on' light that was used however, at the time of our inspection it was not working.

The Operation Room (laser room) did not have a suitable locking system in place. You told us the door could be locked with a standard key and lock system but that it was broken. This means that staff or patients could enter the room during a laser treatment.

There were several smashed windows to the back of the building, toilet area, staff room, and consultation room 2.

There was no evidence of Fire Risk Assessment or Legionella Risk Assessment.

The clinic used an adapted version of the WHO surgical safety checklist. In the ten sets of patient notes we reviewed the check list had not been fully completed or signed on each occasion.

The clinical waste bin in the Staff Room was filled with cardboard boxes and not locked as per the providers policy. Three small yellow sharps bins in the operation room were not dated. Two purple sharps bins used for the disposal of cytotoxic medicines were filled to above the recommended level, not sealed correctly and not signed or dated. The provider told us that there was an arrangement in place with a private company to remove full sharps bins once a year. However, because there was no date on any of the sharps bins we could not be assured of how long they had been in use.

This section is primarily information for the provider

Requirement notices

There was no evidence of any mitigating actions

No evidence that provider had the Core of Knowledge training required to supervise the operation of laser machinery. AA is the Laser Safety Supervisor.

No evidence that the provider had attended appropriate training for the safe handling and management of Mitomycin C.

Poor lighting throughout. Smashed windows. No hot water. Operation Theatre not suitably ventilated, 4 vents taped up on one wall, one air conditioning unit. We were told there was an air exchange unit but we could not be assured of this. Fire exit was not alarmed.

There was no equipment for use in the case of a medical emergency. There was an oxygen kit but the oxygen cylinder had expired December 2015.

We inspected the sterile equipment in the cupboards in the operation room and found that storage was disorganised and a large quantity out of date. For example: two pairs of sterile gloves expired October 2016, one sterile drape expired March 2017, one hand dressing towel expired June 2016, Lieberman Speculum V shaped expired August 2016, box of six Stretton Speculums – no expiry date, box of ten Alcohol Wells expired May 2017, box of seven Lasek Flap Spatulas expired April 2018, box of seven mixed instruments expired December 2017, box of sterile cotton wool balls expired September 2017, three straight short handle tweezers expired November 2016, two single use skin marker pens unpackaged, two skin marker pens expired April 2017, box of sterile medical gloves expired October 2016, two refractive packs expired September 2014, six

Requirement notices

surgical gowns expired November 2016, box of antiseptic wipes expired 2014, box of 10ml sterile syringes expired September 2017, box of unpackaged one use plus sets, ten one use plus sets expired August 2017.

Some surgical implements were packaged in self-sealing sterile pouches. One of the eight pouches we examined was not sterile as indicated by the pink indicator tab. None of the pouches had an expiry date on them. There is a risk that a member of staff could use these instruments during a surgical procedure. The provider told us he no longer sterilised his own instruments.

Some patient seating was unsuitable and worn. There were fabric covered chairs in clinical areas and the examination chair in Consultation Room 1 was so worn the internal filling could be seen. This means they could not be cleaned thoroughly and therefore posed a cross contamination risk.

Electrical equipment in all the rooms we inspected had not been portable appliance tested since March 2013.

The Slit Lamps in consultation room 1 and the Pre – op room had not been serviced and you could not supply a maintenance or service schedule for them.

We were not assured there was enough equipment or medicines to ensure the safety of service users due to the fact of large quantities being out of date. Co codamol expired November 2017, seven bottles of voltarol eye drops expired October 2017and voltarol eye drops were out of date which there was only aspirin available as an analgesic.

We found medicines were not managed in line with recommended guidelines or the providers own policy. For example, in the fridge in the staff room there was two boxes of chloamphenicol eye drops and one box of proxymetacaine eye drops. The fridge was not a

Requirement notices

designated drug storage fridge and the temperature of the fridge was not monitored. In Consultation Room 1 we found a box of tropicamide minims on the work surface, one unpackaged minim of tropicamide, one unpackaged minim of fluorescein and a bottle of contact lens solution which had expired February 2018. We found a box of co codamol in an unlocked cupboard in the Pre – screening room which had expired November 2017. We found a bottle of aspirin on the work surface in the Pre – op Room. We inspected the drug cupboard in the Operation Room. The cupboard was lockable however, the key was in the lock and the lock was broken. We examined the contents of the cupboard and found: in a box of seven single use ampoules of ethanol on ampoule had been used and paced back in the box instead of being disposed of, a tube of sterile eye gel which was open but had no expiry date on it so could not be assured it was still sterile, a box of fourteen amoxycillin 250mg capsules expired July 2015, a box of seven voltoral eye drops expired October 2017.

All the rooms we inspected were visibly dirty. Surfaces were dusty and some equipment had a layer of thick grey dust which we demonstrated to you yesterday. Surfaces and equipment in the operation theatre were dusty and the stainless-steel trollies in the theatre had old surgical tape attached to the handles.

Theatre scrubs hanging in the staff room were dirty including theatre shoes which had visible stains on them.

Some surgical implements were packaged in self-sealing sterile pouches. One of the eight pouches we examined was not sterile as indicated by the pink indicator tab. None of the pouches had an expiry date on them. There is a risk that a member of staff could use these instruments during a surgical procedure.

Some patient seating was unsuitable and worn. There were fabric covered chairs in clinical areas and the

This section is primarily information for the provider

Requirement notices

examination chair in Consultation Room 1 was so worn the internal filling could be seen. This means they could not be cleaned thoroughly and therefore posed a cross contamination risk.

The seal on the work surface in the operation room was broken and visibly dirty underneath.

Only one of the rooms had antiseptic wipes to clean equipment in between patient use.

Waste bins were basic open basket style. Some bins had a bin liner, others did not. The two bins in the staff room had between them approximately 20 discarded lumps of chewing gum in them. All the waste bins were dirty.

Cleaning equipment was not colour coded. There were three mops in the staff room, two were not fit for purpose and one was stored in a damp bucket. This meant the mops could be harboring bacteria and the same mop used to clean the toilet floor was being used to clean the operation theatre floor.

We did not see any evidence of detailed cleaning schedules.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: We found that patient records were not stored securely. We found an unlocked four drawer filing cabinet in the

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Requirement notices

unlocked Consultation Room 2 full of patient records. In addition, in the same room there was a box containing two lever arch files full of patient identifiable information.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment How the regulation was not being met: The employed receptionist who helped escort and attend to patients on the day of surgery had not attended level one or level two safeguarding children training.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met: We were not assured that there were sufficient suitably qualified staff on duty for the refractive eye surgery RES sessions. The provider told us the at the last session in May 2018 there were only two staff on duty the consultant and himself. Eight patients attended this session.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed How the regulation was not being met: On two occasions the provider was untruthful. On 11th June 2018 he told us that his next RES session was on the

This section is primarily information for the provider

Requirement notices

22nd July 2018. He repeated this information to Simon Brown on 12th June 2018. We saw evidence that the next planned RES session was on 22nd June 2018. When we challenged the provider about this he said that session (22nd July 2018) would not go ahead.

On 11th June 2018 the provider told us that he had not been carrying out RES sessions prior to the new machine being installed in March, however we saw evidence of a RES session having taken place in January 2018.

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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment A notice was served on 14 June 2018 under Section 31 of the Health and Social Care Act 2008 to suspend the provider from undertaking regulated activities until 14 September 2018. Before the suspension can be lifted, improvements must be made to the service to reach the standards required of the Health and Social Care Act 2008 and associated regulations. We have taken this urgent action as we believe a person will, or may be exposed to the risk of harm if we do not do so.