Optimax Laser Eye Clinics - Milton Keynes

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

Ratings

Overall rating for this location

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Overall summary

Optimax Laser Eye Clinics – Milton Keynes is operated by Optimax Clinics Limited. The clinic opened in July 2009. Facilities include one treatment room where laser eye surgery is performed, a topography room, two consultation rooms, a counselling room, a preparation room, a recovery room and two reception areas. The clinic is set over two floors, with disabled access.

The service provides refractive eye surgery to patients aged over 18.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 3 October 2017, along with an unannounced visit to the hospital on 12 October 2017.

Summary of findings

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

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

Services we do not rate

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

We found the following areas of good practice:

- Despite the lack of an incident reporting policy, there was a strong culture of reporting incidents.
- The environment was visibly clean.
- All staff had completed their mandatory training.
- The theatre environment met guidance set by the Royal College of Ophthalmologists.
- Patient retreatment rates were within acceptable limits.
- Pain relief was available to patients to take home following surgery.
- The surgeon who performed the laser surgery held the Certificate in Laser Refractive Surgery.
- There were appropriate consent processes.
- Staff provided compassionate care to patients.
- All patient feedback we received was very positive.

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

- There was no incident reporting policy.
- We found some pieces of equipment which were past their expiry or servicing date.
- The service did not use the World Health Organisation's 'Five Steps to Safer Surgery' checklist. The patient verification checklist used was not robust or embedded in practice.
- There was no specialist spillage kit available to clean any spillages of cytotoxic medicines.
- Non-clinical staff had access to medicines.
- Not all staff who worked with cytotoxic drugs had demonstrated competence in this area.
- Patient outcomes were not benchmarked against other services.
- All information leaflets were only available in English.
- Interpretation services, whilst available, had to be paid for by the patient.
- There was no vision or strategy for the service.
- The clinic manager had limited autonomy to make improvements to the service.
- Not all risks identified on inspection were on the service's risk register.
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- Emotional support was provided to patients, where needed.
- Patients had continuity of care throughout their procedure and aftercare.
- The facilities and premises were appropriate for the services that were being delivered.
- Appointments were available on weekends, if necessary.
- Complaints were managed in line with the service's policy.
- There was a clear leadership structure.
- All required staff had appropriate indemnity insurance.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with two requirement notices. Details are at the end of the report.

Summary of findings

Deputy Chief Inspector of Hospitals (Central)

Heidi Smoult

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Refractive eye surgery		We regulate this service but we do not currently have a legal duty to rate it. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

Summary of findings

Contents

Location name here

Services we looked at
Refractive eye surgery

Summary of this inspection

Background to Optimax Laser Eye Clinics - Milton Keynes

Optimax Laser Eye Clinics – Milton Keynes is operated by Optimax Clinics Limited. The service provides refractive eye surgery and opened in 2009. It is a private clinic in Milton Keynes, Buckinghamshire. The service primarily serves the communities of the Home Counties. It also accepts patient referrals from outside this area.

The service is open Monday to Saturday, from 8am to 6pm.

At the time of the inspection, a manager was registered with the CQC in April 2017.

We inspected this location previously in 2011, under the previous methodology. At this inspection concerns were raised regarding discharging medications and incomplete pre-recruitment processes.

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 Bernadette Hanney, Head of Hospital Inspection.

Information about Optimax Laser Eye Clinics - Milton Keynes

The service has one treatment room and is registered to provide the following regulated activities:

- Treatment of disease, disorder or injury
- Surgical procedures
- Diagnostic and screening procedures

During the inspection, we visited all areas of the clinic. We spoke with three staff including the registered manager, an optometrist and a patient advisor. We spoke with two patients who attended appointments during our inspection. We also received four 'tell us about your care' comment cards, which patients had completed prior to our inspection. During our inspection, we reviewed six sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. The service had been inspected three times, in April 2011, October 2012 and January 2014.

Activity (July 2016 to June 2017)

- In the reporting period July 2016 to June 2017, there were 136 episodes of care recorded at the service.
- All of these were privately funded.
- Of the 136 procedures, six of these had been on patients aged 21 years old. No procedures had been performed on people aged under 21.

One ophthalmologist and one optometrist worked at the service under practising privileges. Two technicians were directly employed.

There was one vacancy for a registered nurse and one vacancy for a patient advisor.

Track record on safety (July 2016 to June 2017)

- No never events or serious injuries reported
- 13 clinical incidents with no harm reported
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA) or Clostridium difficile (c.diff).

Services provided at the clinic under service level agreement:

- Clinical and non-clinical waste removal

Summary of this inspection

- Cytotoxic drugs service
- Interpreting services
- Laser protection services
- Five formal complaints

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

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

- There was no incident reporting policy.
- We found some pieces of equipment which were past their expiry or servicing date.
- The service did not use the World Health Organisation's 'Five Steps to Safer Surgery' checklist. The patient verification checklist used was not robust or embedded in practice.
- There was no specialist spillage kit available to clean any spillages of cytotoxic medicines.
- Non-clinical staff had access to medicines.

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

- There was a strong culture of reporting incidents.
- The environment was visibly clean.
- All staff had completed their mandatory training.
- The theatre environment met guidance set by the Royal College of Ophthalmologists.

Are services effective?

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

- Patient outcomes were not benchmarked against other services.

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

- Patient outcomes were within acceptable limits.
- Pain relief was available to patients to take home, following surgery.
- The surgeon who performed the laser surgery held the Certificate in Laser Refractive Surgery.
- Consent procedures met national guidance.

Are services caring?

We found the following areas of good practice:

- Staff provided compassionate care to patients.
- All patient feedback we received was very positive.
- Emotional support was provided to patients, where needed.

Summary of this inspection

Are services responsive?

We found the following areas of good practice:

- Patients had continuity of care throughout their procedure and aftercare.
- The facilities and premises were appropriate for the services that were being delivered.
- Appointments were available on weekends, if necessary.
- Complaints were managed in line with the service's policy.

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

- All information leaflets were only available in English.
- Interpretation services, whilst available, had to be paid for by the patient.

Are services well-led?

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

- There was no vision or strategy for the service.
- The clinic manager had limited autonomy to make improvements to the service.
- Not all risks identified on inspection were on the service's risk register.

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

- There was a clear leadership structure.
- All required staff had appropriate indemnity insurance.
- Staff were positive about working at the clinic.

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
Overall	N/A	N/A	N/A	N/A	N/A	N/A

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery safe?

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.

Incidents and safety monitoring

- Staff understood their responsibilities to raise concerns, to record safety incidents and near misses, and to report them internally and externally. Staff were able to provide evidence of incidents that had been reported and the types of concerns that were reportable.
- The service reported 13 incidents and no serious incidents. These related to the lasers malfunctioning and environmental issues, such as lights not working. None of these were patient safety incidents. There was an incident reporting template, however, there was no incident reporting policy to underpin this process. As such, there was no clear guidance on who would investigate incidents, the process to be followed, or the deadlines for investigations to occur.
- The service reported they had been no never events in the 12 months prior to our inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. Each never event type has the potential to cause serious patient harm or death.
- We reviewed the incident reports and found it was unclear what level of communication was given to patients when something went wrong. None of the incidents led to patients having moderate harm and therefore the duty of candour was not invoked.

Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations is the regulation that introduced the statutory duty of candour. For independent providers it came into effect in April 2015. Staff we spoke with were unaware of the meaning of duty of candour and were unable to explain this to us, despite telling us they had received training in this area. This meant we were not assured that the duty of candour would be implemented if an incident occurred.

- The registered manager told us they had received training in duty of candour. However, this was not reflected in the training matrix which was supplied to us and they were unable to explain what this meant. Whenever an incident occurs, patients should be told about it, given an apology and informed of any actions taken as a result. There were two incidents where the lasers malfunctioned during surgery, although this did not lead to any patient harm. There was limited evidence of what discussions had occurred with the patients from the incident files we reviewed.
- Staff told us that although they reported incidents, they did not get feedback on what happened afterwards. The registered manager was unable to provide any examples of changes to practice as a result of incidents. We were told that the registered manager dealt with low level incidents, such as lights not working, but any clinical or patient safety incidents would be dealt with by the head office. As such, we were not assured learning from these was shared from the head office to the clinic staff.
- Complication rates were monitored for all surgery. In the reporting period of July 2016 to June 2017 there had been nine complications following refractive eye surgery. This equated to less than 7% of all surgery.These included dry eyes, night glare and over or under correction. We did not see any evidence of lessons learnt from these.

- Infection rates for all laser eye surgery were monitored and the service had no reported infections in the reporting period of July 2016 to June 2017.
- Clinic managers were kept updated of any new relevant safety alerts through their regular communication with the head office's compliance manager. The surgeon and optometrist had similar meetings with their clinical supervisors, who were employed by Optimax, which ensured any changes to practice were shared. We saw minutes of these.

Mandatory training

- Staff received mandatory training in the safety systems, processes and practices. The two staff members directly employed by the service; the clinic manager and the patient advisor, had completed their mandatory training. We saw that both staff members had completed all modules of mandatory training, including data protection, equality and diversity, health and safety, manual handling and basic life support.
- For staff employed on practising privileges, such as the surgeon and optometrist, we saw that they also received yearly mandatory training, which was up to date in their employment files.

- All staff working within the clinic had basic life support training. This was refreshed annually.

Safeguarding

- Staff had an awareness of their safeguarding responsibilities in relation to both children and adults. However, staff were unaware who the safeguarding lead was, or whether there was a corporate lead.
- The provider told us in the provider information return that 100% of staff had safeguarding level 2 training and that 50% of staff had safeguarding level 3 training. When we reviewed files on inspection we saw that all staff had safeguarding adults and children training certificates, however, these did not have levels specified. Staff we spoke with were unable to tell us what level of training they had completed.
- There was a policy called 'child protection policy'. This aimed to raise awareness of the need for children to be protected and the steps to take if staff suspected a visiting child was being abused. It outlined the requirement for staff to undergo Disclosure and Barring Service (DBS) checks. However, it stated that if staff believed a child may be at risk of harm, that it should be raised with the child's parent, which could potentially place the child at more risk. It went on to state that staff should refer these matters to their line manager, before referring concerns onto the children's social care department. However, there were no contact details for this department, despite there being a section in the policy for these details to be provided.
- There was a policy called 'vulnerable adult protection policy'. Although this did not include any contact details of who to contact if staff had safeguarding concerns about a vulnerable adult, we saw a contact list on display in the registered manager's office. This also contained details of the local council safeguarding board.

Cleanliness, infection control and hygiene

- Standards of cleanliness and hygiene were generally maintained. All areas of the clinic were visibly clean and tidy. There were daily and weekly cleaning schedules, which were completed by external contractors. We reviewed these and saw they were completed and checked regularly. However, we saw that blood pressure cuffs were not cleaned in between patient use. We asked staff about this and they informed us that the cuffs were never cleaned. This meant that there was a risk of infections spreading.
- There was an infection prevention and control policy. This stated the importance of hand hygiene, the use of personal protective equipment, such as gloves and single use aprons, and dealing with spillages. The policy did not reference any NICE guidance or the World Health Organisation's five moments of hand hygiene. We saw suitable supplies of gloves and aprons within the laser room. However, we found four pairs of medical gloves that had passed their expiry date. The CQC inspector removed these from their location and gave them to the clinic manager to be destroyed.
- We observed staff washing their hands before and after patient contact. This was in line with NICE

guidance QS61 regarding hand washing. Hand hygiene sinks were available in clinical areas. Hand hygiene audits had started in September 2017, however, these were not observational audits.

- There had been no cases of any healthcare acquired infections from July 2016 to June 2017. This included infections such as MRSA and clostridium difficile. These are infections that have the capability of causing harm to patients.
- Patients were not tested for MRSA.
- There was a cleaning policy for treatment rooms. This was in date and version controlled. This stated that a cleaning regime had to be completed every day at the beginning and end of a treatment day. This included ensuring weekly water tests had been completed, surfaces and equipment were clean and the floor mopped. However, the policy stated that if the clinic was short staffed the daily cleaning did not have to be completed. Staff assured us that rooms would always be cleaned prior to patients being treated. On our review of the cleaning checklist, we did not see any occasions where the cleaning had not been completed.
- There was no spillage kit specifically for dealing with cytotoxic spillages. We raised this as a concern, and when we returned on our unannounced inspection, we saw that one had been ordered.
- We saw a copy of the 2017 yearly infection control audit. This indicated that the service had 91% compliance with infection control processes. Areas of concern identified included floor coverings not being washable, furniture not being visibly clean and waste receptacles being dirty. The audit also identified that appropriate measures were not in place for compliance with Control of Substances Hazardous to Health (COSHH) Regulations 2002. An action plan had been put in place to mitigate these concerns.
- All instruments used within the service were single use. There was a policy which underpinned this practice. Used disposable instruments were disposed of in a sharps bin. Sharps bins were kept in a locked dirty utility room and were collected by external contractors on a regular basis. As the day of our inspection was not a treatment day, there were no sharps bins in use. As such, we were unable to check if they were correctly assembled or appropriately labelled.
- All scrubs (theatre clothing) were single use and disposed of after use. Appropriate staff changing rooms were available. This was in line with NICE guidance CG 74 surgical site infections.
- There was a current water testing policy. This stated that all taps, shower heads and outlets should be flushed on a weekly basis, with hot taps run for a minimum of one minute, and cold taps for a minimum of two minutes. This was to reduce contamination of the water supply with waterborne bacteria, such as Legionella. Staff also monitored the temperature of the hot and cold water supply. Tap flushing was recorded on a water check form, which we reviewed on inspection and saw that it was fully completed.
- Cytotoxic waste and clinical waste was collected weekly by an external contractor.
- The humidity and temperature within the laser room was monitored daily and recorded on a checklist, which we saw. All temperatures observed were within acceptable ranges. The temperature and humidity was also logged electronically, which was viewed by the head office's service desk. This meant that any readings outside of the acceptable limits would be identified and an engineer would be called to resolve the problem.

Environment and equipment

- The premises were well maintained. The flooring was non-slip and in a good condition.
- Most equipment was well maintained, and had been electrically safety tested yearly. However, we found some equipment that had passed its expiry or servicing date. This included an oxygen mask, which expired in 2009, a blood pressure monitor, which was due for servicing in August 2017, and four pairs of medical gloves, which expired in August 2017. We raised these as concerns to the clinic manager. The manager removed the oxygen mask and had ordered a new one which we reviewed on our unannounced inspection. At the time of our unannounced inspection, the blood pressure monitor was awaiting servicing and the gloves had been disposed of.

- Oxygen cylinders were stored securely within a locked room.
- We saw evidence that the lasers were regularly serviced, in line with the manufacturer's requirements. Their latest servicing had been in 2017. We were told that an engineer usually arrived within two hours of a call out, in case of the lasers breaking.
- The clinic had access basic resuscitation equipment and medicines. This included two doses of adrenaline, which would be used in case patients had an anaphylaxis reaction. Staff also had access to a defibrillator, in case a patient had a cardiac arrest.
- The service had an optical radiation safety policy, which complied with Medicines and Healthcare Products Regulatory Agency (MHRA) guidance. This was version controlled and in date. It stated that regular risk assessments should be undertaken and that all records should be kept. It also stated that all laser users needed to be trained to an appropriate level, before being allowed to work unsupervised. Goggles were available and used as appropriate with the lasers.
- We saw the latest risk assessment, dated November 2014, which was due to be reviewed in November 2017. The risk assessment was thorough and included risks regarding the laser treatment room, such as warning signs and reflective surfaces, as well as risks specific to the laser used. Risks included the type of toxic gas used by the laser and the delivery of the laser beam.
- The laser room was a controlled area, with the entry doors having keypad locks. All staff members knew the code to gain access to the room. We saw that when laser treatment lists was occurring; one patient was in the laser room, having treatment, while another patient was in the preparation room, which was inside the controlled area. The door between the preparation area and the laser room was not key pad controlled which meant that patients could inadvertently enter the laser room while the laser was in operation. However, staff told us they would always be present with the patient in the preparation room to ensure nobody entered the laser room whilst the previous patient was still undergoing treatment.
- A warning light outside the laser room was turned on when the laser was in use, to alert staff and patients.
- Local rules were in place for both types of lasers used within the service. Local rules summarise the key working instructions intended to restrict exposure in radiation areas. We saw that all applicable staff had read and signed the local rules.

- Staff we spoke with were unaware whether their equipment was suitable for bariatric patients. Bariatric patients are those with a body mass index of over 40. As such, staff were unsure what would happen if a bariatric patient required surgery at the clinic, or whether they would be able to accommodate them.

Medicines

- There were arrangements were for managing medicines and gases. All medicines were stored in lockable cupboards, within the laser room. However, the keys were left inside the locks of the cupboards and that meant all staff, including non-clinical staff, had access to the medicines. We raised this as a concern and were told the keys were only kept in the locks during treatment or aftercare days. Overnight and when no patients were scheduled, the keys were kept in a key cupboard. The key for the key cupboard was kept in a safe, which only the registered manager knew the code to. Keeping medications unsecured is not best practice. If the clinic decided to keep the keys in the cupboard, for ease of access, a risk assessment should be in place. There was no risk assessment during our inspection.
- We checked all the medicines available on site and found them all to be in date. Monthly stock checks were completed, in order to ensure adequate levels of medication.
- Fridges were used to store medications that needed to be kept within a recommended temperature range. We saw the fridge temperature was logged on a daily basis to ensure it was within acceptable limits. All temperatures we reviewed were within appropriate limits. Staff were aware of the need to escalate any temperature concerns to Optimax's head office, who would liaise with an engineer to ensure it was fixed.
- Mitomycin C was used off-licence to reduce post-operative haze. Mitomycin is a medicine that is

usually used in chemotherapy. However, it is also used in refractive eye surgery, to reduce the risk of the cornea clouding after surgery. The fact it was being used off licence was explained to patients during consultations, and was listed on the consent form. We saw a Control of Substances Hazardous to Health (COSHH) risk assessment had been completed for the use of mitomycin. However, on our announced inspection the registered manager could not evidence that nursing staff who prepared and administered the mitomycin had competence in this area. We raised this as a concern with the registered manager. However, when we spoke with the surgeon, we were assured that only they administered the mitomycin and they had evidence of competency in this area. As such, the concern regarding nurses was voided, as they did not have dealings with the drug. Further details regarding staff competencies for the use of mitomycin are listed below in the section titled 'competent staffing'.

- A cytotoxic waste bin was available for disposal of the mitomycin.
- There were no controlled drugs used at the service.
- External pharmacist support was available. The pharmacist wrote the service's medicines policy and offered advice where required.
- Patient allergies were clearly documented on all patient notes, where applicable.

- All medications for patients to take home following surgery were supplied by the surgeon.

Records

- Records were kept electronically and in paper format. Paper records were kept in locked cupboards in the reception area. All records we saw were legible, complete and up to date. Electronic records used a secure sign in system. Records were comprehensive and included pre-operative assessments and past medical histories.
- The records management policy stated all records were stored permanently. We were told that once patients had stopped receiving aftercare, their file was sent for archiving at the head office.
- Audits of patients' records occurred every three months. We reviewed the last three audits and saw that these showed that patient records were being completed appropriately.

- Following surgery, patients were given a letter detailing the procedure they had undergone and their postoperative medications for them to give to their GP.

Assessing and responding to patient risk

- Patients were assessed for suitability for laser surgery during the optometrist's and surgeon's pre-assessment consultation appointments. This included a health questionnaire and eye tests and was in line with NICE NG45 - Routine preoperative tests for elective surgery. This included looking at patients' existing medications and checking pregnancy status.
- The service did not use the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist. The WHO checklists are surgical safety checklists that should be completed before and after surgery occurs, to reduce the risk of errors.
- There was a policy to verify patient identification. This statedstaff should check the name and procedure of the next patient with the doctor and the patient should be called to the treatment room by their full name. Then the patient's name, postcode, date of birth and treatment should be checked against the diary booking and that the patient should point to the eye they want treated. Staff then checked that the eye they pointed to matched that indicated on the consent form. We were told that if a patient was only undergoing surgery in one eye, this eye would be marked, to reduce the risk of wrong site procedures. However, this was not reflected in the policy and therefore, we were not assured that all aspects of this risk had been identified and mitigated.
- A surgical pause safety checklist had been introduced in August 2017. This was a single sheet of paper, which covered all patients treated on the day. This prompted staff to check that they had confirmed the patient's postcode, date of birth, any medications, allergies and which eye was being treated before they carried out any laser surgery. The pause safety checklist included a section for both a checker and a witness. However, as all patients were completed on the same sheet, this was not held within the patients' records.

Refractive eye surgery

- Following surgery, patients were given emergency contact details for their surgeon. They were able to contact their surgeon directly overnight if they were concerned about their recovery. During office hours, patients were able to call the clinic and arrange for a review with either the surgeon or an optometrist, if required. Patients were given an emergency contact card, which included contact details for the surgeon. They were told to call them in the first 24 hours after surgery if they had concerns between 6pm and 8am, when the clinic was shut.
  - From July 2016 to June 2017, there had been no cases of unplanned transfers of patients from the service to another healthcare provider. There was no service level agreement with the local NHS trust to accept patients if required, for example if they suddenly became unwell, or if a procedure went wrong during surgery. We were told in this instance staff would call 999.
  - The service had a contraindications list, which excluded patients who were not safe for admission. This included eye conditions, contraindicated medicines, and high risk clinical conditions.
- The service's policy stated only patients aged over 18 were eligible for treatment. However, there were no processes for ensuring all patients were aged over 18. We were told that if the patient was applying for a payment plan, then identification, including age, was checked. Nevertheless, if the fees were being paid for outright, or by a relative, there was no formalised process in place for checking that the patient was aged over 18.

Nursing and medical staffing

- At the time of our inspection, there were two vacancies; one for a nurse and one for a patient advisor. As the nursing role had been vacant for a year, nurses employed at other Optimax clinics or extended role practitioners were brought in on treatment days, to provide additional cover. One surgeon and one optometrist were employed at the service, under practising privileges.
- An external laser protection advisor was used to provide expert advice and guidance. The advisor conducted inspections at three yearly intervals. If staff required advice between inspections, they could contact the advisor through Optimax's corporate compliance team.
- The clinic manager was the service's laser protection supervisor. They were always present on treatment days. All staff were required to read the local rules and risk assessment and sign to confirm their understanding, before being allowed to work in the laser controlled area.
- The surgeon who performed laser eye surgery at the clinic held the Certificate in Laser Refractive Surgery. We saw evidence of this in their employment file.

Major incident awareness and training

- There was a major incident policy. This outlined the procedures to be taken in the event of a bomb threat, fire, flood and gas leak. Fire alarm tests occurred weekly and fire drills occurred every six months.
- Resuscitation drills occurred every three months. We reviewed the documentation relating to the last three drills. The document used was a corporate template and did not have any space to document outcomes or learning for future improvements. We were told the clinic staff were unable to amend the templates. As such, we were not assured whether the outcomes of the drills were positive or if there were areas, which needed improving.
- There were emergency generators in case of an electrical failure during treatment. These were tested annually.

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

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance.
- Optimax's Medical Advisory Board (MAB) set the standards for all staff to work to. Standards were set in accordance with National Institute for Health and Care Excellence (NICE) guidelines and recommendations from the Royal College of Ophthalmologists.

- All policies were national corporate policies that had been created by Optimax head office. These reflected best practice and national guidance. These were available both on the staff shared computer drive, and hard copies were kept in a folder in reception.
- Patients had their needs assessed in line with best practice, including NICE NG45 - Routine preoperative tests for elective surgery. All patients underwent screening and assessment prior to being deemed admissible to the service for laser eye surgery. Patients' medical histories were discussed and appropriate tests were undertaken to help determine treatment. A contraindications list was in use, which outlined various conditions which excluded patients from treatment at the clinic.
- There had been no postoperative infections or episodes of sepsis from July 2016 to June 2017.

- Discrimination was avoided when staff made decisions about care and treatment. All staff were able to explain the importance of avoiding discrimination and how they would take each patient on an individual basis to see if they were suitable for treatment in the clinic.

Pain relief

- Pain levels were well managed within the service. Anaesthetic eye drops were used prior to surgery, to ensure the patients did not feel any pain. This was monitored and documented on patients' records.

- Patients were given ibuprofen and anaesthetic eye drops to take home following their surgery. Discussions about pain relief following surgery occurred at the consultation stage, prior to surgery. This meant patients knew beforehand, what types of pain relief they would likely to require.

Patient outcomes

- The service did not submit data to the National Ophthalmic Database Audit.

- There had been no unplanned returns to theatre from July 2016 to June 2017. However, there had been some unplanned retreatments in the same period. The surgeon had a retreatment rate of 9%, which was below the Royal College of Ophthalmology maximum limit. Each surgeon's individual outcomes were collected on an annual basis and were used as part of their appraisal.
- Nine experienced complications following their surgery. These included dry eyes, night glare and under or over correction.
- The clinic did not benchmark its outcomes locally against other clinics. They were unaware if any benchmarking occurred at the corporate level. This meant they could not compare themselves with similar services.
- The clinic ensured that eye sight was within expected ranges following surgery. This was completed via a combination of patient feedback and eye tests during aftercare sessions.

- The service did not undertake any optional audits as suggested by the Royal College of Ophthalmologists.

Competent staff

- Staff's clinical qualifications were recorded in their employment files, where appropriate. All clinical staff could evidence their professional registration, professional indemnity insurance and professional revalidation.
- All staff had evidence that they had undergone disclosure and barring service (DBS) checks. This included the date of the check and whether the check had identified any past criminal history.
- All staff files included had employment histories, at least two references and evidence of yearly appraisals, including those working under practising privileges. These were reviewed yearly by Optimax's head office's medical advisory board.
- The internal laser protection supervisor (LPS) attended a certified training course every two years, to ensure they were competent to carry out their duties. Following the course, the LPS completed a test to confirm their understanding and knowledge.
- The external laser protection advisor (LPA) was an accredited LPA who worked for a professional LPA company.
- At our announced inspection there was no evidence all nursing staff who worked with mitomycin were competent to do so. We raised this as a concern, and the registered manager obtained one staff member's written competency record, which was held at another clinic. However, we were not reassured that all staff

who completed these duties held appropriate competencies. On our unannounced inspection we revisited this, and found that although one more staff member's competencies had been obtained, this had not included working with mitomycin. However, the surgeon assured us that the mitomycin came pre-prepared and only they administered it.

- The staff member employed directly by the clinic had monthly 1:1 meetings with the clinic manager. We saw records of these meetings in their employment file.
- The clinic manager was unable to provide assurances regarding the amount of continuing professional development that the surgeon completed. However, on review of their employment file we saw their latest revalidation paperwork, which provided evidence that they had completed the necessary hours.

- All authorised users of laser equipment had certified training and had been assessed as competent in operating laser equipment. The training occurred every two years to ensure ongoing competency.

Multidisciplinary working

- All necessary staff were involved in assessing, planning and delivering people's care and treatment. Treatment was surgeon-led and involved discussions with the optometrist and administrative staff where required.
- The team worked well together, providing cohesive care to patients. There were positive working relationships between the administrative team and the clinical team.
- Non-medical staff performed extended roles, such as laser assistants. We saw they completed training in the core of knowledge of lasers to perform such roles.

- Monthly team meetings were held between the clinic manager and the patient advisor. We saw the minutes of these meetings. Topics discussed included income targets, changes in protocol and new audits. However, we did not see any evidence these were shared with the wider team.

Access to information

- All records were electronic, except consent forms, which were paper based. These were stored on a corporate system, which meant that they could be accessed from any clinic, if required.
- We were told that the clinical staff often preferred to have paper copies of patients' notes. As such, patients' notes were often printed off for the surgeon and optometrist to review during consultations. Following this they were stored in locked cupboards, before being sent for archiving.

Consent and Mental Capacity Act

- Staff understood the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005. There was a robust consent process was and staff were able to explain this. There were different consent forms for the different types of laser eye treatment offered. However, staff did not have training on consent.
- There was a consent policy. This stated it was the doctor's responsibility to gain consent for treatment. It stated that consent should be obtained on the day of treatment. The policy stated that it would not provide treatment to patients who were unable to give consent, therefore excluding patients lacking in mental capacity. Patients who lacked capacity were also on the contraindications list. If staff had concerns about a patient's ability to consent, the surgeon would assess whether the patient had capacity to consent.
- We spoke with staff who confirmed that all the risks and benefits were explained to patients during the optometrist consultation. At this stage, patients were given an initial consent form, which also detailed all risks and benefits. This was then reviewed during the surgeon's consultation, which provided an opportunity for patients to ask any further questions. Patients signed to give consent on the day of surgery, with the surgeon.
- All patient notes we reviewed had signed consent forms.
- The manager assured us that all patients waited a minimum of seven days as a cooling off period between their consultation with the surgeon and their operation occurring. This allowed sufficient time between appointments to allow the patient time to decide if they wanted to proceed with treatment. We were told that the time length between the two stages was usually two to three months. This was because there was only two surgery days per month. This was evidenced in the patients' notes we reviewed.

Refractive eye surgery

Are refractive eye surgery caring?

Compassionate care

- We observed staff providing compassionate care to patients during our inspection. All staff interactions we observed were positive and feedback from patients told us that they received caring and kind care from staff.
- Staff were encouraging and supportive to patients. We observed this during our inspection. Patients' comment cards told us that staff were understanding and sympathetic towards them. This was in line with National Health and Care Excellence (NICE) guideline QS15 Statement 1 which relate to communication with staff, introductions and understanding of the healthcare team and preferences for sharing information.
- Patients' privacy and dignity was maintained. Consultations occurred in private rooms and doors were closed to ensure patients' privacy.
- Staff ensured that patients' confidentiality was maintained. Staff did not give out any confidential information over the telephone until the patient had confirmed their name, date of birth, first line of address and postcode.

- We reviewed the service's patient satisfaction survey from 2016 (the most recent survey available). This showed that the clinic had a 99% satisfaction rate, compared to 97% for the company as a whole. Out of the 136 patients who attended the clinic during the period, 61 responded to the survey. This showed that the clinic in Milton Keynes had higher satisfaction levels than other Optimax clinics.

Understanding and involvement of patients and those close to them

- Staff communicated with patients so they understood their care, treatment and condition. Information was given in easy to understand formats. Time was available at the end of the consultations if the patient wanted to ask any further questions.

Patients were given appropriate information about what they should expect from their refractive laser eye surgery and realistic expectations about outcomes. This was in line with the Royal College of Ophthalmology guidance.

- Patients were given transparent and accurate information about all costs involved as per CQC Regulation 19. This was completed at consultation stage, so that all patients knew how much it would cost before they had their procedure. Approximate prices were displayed on the service's website. Patients were given a written statement, that included the terms and conditions of the service, as well as details of fees, in advance of having their procedure. Advertising information was honest and responsible. This was in compliance with the Committee on Advertising Practice.

Emotional support

- Staff understood the impact that a person's care and treatment could have on their wellbeing. Staff were empathetic to patients who were anxious about their surgery and reassured them.
- If patients were anxious, the patient advisor would go into theatre with them and hold their hand during the procedure.

Are refractive eye surgery responsive to people's needs?
(for example, to feedback?)

Service planning and delivery to meet the needs of local people

- Service planning and delivery was organised to meet the needs of patients. All patients were pre-planned elective patients. This meant that treatment lists were well planned and sufficient staffing numbers were employed to treat all patients.
- The clinic did not offer treatments to patients under 18, those with certain medical conditions, or women who were pregnant. This were specified in the contraindications list. This was due to the potential risks of treating these cohorts of patients. These risk factors were checked during the health questionnaire, which were completed with the clinical staff.

- Lists were planned by a central team at Optimax's head office. We were told lists were on occasion cancelled, if there were insufficient numbers of patients booked on a list. This decision was made by the booking team at Optimax's head office, to optimise use of resources. However, this was not a common occurrence. The cancelled lists were for preoperative consultations. We were told surgical lists were not cancelled in this way.
- As there was only one surgeon and one optometrist who worked at the clinic, this meant that all patients had continuity of care throughout their procedure and aftercare.
- The facilities and premises were appropriate for the services that were being delivered.

- All patients had consultations with the surgeon prior to the day of surgery. Postoperative appointments were held with the optometrist. However, if the optometrist had concerns, they could refer the patient for a surgeon consultation.

Access and flow

- Clinic appointments were available Monday to Saturday 9am to 5.30pm. If patients had laser surgery on a Saturday, the clinic would open 9am to 1pm on a Sunday for those patients' aftercare appointments.
- There was no waiting list for patients waiting for refractive eye surgery. All patients had their appointments booked in a timely manner.
- Three procedures were cancelled for non-clinical reasons from July 2016 to June 2017. This was due to a laser failure in August 2016. Two patients were rebooked on another date, and the third patient decided not to go ahead with treatment.

- If patients did not attend their appointments, clinic staff did not call them to find out why. We were told that the booking team, located at Optimax's head office, liaised with patients to rebook appointments. The clinic did not record the number of patients that did not attend appointments, however, we were told this was a low number.

Meeting people's individual needs

- Services were planned and delivered to take account of the needs of different people. The ground floor of the clinic, which was where the laser room and one consultation room were, were wheelchair accessible. Whilst there was no lift to the upstairs facilities, we were told that if a patient had mobility issues, they would ensure the ground floor consultation room would be available for them. The downstairs toilet facilities were also wheelchair accessible.
- There was an equality and diversity policy. However, this focused on equality within the service for staff, including aspects such as recruitment and bullying. There was no information regarding the steps taken to improve equality and diversity for patients at the service.
- The service did not treat patients with complex health needs or those living with dementia or a learning disability.
- The service provided a translation service, if required. However, the additional cost of this had to be met by the patient.
- A variety of patient information leaflets were available. These contained information about the procedures and common side effects. However, these were all in English.

- A waiting room, with a hot beverage machine, was available for patients.

Learning from complaints and concerns

- There was a complaints policy, which was in date. Staff were aware of the policy and had a strong understanding of the guidance.
- The service received 46 written compliments from July 2016 to June 2017. In the same time, there were three complaints. All of these were managed under the service's formal complaints procedure and upheld. These related to patients being unhappy with their treatment results (leading to further retreatment), and two patients complaining when their surgery was cancelled due to the laser breaking down. All three complaints were resolved within one month. This was in line with the service's policy.
- Notices were displayed in the clinic, which contained information on the complaints process. Patients were also given a guide that outlined the complaints procedure.

- Staff in the clinic aimed to resolve all complaints locally. However, if the complaints remained, they were escalated to the head office.
- We did not see any evidence that learning from complaints was shared within the wider organisation.

Are refractive eye surgery well-led?

Leadership and culture of service

- The clinic was led by the registered manager. There was a clear leadership structure from the clinic up to the corporate level. The corporate management were very involved in the running of the clinic. For example, they investigated all clinical incidents and produced all policies and audit templates. This meant that the clinic manager had limited autonomy in these areas to make changes or improvements. Development and changes were directed from head office for the registered manager to implement.
- Staff told us the registered manager was very approachable, visible and helpful. The registered manager was relatively new to the position but had previously worked at the clinic as a laser assistant. We were unable to establish what support and development the new registered manager had since being in post.
- Staff felt respected and valued and enjoyed working at the clinic. Most of the staff had worked at the clinic for many years.
- Staff told us they felt able to raise any concerns to the registered manager, who would pass them onto the head office. However, we were told they did not always receive feedback on these concerns from the head office.
- Patients were incentivised to refer friends and family to the service. The patients making the referral, and the new patients who came to the service, were given financial discounts for the referral.
- Staff worked well together as a team. The team was small and strong working relationships had been formed.

Vision and strategy

- The clinic did not have a set vision or strategy. We were told this was decided at the corporate head office and that they had not been informed of what their ongoing vision and strategy was.
- The vision and values were not displayed within the clinic. Staff we spoke with were unaware of the corporate vision or values.
- The registered manager was aware of their financial key performance indicators, and staff's conversion rate (the number of enquiries, which turned into paying patients) was monitored and discussed during their monthly 1:1 meetings.

Governance, risk management and quality measurement

- A governance framework was set by the corporate level. The compliance manager from head office investigated all clinical incidents. This included governance meetings and meetings of the medical advisory board. All clinical incidents fed into the corporate governance structure. There was no governance structure locally within the clinic and there appeared to be little opportunity to implement a local governance structure.
- The medical advisory board reviewed staff's practising privileges on a yearly basis. We saw these were reviewed and signed each year.
- We saw copies of compliance conference call updates which detailed changes to audits or policies. However, these calls did not have a list of attendees, so we were unable to see if the clinic manager had attended these calls.
- There was a clinical governance and risk management policy.. This outlined the role of the medical advisory board, who met four times a year. It also stated that local clinic team meetings should be held monthly, and that issues such as complaints, incidents and key performance indicators should be discussed. We spoke with staff who told us that learning from incidents was not always shared with the clinic team.
- We reviewed the last three team meeting minutes. We saw only the manager and the patient advisor attended these, not any staff who worked on practising privileges.

Refractive eye surgery

- At the time of announced inspection the service's risk register was very limited and included generic risks, as opposed to those specifically applicable to the service. For example, risks included walking into a glass door and the risk of people falling on the staircase. There was no evidence that this was linked to any tangible risks within the service. The risk register stated that all risks had mitigating actions, but had no explanations of what these actions were. There was no way to tell when the risks had been added to the register, or when they were due to have been removed. We also identified areas of risk on inspection, such as the lasers malfunctioning (which had occurred on two occasions) and short staffing (the service had been trying to recruit a nurse for over a year) which were not on the risk register.
- We raised this as a concern and the manager completed a new risk register. This was detailed, included the date they had been identified, details of mitigating actions and risk owners. However, none of the risks were due to be reviewed for at least one year, and the risk rating for all risks had not been decreased by the mitigating actions, which did not assure us that the risks were being reviewed and managed appropriately.
- There was no alignment between what was recorded on the risk register and what the registered manager told us was on their 'worry list'. The manager told us their three main worries were staff calling in sick, leading to missing a day's takings, incorrect patient outcomes and ensuring they were up to date with all regulatory requirements. None of these were on the risk register.
- The compliance manager conducted yearly unannounced inspections, to ensure compliance with standards. We saw that the last inspection had occurred in June 2017.
- There was a holistic understanding of performance, which integrated the views of people with safety, quality, activity and financial information. Staff were aware of the importance of positive patient outcomes, as this then in turn led to strong financial returns.

- There was a systematic programme of local audits. However, due to limitations in the audit template, we were not assured that these would lead to improvements in outcomes.

Public and staff engagement

- Patients' views and experiences were gathered through satisfaction surveys and compliment cards. All feedback we saw was positive.
- Staff surveys were not conducted at the clinic or at a corporate level. As the team was small, we were told that staff would tell the registered manager any ideas for improvement that they had and they would escalate this up internally. All staff showed us and told us that they wanted to continually improve the clinic and the care offered to patients.

- Staff meetings were held monthly between those employed directly by the clinic. This was the clinic manager and the patient advisor. The staff who worked on practising privileges, such as the optometrist and surgeon, did not attend the meetings.

Innovation improvement and sustainability

- There were no examples of financial pressures compromising patient care.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that all equipment is safe for use, regularly serviced and in date.
- The provider must ensure that a robust surgical safety checklist is used prior to surgery.
- The provider must ensure that a cytotoxic spillage kit is available at all times, in case of cytotoxic spillages.
- The provider must ensure that all medication keys are kept securely and that only appropriate staff have access to medications.
- The provider must ensure there is incident reporting policy and learning from incidents is shared locally and corporately.
- The provider must ensure the risk register includes all relevant risks and is reviewed and updated regularly.
- The provider must ensure that learning from audits is identified and shared.

Action the provider SHOULD take to improve

- The provider should ensure duty of candour is adhered to and communication with patients is evidenced in incident files.
- The provider should ensure that all staff are aware of the duty of candour.
- The provider should ensure that all equipment is cleaned between use.
- The provider should ensure that patients' ages are checked prior to surgery.
- The provider should review audit templates, to ensure that learning from audits is documented.
- The provider should ensure all relevant staff have consent training.
- The provider should provide free translation services.
- The provider should have access to leaflets in languages other than English.
- The provider should ensure that learning from complaints is shared.
- The provider should ensure that clinic staff are aware of the vision and strategy.

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
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Regulation 12 (2) (a) (e) (g) HSCA (RA) Regulations 2014 Safe care and treatment. How the regulation was not being met: We found six pieces of equipment which were past their expiry or servicing date. The clinic did not have a robust surgical safety checklist in place. All patients were recorded on the same sheet of paper, which meant that they could not be stored in the patients' medical notes. There was no cytotoxic spillage kit. Medication keys were left inside the medication cupboards when patients attended the clinic. Non-clinical staff had access to the medications. There was no risk assessment relating to this practice.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 (1) (2) (b) (f) HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: There was no incident reporting policy. Learning from incidents was not shared. The risk register did not contain all relevant risks and was not reviewed regularly. Learning from audit outcomes was not identified or shared.