Optimax Clinics Limited

Optimax Laser Eye Clinics - Maidstone

Quality Report

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This report describes our judgement of the quality of care at this hospital. 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

We inspected Optimax Maidstone on the 1st July 2015. This was a pilot comprehensive inspection to test our new methodology for inspecting specialist refractive eye surgery services. Therefore we did not rate this service.

Optimax Maidstone is part of Optimax Clinics Limited, a large company established in 1991 which specialises in private laser eye and lens replacement surgery with facilities nation-wide. The clinic offered a wide variety of laser and non-laser vision correction treatments, such as laser assisted in situ keratomileusis (LASIK), laser epithelial keratomileusis (LASEK), refractive lens exchange (RLE), and implantable contact lens procedures on a private basis. The clinic did not treat children.

We found that services at the clinic protected patients from avoidable harm and there were systems to report and learn from incidents that were well understood by the staff we spoke with. There were systems to manage the risks associated with laser use. There were arrangements to prevent infection, although systems in relation to water safety were insufficiently robust. Staff knowledge of understanding the risks of adults in vulnerable circumstances needed improvement.

Patients experienced good clinical outcomes because they received effective care and treatment that met their needs and was in line with national guidance. There were arrangements to ensure that patients gave valid consent prior to their treatment.

Patients were supported, treated with dignity and respect and were involved as partners in their care. Staff ensured that patients and those close to them received adequate psychological support.

Services were organised and delivered to meet patients individual needs and circumstances and were designed to be convenient and flexible. Patients were provided with literature with comprehensive information about their care and treatment, which was supplemented by face-to-face consultations.

There were arrangements to ensure the needs of those with physical difficulties could be met and the environment was pleasant and appropriate for the service delivered.

Patients complaints were treated seriously, they were investigated, actions were taken and people received appropriate responses.

The leadership, governance and culture promoted the delivery of safe and effective care.

However there were also areas of concern where the provider needs to make improvements.

The provider should:

- Ensure its complaints responses meet CQC guidance in relation to informing patients how to escalate concerns if they are unsatisfied with a response.
- Ensure staff have a clear understanding of safeguarding adults in vulnerable circumstances and assessment of mental capacity in the context of a refractive eye surgery clinic.
- Ensure there is an effective system for monitoring water safety which meets national guidance.
- Ensure that medical gases are stored appropriately.
- Review its water quality testing in order to meet corporate policy requirements.
- Review its storage to ensure there are no further instances of medical gases being stored alongside combustible materials.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Optimax Laser Eye Clinics - Maidstone

Detailed findings

Services we looked at
Refractive Eye Surgery

Detailed findings

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Background to Optimax Laser Eye Clinics - Maidstone

Optimax Maidstone is a clinic situated in a busy shopping street in the town centre. It is part of Optimax Clinics Limited, a large company established in 1991, which specialises in private laser eye and lens replacement surgery with facilities nation-wide.

Our inspection team

Our inspection team was led by: Shaun Marten - Inspector CQC.

The team included CQC Inspection Managers and a Specialist Consultant in refractive eye surgery.

How we carried out this inspection

We reviewed a wide range of information including data we already held, as well as information provided by the clinic before the inspection. We visited the clinic on 1st July 2015 and looked at the premises. We observed surgery being performed and other care being delivered. We spoke with the Manager (who was also the Registered Manager and is called manager throughout this report), a Surgeon, two Nurses, and two Patient Advisors/ Treatment Assistants. We also spoke with three patients undergoing treatment on that day. We examined a wide range of records including; audit results, equipment checks, as well as six staff files and six patient records.

Facts and data about Optimax Laser Eye Clinics - Maidstone

In the period June 2014 to May 2015, Optimax Maidstone treated 480 patients.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	
Overall	

Information about the service

Optimax Maidstone is a clinic situated in a busy shopping street in the town centre. It is part of Optimax Clinics Limited, a large company established in 1991, which specialises in private laser eye and lens replacement surgery with facilities nation-wide. The clinic offered a wide variety of laser and non-laser vision correction treatments, such as laser assisted in situ keratomileusis (LASIK), laser epithelial keratomileusis (LASEK), refractive lens exchange (RLE), and implantable contact lens procedures. Services were only provided to adults.

Two Surgeons worked at the clinic; one undertook lens replacement surgery and the other laser surgery for correcting refractive disorders. There were four scheduled surgery sessions per month at the clinic, two for laser treatment and two for lens replacement surgery. On other days the clinic was open to deal with general enquiries, initial and pre-operative assessments, and follow up appointments. The surgeons were supported by a team of nurses employed by Optimax, of which one was permanently based at the clinic. There was also a team of three junior staff who held duel roles as Patient Advisors and Treatment Assistants.

Optimax Maidstone treated 480 patients in the period from June 2014 to May 2015. RLE accounted for 322 (67%) of procedures performed. There were 152 laser eye treatments, of which the majority (72%) were LASIK surgery. Additionally there were six implantable contact lens procedures.

Summary of findings

Patients were protected from avoidable harm and had good outcomes because they received effective care and treatment that met their needs. Patients were supported, treated with dignity and respect, and were involved as partners in their care. Services were organised and delivered to meet patients individual needs and circumstances and were designed to be convenient and flexible. The leadership, governance and culture promoted the delivery of safe and effective care.

Surgery

Are surgery services safe?

Data showed there was a good track record in relation to safety. There were clearly defined and embedded systems, processes and monitoring arrangements to keep patients safe, and risks were managed on a day-to-day basis. Staff received up to date training in safety systems and safety related topics. Care and treatment was provided in well maintained and appropriate environments and the risks of infection were minimised. Equipment was maintained and checked to ensure it was functioning safely. However the arrangements to monitor water safety were insufficiently robust. Staff require a better understanding of safeguarding adults in vulnerable circumstances and the assessment of mental capacity in the context of a refractive eye surgery clinic.

Incidents

There were satisfactory systems in place for the reporting and investigation of safety incidents. There were arrangements to report safety incidents using a corporate reporting system. All staff were trained to report near misses and incidents. We spoke with two junior staff who were able to describe the process fluently and showed a good understanding of what and how they should report. For example, there had been one safety incident reported the previous week relating to difficulties with the telephone system. We saw the reports relating to this incident and the initial investigation which demonstrated an adequate and timely response. There were no serious incident reported in the previous year and no incidents requiring a statutory notification to the CQC.

Any incidents were discussed at monthly team meetings and we saw evidence of this in the meeting minutes we reviewed. We noted any remedial actions taken and were able to check a sample of these. We saw these actions were also discussed and documents showing learning from safety incidents.

Monitoring Safety

We saw a copy of the Annual Quality of Care Assurance Tool that the manager had completed in January 2015. This audit covered a wide spectrum of topics including; patient care being initiated safely, consultation with Doctors, suitable environment for treatment waiting areas, pre-treatment areas, treatment areas, use of laser treatment room, post treatment, training, health and safety, welfare, manual handling, infection control, waste disposal, control of substances hazardous to health (COSHH). We noted that this audit has not identified any safety risks that required action. We judged that this audit was sufficiently detailed and robust in its application.

Cleanliness, infection control and hygiene

Overall we found that the Department of Health's (DoH) 'Code of Practice on the Prevention and Control of Infections and Related Guidance' (2010) was being followed. This was the version in place at the time of our inspection.

We saw the clinics risk assessment for 'Infection Prevention and Control' (IPC) had been carried out and updated annually. We noted the risk controls this assessment identified were in place.

There was an annual IPC audit performed. We examined the latest audit dated January 2015 and noted that no issues requiring action were identified and that the audit was sufficiently robust.

Annual training in IPC was mandatory. We saw records that showed four out of five staff based at the clinic had completed this training, but the person who had not done so had only been in the post a few weeks.

There were no healthcare acquired infections reported in 2014.

We saw that the environment was visibly clean and well maintained. Cleaning was provided by an external company for non-clinical areas. We saw records of the weekly checks relating to cleaning standards that the Manager performed weekly. The operating theatre was arranged to ensure the separation of 'clean' and 'dirty' activities.

We saw there were appropriate hand washing facilities at the clinic. We saw that adequate supplies of hand sanitizer were available throughout the clinic, including patient areas such as reception. We saw staff decontaminating their hands appropriately.

There were cleaning schedules for the treatment areas. We saw daily and weekly checklists that were consistently completed showing that this schedule had been complied with.

Surgery

The vast majority of surgical instruments used were 'single use only' minimising the risk of cross infection. We looked at patient records and saw that the packaging of these was retained thus ensuring traceability of instruments used. Multiple use instruments were de-contaminated by an external contractor who was accredited to carry out this work. We saw an audit trail of instruments sent and returned from de-contamination. We observed that instruments awaiting de-contamination were appropriately stored in closed containers away from 'clean' areas and stores.

There was an air filtration system to ensure that air quality in treatment areas did not present a risk to patients. We saw that there was a monitoring system in operation at all times which showed a green light if the system was operating properly. An orange light showed if the system detected minor issues, in which case the Manager told us that they contacted the company to review the system. If a red light showed then clinical activity ceased, and the manager was able to give us an example of when this happened. We saw documents that recorded the status of the system daily, although the light system was in operation continuously and was visible in the manager office and treatment area. We saw records that showed the system had last been serviced in April 2015.

We found the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 were complied with. There was a risk assessment for sharps injuries completed annually. Sharps were disposed of in approved containers and stored securely awaiting collection by an accredited contractor for disposal.

There were systems for the management of clinical waste which met the 'DoH Guidance Management of Waste' (2011). We saw a risk assessment for waste disposal. We noted that clinical waste was segregated from domestic waste in colour coded bags. We saw that clinical waste was stored securely whilst awaiting removal from the site. Clinical waste was removed by an accredited commercial contractor and we saw the collection receipts for the waste that they provided.

We found that the 'Legionnaires disease: The control of legionella bacteria in water systems. Approved Code of Practice and guidance on regulations'. (Health and Safety Executive, 2013) were not being fully implemented. We were shown a Certificate of Water Analysis provided by an external contractor which gives assurance on the safety of the water supply, especially in relation to the control of Legionella (an organism that is found in water supplies and that can cause serious illness). However, we noted that it was dated 2012 when the clinic had opened. The Manager was aware of the need for this testing to be carried out and we saw email correspondence between the Manager and the National Managers where this was discussed over a protracted period. In the 'Water Testing Policy' supplied by Optimax Maidstone it stated, “All clinics will undergo annual Legionella water tests which will be performed by an external specialist company by prior arrangement.” This meant the provider’s policies were not being followed.

Immediately following our inspection the Manager arranged for the Certificate of Water Analysis to be supplied after testing by an external contractor. They provided us a copy of this certificate.

There was a system for checking the temperatures of hot and cold water supplies weekly and we saw checklists that showed these had been done. However, the minimum hot water temperature of 50 degrees Celsius and maximum cold water temperature had often not been achieved. For example the records for 29th June 2015 showed that of nine taps tested five were below the threshold. We also saw that for the cold taps, where the maximum temperature should be 20 degrees Celsius, this temperature was exceeded in four of the nine taps tested. We asked the junior staff undertaking the tests what actions they would take when obtaining such results and they could not tell us of any formal action apart from informing the Manager. We looked at the 'Water Testing Policy' (version 4 dated August 2008, revised July 2015) supplied by Optimax Maidstone and noted it stated, “Should the temperatures fall outside the ranges; staff will first check that the water heating system is functioning correctly. If this is not the case then the Clinic Manager must report to the helpdesk who will request assistance from the Property Department.”

We spoke with the Manager, who explained that each of the taps was supplied by a small holding tank and that in the case of hot water, if the temperature was tested after flushing, an accurate reading was not obtained. This indicated that although there were systems to carry out required temperature checks, it was acknowledged that the results obtained were flawed; corrective actions had yet to be considered. It also showed that staff carrying out the checks were not aware of the significance of results outside the threshold and were unaware of what actions they

should take. This meant there was an inadequate programme of planned preventative measures to ensure the safety of the water supply, although we acknowledge that the associated risk in this location was low.

Immediately following our inspection the Manager contacted the company who installed the water system and established the taps had thermostats which prevented them from heating above 40 degrees Celsius. They supplied documentary evidence of this. We saw correspondence that confirmed the corporate policy and daily check forms were to be reviewed to reflect this.

There were arrangements for the flushing of all taps to be carried out weekly and we saw records that showed this was completed.

Environment and equipment

Optimax Maidstone had two laser machines in use for treating patients. These were classified as category 3B (medium power) and category 4 (high power) machines. We found that the 'Guidance on the safe use of lasers, intense light source systems and LED's in medical, surgical and dental and aesthetic practices' (Medicines and Healthcare products Regulatory Agency 2008) was followed.

There was a named Laser Protection Advisor appointed from an external agency and we looked at the annual contracts. We saw records of their last visit which was carried out in June 2015. The report from this visit was not yet available but we saw reports from previous visits. We noted the previous year's report was comprehensive and covered all aspects regarding the safe use of the lasers used. This meant that appropriate expert advice on the safe operation of lasers was obtained and followed.

There was a nominated Laser Protection Supervisor who worked at the clinic.

We saw that each of the laser machines had local rules concerning their use and operation and these were displayed where they could be referenced easily.

We saw that staff had signed to indicate that they had read and understood these local rules regarding the use of the laser machines. Staff we spoke with were able to outline the safety arrangements and practices in use with regard to laser safety.

The lasers were sited in controlled areas with appropriate signage indicating their position and associated risks. These areas were accessible via doors with digital locks. There was a safety light which illuminated when the lasers were being fired, warning people not to enter the controlled area.

We noted the controlled area was free from hazardous reflective surfaces.

Daily temperature and humidity checks were carried out in the controlled areas as these were critical in the safe performance of the procedures undertaken. We noted that these checks indicate that there were no issues in relation to these.

The lasers were key controlled, and we saw the key was removed when not in use and stored securely. The class 4 laser could only be fired when in place on a patient's eye. Both lasers were controlled by a shrouded foot switch and there was an emergency off button. This meant the laser was secure from unauthorised or accidental use.

Protective eyewear was available that met the specifications required for the lasers used.

We found a preventative maintenance plan was in place in relation to the laser machines. We also found that the clinic identified laser faults and ensured they were rectified promptly. The lasers were serviced every three months and we saw service reports dated April 2015 for the class 3B laser, and May 2015 for the class 4 one.

We saw records that showed a comprehensive check was carried out on the laser machines by staff each day the clinic was open.

Other optical equipment in use was serviced regularly and we saw records to support this. The last service was dated May 2015.

We examined a detailed Asset Register for the clinic. This recorded all the equipment in use at the clinic along with service details, serial numbers and other essential information that allowed equipment to be monitored and tracked.

We saw there was a maintenance schedule in place for equipment. We looked at 13 records and saw eight were completely current, two were slightly overdue and three were out of date. This showed that although there were systems to ensure the maintenance of equipment, it was

not wholly effective as some equipment had not been maintained according to the schedule. However, we noted the majority of equipment had been maintained according to the schedule.

We saw Portable Appliance Testing (PAT) and socket testing certificates which were valid until June 2016. We also saw records of weekly electrical safety checks carried out by the Manager which showed no safety concerns were identified. This meant electrical equipment in use had been tested to ensure its safety.

A Fire Workplace Risk Assessment had been performed. The fire alarm and emergency lighting systems were last serviced in February 2015. We saw that the staff carried out tests of these safety systems monthly.

In general, we found that where necessary, items that should be stored securely were stored in locked cupboards.

We found the medical gas storage cupboard was secure and adequately ventilated. However, we found that numerous cardboard boxes and MDF shelving, both combustible materials, were also stored in this cupboard alongside cylinders of gas such as fluorine which are highly unstable and reactive substances. The fire risk assessment dated January 2015 showed the gas storage area as a source of fuel. The COSHH risk assessment and inventory dated January 2015 did not identify the gases as a hazardous material and did not provide guidance on safe storage. This meant that the risks associated with gases stored were not fully appreciated, and the storage arrangements we saw posed a fire risk.

Immediately following our inspection the Registered Manager cleared this cupboard of combustible materials and sent us photographic evidence that this had been completed. They explained they had investigated the matter and had found that it was a result of miscommunication with delivery staff.

We saw risk assessments for laser induced eye injury, electric shock and explosion and noted the risk controls identified were in place.

We saw there was a programme of Health and Safety related training that staff were completing. The Manager had completed a Manager Specific Session, and four out of five staff had completed training in general Health and Safety and Health and Safety Risk Assessment. The person who had not completed this training had only been in post a few weeks. All staff were up to date with their annual 'Introduction to Working Safely' training. All staff had completed annual mandatory training in relation to COSHH.

Medicines

We saw that there were arrangements for the supply of medicines required to carry out the procedures that were undertaken at the clinic.

We saw that an audit trail for the ordering and delivery of medicines was kept. We saw completed stock check documents that were performed monthly and this included ensuring all medicines had not passed their expiry date. We noted that no controlled drugs were kept on-site.

We observed that medicines were kept securely and access to cupboards was controlled. We saw a risk assessment for loss of drug keys had been completed.

The temperature of the drug cupboards was monitored to ensure that they were kept in optimum condition. We saw records that confirmed this.

Medicines that needed to be kept in the fridge were kept in dedicated medicine fridges between a temperature of 2 – 8 degrees Celsius. We saw that the fridge temperature was recorded daily and consistently showed a temperature of 7 degrees Celsius.

There were systems for disposing of unused or partially used medicines in approved colour coded containers. They were kept securely and were collected by an accredited external contractor for destruction.

We saw that medicines were administered by Registered Nurses following a Doctor's prescription or by a Registered Optometrist.

We saw that prescription and administration records were fully completed and were retained in patient records. We checked four sets of patient records and found that the recording of medicines was complete.

Annual mandatory training in Medications was required by the clinic. We saw training records which showed four out of five staff had completed this, but noted the Registered Nurse who had not done so was newly appointed.

Surgery

We saw and patients we spoke with told us they were given adequate information about medicines, including eye-drops that they needed to use as part of their treatment. This included how they should be used and at what frequency.

Records

We looked at six sets of patient records, which were kept both in electronic and paper formats. We found that they were complete and accurate and gave a comprehensive account of the care and treatment received by patients. Records were consistent with guidance from the General Medical Council (available on their website).

Confidential patient records were kept securely. Computer records were password protected with users each having a unique log-in which required periodic changing.

There was mandatory Data Protection training annually and all clinic staff were up to date with this.

All other records relevant to the running of the service, including staff personal files could be produced quickly when requested. We found these to be in good order and complete. All staff information required by the Health and Social Care Act 2008 (Regulated Activities) 2014 Schedule 3 was present, such as a full employment history and photographic identification.

Safeguarding

There had been no notifications regarding allegations of abuse from Optimax Maidstone in 2014.

We looked at personal files for five members of staff and saw all staff had undergone Disclosure and Barring Service (criminal record) and other checks to ensure they were of good character.

Although the clinic did not treat children, there was a programme of Safeguarding training. The Manager had completed level 3 Child Protection training. Other staff were required to complete level 2 bi-annually. In June 2015 two out of four staff had done this.

There was training regarding Safeguarding Adults at Risk (SAAR). We saw records that showed staff had completed this. However, we discussed adult safeguarding with two junior members of staff (Patient Advisers/Treatment Assistants) and found that they had difficulty in describing what a safeguarding issue might look like in the context of refractive eye surgery and what their response to any concern might be.

Mandatory training

Optimax Maidstone had a mandatory training programme. We examined training records and saw there were 22 elements for the Manager to complete, and 20 for other staff. We noted that all major risk areas were covered by the programme with the exception of SAAR.

The completion rate was 65%, but this figure was conservative as it included a newly appointed member of staff. Excluding this person, the compliance rate was around 90%.

All authorised users of the laser equipment had certified training to ensure they were competent to use the equipment.

Staff we spoke with were all aware of the mandatory training they were required to complete.

Assessing and responding to patient risk

Patients under 18 years, pregnant or breastfeeding women and those with specific medical conditions were excluded from treatment. Younger people were excluded from lens replacement treatments as well as patients whose spectacle prescription was not stable. This was due to increased risks during treatment, and/or likelihood of poor outcomes.

We looked at the records of two patients who had been declined treatment and saw the reasons for this were clearly documented and explained to them. This showed that people at high risk were not treated.

We saw that patients were required to fill in a comprehensive health questionnaire which was reviewed by the Optometrist and Surgeon to ensure there were no contra-indications to treatment or to alert them to any special precautions to be taken. We saw these health questionnaires in patients' records. We saw that areas such as medication and allergies, past medical history and spectacle prescription were covered. We also saw that social and psychological issues were addressed where these could affect the safety of the treatment.

Surgery

World Health Organization (WHO) Surgical Safety Checklist were used before, during and after surgery to reduce the risk of surgical error. We saw completed checklist in patient records and observed it in use.

There were systems in place for Surgeons to check treatment parameters before the operation of the laser in laser surgery.

In the case of lens replacement surgery, there were checks to ensure that the correct lens has been supplied before the treatment day and before it was implanted and we saw records of these. There was a system of final checks carried out by the Surgeons and Nurses to ensure the correct lens was implanted. We saw this final lens check was recorded on the WHO checklist.

The clinic had arrangements with local providers for macular optical coherence tomography (OCT) scanning if there is doubt of macular function to ensure safe and optimal treatment was given.

We saw that there was emergency equipment available including an advisory external defibrillator (AED). Records showed the AED was checked daily and that all other emergency equipment, including oxygen, was checked weekly to ensure it remained ready for immediate use.

Annual training in use of the AED and basic life support was mandatory and four out of five staff had completed this. We also saw records that there were quarterly resuscitation exercises held.

We saw that all staff had completed the annual mandatory training in the 'Management of Violence and Aggression'.

Patients were supplied with the surgeon's emergency contact number for the first 24 hours following surgery and we observed this happening. Patients we spoke with knew who to contact in an emergency. After this time patients could contact the clinic in the event of difficulties.

Nursing staffing

The clinic employed one Registered Nurse and three Patient Advisors/Treatment Assistants. There were no vacancies and no use of temporary staff in the last three months.

Nurses based at other Optimax clinics worked at Maidstone on days where patient treatment was scheduled. On the day of our visit there were four Registered Nurses on duty with clearly defined roles; one Nurse each providing pre and post-operative care and two Nurses in theatres, one as scrub Nurse and one as the circulating Nurse. Staff told us this was the usual compliment on lens replacement days. During laser treatments there were two Registered Nurses on duty but each was supported by one of the Patient Advisors/Treatment Assistants. This showed there was adequate nursing staff on duty to meet the needs of patients.

We saw that there was a formal staffing needs analysis contained in a staffing risk assessment which was updated annually. We saw the assessment that had been reviewed in January 2015.

Surgical staffing

Two Surgeons provided treatment at Optimax Maidstone. One provided lens replacement surgery and the other laser treatments. Patient initial assessments and aftercare was provided by a Registered Optometrist.

Major incident awareness and training

The clinic had an emergency generator that would allow the completion of any treatment already underway in the event of a power failure. For any other business continuity event, the clinic would cancel treatment and other activities until it was resolved.

Are surgery services effective?

Patient care and treatment was planned and delivered in line with current evidence based guidance and standards and patient outcomes were monitored. Clinical outcomes were positive and the expectations of patients were met. Staff were qualified and had the skills to carry out their roles effectively and were supported by training and appraisal. Consent to care and treatment was obtained in line with relevant legislation and guidance.

Evidence-based care and treatment

We reviewed patient notes, spoke with a Surgeon and Nurses and observed surgery in progress. Overall we judged that the Royal College of Ophthalmologists (RCO) 'Standards for Laser refractive Surgery' (revised 2009) and guidance from the National Institute for Health and Care Excellence (NICE), 'Photo refractive (laser) surgery for the correction of refractive errors' (2006) were followed.

Surgery

For example in meeting the RCO standards we saw appropriately qualified surgeons carry out procedures. Equipment was maintained and calibrated, back-up power supplies were available, information for patients was in concise non-technical language, written post-operative instructions were given, Surgeons ensured their availability for emergencies, quality indicators were regularly review, staff were immunised against Hepatitis B, a surgeon was available for the first post—operative visit and the patient's GP was informed of procedures undertaken.

Pain relief

Treatments at Optimax Maidstone were performed under local anaesthetic.

We saw that patients were provided with eye-drops that would numb sensation after laser surgery. After lens replacement surgery patients were also provided with oral pain relief medication to control any pain or discomfort.

Patient literature and consent forms contained advice on what discomfort should be expected and how patients should manage this. There was urgent advice to follow in the case of excessive pain included on the consent form.

Nutrition and hydration

We saw that as part of post-operative care patients were provided with tea and biscuits.

We saw patient information that advised patients having laser surgery to eat and drink normally pre-operatively to reduce the risk of stomach irritation from the pain killers used post-operatively.

We found that patients scheduled for lens replacement surgery were given written and verbal advice and instructions about the need to fast before their procedure.

Patient outcomes

Surgeons had their treatment outcomes audited for the purposes of re-validation and these were monitored by Optimax centrally. Six data graphs, recommended by the American Society of Cataract and Refractive Surgery to evaluate practice against standard recommended criteria for safety, reliability, stability efficacy and consistency of outcomes, were produced for each Surgeon at the clinic.

We looked at results of the two Surgeons who worked at Optimax Maidstone and found that their results were within expected ranges. For example, no eye lost more than two lines of best corrected visual acuity (BCVA). Three months after treatment, no eye lost more than one line of BCVA for one Surgeon and for the other only, 1% of eyes lost two lines of BCVA.

We saw data that showed 89% of eyes were within 0.5 dioptre of refractive aim for both surgeons at three months after treatment.

There were no unplanned re-treatment or treatment enhancement following refractive eye surgery in the last 12 months

In the 2014 'Patient Satisfaction Survey' 85% of patients described treatment results as 'excellent' or 'good' (excellent 40%). The survey also showed 80% of respondents were happy with the mono-vision treatment provided. In the same survey, 77% rated aftercare as 'excellent'.

Competent staff

Surgeons working at Optimax Maidstone held the 'Royal College of Ophthalmologists Certificate in Laser Refractive Surgery'. We looked at the personal file of one Surgeon and found it contained evidence of the specialist qualifications held in relation to the work they were performing.

We saw that the Surgeons and Optometrist had practicing privileges granted by Optimax but were not directly employed by them. We looked at the practicing privileges documents and found that they clearly set out the responsibilities and expectations of those who practised at the clinic.

The Laser Protection Advisor service was provided by an NHS Foundation Trust. The named Trust representative held current certification by the Association of Laser Safety Professionals.

The Laser Protection Supervisor attended bespoke certified training every two years.

Optimax Clinics Limited provided training to all members of the laser surgery team in 'Core Knowledge and Laser Protection'. We saw certificates displayed in the reception area that showed that Patient Advisors/Treatment Assistants had completed this training in the previous year.

Staff we spoke with told us that Optimax were responsive to additional training requests that were made; for example, additional laser assistant training had been provided.

We saw records in personal files which showed all professional staff were duly registered with the relevant professional bodies. There were copies of personal files for Registered Nurses, who were based at other clinics but also provided care at Maidstone. This meant the Manager could be confident that Nurses working at the clinic were properly registered.

We saw records of induction and probation programmes in staff files. These included a range of competency assessments that demonstrated staff had both the theoretical knowledge and practical skills to do their job.

We saw that all staff had received an appraisal in the past year, after they had been in post at least a year, this included the Manager. We saw evidence that Surgeons practicing at Optimax Maidstone had also a current appraisal and were engaged in the process of professional re-validation.

We saw there was a risk assessment for lack of staff competency which was reviewed in January 2015.

Multidisciplinary working

Post-surgery, all patients were given a letter detailing the procedures they had undergone and their post-operative medication regime to take to their GP surgery to ensure continuity of care.

We noted that there was a close working relationship between the Manager, Surgeons, Optometrist, Nurses and Patient Advisors/Treatment Assistants. Staff appeared clear about their role and how it benefited the patients.

Access to information

We observed that patient records were available when they were required for the Surgeon and Nurses to provide care and treatment. Records contained all the relevant information, and assessment results to enable safe, effective care to be delivered.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Obtaining consent reflected Royal College of Physicians 'Professional Standards for Cosmetic Practice' (2013). We saw that there was a comprehensive system to ensure that informed consent was obtained. Patients were required to complete an initial consent document which out lined the general risks and benefits of the procedure proposed. We saw copies of these in patient records and noted that each paragraph had been initialled by the patient to indicate they had read and understood the point under discussion.

Prior to any specific procedure, a comprehensive consent document was provided that made explicit the specific risk for the proposed procedure and potential complications. Patients were also provided with statistical data, simply presented, that enable them to see the likely benefits of treatment. Patients were provided with this in advance of their procedure day so they had the opportunity to read the information and seek any further information assurances they required. This ensured there was a 'cooling off period' for patients with regard to consent.

Patients were provided with a copy of their consent form to retain for their reference.

On the day of their procedure patients initialled each section of the consent form to indicate they had read and understood each section, and signed the document overall. The Surgeon performing the procedure examined the patient pre-procedure and signed the consent form to indicate they were satisfied the patient understood the planned treatment, its risk and benefits and was happy to continue. We looked at four sets of patient notes and saw that the consent forms were all fully completed.

The Manager told us that the clinic did not treat people who did not have the capacity to consent. We could not establish how staff would recognise if capacity to consent was impaired, as no training on the issue was required.

Are surgery services caring?

There was positive feedback from patients and those close to them about their experience of care and treatment. Patients were treated with kindness and supported to make their own decisions as well as understanding their care and treatment. Staff provided emotional support to assist patients to cope with their treatment.

Compassionate care

The 'Patient Satisfaction Survey' 2014, showed 92% of patients said they would recommend the service to family and friends, with 98% rating the overall approach of the Surgeon as 'good' or 'excellent' (76% as excellent).

Surgery

We listened to a Patient Advisor/Treatment Assistant responding to patients on the telephone. We found that they were courteous and helpful. They provided reassurance and answered queries fully and patiently. We observed the recovery Nurse reassuring a patient who had concerns about "watery vision" and noted they did so with kindness and sensitivity.

We saw numerous recent cards and comments in the visitors book thanking the team at Optimax Maidstone for the care and attention that had been given.

We spoke with four patients who were all very complimentary about the staff and the care and attention they had been shown. The staff were described as friendly and helpful.

We observed that patients were treated kindly and with respect. We saw that treatment and consultations were performed in private.

Understanding and involvement of patients and those close to them

Consent forms also contained a wealth of detailed information to aid patients understanding of their treatment, other alternative treatment options, likely outcomes and risks and benefits. We saw staff talking through consent forms with patients in a calm and helpful manner.

We found that Patient Advisors/Treatment Assistants talked to patients who were making initial enquiries about what to expect, possible costs, what the various procedures involved and possible outcomes.

Emotional support

Patients were assigned their individual Patient Advisor to guide them through the pre-operative processes and to manage their pathway from referral to discharge. This meant patients had a named person with whom they could build a relationship and who co-ordinated their patient journey

Patients considering treatment were provided with telephone numbers (with appropriate consent) of patients who had had similar procedures and who were willing to discuss their experience.

The Clinic Manager had compiled a photo storybook of their personal experience of treatment. It provided a comprehensive account of their pathway and enabled patients to understand what to expect, the people they would meet and how they might feel.

From patients compliments and feedback we especially noted that patients who were nervous felt they had received the support and reassurance they required.

Are surgery services responsive?

Patients needs were met through the way the service was organised and delivered. The importance of choice and flexibility was emphasised with access to care available at a convenient time for patients. There were arrangements to ensure the needs of patients with disabilities could be met. The environment was pleasant and was appropriate for the service delivered. Patients could complain and concerns were always taken seriously and investigated. Appropriate responses were made and actions were taken as a result of complaints, although responses did not inform patients how they could escalate concerns if they are unsatisfied with that response.

Service planning and delivery to meet the needs of local people

Patients self referred to Optimax clinic through a variety of methods; online, via the corporate call centre or by visiting the clinic. This meant there was a range of referral methods to ensure that it was convenient for patients.

Optimax Clinic Ltd advertised its services using a range of local and national media to ensure potential patients would be aware of the services offered, including those at Maidstone.

Optimax offered a range of payment plans to help make treatment affordable to as wide a range of the population as possible. These were advertised in the clinic and staff were able to discuss these knowledgably with patients.

The clinic was open on Saturdays for greater convenience.

Waiting and reception areas were pleasant and comfortable. Toilet facilities were clean and hygienic and checked every hour.

Surgery

We observed that patients were provided with a comprehensive range of information, including 'Patient Information Guides' specific to the procedure which they were undergoing.

100% of respondents rated the clinic 'excellent' or 'good' in terms of appearance and comfort in the 2014 'Patient Satisfaction Survey'.

In the 'Patient Satisfaction Survey' 2014, 89.6% of respondents rated call centre advisors as 'excellent' or 'good' in terms of helpfulness (72.7% excellent).

In the same survey, 77% rated the Optimax website as 'excellent' or 'good'. 99% rated the Patient Advisors as 'excellent' with regard to helpfulness, and 99% in relation to answering questions.

Access and flow

Patients assessed at Optimax Maidstone could receive their treatment at any other Optimax clinic in order to secure a preferred treatment time or Surgeon. This gave patients greater flexibility about when they could have their treatment.

We saw records which showed patients could choose their appointment times, and that they could cancel and re-book these without penalty.

There were no appointment cancellations by the clinic in the previous year.

In the 'Patient Satisfaction Survey' 2014, 65% rated the service as 'excellent' at time keeping for appointments. This meant patients were seen promptly on the agreed day.

Patients were forewarned that when being assessed for treatment, the time at clinic could be lengthy with some waits between various stages of the process. We saw that in response to patient feedback, the time spent at the clinic at assessment was closely monitored in real time, and by the Manager. This monitoring process alone had reduced the time patients spent in the clinic, although there was only anecdotal evidence to support this claim.

We observed that the flow through the clinic from reception to treatment areas, recovery and discharge were seamless. A patient commented that they felt things were arranged to run smoothly.

The operative treatment did not appear rushed. There was a limit to the number of patients who could be treated in any session. For example on the day of our visit there were six patients treated, with a limit of ten.

Meeting people's individual needs

We observed the clinic was fully accessible for people with physical disabilities. There was a disabled toilet available and we saw records that showed the emergency call bell in this lavatory was tested daily.

We observed there was a loop system to assist hearing aid users in reception.

Annual training in 'Disability Discrimination and Awareness' was mandatory. We saw records that showed three out of five staff were up to date with this. This showed there were arrangements to support people with physical disabilities.

Annual 'Equality and Diversity' training was mandatory and all staff had completed this.

There were facilities in the reception area for patients and their visitors to obtain water, or a range of hot drinks free of charge.

The Manager told us that if a patient did not have English as a first language usually a family member accompanied them to interpret. This is not best practice but staff were especially aware of the need to be assured of the patients comprehension of their care and treatment in these circumstances. If there was no one available the Manager told us they would source a translator at the clinic's expense.

Patients were provided with detailed instructions for aftercare, including how they could reduce the risk of complications and help their recovery.

Patients we spoke with told us this information was supplemented by face to face communication and they felt able to telephone for further information and guidance should they require it. We spoke with three patients who told us that they had all received lots of information that enabled them to have realistic expectations and to understand the procedure, aftercare arrangements and any financial aspects.

In the 'Patient Satisfaction Survey' 2014, 99% of respondents rated the patient advisors as 'excellent' or 'good' in relation to answering questions. 94% rated the pre-consultation information as 'excellent' or 'good'.

Surgery

Patients were provided with a profile of their Surgeon outlining their qualifications and experience. This meant they could be sure the Surgeon was the right one for them.

There were arrangements in place that enabled patients to consult with their Surgeon before the day of surgery if they wished.

On the day of their procedure, patients were required to complete an online questionnaire designed to assess their understanding of their treatment. If the test result triggered concerns staff took action to ensure the patients was fully informed of all relevant issues before treatment could commence.

Learning from complaints and concerns

There was information for patients on how to raise a concern or complaint displayed in the reception area. There was a copy of the complaints procedure available for patients to reference and complaint forms for them to complete if they wished to make a complaint whilst at the clinic. This meant there was information on raising a concern and making a complaint readily available.

Optimax Maidstone received six complaints in the previous year. Four were managed informally. Two were managed formally but were not upheld. We noted that four of the six complaints related to the communication style of staff. The CQC received no complaints about Optimax Maidstone in the same period.

Staff we spoke with told us, and we saw from minutes, that complaints were discussed at monthly staff meetings. We saw that the complaints were discussed in detail and that any lessons learnt or actions were shared. This showed there was a system to ensure learning from complaints and concerns.

We looked at complaint responses and noted Optimax offered an apology, an explanation and remedial action where appropriate, including refunds. However they did not advise complainants of what action they could take to escalate their concern if they were unhappy with the outcome. CQC guidance to providers states, "Information must be available to a complainant about how to take action if they are not satisfied with how a provider manages and/or responds to their complaint". This aspect of guidance was not being followed.

Are surgery services well-led?

The Manager had sufficient information to manage the current and future service, with appropriate oversight from the provider. There was a culture of collective responsibility that was transparent, open and collaborative, and was focussed on the provision of good quality services that met patient needs. This ethos was shaped through effective engagement of staff and patients.

Vision, strategy, innovation and sustainability for this core service

Staff we spoke with were aware that Optimax Maidstone was part of the wider Optimax organisation and understood its purpose of providing private refractive eye surgery.

The Manager told us that agreed corporately led key performance indicators (KPI's) were in place and their performance and ultimately the performance of the clinic was based on these. They further explained that these KPI's were centred on the commercial aspects of the business, for example the conversion rate of enquiries to treatment. We saw that performance, based on these indicators was shared with the team at team meetings so that the achievement of them was viewed as a team enterprise.

Governance, risk management and quality measurement for this core service

We saw that risks were formally assessed using a risk assessment methodology and that these assessments were regularly reviewed. We reviewed the current risk assessments and found they clearly identified risks and any mitigating actions. We sampled a selection of these mitigating actions, for example those concerned with fire safety, and found they were in place.

We saw that there was a comprehensive system of checks surrounding key safety issues and we found these were consistently recorded.

All professional staff with practicing privileges had professional indemnity insurance. We saw evidence of this in personal files that we examined.

The Manager told us there were quarterly Corporate Managers meetings, where any governance issues were

discussed if they had implications for the company's operations overall. Otherwise assurance regarding safety and quality issues was managed as part of scheduled monthly meetings with their Line Manager.

There was a corporate medical advisory committee (MAC) and the Surgeons with practicing privileges at the clinic attended. The Manager told us they could access the minutes of the meeting through shared information systems, and that if there were issues specific to Optimax Maidstone, they would be informed of these separately. This meant there were arrangements for consultants to raise, and discuss any issues of quality and safety with the provider.

Leadership/culture of service related to this core service

Staff we spoke with all described their Manager, at local or corporate level as being supportive, visible and accessible.

Junior staff advised us that National Managers kept in regular contact with the Clinic Manager and visited each month and spoke individually and confidentially with all grades of staff.

There were formal staff meetings monthly and we saw the minutes of these. We noted they contained an update on matters of corporate interest to ensure that staff at the clinic were not isolated from what was going on in the rest of the organisation.

These were supplemented with informal 'huddles' held each morning with current issues of concern.

There had been no episodes of staff sickness in the previous year.

Innovation

We found the clinic was engaged in developing services. For example, we found that the clinic was moving toward surgeon based rather than optometrist pre-assessment and investment in software for auditing and assessing the results of treatment.

Outstanding practice and areas for improvement

Areas for improvement

Action the hospital SHOULD take to improve

- Ensure its complaints responses meet CQC guidance in relation to informing patients how to escalate concerns if they are unsatisfied with a response.
- Ensure staff have a clear understanding of safeguarding adults in vulnerable circumstances and assessment of mental capacity in the context of a refractive eye surgery clinic.
- Ensure there is an effective system for monitoring water safety which meets national guidance.
- Ensure that medical gases are stored appropriately.
- Review its water quality testing in order to meet corporate policy requirements.
- Review its storage to ensure there are no further instances of medical gases being stored alongside combustible materials.