

Optegra Leeds

Quality Report

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Date of inspection visit: 10, 12 October 2017
Date of publication: 20/02/2018

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

Overall summary

Optegra Leeds is a private clinic operated by Optegra UK Limited. Facilities include an operating theatre, assessment and consultation rooms and a patient waiting area. The service is accessible from Leeds train station and car parking is available.

The service provides refractive (laser) eye surgery only. The service is provided to adults. All patients are privately funded, referring and paying for their refractive (laser) eye surgery themselves.

We inspected this refractive (laser) eye surgery service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 10 October 2017 along with an unannounced visit to the hospital on 12 October 2017.

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.

The main service provided by this hospital was refractive (laser) eye surgery.

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

We found the following areas of good practice:

- There were low levels of incidents and complaints.
- Patients were consistently positive about their experience and the outcomes from their surgery.
- Effective governance and risk management processes were in place.
- Suitable numbers of competent, trained staff were available.
- Staff worked well as a team and were engaged with the local vision to expand the service.
- Staff were up to date with mandatory training and most staff had received an annual appraisal.
- Patients told us they felt involved in decisions about their care because staff took time to listen and explain.
- Medicines were managed and administered in a safe and appropriate manner.
- A surgical checklist was effectively used to ensure safe treatment for patients.

Summary of findings

- Laser safety was well managed and records were appropriately maintained.
- Surgical outcomes were benchmarked internationally, to contribute to continuing improvement.

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

- Although we saw evidence incidents were addressed and actions taken to minimise patient safety risks, we found not all low or no-harm incidents were recorded as per Optegra policy. This meant some incidents or themes could be missed.
- Although an observational audit and training were in place to support nursing staff in infection prevention and control, this did not include optometrists.
- The optometrist-led pathway meant patients were not being seen by the surgeon carrying out treatment until the day of the procedure, which is best practice. However patients were seen by the consultant prior to undergoing surgery on the treatment day.

- Arrangements for managing emergencies did not include a service level agreement with the local NHS hospital or a written policy for managing ophthalmic emergencies, which are best practice. However, the service had not had any emergencies in the last 12 months.
- Patient information was not routinely available in easy read format, to assist people with impaired sight.

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

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Optegra Leeds

Services we looked at: Refractive eye surgery

Summary of this inspection

Background to Optegra Leeds

Optegra Leeds is operated by Optegra UK Limited and is part of Optegra Yorkshire Eye Hospital (OYEH). It provides refractive (laser) eye surgery only.

The service opened in its current location in Leeds city centre in 2010. It receives private patients from across Yorkshire. It also accepts patients from outside of this area.

The service has had a registered manager in post since May 2011. The current registered manager has been in post since March 2017. At the time of this inspection, the registered manager was the director of two Optegra Eye hospitals in the region.

The service is registered to provide the following regulated activities:

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

Optegra Leeds was previously inspected in December 2013 when we found that the essential standards of quality and safety were met.

Our inspection team

The team that inspected the service comprised a CQC lead inspector; a specialist advisor with expertise in ophthalmic nursing, and one other CQC inspector. The inspection team was overseen by Lorraine Bolam, Interim Head of Hospital Inspection.

Information about Optegra Leeds

Optegra Leeds offers refractive (laser) eye surgery only, for adults. The service does not offer treatment to children or anyone under 18 years old. If a patient required a different procedure, for example surgery requiring anaesthesia or sedation, or lens replacement surgery, they would be referred to Optegra Yorkshire Eye Hospital or another Optegra UK service.

The service is open three days per week: Tuesday, Thursday and Friday, from 09:00 to 17:00. Surgery days at Optegra Leeds are usually scheduled twice per month and other days are used for assessments and aftercare.

Facilities include an operating theatre, assessment and consultation rooms and a patient waiting area. The service is accessible from Leeds train station and car parking is available.

All patients are treated as 'day cases' and discharged the same day, with no inpatient stays. All patients are privately funded, referring and paying for their refractive (laser) eye surgery themselves. No intra-ocular surgery (e.g. refractive lens exchange) was carried out at this location.

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 areas of good practice:

- Learning from incidents prompted changes to improve the service.
- Staff were up to date with mandatory training.
- The environment was visibly clean and hygienic.
- Laser safety was well managed and records were appropriately maintained.
- Medicines were managed and administered in a safe and appropriate manner.

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

- Although we saw evidence incidents were addressed and actions taken to minimise patient safety risks, we found not all low or no-harm incidents were recorded as per Optegra UK policy. This meant some incidents or themes could be missed.
- Although an observational audit and training were in place to support nursing staff in infection prevention and control, this did not include optometrists.
- Arrangements for managing emergencies did not include a service level agreement with the local NHS hospital or a written policy for managing ophthalmic emergencies, which are best practice. However, the service had not had any emergencies in the last 12 months.
- Post-operative calls from patients were logged in patient notes, although we did not see evidence that these calls or calls to the out of hours on-call line were monitored or analysed. This meant the service did not have oversight of any common themes or trends affecting patients post-operatively.

Are services effective?

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 areas of good practice:

- Suitable numbers of competent, trained staff were available.
- Staff were positive and worked well as a team.

Summary of this inspection

- Patient feedback was consistently positive about their experience and the outcomes from their surgery.
- A surgical checklist was effectively used to ensure safe treatment for patients.
- Staff had received an annual appraisal.
- Surgical outcomes were benchmarked internationally, for continuing improvement.

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

- The optometrist-led pathway meant patients were not seen by the surgeon carrying out treatment until the day of the procedure. Patients usually saw an optometrist at the initial stage and the consultant (surgeon) at the second. It would usually be best practice to see the same member of staff at each stage. However patients were seen by a consultant prior to undergoing surgery on the treatment day.

Are services caring?

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 areas of good practice:

- Patients told us they felt involved in decisions about their care because staff took time to listen and explain.
- Patient feedback was consistently positive about the approachable, supportive and friendly staff team.

Are services responsive?

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 areas of good practice:

- An optometrist-led pathway had been introduced to support timely access to initial appointments for patients.
- Staff were ready to support patients' individual needs, as required.
- Complaints were managed appropriately.

Are services well-led?

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 areas of good practice:

Summary of this inspection

- There was a clear leadership and governance structure.
- Effective governance and risk management processes were in place.
- Patient feedback was valued and sought in a variety of ways.
- Staff members we spoke with were positive and engaged with the local vision to expand the service.
- Surgical outcomes were benchmarked internationally, to contribute to continuing improvement.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Information about the service

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All patients are treated as 'day cases' and discharged the same day, with no inpatient stays. All patients are privately funded, referring and paying for their refractive (laser) eye surgery themselves. No intra-ocular surgery (e.g. refractive lens exchange) was carried out at this location.

The service is managed by the Optegra Yorkshire Eye Hospital (OYEH), based in Bradford. Two surgeons worked at the Leeds site, under practising privileges. Optegra Leeds employs three registered nurses, two optometrists and a patient liaison officer. Nursing staff from OYEH, including bank staff, also work at Leeds, as required.

During our inspection, we visited the clinic and we spoke with two patients who were attending for pre and post-operative assessments and laser surgery. We spoke with seven members of staff including; registered nurses, optometrist, patient liaison and senior managers. We also

received five 'tell us about your care' comment cards which patients had completed prior to and during our inspection. During our inspection, we reviewed five sets of patient records.

From July 2016 to September 2017, Optegra Leeds performed 64 refractive (laser) eye surgery procedures. During this reporting period;

- There were no Never Events and no serious incidents.
- There were no special reviews or investigations of the service ongoing by the CQC.
- There were no incidences of hospital acquired infection.
- The service had received one complaint.

The service had been inspected once before, in December 2013, which found that the service was meeting all standards of quality and safety it was inspected against.

Services provided at Optegra Leeds under service level agreement:

- Clinical waste removal
- Cytotoxic medicines service
- Pathology
- Microbiology
- Laser protection service
- Interpreting services
- Records storage and disposal
- Secure transport
- Security / building maintenance
- Domestic cleaning
- Maintenance of medical equipment.

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.

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Incidents and safety monitoring

- The service had a system in place for reporting and recording significant events. A central incident tracker spreadsheet was used to log incidents, reported via paper alert forms.
- A corporate incident reporting and management policy and procedure was available to all staff via the intranet. It had been updated (revised July 2017) and included information to support investigations of serious incidents and to meet external reporting requirements e.g. in relation to the Duty of Candour, NHS Improvement National Framework for Reporting and Learning from Serious Incidents (NRLS) and Strategic Executive Information System (STEIS).
- The service had reported no Never Events or serious incidents during the reporting period. 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.
- During the inspection, we identified some patient safety incidents which had been addressed, but had not been logged or reported. For example; an incident where a consultant could not be contacted out of hours; incidents when staff told us theatre staffing was not as per the staffing policy on some days; patient records not being securely stored during transportation; and two equipment failures; a broken medicines fridge lock and the magnetic door locks not working correctly on the laser room.
- These incidents met the definition of an incident or near miss in the Optegra UK incident reporting and management policy, although as low or no harm incidents, they did not require a full investigation. While we saw that timely action had been taken to mitigate the risk and ensure patient safety in each case (e.g. changing the on-call arrangements, changing the policy for secure transport of records, fixing equipment or adjusting the theatre timings), the incidents had not been reported using an alert form or recorded centrally on the incident tracker, as per Optegra UK policy. However, the system for using the alert form was relatively new. The service did not yet have had full oversight of all alerts and incidents, to identify any emerging themes, risks or further learning.
- We saw that the incident policy (July 2017) had twice been communicated with staff via email. Although the process had yet to be used at Optegra Leeds, we saw that alert forms had been raised from other parts of Optegra Eye Hospital (OYEH), including low or no harm incidents (graded as a 'concern' across Optegra). The Integrated governance meeting (September 2017) had highlighted a need to clarify what staff should report on an alert form and what would constitute an incident or a concern. This is important as incidents involving patient harm or indicating emerging safety themes could potentially be missed if staff are not confident in recognising or low or no-harm incidents which should be reported.
- Operational concerns were discussed and actioned at the OYEH 'huddle meeting'. Although notes from the daily 'huddle' meetings at OYEH were shared with Optegra Leeds staff via an email bulletin, Leeds-based staff did not join the meeting. Topics included operational issues such as staffing, health and safety, policy changes, compliments / complaints, infection control. We saw that service and policy changes, which may arise from learning from incidents, were discussed here and staff were able to raise concerns.
- Issues that may affect clinical effectiveness were discussed at the Medical Advisory Committee (MAC) meetings and the integrated governance (IG) meetings. Although clinical team meetings had not been consistent in recent months, minutes from the MAC and IG meetings were recorded and shared amongst staff to raise awareness and learning from incidents.
- We reviewed learning from two non-patient safety incidents which had been reported and investigated under the previous incident policy. Both were reported, graded, investigated and actioned appropriately, although the service had incorrectly identified one as a serious incident in the pre-inspection information to CQC, which was clarified on inspection. The incidents had been reviewed by the hospital director and were recorded on the central incident tracker, to enable learning to be shared across Optegra UK locations.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.

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- The service had reported no complaints or incidents which triggered the duty of candour (DoC), during the reporting period. A 'Managing Duty of Candour Policy' was available (revised July 2017) and the hospital director described how they were familiar with the DoC as it had been applied at other locations they were responsible for.
- We saw that DoC was referred to in the incident reports we reviewed. They recorded whether the patient was made aware of the incident, irrespective of level of harm, although we noted there was no prompt for DoC on the new incident investigation forms, which were introduced in July.

Mandatory training

- Five out of six staff at Optegra Leeds (nursing, optometry and patient liaison) met or exceeded the 90% target for mandatory training compliance. One member of staff had achieved 88% compliance.
- Mandatory training included fire safety, infection control, manual handling, slips, trips and falls, equality, diversity and human rights, safeguarding, stress awareness, and life support. Other online courses included stress awareness and data protection and display screen equipment.
- Records showed 100% clinical staff had completed annual intermediate life support (ILS) training. 100% of non-clinical support staff had completed basic life support (BLS) training.
- There was a system in place to monitor staff training, staff were emailed when training was due and compliance was reviewed at the integrated governance meeting.

Safeguarding

- Records showed 100% nursing, medical and patient liaison staff at Optegra Leeds staff had completed safeguarding adults training to level 2 at the time of inspection. Of the two optometrists, one had completed this training and one had not, but was due to leave the organisation.
- There was an up to date safeguarding policy in place which was regularly reviewed at a national level and a corporate safeguarding lead, to provide advice and oversight.
- Locally, the safeguarding lead was the hospital director, who had completed level 3 safeguarding training in line with Optegra UK policy. There was a safeguarding

named nurse and a named doctor. Further level 3 training was scheduled for the named nurse and the new clinical service manager. Following the inspection, managers told us they had attended a local authority safeguarding meeting to link with local work.

- Safeguarding vulnerable adults and children was included in the mandatory training programme. Although the service did not treat children, staff had completed child protection training to ensure they were aware to recognise and respond to potential safeguarding issues concerning children associated to their patients. Nursing staff we spoke with were familiar with their obligations regarding safeguarding and told us they would contact the named nurse lead, if they had concerns about a patient or their family. Staff knew information on how to contact the local authority was available via OYEH, although we did not see this on display at Optegra Leeds.
- Staff training was monitored and the tracker showed 84% of Optegra Leeds staff had completed safeguarding level 2 training for both adults and children. Three staff had also completed 'Prevent' training, a programme designed to help healthcare professionals safeguard people from getting involved or supporting terrorism or extremist activity.
- The service had not reported any safeguarding concerns since its opening in 2010 and there were no safeguarding issues logged with CQC. The hospital director confirmed that there had never been a safeguarding concern in the service.
- Although Optegra UK safeguarding policy says; 'leads will ensure that safeguarding will form part of the agenda items for the hospital Integrated governance committee', we did not see safeguarding discussed in the minutes we reviewed.

Cleanliness, infection control and hygiene

- All areas were observed to be well maintained and provided a visibly clean environment.
- From July 2016 to September 2017, the service reported no incidences of hospital acquired infection such as methicillin-resistant *Staphylococcus aureus* (MRSA), methicillin-sensitive *Staphylococcus aureus* (MSSA), E-Coli or *Clostridium difficile* (c.diff).
- There was an infection, prevention and control policy (January 2015) and a manual cleaning policy in place and these were accessible to staff. The policies included

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directions on safe working practices, hand hygiene, protective clothing, cleaning policy, waste disposal, MRSA policy, handling of sharps and the labelling, handling and transportation of pathology specimens.

- Managers told us staff maintained skills in sepsis identification via policy review and that escalations and endophthalmitis (inflammation of the eye) treatment protocols were in place for treatment and management. Staff were aware of these and although the policy did not say how infections or concerns should be reported and recorded, we saw the clinical team had discussed this at a clinical team meeting. Staff told us patients were asked whether they had recently been in hospital or had an infection as part of the pre-operative process, as per Optegra UK policy, although we did not observe this in practice, during our inspection.
- The service completed an observational hand hygiene audit, which showed 100% compliance in September 2017. However, records showed optometrists had not completed infection control training and were not included in the hand hygiene audit. This was not in line with Optegra UK policy or NICE guidance QS61 S3, as the service was not supporting all staff to maintain basic hygiene standards. During inspection, we observed staff practice during initial and follow-up appointments and noted that one member of staff did not wash their hands before or after administering eye drops.
- In theatre, we observed staff clean equipment before and after use and between patients. Staff used personal protective equipment (PPE), such as gloves, to assist in the reduction of the spread of infection, and were observed to be used appropriately. Staff used disposable, single-use instruments, to eliminate the need for decontamination. Waste bins were operated hands-free, suitable waste bins were available for sharps and cytotoxic waste and a service level agreement was in place for collection and disposal of clinical waste.
- We saw that theatre temperature and humidity was monitored before and during theatre sessions, in line with laser manufacturer guidance. This was in line with Royal College of Ophthalmology guidance for refractive surgery (April 2017) and for the theatre environment (2013).
- Sink taps were operated hands-free throughout the service and water temperature was automatically maintained at a safe level.
- We reviewed cleaning schedules and found them to be signed and up to date. There was a service level

agreement in place for domestic cleaning. Records showed the service scored 85% on a hygiene spot check against a target of 90% and staff told us about an observational check to ensure domestic cleaning was effective for the theatre area. One patient commented; 'it has always been spotless, including the toilets and waiting area'.

- Meeting minutes showed infection control issues were included as a set agenda item and regularly discussed at the integrated governance meeting and Medical Advisory Committee and action taken. There was also an OYEH infection control meeting in place, where the service sought advice from a microbiologist, as required.

Environment and equipment

- The environment was tidy and free from clutter, enabling patients, visitors and staff to move around freely.
- We looked at clinical areas including examination rooms, consultation rooms and the laser room. Clinical areas were observed to contain equipment that was suitable to the diagnosis, laser surgery and recovery of patients. The theatre environment was in line with Royal College of Ophthalmology guidance for refractive surgery (April 2017).
- Records available indicated that the service had a schedule for routine maintenance and equipment checking, including the lasers used for surgery.
- We saw controlled areas were clearly defined and there was a sign in and out book for laser keys which were kept securely.
- There were local rules in place for laser safety. We saw evidence that the service followed guidance from the laser protection advisor and there were appropriate risk assessments in place.
- A laser protection supervisor (LPS) was in place, as well as a deputy and a clinical LPS. We saw evidence that all relevant staff had read and signed the 'Local Rules' and we saw these were followed in theatre. This was in line with the Medicines and Healthcare products Regulatory Agency Surgery (MHRA) guidance on lasers, intense light source systems and light-emitting diodes (LED's) – guidance for safe use in medical, surgical, dental and aesthetic practices (September 2015).
- Each patient who received laser treatment was logged into the theatre register with the procedure performed and labels from any disposable instruments used were attached to each patient record for tracking purposes.

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- Resuscitation equipment was available for use in an emergency. Managers told us a registered nurse was now allocated to check resuscitation and other equipment weekly. Records showed that during July and August, there were two occasions where resuscitation equipment had not been checked for three weeks. We saw a standard operating procedure had been introduced in September 2017 and that weekly checks had been completed since then.
- Security measures were in place that meant that staff had to allow access to visitors and could observe them arriving in the building.

Medicines

- Staff carried out weekly checks of stock and expiry dates, to ensure medicines remained safe to use, although no external medicines audit was in place to verify this. Minutes showed the need for a medicines management audit for Optegra Leeds was discussed at the integrated governance meeting (September 2017). Managers told us a service level agreement was being considered with an external pharmacy, which already provided this service at OYEH.
- Medicines were stored in a secure pharmacy room with a coded lock, although we found staff were unsure when the code was last changed and that non-clinical staff also used the code. This was not in line with the corporate medicines management policy which says; 'Access codes should only be given to staff that have a legitimate need to access the keys and a list of staff granted access should be kept. These access codes should be changed every six months'.
- Fridge temperatures were checked and recorded daily to ensure that medicines which required refrigeration remained suitable for use. Staff knew what to do if the fridge temperatures went out of range. Emergency medicines on the resuscitation trolley were stored using an anti-tamper system and weekly checks were completed.
- Managers confirmed no controlled drugs, no intravenous sedation or needle-based blocks were used on site and no cytotoxic medicines were prepared on site.
- Optometrists, nurses and consultants gave medicines such as eye drops and this was recorded appropriately in patient notes and in a pharmacy log book, with dose, site and strength of medicine given. Following inspection, the service told us the pharmacy service had recently provided medicines management training for nursing staff.
- In theatre, staff recorded medicines expiry and batch numbers on a separate sheet for each patient. At discharge, we observed medicines were checked by two registered nurses and medicines information leaflets were given to patients with eye drops, together with written information giving emergency contact telephone numbers.
- At the time of inspection, the service was not using cytotoxic medicines as their use had been suspended by Optegra UK in August 2017. Cytotoxic medicines contain chemicals which are toxic to cells, preventing their replication or growth. Managers explained their use was suspended in response to a safety issue which had been identified at another Optegra UK location following a CQC inspection. A new policy and staff competencies regarding the use of cytotoxic medicines had been developed and were due to be implemented in November. Managers told us the operations that could be completed without using cytotoxic medicines had gone ahead and where others had been postponed the service had explained the reasons to patients.
- Following inspection, the service provided a new standard operating procedure, consent form, risk assessment and staff competency for the use of cytotoxic medicines. Managers told us the new process had been piloted successfully and cytotoxic medicines were being used again from November 2017. Feedback was being sought from all Optegra UK locations and an audit was planned for December, to check the arrangements were effective.
- Patient records showed patients had been appropriately informed about off-licence use of cytotoxic medicines (when they were in use) as part of the consent process and that this was documented in patient records.
- Patient records detailed current medicines, any allergies and a medical history to make sure that any medicines prescribed by the consultants were safe to be given.
- The service had a corporate medicines management policy in place. This was up to date and accessible to staff via the organisation's electronic system. There was a new local policy for the transfer of medicines to Optegra Leeds from OYEH. Annual medicines management training for nurses was completed as per the policy and this was monitored centrally.

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Records

- The service used a paper medical record system, supported by an electronic system. The paper record was the primary record. Notes were kept within the department and made available as needed. Electronic records were only accessible to authorised people. Computers and IT systems used by hospital staff were password protected.
- During inspection, we observed that arrangements for transporting patient paper records to Yorkshire Eye Hospital were not fully secure and that this had not been identified or reported. When this was raised, the hospital director took immediate action to put arrangements in place to secure records for transit. Following inspection, Optegra Leeds provided a new policy for the transfer of medical records between sites, which included a prompt to record any breaches using the incident reporting system.
- We reviewed records for five patients. Patient records included information on the patient's medical history, previous medications, absolute or relative contra-indications, consultation notes, treatment plan and consent form, in order to keep the patient safe and to determine suitability for surgery. The record accompanied the patient into surgery and a contemporaneous record of treatment was maintained. Appropriate records were maintained each time a laser was operated. The operation record, follow-up notes and aftercare information were also recorded.
- There was an audit plan which identified patient records were audited every six months. We saw that ten sets of records were audited twice in September 2017 and compliance varied on the criteria checked e.g. legible handwriting 40% compliance; consent recorded appropriately 100% compliance. We reviewed five sets of records and noted improvements in several areas identified in the audit action plan, however some handwriting was not legible in the records we reviewed and a printed patient ID name label was not seen on every relevant page (e.g. no space on post-operative examination sheet). We noted that the service had scheduled a re-audit for November 2017 and managers confirmed that legibility of documentation was an area for improvement.

- Records showed clinical audit results were discussed at the Medical Advisory Committee and importance of the level of consultant compliance re: capturing post-operative complications in the electronic record system was discussed (March).

Assessing and responding to patient risk

- Prior to commencement of treatment, patients were assessed for their suitability for laser surgery. As this initial appointment was led by an Optometrist, we found patients may not meet their consultant before the day of surgery.
- Patients met with an Optometrist at the initial consultation and completed a patient medical questionnaire. There was a detailed assessment form to guide the optometrist through the information to be gathered from the patient, although there was no accompanying standard operating procedure in place for the Optometrist-led pathway. The Optometrist carried out a range of vision and eye health tests and had a discussion with the patient, to gather defined information and identify any complications for surgery.
- Although we saw information from the initial assessment was passed to the surgeon for review and the surgeon made the decision about the treatment, we were not assured this Optometrist-led pathway was in line with Optegra policy or best practice guidelines. The Optegra UK theatre pathway standard operating procedure (SOP) assumes the patient has been previously seen by a consultant, before the day of surgery. The Royal College Professional Standards for Refractive Surgery guidance (April 2017) say; 'the consultation at which the procedure recommendation is made should be with the operating surgeon'. This is important as the surgeon must assess whether the intervention is appropriate and likely to meet the patient's needs, ahead of the day of surgery. Staff told us that there is not always a consultant available at Optegra Leeds and patients did not always meet their surgeon ahead of the day of surgery.
- The Optegra UK theatre (including laser) pathway standard operating procedure (SOP) says; 'All patients should have a face to face pre-assessment with a nurse including the recording of baseline observations'. Staff told us patients were not receiving a pre-assessment with a nurse ahead of the day of surgery, as this was; 'a

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work in progress' and that patient liaison staff would raise any issues from the patient medical questionnaire with the nurse. This was not in line with the SOP and it was unclear who was responsible for pre-assessment.

- On the day of surgery, we saw that the patient met with the consultant surgeon and separately with a nurse. We observed pre-operative checks and we reviewed patient records. Staff checked the patient's name, date of birth, address, allergies, consent and correct procedure with the patient, prior to surgery commencing. Patients were also asked if there were any changes to general health and their blood pressure, pulse and oxygen level were checked. We saw the consultant spent time with the patient in a 30 minute appointment. They reviewed the information collected at the initial appointment by the Optometrist, including information about contra- or relative indications, and the consultant took the final decision about the treatment.
- Theatre staff followed the World Health Organisation (WHO) surgical checklist and we saw this was followed in each of the procedures we observed. Completion of this documentation was audited monthly and the service had achieved 100% compliance over the past 6 months. Although the service did not carry out its own observational audits of practice around the WHO checklist, we observed good compliance with the checklist in practice, during inspection.
- We saw staff gave patients written information about post-operative care and an emergency contact number for the on-call nurse up until 22:00 and for their surgeon (24 hours). Patients were also advised they could contact their local hospital's emergency department if necessary.
- The on-call policy stated patients would be directed to their local hospital's emergency department in the event a consultant was not available; however it was unclear how this would be monitored. Similarly, post-operative calls from patients were logged in patient notes, although we did not see evidence that these calls or calls to the out of hours on-call line were monitored or analysed. This meant the service did not have oversight of any common themes or trends affecting patients post-operatively.
- A new corporate policy for managing medical emergencies and the deteriorating patient had recently been introduced (August 2017) which included a national early warning score (NEWS) scoring tool.

- Staff told us in a medical emergency, they would call 999, as a doctor may not be working on site every day. A policy for responding to a medical emergency and a policy for the transfer of patients out to another hospital in the event of needing critical care were in place, although there was no service level agreement with the local NHS hospital. In the event of an ophthalmic emergency, managers told us consultant colleagues at OYEH could be contacted for advice, although there was no written policy in place to support this. These arrangements did not fully meet best practice guidelines as the Royal College Professional Standards for Refractive Surgery guidance (April 2017) say; 'There should be clear arrangements for transfer to another provider where appropriate in the case of an emergency or where additional specialist treatment is required for the treatment of complications.'
- In the previous 12 months there had not been any complications for patients that required a patient to transfer to hospital.

Nursing and medical staffing

- Staffing levels we observed were appropriate for the type of service offered, there was no agency use and the service took action to maintain patient safety and mitigate staffing pressures. For example, staff told us theatre lists could sometimes be slowed down to ensure safe staffing and patients would be informed of any delays on the day.
- The service was open three days per week: Tuesday, Thursday and Friday, from 09:00 to 17:00. An emergency telephone line was staffed by an on-call nurse until 22:00. Surgery days were usually scheduled twice per month.
- Two surgeons worked at the hospital under practising privileges. Three registered nurses, two optometrists and a patient liaison officer were usually based at Optegra Leeds. Nursing staff and patient liaison staff from OYEH also worked at Optegra Leeds, as required, to cover holidays and sickness.
- There was a theatre safe staffing policy in place and the theatre team lead assessed and anticipated the numbers of staff required based on the number and type of procedures that were being undertaken for each session. This information was then used to plan and

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schedule the appropriate numbers of nursing staff and skill mix required. Due to the size and nature of the service provided, it did not use a formalised staffing acuity tool.

- Consultants worked across both Optegra Leeds and OYEH and nurses travelled between sites as necessary. The service also had its own 'bank' of staff that could be called upon when required to help with staff absence or vacancies. These individuals had experience and knowledge of the service and were current or former Optegra Leeds staff. These flexible arrangements meant the service did not use agency or locum staff during the reporting period.
- The operating theatre team comprised; a surgeon, a scrub practitioner, a circulating practitioner and a laser technician (who was also an optometrist). They worked with a pre- and post-operative nurse. Patients were recovered in a separate consultation room, where at least one registered nurse was present.
- At the time of inspection, there were three vacancies - scrub nurse, clinical service manager and patient service manager. 'Inability to recruit scrub nurse as RN resources are limited nationally' was recorded on the strategic risk register. Managers told us three healthcare technicians had been recruited to mitigate this at OYEH and free up skilled staff.
- Staff told us sometimes a separate pre and post-operative nurse was not available. In this case, the theatre list would be slowed to allow one member of the team to perform both roles. On the day of inspection, we also observed a nurse from OYEH was shadowing to learn how to complete pre and post-operative checks at Optegra Leeds.

Major incident awareness and training

- The service had a new business continuity plan in place (July 2017).
- There was a back-up generator system in place to ensure treatment is not compromised if power to the laser failed mid-treatment.
- Fire safety arrangements were in place and staff were aware of the evacuation procedure, although we saw no sign visible to patients and staff to indicate the fire assembly point in the event of evacuation.

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

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.

Evidence-based care and treatment

- We saw that the majority of policies and procedures and the treatment we observed, aligned with recognised national standards and guidance, for example the Royal College of Ophthalmology Standards for Laser Refractive Surgery guidance (2017) and the National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery.
- The service worked to an Optegra UK theatre patient pathway standard operating procedure (August 2017), which referenced National Safety Standards for Invasive Procedures (2015) (NatSSIPs); and the World Health Organisation (WHO) Surgical Safety Checklist (2011) and Guidelines for Safe Surgery (2009).
- Patient records showed and both patients and staff confirmed that a seven-day cooling off period applied between initial agreement and having the surgery, which is in line with the Royal College of Surgeons' Professional Standards for Cosmetic Surgery. The patient usually saw an optometrist at the initial stage and a consultant at the second, although it would usually be best practice to see the same member of staff at each stage.
- We observed practice and reviewed records which showed the WHO team brief / debrief record sheet and discharge checklist were completed in accordance with best practice. A recent local audit of WHO surgical safety for laser treatments confirmed 100% compliance (September 2017).
- The theatre lead and clinical lead received national patient safety alerts and alerts from the Medicines and Healthcare products Regulatory Authority. This meant the service had accurate and up to date information to improve care and treatment.
- We were told the service had responded to suspend the use of cytotoxic medicines in response to a safety issue which had been identified at another Optegra UK location. Appropriate action had been taken to ensure patients were treated safely and risks were controlled.

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Pain relief

- Pain relief was administered in the form of anaesthetic eye drops prior to surgery or procedures. Patients were asked about pain levels during and after procedures.
- Staff could seek advice and input from surgeons where patients complained of pain after surgery in the recovery area.
- Patients were advised on pain relief during discharge discussions and advised on recovering at home. 24 hour on call advice was available, covered by registered nurses and consultants.
- Staff told us about a recent incident where a patient was in pain and could not contact their surgeon over the weekend. The Royal College Professional Standards for Refractive Surgery guidance (April 2017) say that; 'immediate onward communication to the surgeon on-call should be available'. The patient went to A&E at two hospitals but was told they would not help until A&E staff had spoken to the Optegra Leeds consultant. The consultant did call back later and spoke with the A&E ophthalmologist. The patient was able to come in to see the consultant at Optegra Leeds after the weekend. This had not been logged as an incident, however managers told us the on-call procedures were reviewed and a standard operating procedure was put in place to manage this, as a result.

Patient outcomes

- The service did not participate in any national audits and did not contribute to the National Ophthalmic Database Audit (NODA). The purpose of NODA is to collate anonymised data collected as a by-product of routine clinical care using electronic medical record (EMR) systems for the purposes of national audit, research and establishing meaningful measures for revalidation.
- Optegra UK Eye Sciences division managed the collection and reporting of clinical data for all seven UK locations. The eye sciences team had recently started to audit the Optegra services outside the UK, which included Poland, China, Germany and the Czech Republic. The data covered clinical complications, visual and refractive outcomes for laser, lens replacement and cataract patients, to an agreed protocol. Data was captured using an electronic patient record (EPR) system. This data was reported quarterly at meetings of the Board, Medical Advisory Committees,

and at both the OYEH integrated governance committee and the Optegra UK corporate governance committee. The measures were compared against industry standards for cataracts, laser and lens exchange patients.

- The eye sciences division collected data for all Optegra UK services every three months. The results showed Optegra Leeds scored 100% for the percentage of treatments with no recorded complications for refractive laser patients, during the reporting period. This was above the 99% achieved across the rest of the Optegra UK and international locations.
- For the same period, Optegra Leeds achieved visual outcomes for patients that were above average, compared to those achieved by the rest of the UK and international Optegra locations (e.g. 100% patients achieved 6/6 unaided vision at Leeds, compared to 96% overall).
- The service reported there had been no unplanned returns to theatre and no unplanned re-treatment or treatment enhancement following refractive eye surgery in the last 12 months. The re-treatment rate for Optegra UK overall was 4.8%, defined as return to theatre within 28 days, although this was based on 2015 data.
- Patient outcomes were reported to the Medical Advisory Committee and minutes showed action was taken to address outliers in individual performance of consultants.
- Optegra UK also collated patient satisfaction data using an electronic questionnaire which patients completed using a tablet, at follow-up appointments. We looked at the results for 17 Optegra Leeds laser surgery patients who completed the questionnaire from April to November 2017. 100% of patients said they agreed or strongly agreed with the statements; 'I would recommend treatment to family and friends'; 'I feel my quality of life has improved following treatment'; 'I feel that my treatment has been successful', and; 'I am satisfied with the results of my treatment'. These results were slightly higher than for Optegra UK services as a whole and exceeded the target of 85% patient satisfaction.
- Patients positively agreed with all the statements, although Optegra Leeds scored lower than for Optegra services across the UK on two measures. 77% patients agreed or strongly agreed with the statement; 'I was able to carry out my normal activities a few days after my treatment' compared to 87% recorded for Optegra

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UK services overall. 77% of laser vision correction patients agreed or strongly agreed with the statement; 'My treatment was comfortable', compared to 91% recorded for Optegra UK services overall. The service attributed this difference to the type of treatment used at Optegra Leeds, compared to the different type of treatments used in other locations, which are known to provide more rapid results. Sample sizes were small which meant more detailed comparison by treatment type was limited. However, managers told us planned equipment changes would mean that different treatments could also be made available in Optegra Leeds, as appropriate to patient needs.

Competent staff

- All new staff completed an online induction programme which included health and safety, system access, mandatory training, human resources and policies and procedures. Staff completed a six month probationary period.
- An induction booklet was issued to new staff which informed them of the fire evacuation procedures, emergency contingencies, local contact numbers, health and safety policy statements and contractor rules.
- We reviewed five personnel files during inspection and found recruitment checks had been carried out, including DBS checks and references as appropriate. Pre-inspection information showed 100% staff were up to date with their professional revalidation and had their registration checked by the provider within the last 12 months.
- Any new doctor applying to work at the hospital was discussed at the Medical Advisory Committee (MAC) to consider their suitability through experience, appraisals and skill levels and determine practicing rights. The MAC considered removal from the list if a doctor had not practised at the hospital for 12 months or more.
- All consultants who worked under practicing privileges at Optegra Leeds had appropriate and up to date professional indemnity insurance in place and had been approved by the MAC. Ophthalmologists who worked under practicing privileges at the location were not allowed to invite external staff to either work with them or on their own.
- Surgeons working at the service under practising privileges were registered on the General Medical Council (GMC) Specialist Register in Ophthalmology. Consultants declared specific procedures they carried out as part of their regular practice, in their practising privileges application.
- The hospital collected comparative outcomes by clinician and used this for competency and revalidation purposes as well as for quality improvement through the MAC and clinical governance processes. Each surgeon also had an annual NHS appraisal.
- We reviewed two personnel files of surgeons and these were up to date. These included; practicing privileges interview forms, references and MAC approval, ophthalmic surgery registration, professional indemnity insurance, annual appraisal and disclosure and barring service (DBS) checks.
- The hospital register of authorised users identified all consultants who operated laser equipment and clinical team members who assisted with the procedure. All registered users signed to confirm they had read and understood the local rules for each laser room and procedure. This was in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance on lasers, intense light source systems and light-emitting diodes (LEDs) – guidance for safe use in medical, surgical, dental and aesthetic practices (September 2015).
- The laser protection supervisor and deputy (LPS) had completed 'Core of Knowledge - Laser Safety' training and were supervised through a service level agreement with an external laser protection advisor. Public Health England (PHE) reviewed competency, local rules, provided training and carried out an annual audit of the LPS competence, laser checks and safety. Managers told us training was provided by manufacturers when new refractive lasers were introduced.
- We saw consultants and clinical team members had received 'Core of Knowledge' training and this was monitored through the hospital training tracker. We found one surgeon did not have evidence of up to date training on file. The hospital director told us the service had sought advice from the LPA when this training had been postponed and also provided evidence of completed training, following inspection.
- Competence assessments were carried out for the roles of pre-operative nurse, circulating nurse / technician

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and discharge nurse, for intravenous cannulation and safe use of sharps. One staff member was undertaking skills development and shadowing at the time of our inspection, to develop extended role competencies.

- The hospital director told us a new process and competency for the use of cytotoxic medicines had recently been developed. At the time of inspection, records showed team leads had completed the new individual competency assessments. Following inspection, managers told us staff had completed a 'dry run' of the new process, followed by a pilot procedure in early November 2017. The hospital director oversaw the pilot to ensure compliance with the new process and provide feedback to further improve the process, before beginning full implementation. Managers told us performance against this process would be audited in December 2017.
- At the time of inspection four out of six staff had received an annual appraisal. The hospital's annual appraisal programme ran from 1st July to 30th June each year. Two Optegra Leeds staff appraisals were overdue by 3 months although one member of staff was due to leave the organisation.

Multidisciplinary working

- During our inspection, we saw effective multidisciplinary teamwork between disciplines in theatre. There was a sense of respect and recognition of the value and input of all team members in the service.
- A number of staff were able to work across both Optegra Leeds and OYEH locations. Staff explained that this meant they worked well together as a team to deliver both the refractive (laser) eye service and other types of surgery and outpatient appointments at OYEH.
- Some staff had extended roles which increased flexibility of the service, for example, one Optometrist was also trained as a laser technician and optometrists led initial appointments to assess suitability of patients for surgery.

Access to information

- Optegra Leeds used an electronic clinical record system which was accessible from all Optegra UK locations. All patient administration, including patient, GP and consultant letters were held within the electronic patient administration system.

- The system held records of clinical information including tests and scans which upload to the system. This meant medical records generated by medical staff working under practising privileges were available to staff or other providers, if necessary.
- The same consultant saw the patient from initial consultation through to surgery and post-operative appointment ensuring continuity of care.
- If a patient experienced a post-operative complication, the unique patient ID number was used to access the electronic record system, which enabled messages to be sent requesting the clinical team to contact the patient.
- Patient records were both electronic and paper based. All staff had access to full details of a patient's past medical history, medicines, allergies, referral letters, consent information, clinic notes, pre-assessment notes, and consultants' operation notes.
- Paper records were kept on site for three months before being archived to an external storage facility. Documents could be recalled should they be needed after being archived.
- Staff had access to the information required to undertake their role. They had access to a range of policies, standard operating procedures and open source material through the online system.
- At discharge, patients were given a letter to share with their GP or other healthcare professionals. Patients were asked for their consent to send the letter to their GP (and optician if applicable).
- Patients were given verbal and written information on when and how to take their prescribed take-home medicines.

Consent and Mental Capacity Act

- The Royal College Professional Standards for Refractive Surgery guidance (April 2017) says; 'Consent for refractive surgical interventions should include a two-stage process in which consent forms are taken away from the consultation at which the procedure recommendation is made by the operating surgeon, and patients are given an open line of communication with their surgeon (email, telephone, or optional repeat consultation) for follow-up questions during a cooling off period.'
- The Optegra UK consent policy stated; 'Although preparatory information may include written material, video material or advice from suitably trained non-medical staff, the consultation at which the

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procedure recommendation is made should be with the operating surgeon. This should be a face-to-face consultation (not conducted by telephone) and should not occur on the day of surgery.'

- We were not assured the arrangements within the Optometrist-led pathway met best practice guidelines or Optegra UK policy on consent. We saw that there was a two-stage process in place however; we found the patient did not meet their surgeon at stage one i.e. before the day of surgery, when the recommendation for treatment was made. Patients instead met with an Optometrist at the initial appointment, where they had a discussion about the reasons for surgery, the procedure options, risks and benefits and completed a medical questionnaire and vision tests. Patients were given written information on procedures and relevant consent forms to take away. They were given information on how to contact the service with questions and how to book for surgery. We saw the optometrist took time to answer patient questions. However, it was not clear how patients could maintain an open line of communication with their surgeon for any follow-up questions during the cooling-off period if they had not met them at stage one, prior to the day of surgery.
- Records confirmed that patients were given time and information to reflect on a decision for surgery and there was a minimum of seven days between the procedure recommendation and surgery. Staff were aware of this requirement. The patient then brought the consent form with them to sign on the day of surgery and this was reviewed during the consultation with the surgeon and checked pre-operatively by a nurse.
- There was a consent policy and Mental Capacity Act policy in place, which included deprivation of liberties safeguarding (revised Sept 2017). Staff demonstrated an understanding of the principles of the Mental Capacity Act and deprivation of liberties safeguarding. No formal assessment of capacity was made, however staff told us that capacity would be informally considered during a consultation with a patient and if a patient lacked capacity to make the decision they were not generally offered the laser surgery. This was because it was an elective procedure and not a treatment which would need to be provided in the best interests of the patient.

- Staff completed training in equality and diversity annually. Training records showed 94.6% compliance for staff working across Optegra Leeds and OYEH.
- There was a corporate equality, inclusion and human rights policy in place. The policy outlined that every manager employed by Optegra UK was responsible for promoting equality inclusion and human rights in their sphere of management and for preventing undue discrimination in practice. It also acknowledged the service's responsibility to make reasonable adjustments for patients and staff with a disability.

Are refractive eye surgery caring?

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.

Compassionate care

- All staff, including reception staff and non-clinical staff, were observed to be compassionate and respectful to every patient who used the service. We spoke with four patients during inspection, who all spoke positively about their care.
- Results from 17 Optegra Leeds laser surgery patients who completed an electronic patient satisfaction questionnaire from April to November 2017 showed 100% of patients would recommend treatment to family and friends.
- We observed that the privacy and dignity of patients was maintained at all times, with consulting rooms available for private discussion with staff. We observed staff introducing themselves and wearing name badges during our visit, as per the Optegra UK privacy and dignity policy.
- We received five comment cards from Optegra Leeds patients, all of which were positive about the care they had received. One family member, who had also been a patient at the service, commented; 'It is a warm and friendly environment with a strong work ethic and employees always have addressed my needs'. Another patient explained that; 'Having had an unpleasant experience at another hospital, I was hesitant about undertaking the treatment. However, staff were

Equality and human rights

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informative, helpful and allayed my fears. There was a little mix-up re the price of the treatment, but this was resolved to my satisfaction. I would definitely recommend Optegra to other people’.

Understanding and involvement of patients and those close to them

- Staff explored the reasons for patients wanting treatment and explained the treatment options during the initial appointment. Patient records recorded that staff ensured that patients had realistic expectations of their procedure and understood treatment options and likely outcomes before consent was obtained.
- We observed information available about services and costs was clear and transparent, in line with the Royal College of Ophthalmology Refractive Surgery Advertising and Marketing Standards (April 2017). Patients received a statement that included terms and conditions of the service being provided, the cost, and method of payment for the laser eye surgery.
- Patients we spoke with during inspection, said they felt involved in decisions about their care and did not feel any pressure to make decisions or accept treatment. One patient who completed a comment card said; ‘I have had problems in the past getting information. I was listened to at Optegra Leeds, they were very helpful and took my concerns seriously.’
- On the day of surgery, we found staff explained what was happening during each stage of the procedure and checked on the patient’s welfare.
- We observed staff taking time to explain follow up care and instructions to patients and to answer their questions following surgery. This included how to correctly insert eye-drops at home, advice on take home medicines and after-care such as bathing and cleaning the eye.
- Staff ensured that patients had the support they needed following a procedure and involved those close to patients to ensure they were supported when they returned home e.g. family members were invited in to consultations, subject to patient choice. One patient comment card said; ‘Staff have been informative, patient and accommodating at all stages of my care and I have felt able to contact someone out of hours if necessary.’

Emotional support

- Staff demonstrated empathy and understanding about the emotional impact that sight problems might have on patients.
- We observed staff provided reassurance to patients who were undergoing procedures. They supported nervous or anxious patients by putting them at ease and calmly explained the procedure. We observed that staff offered to hold a patient’s hand during the procedure, if wanted, to give additional reassurance.
- After the procedure, patients’ relatives were invited to join them in the recovery area, which also meant both patient and relative could take in the discharge and post-operative advice given by the staff.
- One patient who completed a comment card said; ‘The staff have always been friendly and helpful since my first visit and always put me at ease should I ever feel uneasy about the treatment. The staff provided excellent support and reassurance throughout my treatment.’
- Other comments referred to genuine care received from patient liaison staff at Optegra Leeds, which had put them at ease, made them feel well looked after. The hospital director explained this was a demonstration of the Optegra UK values in action; ‘looking after our colleagues, who then look after our patients’. They described how the patient liaison role demonstrates this - as the first point of contact for queries; ‘they conduct the welcome call with patients and form the relationship between the patient and the consultant’.
- We reviewed comments from patients on a website which publishes customer reviews. One patient specifically commented on a surgeon based at Optegra Leeds, demonstrated patients valued a supportive manner in giving information; ‘I would recommend [my surgeon] without hesitation. He listens very carefully with patience and concern, explaining everything in as much detail as you would like and takes the time to answer questions. He is in no way patronising, which was appreciated.’

Are refractive eye surgery responsive to people’s needs?

(for example, to feedback?)

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.

Refractive eye surgery

Service planning and delivery to meet the needs of local people

- The service was designed to provide refractive (laser) eye surgery to adults, from across Yorkshire. It also accepted patients from outside of this area. All appointments and treatments were pre-planned.
- There was an admission and discharge policy which set out the treatments available across OYEH and stated patients considered for admission must be over 18 years of age and a full health assessment must be undertaken by the admitting consultant to assess suitability.
- Following inspection, the service provided further information which showed that a patient would not be able to access OYEH services if they required a general anaesthetic for a procedure, if they were not in good health (e.g. ASA level 3 severe systemic disease); if they had a BMI greater than 30; if they had severely limited mobility; or, were living with dementia or Parkinson's disease.
- If a patient required surgery under anaesthesia or sedation, or a different procedure such as lens replacement surgery, they would be referred to Optegra Yorkshire Eye Hospital or another Optegra UK service, to ensure their needs could be met appropriately.
- If a patient was aged 21 or under, they were asked to provide evidence they had a stable prescription for at least the last 3 years, which complied with best practice guidance from the Royal College of Ophthalmology. No patients under age 21 had received refractive eye surgery in the last 12 months.
- Patients could arrange a free no obligation consultation to discuss potential treatments and procedures.
- We observed the initial appointment gave patients clear information about the options, what to expect and a detailed prediction of their likely outcome. There was an opportunity to discuss their motivation for surgery and any questions, to ensure patients knew what to expect from the procedure and how to contact the service with any questions.
- After surgery, patients saw their optometrist and operating surgeon at follow-up appointments, to provide continuity of care.
- The service was designed to facilitate patient flow respecting patient privacy and dignity. Facilities

included an operating theatre, private assessment and consultation rooms and a patient waiting area. The service was accessible from Leeds train station and car parking was available.

Access and flow

- The service generally provided timely access to appointments and treatment, subject to the service being open three days per week. All patients were treated as 'day cases' and discharged the same day, with no inpatient stays. Patients saw their operating surgeon at post-operative appointments.
- Patients were able to self-refer without a GP or optician's referral. Patients were offered a choice of appointments where possible. The service was only open on Tuesday, Thursday and Friday, from 09:00 to 17:00. Surgery days were usually scheduled twice per month. The service did not open at the weekend. Telephone calls were managed centrally via OYEH six days per week.
- The provider routinely monitored performance in areas such as patient wait times, consultation to treatment times and patients that did not attend appointments. This was combined across both Optegra Yorkshire Eye Hospital (OYEH) and Optegra Leeds. We were not provided with data specifically for Optegra Leeds.
- Across OYEH, private patients waited an average of 27 days from referral to first appointment and 35 days from consultation to surgery. This meant overall patients waited an average of 56 days from referral to treatment. Overall, 32% of all private patients at OYEH were seen within ten days, 57% within 20 days and 77% within 30 days. There was no specific data for refractive (laser) patients.
- Overall, 11% of patients did not attend (DNA) first appointments during the reporting period, which meant OYEH was performing better than the target of 15% or less. Staff followed-up patients who did not attend, to offer an alternative appointment. Overall, 23% of OYEH patients cancelled appointments during the reporting period, which was better than the target of 15% or less.
- The service had identified length of wait for initial appointment as the main reason for cancellation of laser appointments, as the service was only open three days per week. An optometrist-led treatment pathway had been introduced to provide more flexibility in initial

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appointments for patients. Six-day opening was identified as a key local objective, to better accommodate patient needs and the service was recruiting a full-time optometrist to support this.

- From July 2016 to June 2017, no appointments were cancelled by the service and there was no waiting list for appointments. However, treatments had been delayed or cancelled for a small number of patients from August to October 2017. This was because the service had suspended the use of cytotoxic drugs, to review its procedures. These patients were offered alternative treatments where appropriate. Some had their treatment postponed and some decided not to go ahead with the treatment. As refractive (laser) treatment is elective, there was likely minimal impact on patients from these cancellations.
- Although outpatient clinic wait times (from arrival to being seen) were not monitored, we observed and patients told us, they did not usually wait longer than 15 mins from arrival. The Optegra UK patient survey also asked patients if they had experienced any delays. Results showed 84% patients said they were seen on time, across Optegra UK as a whole.
- Staff told us theatre lists could sometimes be slowed down to ensure safe staffing and patients would be informed of any delays on the day.
- In the previous 12 months there had not been any complications for patients that required a patient to transfer to hospital and there were no unplanned returns to theatre.

Meeting people's individual needs

- Two car parking spaces were available directly outside the building, which allowed step-free access into the building. Staff were ready to reserve these spaces if a person had a mobility need and staff were available to support patients as required.
- We saw that portable hearing loop equipment was available at reception to support people with a hearing impairment. There was a sign in the waiting area offering a chaperone on request.
- We saw the waiting area was comfortable and hot drinks, water, snacks were available free of charge. Magazines and information leaflets were available. Sufficient space and seating was provided, although seating design did not include arm-rests to assist someone with a mobility disability.

- We did not see patient information available in different languages or formats e.g. large print. The availability of information in formats to meet the needs of people with impaired sight would benefit patients in their understanding and involvement of the treatment they are to receive. Providing information in easy to read format and reasonable adjustments is best practice in line with Royal College of Ophthalmology guidance (2017). The Optegra UK consent policy also states written information will; 'be available in large print / different languages'.
- Staff we spoke with knew who to contact to arrange a face to face or telephone interpreter to assist a patient with English as a second language, but had never used the interpreting service. There were welcome signs in other languages in reception, although staff were unsure what language this was. Managers told us a British Sign Language interpreter could be obtained and that no charge would be made to a patient for any interpreting. Written patient information was not routinely available in other languages on site.
- Although there were no specific arrangements in place for providing a service to people with a learning disability, bariatric patients or nervous patients, staff gave examples of reasonable adjustments e.g. patients could visit to see the theatre in advance, to familiarise themselves. Staff told us that if a patient had any additional needs, they would be recorded in the pre assessment information and could be flagged on the electronic record system.
- All Optegra Leeds nursing, optometry and patient liaison staff had completed dementia awareness training.

Learning from complaints and concerns

- The service had a system in place to receive, log, act and learn from complaints and compliments. There was a complaints policy in place, this was in date, reviewed and updated regularly and was accessible to staff.
- A 'Feedback, comments and complaints' leaflet for patients was displayed in the waiting area. This advised patients who to contact if they had any concerns about their care and included information on how to progress a complaint with the Independent Complaints Adjudication Service (ISCAS) if they were not satisfied with the Optegra UK complaints process.
- The service had reported one complaint during the reporting period (July 2016 to September 2017). Optegra Leeds had received feedback from a patient who was

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unhappy with their outcome and posted their dissatisfaction on an online review site. The patient was contacted and it was pro-actively investigated as a complaint by Optegra Leeds. Learning was shared at the Integrated Governance meeting and staff were aware of this.

- Complaints were logged on a central system which was available to all Optegra UK hospital directors for learning and this was reviewed at local and national governance meetings.

Are refractive eye surgery well-led?

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.

Leadership and culture of service

- The service was led by the hospital director who was also the registered manager and had been in post since March 2017. The hospital director was responsible for Optegra Yorkshire Eye Hospital (of which Optegra Leeds was part) and also Optegra Manchester Eye Hospital.
- Although the clinical services manager (CSM) and patient services manager posts were vacant at the time of inspection, the service had appointed a new CSM, with responsibility for clinical skills and supervision of team leads. The theatre lead and diagnostic team leads who worked at both Optegra Leeds and OYEH sites supported operational staff on a day to day basis and had covered some of the clinical services manager duties during the last 12 months.
- There was a clear leadership structure and a patient-focussed approach. The hospital director described the organisational culture as that of; 'an experienced, talented team, who were patient focussed, with a warmth applied to patient contact which embodies the organisation's values'. Optegra Leeds offered a 'colleague recognition scheme' to reward staff.
- Staff told us they worked well together as a team across Optegra Leeds and OYEH. They were clear about who their line managers were and their individual roles and responsibilities although clinical and patient liaison team meetings had not been routine in recent months.
- The main themes from the annual OYEH staff satisfaction survey (Feb 2016) were access to IT and

communications. There was a clear action plan in progress, including action to introduce the new daily 'huddle' meeting and include business updates at the whole hospital meeting, (which formed the main communication channels at the time of inspection), and work to improve internet access.

Vision and strategy

- The corporate vision was 'To ensure Optegra UK is a market leading profitable provider of first choice, famous for patient service and eye care excellence because we look after our colleagues, who look after our patients'. This was echoed by the hospital director and staff at Optegra Leeds who outlined expanding the opening hours of the service and supporting the team with skill development as key priorities for; 'the safe delivery of growth'.
- We saw the corporate values were available on the website and the vision and strategic plan were shared with staff at quarterly whole hospital meetings.
- Staff we spoke with understood the local vision to increase the number of days the service was open and to update the laser equipment, in order to increase the volume of patients. Staff were also aware of ongoing work to consolidate policies and procedures across Optegra UK locations.

Governance, risk management and quality measurement

- There were structures in place to maintain clinical governance and risk management. There was ongoing work to update policies and procedures. Performance data was collected and analysed and work was underway to develop a more robust system to identify themes and trends from different data sources.
- Optegra UK held clinical service managers (CSM) meetings and integrated governance steering group (IGSG) meetings every three months. These were attended by the corporate clinical lead and head of clinical governance and risk, together with CSM's and hospital directors from UK Optegra services.
- Key areas discussed were medicine management, infection control, safeguarding, clinical incidents and health and safety.

Refractive eye surgery

- The CSM meetings ensured commonality across the services, shared pathways, documentation and encouraged staff recognition of their relationship with the provider. Minutes demonstrated evidence of shared learning.
- The IGSG led corporate work to review and standardise patient pathways, update policies and improve the corporate governance framework and systems. For example, it was responsible for commissioning a new electronic corporate governance system, to bring together existing data on incidents, complaints and mandatory training compliance.
- The provider had introduced a local balanced scorecard that measured 'Key Performance' across all areas including colleague satisfaction, impact on patients, processes and financial performance. This incorporated eleven metrics and was benchmarked monthly against best practice.
- Weekly operational review calls and monthly Operations Meetings were held across Optegra UK's seven hospitals to share insight and benchmark across all hospitals.
- A governance structure was in place to ensure information and learning was cascaded up to the provider's board. Audits were conducted in line with national standards. Actions fed into the Yorkshire action plan and were monitored at the IG meetings.
- The outputs from the hospital integrated governance meeting were reviewed to ensure consistency, monitor trends and adherence to policy and outcomes data, complaints and serious incidents were also reviewed. We saw evidence of this by reviewing the minutes from the last three OYEH integrated governance (IG) meetings.
- Surgical outcomes were collated by the provider's Eye Sciences division and shared with the hospital director. They were discussed and reviewed at the MAC, with individual consultants, and at the corporate Governance Committee on a Quarterly basis.
- Quality clinical reports were discussed at the local IG meeting and the local MAC – agenda items included incidents, never events, SUIs, returns to theatre, unplanned outpatients, transfers and duty of candour.
- There was a 'strategic risk register' in place for OYEH, including Optegra Leeds. The risk register accurately reflected risks within the hospital and was reviewed via integrated governance meetings. The risk register

described the cause and consequence of each risk. The type of risks were categorised as financial, quality or operational and risks could be added to the register as a result of incidents.

- Specific risks included theatre recruitment, medication for non-standard procedures, consultant management and patient outcomes and the hospital structure. None of the strategic risks identified solely related to the Optegra Leeds site. Operational risk assessments were in place for Optegra Leeds, including for fire safety.
- The MAC met quarterly and was attended by the chair, an optometrist, clinical nurse, consultant and a spread of sub-specialities from other parts of OYEH for glaucoma, refractive eye surgery, cataract, cornea and retinal. Safety, adverse events, infections, complaints and incidents were discussed and learning taken from critical incidents and events. Potential new procedures were also discussed at the MAC and had to be signed off by the medical director as safe.
- The governance structure identified monthly team meetings (clinical team and patient services team) as the key route for sharing learning e.g. from incidents, complaints and changes in practice and policies. However, at Optegra Leeds, team meetings had not been consistent in recent months due to vacancies in the management team. The daily 'huddle' meeting and whole hospital meeting were the main routes for staff updates. Staff we spoke with were aware of an ongoing project to update policies and procedures and received updated policies circulated to staff via email following the huddle.

Public and staff engagement

- The hospital had a website where full information could be obtained about the treatments available for patients. It was very comprehensive including information about costs and finance.
- Patient views were sought in a number of ways, e.g. electronically, survey, comment books and a friends and family test. The patient experience survey (2016/2017) showed 97% of patients would recommend the hospital to family and friends (81% highly likely to recommend).
- Patient comment cards were positive and described the service as; 'clean, nice staff, friendly welcome'; 'good all round treatment and service' and staff were; 'extremely helpful staff, relaxed atmosphere, everything explained in full'.

Refractive eye surgery

- Regular refractive (laser) surgery open evenings were held at OYEH where consultants gave a presentation and discussed the various treatments on offer. Potential patients could meet prospective consultants, receive procedure information, ask questions and tour the hospital.
- The Eye Sciences division had developed a patient questionnaire for those who had undergone cataract surgery, laser vision correction or refractive lens exchange. The questionnaire was used at Optegra Leeds via a touch screen tablet or a paper version was also available.
- A patient forum was not in place at the service. Patient forums are usually open to any patient or relative to discuss any concerns or anxieties they may have about the hospital and treatment.
- The hospital developed an action plan (March 2017) from the results of the 2016 staff engagement survey for OYEH, including Optegra Leeds. This highlighted a number of issues about clarity on targets and progress, information technology, job satisfaction, infrastructure, communication between teams and staff shortages. The action plan identified outputs for each action and identified accountability and timescales. For example a daily bulletin and daily staff huddle meetings were introduced to improve communication between teams; IT access was improved to reduce problems in accessing records, and; recruitment of key management roles – the CSM and PSM was progressing. A planning meeting and regular clinical team meetings were to be introduced from November 2017.

- The provider ran a staff recognition scheme where staff could nominate individuals and teams.

Innovation improvement and sustainability

- There was innovation in monitoring clinical data and the service had commissioned a new integrated clinical governance system.
- Optegra UK Eye Sciences division manages the collection and reporting of clinical data for all 7 UK locations. This team had recently started to audit Optegra services provided outside the UK, which included Poland, China, Germany and the Czech Republic. The data covers clinical complications, visual and refractive outcomes for laser, lens replacement and cataract patients, to an agreed protocol. Data is captured using an electronic patient record (EPR) system.
- This work meant performance and patient outcomes at each service could not only be benchmarked with the seven UK locations, but across a wider sample, internationally. Managers told us bi-weekly calls were held to share information nationally and contribute to continuous improvement and performance across the group.
- Managers told us a new electronic system to co-ordinate reporting and learning from incidents, mandatory training and alerts was piloted in November 2017. We were also told that this system would be fully introduced across all hospitals in January 2018 to provide a more robust approach to corporate governance.

Outstanding practice and areas for improvement

Outstanding practice

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visual and refractive outcomes for laser, lens replacement and cataract patients, to an agreed protocol. This work meant performance and patient outcomes at each service could not only be benchmarked with the seven UK locations, but across a wider sample, internationally.

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should ensure it identifies and reports all incidents, including low and no-harm incidents, in line with Optegra policy and CQC reporting requirements and has robust arrangements in place to review trends and themes.
- The provider should ensure optometrists are included in infection control training and observational hand hygiene audits and consider reviewing arrangements for the optometrist-led pathway, in light of best practice guidelines.
- The provider should consider formalising arrangements for emergency transfer to another provider in the case of an emergency, or where additional specialist treatment may be required for the treatment of ophthalmic complications.
- The provider should consider routinely providing patient information in easy to read format to better meet the needs of people with impaired sight.