Optical Express - Chelmsford

Quality Report

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Date of inspection visit: 28 November 2017 and 19 April 2018
Date of publication: 02/07/2018

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

Summary of findings

Letter from the Chief Inspector of Hospitals

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 28 November 2017. We carried out a re-inspection on 19 April 2018 which was unannounced. Optical Express Chelmsford is operated by Optical Express Limited. Optical Express is a nationwide company offering general optometric services. The Chelmsford clinic provides intra-ocular refractive lens surgery for adults aged 18 years and above. Patients are self-referring and self- funded. The clinic is based on the ground floor of a multipurpose building in Chelmsford.

The clinic was registered in July 2014 but ceased operating in December 2015 due to a drop in demand. The clinic re-registered and re-opened in August 2017.

The clinic provides services approximately four days a month but does not have set surgery days. The clinic does not have any resident staff members. The clinic is staffed on surgery days with Optical Express employees from across the organisation and regions.

The clinic has pre-screening amenities, a dirty utility room, consultation rooms, an anaesthetic room, a laser room, operating theatre and a post-operative room. The service shares premises and optical equipment with an Optical Express practice.

During our inspection on 28 November 2017, we visited the theatre, laser room, anaesthetic room, pre and post-operative rooms, dirty utilities and examination rooms. We spoke with seven members of staff, including the ophthalmologist (surgeon), anaesthetist, registered nurses, health care assistant and surgical services manager. We spoke with five patients. During our inspection, we reviewed four sets of patient records and the staff personal files of five of the staff present on the day of our inspection including registered nurses and the surgeon.

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.

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

On our November 2017 inspection we found the following issues that the service provider needed to improve:

- Patients' observations, such as oxygen saturations and pulse rate, were not recorded during the surgical procedure.
- Prescription medicines to take home, consisting of eye drops and oral medication, were supplied by a registered nurse without being prescribed by the doctor or anaesthetist.
- Registered nurses were supplying prescription medicines without having assessed competencies to meet this extended role.
- Anaesthetic and medicated eye drops were stored loosely in the anaesthetic fridge without original sterile packaging. This meant that sterility was compromised and efficacy could not be assured, as no expiry data information was evident.
- Patients having received intravenous sedation were required by staff to walk from the theatre corridor to the recovery room. These patients were not offered a wheelchair for the transfer which was not in line with the providers policy.
- The World Health Organisation (WHO) and five steps to safer surgery checklist was not used appropriately. All sections of the form were completed before the surgeon had commenced scrubbing for the procedure.

Summary of findings

- Effective infection control practices and processes were not in place, which posed a risk to patients from healthcare associated infection.
- Resuscitation equipment storage was not secure. Equipment and emergency medicine was accessible to staff and patients.
- Processes to ensure equipment was in date and ready for use were not always effective.
- The service was not complying with national guidance.

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

- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately.
- Surgical outcomes were audited and benchmarked across the organisation.
- Staff kept appropriate records of patients' care and treatment. Records were clear, up-to-date and available to all staff providing care.
- Patients could access the service and the booking system was efficient and easy to use.
- Patients we spoke with were positive about the care provided by staff.
- Patients were offered consultations and follow up appointments at other Optical Express Limited clinics to ensure patients were treated at their preferred location.
- The service had a weekly staff recognition scheme.
- On 6 December 2017 we sent the provider a letter setting out the significant concerns that we had identified on the November 2017 inspection. The letter detailed that we would have to take urgent action unless the provider immediately addressed the risks we had identified. In response, On 7 December 2017 the provider decided to voluntarily suspend surgical services at the clinic with immediate effect and submitted an action plan to address the concerns prior to recommencing services at the Chelmsford site.

  This action negated the requirement for CQC to take urgent enforcement action as major safety concerns and risks for patients were addressed by Optical Express suspending services at Chelmsford. Since 7 December 2017, CQC has been closely monitoring actions taken and reviewing progress. On 12 January 2018, we received written confirmation that the service intended to continue the suspension until 5 February 2018 to allow them to ensure all areas of their action plan had been addressed. On 17 January 2018 the service submitted documents that supported their compliance with their action plan. On 5 February the service re-instated surgery services at the Chelmsford location with increased presence from the registered manager.

  We inspected the service on 19 April 2018. We solely inspected the areas of concern which we had identified in our letter to the service on 6 December 2017. These concerns lay in the safe and well led domains of our inspection key lines of enquiry. The inspection looked at whether the patient safety concerns had been addressed and whether the new processes and policies put in place had been embedded.

  On our inspection on 19 April 2018 we found the following improvements at the service:

- New processes had been introduced and embedded in the service to ensure that patient's observations were monitored during surgery.
- Nurses had completed dispensing competencies to meet the requirements of this extended role.
- Medicines and consumable equipment was found to be in date.
- Patients were assisted to the recovery room post-operatively by using a wheelchair in all cases to prevent the risk of patients falling.
- The adapted World Health Organisation (WHO) and five steps to safer surgery checklist was fully implemented and all staff were engaged in the process.
- Infection prevention and control risks had been addressed.
- Emergency medicine was now securely stored.
- The service had improved staffing levels and was now compliant with national guidance.

Summary of findings

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

Heidi Smoult

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Refractive eye surgery.

Summary of this inspection

Background to Optical Express - Chelmsford

Optical Express Chelmsford is operated by Optical Express Limited. Optical Express is a nationwide company offering general optometric services. The clinic provides intra-ocular refractive lens surgery for adults aged 18 years and above. The service opened in July 2014. The service primarily serves the communities of Essex and accepts patient referrals from outside this area.

The service has had a registered manager in post since August 2017.

We inspected the service on 28 November 2017. The inspection was announced. We re-inspected the service on 19 April 2018. This inspection was unannounced.

Our inspection team

The team that inspected the service on 28 November 2017 comprised of a CQC lead inspector and one CQC inspector with expertise in ophthalmology. The team that inspected on 19 April 2018 comprised of two CQC inspectors.

The inspection teams were overseen by Fiona Allinson, Head of Hospital Inspection.

Information about Optical Express - Chelmsford

The service is registered to provide the following regulated activities:

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

During the inspections, we spoke with sixteen members of staff including; registered nurses, health care assistants, reception staff, medical staff, operating department practitioners, anaesthetic nurses, anaesthetists, surgeons and senior managers. We spoke with eight patients.

The service had not been operational between December 2015 and August 2017. We were told on our inspection that this was due to a decrease in demand. The service was reinstated in August 2017.

Since the service has been reinstated, there had been approximately four operating lists per month depending on patient numbers.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC. The inspection found that the service was not meeting the regulations it was inspected against.

Activity

For all reporting activity, we are using the period of August 2017 to October 2017, as the service was not operational between December 2015 and August 2017.

In the reporting period between August 2017 to October 2017 there were 38 day case episodes of care recorded at the service. All of these cases were refractive intra-ocular lens surgery.

The service had received no complaints between August 2017 to October 2017.

Track record on safety (August 2017 – November 2017)

- No never events.
- No clinical incidents.
- No incidences of healthcare acquired meticillin-resistant Staphylococcus Aureus (MRSA), or healthcare acquired meticillin-sensitive Staphylococcus Aureus (MSSA).

Summary of this inspection

- No incidences of healthcare acquired Clostridium difficile (c.diff).
- No incidences of healthcare acquired Escherichia coli (E-Coli).
- No formal complaints.

Services provided at the clinic under service level agreement:

- Clinical and or non-clinical waste removal.
- Maintenance of medical equipment.
- Uninterrupted Power Supply.
- Maintenance of medical equipment.
- Lens bank.

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?

- **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.

  On our inspection on 28 November 2018 we found the following areas of good practice:

- Staff kept appropriate records of patients' care and treatment. Records were clear, up-to-date and available to all staff providing care.
- The service managed patient safety incidents well. Staff recognised incidents and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service.
- Staff had training on how to recognise and report safeguarding concerns and they knew how to apply this.
- Medicines management was poor. We found safety concerns and inappropriate practices relating to medication storage, administration and dispensing.
- Patient safety risks were not appropriately managed. Patients were being asked to walk from the theatre trolley to the recovery room having had intravenous sedation.
- Staff were not monitoring patient's vital signs throughout the surgical procedure.
- The World Health Organisation (WHO) and five steps to safer surgery checklist was being completed prior to surgery commencing.
- Nurse staffing levels were not in line with the Royal College of Anaesthetists (RCA) guidelines for the provision of ophthalmic anaesthesia services 2017.
- Staff voiced concerns that they were unhappy with staffing levels and often did not receive breaks.
- Infection prevention and control standards were not maintained in theatres.
- The emergency trolley was not tamper proof.
- We found consumable medical equipment that had passed its expiry date.
- On our re- inspection on 19 April 2018 we found the following improvements:

Summary of this inspection

- Medicines management had improved. Medicines were stored appropriately and staff had up-to-date competencies for dispensing medicines.
- Patients were being safely transferred between the theatre and recovery room.
- Staff monitored patient's vital signs throughout the surgical procedure.
- The World Health Organisation (WHO) and five steps to safer surgery checklist was being used and staff were engaged with the process.
- Nurse staffing levels were now in line with the Royal College of Anaesthetists (RCA) guidelines for the provision of ophthalmic anaesthesia services 2017.
- Infection prevention and control standards were maintained.
- The emergency trolley was tamper proof.
- All consumable medical equipment checked was in date.
- However, we found the following issues that the service provider needs to improve:

Are services effective?

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:

- Surgical outcomes were audited and benchmarked across the organisation.
- Patients' pain was well managed.
- Staff with different roles worked together as a team to benefit patients.
- Staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment. All staff had access to an electronic records system that they could all update.

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

- The consent policy did not reflect Royal College of Ophthalmologist guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Staff did not have the necessary competencies to dispense medicines.

Summary of this inspection

Are services caring?

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:

- Staff maintained the privacy and dignity of patients.
- Staff gave patients transparent and accurate information about all the costs of potential treatment.
- Patients we spoke with were positive about the care provided by staff.

Are services responsive?

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:

- Access to the service and booking appointments was easy.
- Patients were offered consultations and follow up appointments at other optical express limited clinics to ensure patients were treated at their preferred location.
- There were no unexpected returns for treatment between August and October 2017.
- The service made reasonable adjustments for wheelchair users.
- The services provided clear information to patients on how to make a complaint.

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

- Patient information leaflets were not available in different languages.
- Staff were not aware that the service could offer interpreter services.

Are services well-led?

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 issues that the service provider needs to improve:

Summary of this inspection

- There was no surgery manager at the clinic. This had not been addressed when we re-inspected five months later in April 2019.
- The registered manager did not have oversight of the safety issues at the clinic.
- Governance and risk management systems were not embedded.

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

- There was a corporate vision and strategy for this service.
- The service conducted patient feedback surveys to encourage patient engagement.
- The service had a weekly staff recognition scheme.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- There were established processes for staff to report incidents. Staff were able to report incidents through downloadable forms on the staff computers. Once an incident had been reported it would go to the surgical services manager and medical director to assess whether it needed investigating.Staff we spoke with explained how they accessed incident forms and gave examples of occasions where they had reported incidents at other Optical Express clinics.
- Outcomes of investigations were shared with individuals involved. Learning from incidents was shared with all staff using the internal system of surgical services directives. The system involved sending a directive out to all staff that detailed what happened in the incident and any learning. The directives had to be signed by all members of the team to evidence that they had read the directive. We saw examples of this on our inspection. Staff told us that learning from incidents was also shared at team meetings. We saw this in the minutes from a team meeting on October 2017.
- Staff could give examples of practice changes which occurred as the result of learning from incidents. An example was a change to the pathway documentation following an incident where a medicine had caused irritation to a patient's skin.
- The clinic had no never events or serious incidents in 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.
- The service shared Medicines and Healthcare Products Regulatory Agency (MHRA) alerts through surgical service directives. The directives contained the content of the MHRA alerts. They were shared through email and kept on site in a directives folder at the Optical Express clinics with a signature page for staff to sign that they had read the alerts. We viewed this folder on our inspection.
- The surgical services manager had completed route cause analysis training. Quality management training was available for surgery managers which included information on incident management.
- The service covered the duty of candour as part of their mandatory training module, the duty of care. 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.

Mandatory training

- The service did not have any regular staff assigned to the clinic. We reviewed five personnel files of staff present on the day of our inspection and saw that four out of five members had completed all mandatory training modules. The remaining member of staff had four out of eleven mandatory training topics outstanding. Mandatory training was completed yearly from January to December meaning there was time for the member of staff to complete the remaining modules.
- Mandatory training was a mix of face-to-face and e-learning. Staff were given protected time to complete training at work or were paid if they completed the training at home. The topics covered by mandatory training were: consent, information governance, duty of care, safeguarding adults and children level 1 and 2, health, safety and welfare, equality and diversity, conflict resolution, infection prevention and control for clinical staff, fire safety, moving and handling patients and objects and basic life support.

- The surgical services manager had responsibility for ensuring all clinical staff except anaesthetists and surgeons had completed their training. The medical director was responsible for ensuring that surgeons completed their training. They were able to do this through an online tracker, which showed which member of staff had outstanding training on the e-learning system. We viewed this on our inspection and saw there were very few members of staff who had outstanding mandatory training across the organisation.
- All clinical staff present on the day of our inspection had completed annual basic life support training. The anaesthetist present on the day of the inspections had completed annual advanced life support training.
- The registered manager told us that bank staff were treated the same as permanent staff and had to complete all the mandatory training. We saw this in the staff files that we viewed on the day which included bank staff.

Safeguarding

- The clinic had a safeguarding policy, which described the types of abuse, and concerns staff should report. There were clear lines of escalation and contact details for the local authorities. We saw contact details displayed in a folder, which was accessible to all staff.The policy referenced the Care Act 2014, which included key changes to information relating to adult safeguarding.The safeguarding policy included information on the PREVENT strategy, which is a government directive. At the heart of PREVENT is safeguarding children and adults and providing early intervention to protect and divert people away from being drawn into terrorist activity. The policy was in date, had version control and had a review date.
- No safeguarding concerns were reported to the CQC between the reporting period of August to October 2017.
- Safeguarding was part of mandatory training. The safeguarding training was an online training package that staff could complete using the service's computers or at home. All clinical staff were trained to Level 2 safeguarding adults and children. We looked at five staff files who were present at the clinic on the day of inspection which confirmed this.
- The surgical services manager was the safeguarding lead for the organisation. They informed us that they were trained to adults and children Level 2 but had access to someone trained to Level 4 children's.
- Any safeguarding concerns were reported to the surgical services manager, who escalated these to the necessary local authority safeguarding teams.
- Staff that we spoke with could explain what constituted a safeguarding concern and how they would raise a safeguarding concern. Staff told us that they had not raised a safeguarding concern before but they could name the safeguarding lead for the organisation.
- The clinic did not provide treatment to young people under the age of 18 years of age and children were not allowed in the treatment area.

Cleanliness, infection control and hygiene

- On our inspection on 28 November 2017 we found that standards of cleanliness and hygiene were not maintained or embedded at the clinic. In response to our findings the service introduced new infection prevention and control (IPC) training, competency assessments and processes. On our inspection on 19 April 2018 we found that IPC standards had improved.
- On our November 2017 inspection we observed poor cleanliness in respect to staff footwear. Staff theatre shoes were visibly dirty. The footwear policy, dated January 2017, stated that staff were responsible for cleaning footwear at the start and end of the day. Surgery staff told us that they were not aware of any process for cleaning shoes, demonstrating that this practice was not embedded.
- Surgical staff wore disposable scrubs. We observed that the surgeon's gown remained untied at the back throughout procedures. We observed the surgeon walking closely past the instrument trolley with their gown untied, which risked compromising the sterile field, putting patients at risk of infection.
- Not all equipment was cleaned appropriately between patients. In the recovery area we observed the blood pressure machine and cuff were not cleaned in between patients.
- There was no demarcation between clean and dirty areas within theatres. We observed that used disposable instruments were carried past the area for clean scrubs and gowns for the next case. This posed a contamination risk.
- We observed staff cleaning patient and theatre areas with the same mop and bucket which put patients at

risk of infection. The clinic did not employ any cleaners and the cleaning of all areas was conducted by theatre staff. Staff told us that they were aware they had to clean theatres and clinical areas.

- Staff completed IPC mandatory training annually. The training did not adequately teach the staff how and why a theatre environment should be properly cleaned. The training was at a very basic level and not theatre specific. All staff present on the day of our November 2017 inspection had completed this training. We viewed a script from the IPC mandatory module and saw that whilst the training did state that separate equipment should be used to clean different areas, the training was not theatre specific and was not sufficiently detailed.
- We raised the issues we identified in our November 2017 inspection with the registered manager on the day of our inspection. The registered manager responded that staff should have been aware of the correct processes for cleaning theatre and that it was staff member's individual responsibility to ensure their shoes were clean.
- We raised the above issues again in our letter to the service on 6 December 2017. In response, the service's action plan included implementing team training on cleaning the theatre environment. The registered manager provided evidence that in January 2018 eight members of staff attended training which included the topics of gown tying, decontamination routes in theatre, surgical scrub technique and environment cleaning. This training was an improvement on the former mandatory training as it was detailed and theatre specific. On our inspection on 19 April 2018 we were informed that there was a plan to roll out this training to all theatre staff within Optical Express.
- We found that significant progress had been made to address the above IPC concerns when we re-inspected in April 2018. We found that footwear was visibly clean and all staff that we spoke to were aware of the footwear policy. Staff said that shoes should be cleaned at the beginning and end of a surgery list. Staff informed us that they used antibacterial wipes to clean their shoes and we saw that these were available in the changing room.
- Further improvements included that all members of the theatre team wore scrubs that were appropriately tied and we observed that equipment was being cleaned in between patient use.
- The service's action plan included that separate mops and buckets would be provided for use in theatres and patient areas. On our inspection on 19 April 2018 staff could all tell us that a separate mop should be used for clinical areas and explained that all the mop heads were disposed of after one use.
- The registered manager had stated that a cleaner would be employed for non-clinical areas as part of the service's action plan. However, staff were not aware whether there was a cleaner in post.
- The clinic had an Infection Prevention and Control (IPC) policy, which provided staff with guidance and IPC procedures that they should follow to minimise risk. The policy was in date, had version control and had a review date.
- There was a daily checklist which involved ticking off the cleaning of clinical areas. We viewed the daily cleaning schedules from August to November 2017 and saw that they were all signed and up to date. The service conducted a monthly deep clean; we saw evidence that this had been completed for the months prior to our inspections.
- There were staff competency assessments in place in relation to IPC procedures. We reviewed one for healthcare assistants which assessed cleaning after an infectious patient, effective cleaning techniques and knowledge of what is cleaned at what time during a surgical list. Further competency assessments were carried out in the January 2018 infection prevention and control training.
- Hand-sanitising gel was available at points of care in all clinic rooms. This was in line with Health Technical Memorandum (HTM) 'Infection control in the built environment'. The sinks had elbow operated taps, which was in accordance with the Health Building Note 00-09: 'Infection control in the built environment'. We observed staff using the handwashing stations throughout the clinic.
- Posters were displayed throughout the clinic, which provided information on the 'five moments for hand hygiene' in line with World Health Organisation (WHO) guidance.
- The service conducted monthly hand hygiene audits. We viewed the hand hygiene audit from October 2017 and observed there was 100% compliance.
- The surgical services manager who was also the registered manager for the clinic was the infection prevention and control (IPC) lead for the service as well

as being an IPC link nurse. We were told that the IPC link nurses for the organisation communicated by email but do not have formal meetings. We were not assured that the link roles or IPC training were effective as the concerns we raised had not been previously identified or challenged by any staff including the IPC lead/link.

- Staff recorded the humidity and temperature in the laser room on the treatment days to ensure these were correct and to maintain patient safety. We observed that this had been done twice monthly for August, September, October and November 2017.
- The service screened patients for MRSA during the initial consultation with the optometrist.
- The service did not have any incidences of a healthcare acquired infection in the last 12 months.
- An annual legionnaire test was conducted and we saw the documentation; which showed the necessary checks had been made. Legionella is a water-borne bacteria that can be harmful to people's health. The water tests for legionnaires disease complied with the Control of Substances Hazardous to Health Regulations 1989; Section 3(2) of the Health and Safety at Work Act 1974. Water temperature checks were completed monthly and the taps were run whenever there was a staff member present at the clinic, which was usually four days per month.
- The service monitored air quality in the operating theatres. The service conducted twice yearly airborne particle measuring and microbiological monitoring using an external company. Air filters were changed in the condensers every six months. We saw the documentation that confirmed this.
- The service used mostly disposable instrumentation but had a service level agreement with a local hospital for the sterilisation of reusable instrumentation. There was a system for tracking and traceability of the instrumentation which we observed staff complying with.
- The service had processes in place to deal with clinical and sharps waste. We observed staff using a sharps bin that had been dated and signed and marked with the location. Clinical waste was removed from theatres after each case. The service stored clinical waste securely. Waste was collected by an external clinical waste management company fortnightly. On our inspection on 19 April 2018 we observed that there was not a clinical waste bag placed in the clinical waste bin in use in the recovery area. Instead there was a black refuse sack in use which was disposed of in the domestic waste. Patient gowns worn in theatre were being disposed of in this black refuse sack. We raised this with the surgery support manager and were informed a clinical waste bag would be placed in the bin in future.
- There was no specific sepsis training at the service but we reviewed the team meeting minutes on 05 October 2017 which stated that a sepsis presentation had taken place; this included explaining what sepsis is and how to identify it. The surgical services manager had also recently sent by email a sepsis awareness document to all staff that was placed in the policy folder at all clinics.

Environment and equipment

- The service had appropriate facilities. There was a large waiting area with adequate seating for both patients and relatives. There was a separate pre-operative waiting room for patients who were due to be operated on imminently. Patients were seen in a consultation room for a preoperative assessment and another consultation room for diagnostic tests. There was an anaesthetic room, a laser room and a theatre. These rooms had internal doors which meant the patient went straight into the anaesthetic room from the laser room and straight into the theatre from the anaesthetic room. This design facilitated uninterrupted and efficient patient flow. The anaesthetic room had appropriate facilities and equipment; which included oxygen and suction equipment. There was a recovery room equipped with two recliner chairs, medicine cupboards and a handwashing area. The clinic and treatment areas were free of clutter.
- The dedicated laser treatment room was visibly clean and suitable precautions had been taken to meet the requirements of the laser local rules, health, and safety at work requirements. The controlled area was clearly defined with warning signs displayed so staff and patients knew not to enter.
- The clinic had a contract with an external Laser Protection Advisor (LPA) who was responsible for providing advice, and training on laser safety. They also drafted and issued suitable local rules and working practices and investigated adverse laser incidents.
- Staff attended core knowledge of training every three years with the LPA. We viewed staff records, which showed relevant staff had completed this training.

- The local rules also contained contact information for the Laser Protection Advisor (LPA). The LPA was external to the service and based in London. Staff could contact the LPA for personal questions such as safety precautions for pregnant members of staff.
- Local rules were stored in a folder in the registered managers' office. There was a list of authorised users. We viewed the list and noted the operating surgeons name was on the list of authorised users. Staff had signed to state they had read and understood the local rules.
- The laser technician checked the calibration and the safety of the laser machine before each laser treatment session. Calibration and checks took place according to local rules. We viewed the check sheets and noted they were completed, signed, and dated by staff.
- The laser-controlled area was clearly defined with a warning sign stating 'do not enter' when the laser was in use. This could be seen from the pre and post treatment rooms.
- On our inspection on 19 April 2018 we were told that the laser keys had been left in the laser machine overnight and staff were not aware of where the keys should be kept. This was not in line with the Medicines and Healthcare products Regulatory agency guidance on Lasers, intense light source systems and LEDs which states that at the end of the clinical session the key should be removed to an appropriate storage location. We raised this with the surgical support manager who informed us that there was an appropriate locked cupboard for the storage of laser keys and that this information was in the local rules. They informed us that he would remind staff of these arrangements.
- The provider held risk assessments for a range of chemicals including gases and cleaning fluids in line with the Control of Substances Hazardous to Health (COSHH) regulation. We noted that all items were stored correctly and securely.
- The service had established systems and processes to monitor servicing and electrical testing requirements of equipment. We observed that all the clinic's equipment servicing and electrical testing details were monitored and records kept in an onsite maintenance folder. The service conducted regular audits to check which pieces of equipment would need servicing or testing in the near future. Electrical testing was conducted in-house by the Optical Express' engineers. All of the equipment that we reviewed at on our inspection was up to date with electrical and servicing requirements. This included optical lamps, fridges and blood pressure monitors.
- On our November 2017 inspection we found that the emergency resuscitation trolley was not tamper-proof and the emergency medication in the trolley was accessible. This posed a risk to patients that medicines could have been tampered with, making them unsafe to use. However, on our re-inspection on 19 April 2018 we observed that the trolley had been secured with tamper proof tags. The administration of sedation and local anaesthesia policy had been updated to include the new process for sealing the trolley. These actions formed part of the service's action plan.
- There was an organisation-wide process to check stock levels on the resuscitation trolley on surgery days. On our November 2017 inspection we found that the clinic was not adhering to policy as there was no checking sheet with the resuscitation trolley to ensure that all equipment required was present. On our re-inspection on 19 April 2018 we saw that daily trolley check sheet was with the trolley and had been completed for the surgery days at the location. However, the monthly check which included changing the seal on the trolley had not been completed in March 2018. The check had been completed for January, February and April. This was a new process that had been implemented as part of the services action plan. The service had sent a directive on 26 January 2018 alerting staff to the new process.
- Emergency equipment was checked on surgery days. However, on our November 2017 inspection we found a number of out of date consumables in the clinic. Out of date equipment may be ineffective. There was a bag valve mask with an expiry date of 2015 found on the resuscitation trolley in the recovery area. In the recovery room there was a resuscitation mask that had expired in May 2017 and oxygen mask and tubing that had been removed from the packaging so it was open to air and sterility was compromised. With surgical lists only occurring weekly there was no way of knowing how long this had been open. On our April 2018 inspection we viewed a sample of consumable equipment and found that it was all in date.
- On our November 2017 inspection we found that oxygen cylinders were stored safely in secure upright trolleys. The cylinders examined showed good levels of oxygen

and were within date. However, on our inspection in April 2018 we found two expired oxygen cylinders that had been stored inappropriately. The cylinders were stored loosely in a cleaning cupboard, there was no signage on the door to inform users that there were medical gases stored in the room and the cupboard did not have any ventilation. There was a risk that the oxygen cylinders could have fallen on a member of staff as they were not secured. We raised this with the surgery support manager who informed us that the cylinders had been stored there temporarily to take them out of circulation before they were collected. The clinic had a contract with an external supplier, which provided delivery and collection of oxygen cylinders.

- The service had a lens bank situated in a separate room. The stock of the bank was organised by an external company, we were informed by the registered manager that the lens bank staff check the stock for expiry dates. The service did not perform any internal checks on the lens bank but did check the expiry dates of lenses prior to their use in theatre.

Medicines

- The clinic had a medicines management policy, which described the handling, storage, prescribing, recording, and safe administration, and disposal of medicines. However, on our inspection we found issues with the storage, prescribing and dispensing of medicines, which did not adhere to the local policy or national guidance.
- It was the responsibility of the surgeon and anaesthetist to prescribe medicines used during the procedure and those given to the patients to take home. However, we observed on our November 2017 inspection that prescription medicines to take home, consisting of eye drops and oral medication were dispensed by a registered nurse without being prescribed by the doctor or anaesthetist. There was no patient group directive (PGD). PGDs provide a legal framework which allows some registered health professionals to supply and/or administer specified medicines, such as painkillers, to a predefined group of patients without them having to see a doctor. Providing medicines without prescription is against Optical Express Limited's medicines management policy and the Humans Medicines Regulations 2012. The impact of this practice was a potential risk of patient harm due to incorrect medication, incorrect dosage or contraindication. We raised this with the surgeon and surgical services manager and in response, the surgeon amended the documentation to correctly prescribe medicines dispensed on the day of inspection.
- We observed that there was no prescription template on the patient pathway documentation. The surgical services manager showed us a newly drafted pathway documentation that had an area for the surgeons to sign for the prescriptions. This pathway however had not been approved at board level at the time of our November 2017 inspection. The service provided information following the inspection that the new pathway had been approved in December 2017 and was subsequently in use throughout the organisation.
- On our inspection on 19 April 2018 we observed that the new pathway documentation was in place. However, the surgeon was signing the prescription template without ticking which medicine they were prescribing or indicating which eye the prescription was for, this was instead completed by the registered nurses. The prescription sheet stated at the top that the surgeon was to indicate which eye and to tick which drugs are to be prescribed for the patient. This meant that the medicine was not being properly prescribed by the surgeon and the practice was not in line with optical express policy. This practice posed a risk that the wrong medicine could be prescribed for the wrong patient. However, the service had mitigation in place in the form of thorough contraindication checking by the registered nurses. We were given assurances by the surgeon that in future the prescription template would be completed by them in full.
- The service dispensed take home medicines of anti-inflammatory and antibiotic eye drops. The labels were computer generated and attached to stock drugs. On our November 2017 inspection one nurse who dispensed this medication told us that they did not have additional dispensing competencies. Dispensing is "to label from stock and supply a clinically appropriate medicine to a patient, usually against a written prescription, for self-administration or by another professional and to advice on safe and effective use" (MHRA, 2006). The Nursing and Midwifery Council (NMC) Standards for Medicines Management state that nurses involved in dispensing medicines represent an extension to professional practice and that the patient has the right to expect that the dispensing will be carried out with the same reasonable skill and care that

would be expected from a pharmacist. Standard 4 states that nurses may dispense medicines in exceptional circumstances, however nurses were routinely dispensing at the Chelmsford clinic.

- On our inspection on 19 April 2018 the registered nurses continued to dispense medicines. However, the registered manager had provided up-to-date competencies for four members of staff who dispensed in the south region. The nurses dispensing on the day of our inspection told us that they had recently completed dispensing competencies. The service had also introduced an additional control measure where all dispensed medicine was checked by either a registered nurse or a registered operating department practitioner before being given to a patient. We observed this happening on our inspection and staff told us that they felt the new checks made the process safer.
- On our November 2017 inspection anaesthetic and medicated eye drops were stored loosely in the anaesthetic fridge without original sterile packaging. The sterility was compromised and no expiry date information was evident. The risk to patients of using expired or unsterile eye drops could include inflammation, irritation or infection of the eyes. When we raised this with the assistant surgery manager they immediately disposed of the drops.
- In response to our inspection findings the registered manager sent a directive to all staff reminding them of the appropriate storage of eye drops on 20 December 2017. The handling of eye drops was also discussed as part of a training session provided to staff in January 2018. On our inspection on 19 April 2018 we observed that medicines were stored appropriately and were in date.
- The service offered intravenous sedation to patients. We observed on our April 2018 inspection that patients were assessed individually for their suitability for this. .
- The clinic had no Schedule 2 controlled drugs. Midazolam (a schedule 3 controlled drug) was securely managed and its usage entered into a controlled drugs register. Midazolam was ordered by the anaesthetist through a home office ordering form. We viewed the register and saw that stock levels and dates were checked prior to and following a surgical list on operating days.
- The service checked and clearly documented any allergies a patient had.
- Registered nurses were responsible for ordering, receiving, recording and storing of medicines. One pharmacy supplied all medicines for the clinic.

Records

- The service had effective systems to manage patient records. The clinic had an electronic medical system and a hardcopy of surgical records. Patient's records were delivered on site the day before surgery. The patient pathway documentation could be printed off directly from the patient's electronic record. The information from the patient pathway documentation hard copy was entered onto the electronic file. The hard copy record was archived off site and a full-time archivist managed these records. On receipt of the hard copy, it was scanned and saved. The electronic record was, therefore, integrated with the hard copy file with the exception of the instrument traceability records and signed patient consent form. This information could be retrieved through the archivist who was able to send the scanned record.
- The records contained implanted lens stickers showing the type and traceability codes for the replacement lenses used. Details of single use items were also present.
- An audit of records was completed on a quarterly basis and overseen by the surgical services manager. The clinic checked 10 sets of hard copy patient records and three on the electronic system. The audit looked at the following: consent, consultation date, surgery date, standard of initial consultation notes, the health questionnaire, all scans included, anaesthetic sheet completed and signed, presence of drug sheet and instrument traceability sheet, evidence that patient has been seen post-operatively and whether the WHO checklist had been completed. The audit from October 2017 showed that there was one missing surgeon signature on a consent form and one error with inputting the laser information on the system but they had the correct paper record. We viewed the action plan from the audit which stated that the information would be shared with the team at the next team meeting. However, there was no evidence that any direct actions were taken to notify the surgeon responsible.

Assessing and responding to patient risk

Refractive eye surgery

- Patients were assessed for their suitability for treatment. Patients completed a health and lifestyle questionnaire prior to surgery. This enabled staff to identify any allergies and risk factors specific to the patient.
- The provider had an exclusion criteria and safeguards in place to identify patients unsuitable for surgery. The optometrist, the surgeon and the anaesthetist saw patients pre-operatively. The optometrist would check the refraction of the patient's eyes. If the optometrist was happy with the patients' refractions the patient would see the anaesthetist and surgeon to prepare them for surgery. Staff told us they would cancel patients with high blood pressure and tested for this on the day of surgery. Patients with type 1 diabetes were treated by the service on receipt of a letter from the patients GP to confirm that their condition was stable and well controlled. The service's exclusion policy included patients that they deemed high risk because they had a pacemaker, uncontrolled diabetes or had previous heart attacks (assessing patient's needs, accessing care, promoting and supporting choice and independence policy, January 2017).
- There was an established process for escalating post-operative treatment and complications. If a patient needed to contact the service post-operatively during working hours they were provided with the central phone number. This would put them through to customer services who referred the patient to clinical services. Patients were provided with an out-of-hours telephone number which was staffed by optometrists. If the optometrist felt they needed to escalate the call they would forward it to the surgeons who were available out-of-hours. The post-operative record for the patients check-ups included a mandatory field which indicated whether: the patient had a complication, the nature of the complication and whether the patient needed to be referred back to the surgeon, or whether the patient file needed to be reviewed remotely (by the clinical services team in Head Office) for further advice. If the complication required urgent intervention, the examining optometrist was required to contact the clinical services team on their dedicated 'pre and post-operative advice' telephone line.
- On the day of our November 2017 inspection, we found a number of patient safety risks which were not being positively managed by the service. We raised these with senior staff during the inspection.
- Following surgery patients were taken from theatre into an adjacent corridor on the theatre trolley. Patients were then asked to stand and walk to the recovery room which was about ten metres away. We observed patients being hurried to stand despite voicing concerns that they felt dizzy. The service had a risk assessment for the transfer of patients which stated that a control measure to reduce the risk of falls was that patients should be transferred in a wheelchair wherever possible; staff were not adhering to this measure.
- Staff were not monitoring patients' oxygen saturations and pulse rate during the surgical procedure. The anaesthetist and operating department practitioner gave the intravenous sedation in the anaesthetic room but did not follow the patient into theatre. The audible alarm for oxygen saturations was turned off and the monitor could not be seen by the registered nurse who was undertaking the role of ophthalmic scrub. This put patients at risk of harm because deterioration may go undetected. In addition, this was in direct conflict with the Royal College of Anaesthetists (RCA) guidelines for the provision of anaesthesia services 2017 which state that if no anaesthetist is present in theatre, an appropriately trained anaesthetic nurse, ophthalmic theatre nurse or operating department practitioner (ODP) should be present to monitor the patient during establishment of local anaesthesia and throughout the operative procedure. This should be their sole responsibility.
- The service had created an adapted World Health Organisation (WHO) and five steps to safer surgery checklist which we observed staff using. However all sections of the form were completed before the surgeon had commenced scrubbing for the procedure. This meant a potential risk to patients as processes were not effective to ensure the correct patient, correct site of surgery and correct implant was used.
- On our April 2018 inspection we found that significant progress had been made to address the above risks. The provider sent an action plan on 07 December 2017 that detailed the new policies and safeguards that would be put in place to improve patient safety.
- The service created a local policy and competency assessment on the safe transfer of patients from theatre to the recovery area. The policy detailed that all patients were to be transferred from theatre to the recovery

room using a wheelchair in order to minimise the risk of patient fall. On our April 2018 re-inspection we observed that every patient was transferred to the recovery area using a wheelchair.

- The service had improved the monitoring of patient's vital signs during surgery. The service's action plan stated that the monitor would be repositioned to ensure it could be viewed by relevant theatre personnel. We observed on our re-inspection that the monitor had been moved and was visible to all members of the surgical team.
- The provider implemented a new daily checking sheet to ensure that the patient monitors in the anaesthetic room and theatre are set up in accordance with policy. This included ensuring that the monitors were set to audible mode and had appropriate parameters set for the monitoring of patient's vital signs. On our re-inspection we saw that the daily monitoring sheet had been signed and completed for all surgery days since the service had recommenced. Staff could clearly explain the parameters that had been set on the monitors for patients' blood pressures, heart rate and pulse oximetry.
- The service had updated its administration of sedation and local anaesthesia policy to state that the anaesthetic nurse or operating department practitioner (ODP) must be present throughout the procedure and have defined responsibility for the monitoring of the patient. On our re-inspection we observed that the anaesthetic nurse was present in theatre monitoring the patient.
- The service conducted training on the World Health Organisation (WHO) and five steps to safer surgery checklist (WHO checklist). The service also created competency assessments on the WHO checklist for operating theatre staff. We observed on our re-inspection that all members of the theatre team were fully engaged with the WHO checklist process. We observed that staff were completing the WHO process in full, at the relevant stages. All staff spoke positively about the improvements to the WHO process. Staff felt that the checks ensured accuracy and felt that the brief and debrief were really beneficial.
- The service had an emergency and patient collapse policy for Intra Ocular Lens (IOL), version 2, dated January 2017, with a review date of January 2020. The policy stated that in the event of patient collapse the attending anaesthetist will take the lead in managing the patient and where the patient has severely collapsed the service would call 999. The policy also detailed the emergency contacts for patients if they needed assistance out of hours. Staff that we spoke with knew how to recognise a deteriorating patient and the process to follow in the event of a patient collapse.
- The service had an emergency resuscitation trolley but this was not located in theatres and was situated down a corridor behind a door. As a result, there would be a delay in getting the trolley to the patient in the event of a cardiac arrest. However, there was access to emergency medicines in the anaesthetic cupboard in the anaesthetic room.

Nursing and medical staffing

- The provider did not have specific staff assigned to the clinic. The service was staffed using a master rota of the surgical team. The scheduling for the clinic was conducted by the head office at Optical Express. The service was staffed from teams throughout the region.
- On the day of our November 2017 inspection the service had an operating list of 14 patients. There were three members of theatre staff, one scrub nurse, one healthcare assistant and one operating department practitioner and two consultants, the surgeon and anaesthetist. The anaesthetist and operating department practitioner stayed in the anaesthetic room and did not follow the patient into theatre or recovery. In the ward area there was one registered nurse discharging the patients. Staffing numbers on the day did not comply with the Royal College of Anaesthetists (RCA) guidelines for the provision of anaesthesia services, guidelines for the provision of ophthalmic anaesthesia services 2017, which states that for most operating sessions, staffing should include two theatre-trained scrub practitioners. It was unclear how the provider had risk assessed the staffing levels for the number of patients that were scheduled.
- The surgical services manager informed us that staffing the clinic did not present any issues and that the schedulers ensured that the right skill set is present for the surgical lists. The schedule was completed around two months in advance to allow staff to have advance notice of where they will be working. However, we viewed the October 2017 team meeting minutes and saw that nurse staffing concerns on intra-ocular lens

surgery list days were raised by staff members. The minutes stated that where a list had 11 or more patients a second scrub nurse would be scheduled. This practice had not been put in place at the Chelmsford clinic.

- We observed that during the operating list the scrub nurse was rushed and was trying to teach the healthcare assistant the circulating role and was instructing them to open consumables whilst maintaining sterility to assist.
- Staff that we spoke with said that staffing levels were an issue across the organisation. An example given was that there would be only one scrub nurse for any list with less than 15 patients when previously there would have been two scrub nurses. Staff told us that they worked long shifts and that they did not get breaks at times.
- We raised our concerns regarding staffing levels with the service in our letter dated 6 December 2017. In response the service included in their action plan that they would re-evaluate and risk assess local staffing requirements. Upon doing so the service changed its 'Staffing Levels and Skill Mix Policy'. The updated policy stated that two scrub nurses must be present for each theatre surgery list. On the day of our re-inspection in April 2018 there were two scrub nurses present for a list of 14 patients. Staff numbers on the day of inspection were compliant with RCA guidelines.
- Staff told us that for all theatre lists in the Chelmsford clinic since February had two scrub nurses scheduled for them. Staff were positive about this change and we observed that the surgery environment was calm and focused.
- The registered manager told us told us that they use bank staff regularly. Between August 2017 and October 2017 the service had used bank nurses ten times and a bank operating department practitioner once. The registered manager told us that they had a large bank of staff, some of which had been working on the bank for over ten years.
- All anaesthetists working for Optical Express were employed through a medical agency.

Major incident awareness and training

- The service had an equipment or mains services failure-emergency measures policy which detailed what to do in the event of a power failure, faulty equipment, environmental conditions, fire, water failure and occasions where surgery would need to be cancelled or postponed. The policy was dated January 2017 and had a review date of January 2020.
- The clinic had its own fire and emergency response plan and staff received training as part of their mandatory training package.
- The clinic had an uninterruptible power supply back-up system and protocols in place to inform staff of what to do should the main electricity fail.
- We observed fire exit signage throughout the premises. There were fire extinguishers in all clinic areas which had been serviced by an external company. All fire exits and doors were kept clear and unobstructed.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence based guidelines. Policies and guidelines had been developed in line with the Royal College of Ophthalmology (RCOPTH) Standards for laser refractive surgery and National Institute for Health and Care Excellence (NICE) guidance on photorefractive surgery.
- Pre-operative assessments included screening against a defined set of criteria to ensure patients were suitable for the treatment. The patient filled out a health questionnaire during their first consultation.
  Pre-operative tests for elective surgery were in line with the National Institute of Clinical Excellence guidelines NG45, routine preoperative tests for elective surgery. Patient's medical history and allergies were discussed and appropriate tests and scans were taken to help determine treatment.
- Suitability guidance and treatment criteria were subject to critical review annually by the International Medical Advisory Board (IMAB). The IMAB comprised of refractive eye experts who had no link to the company. Guidance and any recommended changes were discussed and reviewed internally via Optical Express Medical Advisory Board (MAB). The service would review their own audit processes and results at the MAB and any changes in guidance would be determined and shared with staff. We were informed by the surgical services manager that

one example of a change implemented by the MAB was a new approach of guiding patients who are long sighted towards intra-ocular surgery rather than laser surgery as data showed better outcomes for this group.
- The clinic conducted regular audits for infection control, incidents, complaints, record keeping, maintenance of equipment, medicines management and health and safety. We viewed a variety of audits from September to November 2017, which showed actions were taken against any areas of concern. However, we were concerned that the audits did not identify the patient safety and IPC issues we identified on our inspection.

Pain relief

- All patients undergoing surgery had both anaesthetic eye drops and sub-tenon (an injection through the membrane covering the muscles and nerves at the back of the eye) local anaesthetic administered by the anaesthetist. The patients were also given a short acting intravenous sedation to produce drowsiness and to relieve anxiety before surgery. The effects of the local anaesthesia generally lasted around six hours.
- Patients were told that if they experienced pain post operatively that they could take over the counter medications such as ibuprofen and paracetamol.
- Patients were asked about their pain in their next-day follow up consultation with optometrist and in their post-treatment patient questionnaire.
- Patients that we spoke to on inspection told us that they thought their pain was well managed.

Patient outcomes

- Outcome data was collected for every treatment undertaken including long term follow up data. This data was reviewed by the independent medical advisory board and the Optical Express medical advisory board. The data could be analysed in terms of clinic but this was not routinely done due to the low patient volumes in the clinic. The data collected enabled the service to monitor the demographics of their patients in terms of patient age, gender, treatment type, and procedure type and whether they experienced any complications.
- Patient outcomes were monitored through individual surgeon outcome results. A full time biostatistician collected data from the patient's electronic files. The audits measured the patient outcomes of uncorrected distance visual acuity and change in uncorrected near vision one month after surgery. The surgeon's efficacy and safety data was rated. A score of 50 represented outcomes that were on par with expected Optical Express levels. The audits also monitored cancellation rate by surgeon but did not specify whether the cancellation was for clinical or non-clinical reasons.
- We viewed one surgeons clinical outcome compiled data. The surgeon scored 55 for both efficacy and safety. They had a complication rate of 1% which was in line with the Optical Express average. The surgeon had an estimated enhancement rate of 4.3% which was in line with the Optical Express average of 3.3 to 5.3%.
- Each surgeon's outcomes were assessed at the International Medical Advisory Board (IMAB) meeting. The IMAB were an independent board who reviewed Optical Express' national performance. The IMAB recommendations would be fed back to Optical Express' Medical Advisory Board which consisted of Optical Express employed clinicians. The MAB had the responsibility to ensure that any necessary changes which may impact patient safety were reviewed.
- There had been no incidences of an unplanned return of a patient to theatre following refractive eye surgery between August and October 2017 at the clinic.
- Six patients had experienced complications following refractive eye surgery at the clinic between August 2017 and October 2017. All six instances had been mild corneal oedema (swelling) which had resolved itself without further intervention.
- There were no incidences of unplanned transfer of a patient to another health care provider in the 12 months prior to our inspection.
- Optical Express clinics contributed data to the National Ophthalmic Database Audit (NODA) and benchmarked data against it. Results from NODA showed that Optical Express patients had a higher likelihood of excellent visual outcome with a lower chance of suffering an intraoperative r post-operative complication than the comparator group.

Competent staff

- The service had a role-specific induction that lasted between two and six weeks. This involved competency assessments and training. The staff member was counted as supernumerary until they had their competency assessments signed off by the surgery manager or surgeon.

Refractive eye surgery

- Each surgeon's individual outcomes were collected on an annual basis and were discussed and evaluated as part of the surgeon appraisal process.
- Staff performance was audited on a regular basis and we saw this in staff personnel records. Performance of the surgeons was managed by the medical director who monitored performance by observing each surgeon at least once a year. The service also monitored performance of surgeons by auditing patient outcomes, cancelled cases and complication rates.
- The surgical services manager told us on inspection that if there were performance issues with any member of staff then shadowing and further training opportunities would be offered. We were given an example of an instance where a member of staff had struggled with computer skills so had been offered additional training and support.
- We saw evidence that permanent and bank staff present on the day of inspection had recently had an appraisal or where scheduled to have one within the coming months. The service appraised its staff yearly and the appraisal year ran from January to December.
- Anaesthetists were agency based and generally worked within the NHS. The manager from the agency completed the training and updates, which was accessed by the organisation. We saw evidence that training, Disclosure and Barring Service (DBS) and insurance indemnity checks for the anaesthetists working at the clinic were up to date and in place.
- The surgeon's file contained the following information; General Medical Council (GMC) registration, personal indemnity insurance certificate, DBS checks and references, continual professional development information and appraisals. The files also contained the surgeon's CV and copies of their professional training certificates.
- We observed that all relevant members of staff present on the day had valid professional registration. A record of their registration was kept in their personnel file. However, there was not an effective system to check staff members' professional registration was up to date. One member of staff's professional registration certificate in their file was valid until October 2017 and therefore had expired. When we raised this with the registered manager, they immediately printed an up to date certificate for that staff member that did not expire until October 2018.
- The provider kept records of the review dates for nurse's revalidation.
- All nurses were trained in basic life support and some nurses had intermediate life support (ILS) training. On the day of surgery, there was a nurse trained in intermediate life support present and the anaesthetist was trained in advanced life support. This skill mix complied with the Royal College of Anaesthetists (RCA) guidance on the provision of Ophthalmic Anaesthesia Services 2015.
- All staff operating laser equipment were trained in this role. All staff completed the laser core of knowledge training day. The laser technician attended a one week course in the use of the lasers and associated equipment which was run by the laser manufacturer. Laser technician's competencies were reviewed every three years. Optical Express employed senior refractive trainers who carried out the laser competency assessments locally and supported technicians and the laser protection supervisor to ensure they remained skilled.
- The laser protection advisor (LPA) was a certified member of the association of laser safety professionals.
- The service offered some career development opportunities by offering secondments into surgery manager roles for assistant surgery managers and surgery associates. However, staff we spoke with stated that development opportunities within the organisationwere limited.
- Information sharing and development opportunities were available through clinical meetings, equipment training by individual manufacturers and attendance at conferences such as the European Society of Cataract and Refractive surgery.

Multidisciplinary working

- We observed good multi-disciplinary working by the team at the clinic. The operating department practitioner and health care assistant assisted the scrub nurse where they could with opening the instrument packs.
- Staff worked across multiple sites in Optical Express, which meant there was consistency within the service.
- The surgeon told us that surgeons were training optometrists to develop skills by observing surgeries with the aim of becoming a more inclusive team.

Access to information

- Patient records were mostly stored electronically, which meant staff at other clinics had access if the patient had an appointment elsewhere. Access to electronic records was for authorised staff and password protected.
- At initial consultation, the patient was required to indicate on their health questionnaire whether they consented to the clinic contacting their GP. The electronic system automatically sent a 'discharge' letter to the GP if the patient had consented and they had been for their final post-operative examination.
- The organisation's policies were accessible through the service's intranet. Hard copies were kept at the clinic.

Consent and Mental Capacity Act

- There was a consent policy dated September 2017, which stated it was the surgeon's responsibility to make sure the patient understood the treatment plan including the finer details of risks associated with the treatment. The surgeon was responsible for ensuring the consent form was signed prior to treatment. The consent policy stated that it was good practice to have a reflection period of seven calendar days between the discussion with the surgeon and the day of surgery but in instances where this is not appropriate there should be a time lapse of at least 48 hours. The policy was not in line with Royal College of Ophthalmologist guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- At the initial consultation, the patient was provided with an information folder, which contained a copy of the consent form, the terms and conditions document, information on the procedure including the costs, which included the benefits and the risks. During the appointment, the patient watched a video, which reaffirmed the information provided during the consultation appointment.
- Consent forms were signed on the day of the surgery by both the patient and the operating surgeon. We observed evidence of this in all four of the patient records we looked at.
- The service included training on Mental Capacity Act 2005 in the duty of care mandatory training module. The service screened for mental health and capacity issues in their health questionnaire and it was the service's policy that an optometrist could advise that a patient was unsuitable for refractive surgery if there was capacity to consent issues (assessing patient's needs, accessing care, promoting and supporting choice and independence policy, January 2017). If the service had doubts as to patient's capacity to provide consent they could request further information from the patient's GP.

Are refractive eye surgery services caring?

Compassionate care

- We observed kind interactions between staff and patients with staff taking time to interact with patients. We observed a staff member stopping in the corridor to observe a patient undergoing their second eye treatment and asking how they had slept following their first procedure.
- Patient's dignity was respected and staff ensured that they introduced themselves to patients. Staff were discreet and ensured patient discussions on treatment took place in private consultation rooms.
- Patients were asked to complete an online survey at various points during their care. The surgery survey is a number of questions relating to the overall patient experience and is completed at the 24-hour post operative visit. A reminder pop up is generated on the patient's electronic file during the post-operative examination as a reminder for the optometrist to guide the patient to complete the survey. The results of the survey are provided each month to the Manager. The patient is asked to score each question. The Surgery Manager can then monitor trends and track any areas where the provider could look at making improvements. The scores were benchmarked against other clinics within the organisation. We requested the feedback data for the Chelmsford clinic after our April 2018 inspection but this was not provided by the service.
- On our April 2018 inspection we observed that when transferring patients into a wheelchair from theatre that staff took time to reassure patients and allowed the patient time to sit up and move at their own pace.
- All patients we spoke to on the day of our inspection spoke positively about the staff and their experience. One patient said that the staff are "lovely group of people".

Understanding and involvement of patients and those close to them

Refractive eye surgery

- We observed that throughout treatment patients were given explanations that were adapted to varying patient needs to ensure patients' understanding.
- The patients we spoke with told us they had been provided with good information regarding their treatment and staff had asked them if they understood everything throughout their care. Patients that we spoke with told us that they were given the opportunity to ask questions about their treatment and that the information they were given, both written and verbal, was very clear.
- Information on the use of chaperones was displayed at the reception area. This meant patients were able to involve relatives, friends, and chaperones in their discussions about treatment and care; with the patient's consent.
- Patients were given information about the cost of their treatment at their initial consultation with an optometrist. Patient's that we spoke to confirmed that this information was provided to them and that the service was transparent about costs.

Emotional support

- We observed staff offering reassurance to all patients. Staff were calm and professional, which helped patients feel relaxed.
- Patients we spoke with said staff made them feel relaxed and did not pressurise them into going ahead with treatment.

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

Service planning and delivery to meet the needs of local people

- The clinic provided intra-ocular refractive lens surgery for the immediate and local population across the Essex area. Patients accessed the service either through the website or telephone line. Patients could find out about the service through word of mouth, marketing or internet research. The clinic did not undertake any NHS work.
- The clinic did not have set opening times and held clinics on various days throughout the year. The service did not operate surgical lists on the weekend but patients were given the option to attend other Optical Express clinics that did. The registered manager told us that any patient could attend any of the Optical Express clinics nationwide as the service could access electronic patient records from every clinic. This allowed them to get the latest information on the patient's treatment and allowed for continuity of care.
- The service tried to ensure patients were treated at their preferred clinic. Patients that we spoke to said that they had been offered follow-up consultations at clinics closer to them which was helpful.
- The service did not treat patients under the age of 18.

Access and flow

- Patients accessed the service through the internet or telephone service where they were given an appointment with an optometrist to assess their suitability for surgery. If they chose to proceed then they had a consultation with a surgeon either in person or over the telephone. Following the surgeon consultation the patient would be booked in to attend a clinic for surgery. Patients that we spoke with told us that they found the entire process easy and were promptly offered appointments.
- Patients gained access to the clinic through the main entrance of a multi-purpose office building.
- Appointments were not available at the weekends but the clinic offered appointments at other clinics nearby, which allowed for better patient choice of appointment times.
- Emergency eye surgery was referred to the nearest NHS emergency eye care services.
- The clinic monitored cancellation rates locally. We saw that the service had one instance where a patient was cancelled on the day of surgery and two instances where patients did not attend from August 2017 to May 2018.

Meeting people's individual needs

- The service made reasonable adjustments for wheelchair users and people with restricted mobility.
- The registered manager informed us that they tried to ensure that patient's individual requests could be met and gave the example of fulfilling a patient's request to use medicines with no animal products.
- The service did not treat patients with, learning disabilities, dementia or patients with complex health

conditions. Screening procedures at the start of the patient's journey ensured those patients who required additional support were referred to alternative services with the support of their GP.

- There was a range of information leaflets available throughout the clinic. They provided information on treatments and various conditions; however, they were only available in English. The surgical services manager informed us that the service leads had discussed translation of leaflets into other languages and were looking into printing leaflets in other languages. At the time of inspection, they had not yet agreed the languages to be used or set a date for completion.
- The service's assessing patient's needs, accessing care, promoting and supporting choice and independence policy stated that patients were expected to bring their own interpreter/translator for their consultation for patients whose first language was not English.
- The service provided interpretation services on the planned day of surgery if the patient was willing to cover the costs of the service. Clinical staff we spoke to were not aware of this part of the policy or that the clinic could provide interpreter services. This information was not available in the leaflets or information the clinic provided to patients.
- The organisation's website was informative and patient friendly to use. There was a good description of each procedure as well as examples of patient feedback.

Learning from complaints and concerns

- The complaints policy dated January 2017 described the process staff should follow in the event of a patient making a complaint. The principles of duty of candour were described in the policy.
- The patient's consent form and terms and conditions document contained information about how to make a complaint and a poster detailing how to make a complaint was displayed in the reception area.
- The service had not had any complaints at the clinic since recommencing surgery services in August 2017.
- The service kept a log of verbal complaints they had received on site, we reviewed this log and saw that the only verbal complaint the clinic had received was in 2015. The service had reviewed the complaint and had provided a reasonable solution for the patients concerns. There was a complaint folder on site detailing complaints, responses and actions taken at other Optical Express clinics to ensure shared learning across the organisation.
- All written complaints were responded to by the clinical services team. The patient's electronic record was updated so the information regarding the complaint was accessible to the registered manager who was then able to monitor progress.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was no embedded leadership in place at the clinic. The registered manager at the Chelmsford clinic was also a registered manager at another two clinics, lead nurse for infection prevention and control, safeguarding lead, as well as being responsible for 18 Optical Express clinics in their role as surgical services manager. The registered manager was not onsite for all of the surgical lists run in Chelmsford and did not have oversight of the day-to-day running of the location. We were concerned that the registered managers multiple roles impacted on their operational capacity, ability to be effective in governance and their oversight at the clinic. For example, safety issues we found on inspection, such as medicines management, infection prevention practices and low staffing levels, had not been identified by the registered manager.
- The clinic did not currently have an onsite surgery manager like other optical express clinics. The surgical services manager informed us that the company were looking to recruit internally to the post in the coming months. A member of staff was acting up in to the role currently on surgery days at the service but the surgical services manager was still taking responsibility for the governance arrangements at the site.
- Prior to our April 2018 inspection we were informed by the registered manager that the service was looking to create a joint management role with another clinic and to transfer the management of the Chelmsford location from the current registered manager. However, at the time of our inspection in April 2018 there was not a new

manager in post and staff were not aware of the plans for a joint manager. We were concerned that this had not been resolved in the five months after our inspection.

- Our findings indicated a lack of effective leadership. Due to no permanent staff or clinical service manager being present, issues and concerns raised by staff were not being addressed. Staff provided examples where concerns regarding staffing were raised through the formal processes but had not been responded to in a timely manner. Staff felt unsupported by head office as a result.
- Following our November 2017 inspection, the registered manager responded to our concerns in a timely manner and introduced effective new systems to address the risks we had identified. Upon re-inspection in April 2018 we saw that these new systems were embedded and staff were engaged with the new processes.
- The surgical services manager reported directly to the chief executive officer of the organisation but had not had an appraisal for 14 months and did not have one booked in for a future date.
- The service provided training in order to help leaders in their roles. We observed that the assistant surgery manager had attended in-house quality and safety management for managers and registered managers training.

Vision and strategy

- The provider's vision was to "lead in the global elective and healthcare industry through utilising the most advanced technologies, scientifically analysing our clinical outcomes and by working with the pioneers, innovators and opinion leaders in the healthcare industry."
- Staff we spoke to on inspection were aware of the service's vision.
- There was a poster in the clinic displaying the vision and stating that the service's mission was "to grow and develop our network of clinics globally and provide the highest quality science based technology superior products and services that enhance people's lives."
- The surgical services manager told us that the main focus for the clinic was securing a permanent member of staff into the surgery manager position to run the site. Following this, the organisation would look to have a resident nurse associated with the clinic. There was not a set timeline for implementing these changes or a written strategy for the Chelmsford clinic.

Governance, risk management and quality measurement

- There were policies and risk assessments in place to support Optical Expresses' governance structures. These included topics such as, incident management, information governance, risk management, medical management, and management of complaints. However there was a lack of local oversight of governance, risk and quality improvement.
- Risks were managed through risk assessments, which were colour rated, so the clinic were able to assess the severity of each risk. The risk assessments were stored on the services computers and could be updated by any member of staff. Risks were reviewed annually by the surgical services manager; we saw this on our inspection.
- Risk management systems were not robust and did not identify all risks at the clinic. The risks that the service had risk assessments for were well documented but the control measures were not being used by staff. This was despite staff signing the risk assessments to agree they had read and understood the risks and the control measures in place. For example, the risk of a patient falling on transfer from theatre to the recovery room had been identified in the services risk assessment and it included the control measure that patients should be offered a wheelchair transfer. This control measure was not being used at the clinic and all patients were being asked to walk to the recovery room despite voicing concerns over being dizzy. Further examples of a lack of embedded governance included that we observed staff were not adhering to the footwear policy, medicines management policy or their infection prevention and control training.
- On our inspection on 19 April 2018 we saw that the risk register had not been updated since our previous inspection to capture the risks that we had identified. Whilst the service had addressed the risks identified we were concerned that they had a reactive rather than a proactive approach to risk.
- Although the service had measures in place to review and implement professional guidance they were not following guidance from the Royal College of

Anaesthetists (RCA) in respect of staffing levels and Nursing and Midwifery Council (NMC) guidance in respect of dispensing medicines. This indicated that these arrangements were not effective.

- There was an organisation-wide clinical committee meeting held by teleconference on a monthly basis. The meeting was attended by the clinical services director, medical director, surgical services manager, and responsible officer. We reviewed recent minutes, which showed topics such as, clinical suitability guidelines, laser surgery outcomes, complications with surgery and new technologies were discussed. The minutes provided actions the organisation needed to take.
- There was no team meeting at the clinic as there were no staff based there, however all staff across the clinics were assigned team meetings to attend. The team meetings were newly implemented. We viewed the minutes from a team meeting on 5 October 2017 and saw that the following topics were discussed: duty of candour, incidents, cleaning responsibilities, data protection and sepsis awareness.
- Quality indicators for the service covered incidents, local audits, and complaints. This information fed into the clinical governance committee and in turn to the Medical Advisory Board (MAB), of which the CEO headed. All surgeons and heads of departments were members of the board. The MAB had overall management of changing practices to surgery treatment techniques.
- Following our inspection, we wrote to the service outlining our concerns that affected patient safety. The registered manager responded immediately to the concerns we raised and undertook voluntary suspension of the clinic. The service devised an action plan which involved policy changes and training to address our concerns.

Public and staff engagement

- The service conducted four patient surveys, one 24 hours after surgery, another a week after surgery, another one month after surgery and a final one three months after surgery. Patients were asked a number of questions based on their patient journey ranging from environment, care, staff interactions and outcomes. The surveys were conducted when patients came in for post-operative check-ups and patients were asked to fill in the electronic surveys at a computer terminal in the clinic.
- The service did not have a staff survey. Staff could raise complaints formally through the human resources department or informally through the line management structure. However staff we spoke with told us there were significant delays when issues had been raised. The service were looking to implement a staff survey and had released two prototype surveys to two surgical teams but determined further work needed to be completed on them. There was not a set date for finalising this piece of work.
- Although this was not a service requirement the surgical services manager had been on a course with the intention of implementing a freedom to speak up guardian in 2018. The role of the National Guardian is to advise NHS trusts and Freedom To Speak Up Guardians on best practice to encourage and enable staff to speak up safely within their own workplaces. However, there was not a set date or formal plan for this.

Innovation improvement and sustainability

- A staff recognition scheme called 'wonderful Wednesdays' took place every week, where staff were nominated to receive awards such as spa days. The scheme was a way for the organisation to recognise valued members of staff.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Following this inspection, on 6 December 2017 we sent the provider a letter setting out our significant concerns and the fact that we would have to take urgent action unless the provider immediately addressed the risks we had identified. In response, the provider decided to voluntarily suspend surgical services at the clinic with immediate effect.

This action negated the requirement for CQC to take urgent enforcement action as major safety concerns and risks for patients were addressed by Optical Express suspending services at Chelmsford. Since 7 December 2017 CQC has been closely monitoring actions taken and reviewing progress. On 12 January 2018 we received written confirmation that the service intended to continue the suspension until 5 February 2018 to allow them to ensure all areas of their action plan had been addressed.

We re-inspected the service on 19 April 2018. We found that the concerns we had identified on our November 2017 inspection had been addressed and the new processes and policies were embedded.

Action the provider MUST take to meet the regulations:

- The provider must ensure all medication is prescribed in accordance with policy.
- The provider must ensure medical gases are stored appropriately.
- The provider must ensure it embeds governance and risk systems within the service.

Action the provider SHOULD take to improve

- The consent policy should reflect Royal College of Ophthalmologist guidance 2017 for a seven day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The provider should consider how it obtains and uses staff feedback.
- The provider should review its arrangements for the provision of patient information in other languages apart from English.
- The provider should review the implementation of clinical waste bags in the recovery area.
- The provider should update staff on the arrangements for laser key storage at the clinic.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for service users. Registered persons must assess the risks to the health and safety of service users receiving treatment and doing all that is reasonably practicable to mitigate any such risks. The service had stored expired oxygen cylinders in a cleaning cupboard. These were not secured, there was no ventilation in the room and there were no signs on the door alerting persons that medical gases were stored there. The service was not prescribing medicines in accordance with their patient pathway documentation. The surgeon signed the sheet prescription sheet without specifying which medicine was to be prescribed and for which eye.

Regulated activity	Regulation
Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively. Governance and risk management systems were not embedded and there was not oversight of the risks we identified on inspection.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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