

Optical Express - Northampton Clinic

Quality Report

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Date of inspection visit: 22 November 2017
Date of publication: 21/02/2018

This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Are services safe?

Are services effective?

Are services caring?

Are services responsive?

Are services well-led?

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Summary of findings

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Overall summary

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 22 November 2017.

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

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

Services we do not rate

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

We found the following areas of good practice:

An incident reporting process and policy was in place and staff understood their responsibilities to raise concerns and incidents. Optical Express – Northampton Clinic is operated by Optical Express. Facilities include one laser treatment room, one surgeon's examination room, two discharge rooms and one consultation room.

The service provides refractive eye surgery.

- There had been no infections from September 2016 to August 2017.
- All staff had received mandatory training and basic life support training.
- All staff were trained to level 2 safeguarding adults and level 3 safeguarding children.
- All areas of the clinic were visibly clean and cleaning mechanisms were in place.
- The humidity and temperature of the laser room was checked regularly and recorded.

- All equipment was regularly serviced and maintained.
- All medications in the clinic were in date.
- All records were stored securely and complete and up to date.
- Patients had appropriate preoperative risk assessments completed prior to surgery.
- The clinic used the World Health Organisation's 'Five Steps to Safer Surgery' checklist appropriately.
- Arrangements were in place for the provision of a laser protection advisor and laser protection supervisor.
- An emergency generator was in place and checked regularly.
- Policies were easily accessible and contained relevant information for staff.
- Patients had their needs assessed in line with national guidance.
- Patient outcomes were monitored through the surgeon's performance. These showed positive outcomes for patients.
- All staff had evidence of their professional registration, disclosure and barring service checks and yearly appraisals.
- The surgeon held a Royal College of Ophthalmology Certificate in Laser Refractive Surgery.
- Staff from any clinic could access patient records. This meant that if patients attended for follow up appointments at another clinic, they still had access to the relevant medical records.
- Staff were encouraging and supportive to patients.
- Patients' privacy and dignity was maintained.
- 94% of patients would recommend the service to their friends and family.
- Patients were given accurate information regarding the risks and benefits of the procedure and any associated costs.
- Relatives were encouraged to join patients in the recovery room.
- Patients were given the choice of other local clinics to go to for their preoperative and follow up appointments.

Summary of findings

- From review of the patient records, all patients observed the seven day cooling off period. This is to ensure that patients have sufficient time to think about the procedure and confirm that they want to go ahead.
- All areas of the clinic were wheelchair accessible.
- All complaints were dealt with in a timely manner.
- The clinic had strong leadership in place, with a longstanding manager in post.
- All patients were provided with a copy of the terms and conditions before undergoing surgery.
- A local strategy was in place to improve areas of development within the clinic.
- A corporate governance structure was in place.

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

- The medication keys were not kept securely when the clinic was closed.
- Bariatric equipment was not available for patients over a certain weight. However, these patients were not listed as inadmissible in the clinical suitability guidance. As such, there was a risk that these patients could be admitted, without appropriate equipment.

- Consent consultations occurred over the telephone prior to surgery. However, the consent was then reconfirmed on the day of surgery in person.
- The consent policy was not in line with national guidance.
- Due to limited opening days, patients often had to attend follow up appointments at different clinics.
- There were no formal translation services in place.
- There was no hearing loop in place.
- There was no local vision for the service, however, there was a corporate vision.
- The risk register was reviewed yearly as a minimum, or on addition of a new risk or in the event of an incident where control measures identified in an existing risk assessment have failed.

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

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating

Summary of each main service

0We 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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Location name here

Services we looked at

Refractive eye surgery;

Summary of this inspection

Background to Optical Express - Northampton Clinic

Optical Express – Northampton Clinic is operated by Optical Express. The service opened in 2013. It is a private clinic in Northampton, Northamptonshire. The clinic primarily serves the communities of Northamptonshire. It also accepts patient referrals from outside this area.

The service provides refractive eye surgery to patients over the age of 18. The clinic provides surgery approximately one day per month, depending on activity levels.

The service has had a registered manager in post since 2016.

This was the first inspection of the clinic.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and a specialist advisor with expertise in refractive eye surgery. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- An incident reporting process was in place and staff were aware of it.
- There had been no infections from September 2016 to August 2017.
- All staff had received mandatory training and basic life support training.
- All staff were trained to level 2 safeguarding adults and level 3 safeguarding children.
- All areas of the clinic were visibly clean and cleaning mechanisms were in place.
- The humidity and temperature of the laser room was checked regularly and recorded.
- All equipment was regularly serviced and maintained.
- All medications in the clinic were in date.
- All records were stored securely and complete and up to date.
- Patients had appropriate preoperative risk assessments completed prior to surgery.
- The clinic used the World Health Organisation's 'Five Steps to Safer Surgery' checklist appropriately.
- Arrangements were in place for the provision of a laser protection advisor and laser protection supervisor.
- An emergency generator was in place and checked regularly.

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

- The medication keys were not kept securely when the clinic was closed.
- Bariatric equipment was not available for patients over a certain weight. However, these patients were not listed as excluded in the clinical suitability guidance. As such, there was a risk that these patients could be admitted, without appropriate equipment.

Are services effective?

We found the following areas of good practice:

Summary of this inspection

- Policies were easily accessible and contained relevant information for staff.
- Patients had their needs assessed in line with national guidance.
- Patient outcomes were monitored through the surgeon's performance. These showed positive outcomes for patients.
- All staff had evidence of their professional registration, disclosure and barring service checks and yearly appraisals.
- The surgeon held a Royal College of Ophthalmology Certificate in Laser Refractive Surgery.
- Staff from any clinic could access patient records. This meant that if patients attended for follow up appointments at another clinic, they still had access to the relevant records.

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

- The consent policy was not in line with national standards.
- Consent consultations occurred over the telephone prior to surgery. However, the consent was then reconfirmed on the day of surgery in person.

Are services caring?

We found the following areas of good practice:

- Staff were encouraging and supportive to patients.
- Patients' privacy and dignity was maintained.
- 94% of patients would recommend the service to their friends and family.
- Patients were given accurate information regarding the risks and benefits of the procedure and any associated costs.
- Relatives were encouraged to join patients in the recovery room.

Are services responsive?

Are services responsive?

We found the following areas of good practice:

- As the surgery was elective, all lists were planned in advance.
- Patients were given the choice of other local clinics to go to for their preoperative and follow up appointments.
- From review of the patient records, all patients observed the cooling off period.
- All areas of the clinic were wheelchair accessible.
- All complaints were dealt with in a timely manner.

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

Summary of this inspection

- Due to limited opening days, patients often had to attend follow up appointments at other clinic locations which could have impacted on their continuity of care.
- There were no formal translation services in place.
- There was no hearing loop in place.

Are services well-led?

We found the following areas of good practice:

- The clinic had strong leadership in place, with a longstanding manager in post.
- All patients were provided with a copy of the terms and conditions before undergoing surgery.
- A local strategy was in place to improve areas of development within the clinic.
- A corporate governance structure was in place.

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

- There was no local vision for the service; however, there was a corporate vision.
- The risk register was reviewed yearly as a minimum, or on addition of a new risk or in the event of an incident where control measures identified in an existing risk assessment have failed.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Refractive eye surgery	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	N/A	N/A	N/A	N/A

Notes

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

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

Incidents and safety monitoring

- Staff understood their responsibilities to raise concerns and incidents. Staff we spoke with were able to explain how to report incidents and the types of incidents that needed to be reported. These included laser calibration issues or laser breakdowns.
- An incident and near miss events policy was in place. This outlined the different types of incidents that needed to be reported. However, it did not provide a timescale for when incidents should be investigated within the clinic. The surgery manager completed investigations into incidents under the supervision of the corporate clinical services manager.
- The service had no incidents in 2017, up to and including the date of the inspection; 22 November 2017. One incident was reported in 2016, this involved the accidental overcharging of a patient, for which they were then refunded. Events such as cancelled procedures were not classified as incidents, but were recorded separately.
- The service had reported no never events from September 2016 to August 2017. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. Each never event type has the potential to cause serious patient harm or death.
- Staff had an awareness of the duty of candour and had received training in this. Regulation 20 of the Health and

Social Care Act 2008 (Regulated Activities) Regulations is the regulation that introduced the statutory duty of candour. For independent providers it came into effect in April 2015. As there had been no clinical incidents, the duty of candour had not been invoked.

- We were told that if an incident occurred, any resulting lessons would be shared within the team, through a process called an internal staff directive. The requirement for managers to share learning from incidents was reflected in the incident and near misses policy. All staff had to read and sign the directives and this was audited to ensure compliance. However, as there had been no incidents at the clinic in 2017, we were unable to see this in practice.
- Complication rates were monitored for all surgery. In the reporting period of September 2016 to August 2017 there had been 20 complications following refractive eye surgery. This equated to less than 5% of all surgery. These included two abrasions (scratches), three flap microstriae (wrinkles in the epithelium), one flap macrostriae (folds of the eye flap), seven incidents of haze (clouding), two sterile infiltrates (inflammation) and five cases of dry eyes. These were detected when patients attended for their postoperative consultations. The surgeon's complication rates were assessed during their annual appraisal, to ensure any learning was identified.
- Infection rates for all laser eye surgery were monitored and the service had no reported infections in the reporting period of September 2016 to August 2017.
- The registered manager was signed up to receive patient safety alerts from the Medicines and Healthcare Products Regulatory Agency (MHRA). If there were any new alerts that were relevant to the service they were shared with staff through the internal staff directives mentioned above.

Mandatory training

Refractive eye surgery

- Staff received effective mandatory training in safety systems, processes and practices. We saw all staff received training in modules including fire safety, manual handling, conflict resolution, information governance and consent, among others.
- We reviewed two staff files and saw that all their training was complete and up to date.
- All staff who worked within the laser room also received core of knowledge laser training, every three years.
- All staff within the clinic received training in basic life support (BLS). We saw evidence of this in staff files.

Safeguarding

- All staff were trained in level 2 safeguarding adults and level 3 safeguarding children. The registered manager was the safeguarding lead for the service. The staff we spoke with were able to provide examples of concerns that they would raise with the safeguarding team.
- A safeguarding policy was in place. This outlined the various types of abuse and the actions to take in the event that staff had safeguarding concerns about a patient or visitor. However, as this was a corporate policy it did not contain the details of the local safeguarding boards within the local area. Staff told us that if they had any concerns they would raise this with the registered manager.

Cleanliness, infection control and hygiene

- Standards of cleanliness and hygiene were well maintained. At the time of our inspection all cleaning was completed by staff, but there were plans in place to contract an external company in the future.
- Reliable systems were in place to prevent and protect people from infections. The premises were cleaned at the start and end of every laser day. A further monthly deep clean occurred if the clinic opened that month. We saw a cleaning checklist, which confirmed that this cleaning was completed.
- All areas of the clinic were visibly clean and tidy.
- Cleaning was conducted in compliance with the Royal College of Ophthalmology guidance. No alcohol based products were used, as these can interfere with the lasers, and instead staff used disinfectant wipes and hot water.
- All equipment and scrubs (theatre clothing) were single use. This meant they were disposed of after use and did not need to be cleaned or decontaminated.

- Legionella testing occurred once per year, to ensure that the water supply did not contain any water borne bacteria which could be harmful to patients. At the start of every laser day, all the taps were run for three minutes and the water temperature tested. We saw this was documented within the clinic's calibration log.
- Patients were not routinely screened for MRSA. However, patients were asked to declare on their health questionnaire whether they were a carrier or if they were at risk of being a carrier of MRSA. If they were at risk of MRSA the clinic prescribed antibiotic eye drops prior to surgery. If patients confirmed that they were a known carrier of MRSA, patients were sent to their GP to obtain treatment for this, prior to surgery.
- There had been no recorded incidences of infection within the service. This included MRSA, Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (c.difficile) or E-Coli.
- We saw that the temperature and humidity of the laser room were checked at the start of every laser day, and in between every patient. This was recorded in both the calibration log and within the patient's medical records. In all records we reviewed, the temperature and humidity were within the acceptable limits.

Environment and equipment

- We reviewed all equipment within the clinic, including the lasers and diagnostic testing machines and saw all these were maintained appropriately and serviced according to the manufacturers' requirements. All equipment we reviewed had been electrically safety tested.
- An anaphylaxis kit was available, in case patients suffered an anaphylactic reaction following their procedure. We saw that this was checked at the start of every laser day by either the nurse or scrub assistant.
- The service's chairs and trolley were not suitable for patients over 134kg. Patients with a high weight were not specifically excluded in the patient suitability guidance, and therefore, there was a risk that a patient over 21 stone could be admitted to the service without the appropriate equipment in place.
- Arrangements for managing waste were in place. A service level agreement was in place with an external contractor who collected clinical and non-clinical waste, including sharps.

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- A laser protection policy was in place. This outlined the roles of the laser protection advisor (LPA) and laser protection supervisor (LPS). It stipulated that all laser technicians, surgeons and surgery support staff attend core of knowledge training every three years.
- Laser risk assessments were conducted by the LPA every three years. If any equipment was changed in between the three years, then further risk assessments were completed.
- Staff ensured that the use of lasers was in line with MHRA and manufacturers' guidance. Staff locked the laser room from the inside during procedures and a laser warning sign was illuminated when the laser was in use.
- The local rules were reviewed every three years by the LPA. We saw that all staff had read and signed the local rules and had attended the core of knowledge training.
- Eye drops for patients to use at home following surgery were dispensed by the laser technician, under the supervision of the surgeon. We saw that the laser technician who was based at the service had competencies in dispensing eye drops.
- The expiry dates of the medicines were checked during the routine monthly stock take. We reviewed the October 2017 stock take and saw that all relevant expiry dates were noted.
- Fridge temperatures were monitored at the start of every laser day and recorded in the calibration log. We saw these were always within acceptable limits. There was no evidence fridge temperatures were monitored when the clinic was closed. Staff were not able to tell if the fridge temperatures had gone out of acceptable range on the days the clinic was closed.
- Allergies were clearly documented within patients' medical records. We were told that if a patient had a latex allergy they would be operated first on the list, to avoid any risk of cross contamination.
- Antibiotic eye drops were used during procedures and as part of the postoperative aftercare.
- The service's consent policy included details on the use of Mitomycin C. Mitomycin C eye drops were used 'off licence' during laser procedures to reduce post-operative haze. The policy stated that the surgeon must explain to patients why they wanted to use the medication and this was included within the consent form.
- We reviewed four consent forms and saw that the use of Mitomycin was discussed with patients. The patients then initialled next to this section to confirm they had read and understood it.
- The Mitomycin was delivered pre-prepared, so staff did not have to dilute the solution.

Medicines

- A medicines management policy was in place. This stated that all medicines should be stored in a lockable cupboard or refrigerator, depending on whether the medicines required temperature control. The policy also outlined the process to follow if fridge temperatures were beyond acceptable parameters.
- We found that the medication keys and laser keys were not stored securely when the clinic was not open. During opening days, the medication keys were held by the registered nurse or operating department practitioner and the laser keys were held by the LPS. At the end of the day, these keys were locked inside a key cupboard. However, the key to the key cupboard was then hidden within a piece of equipment within the clinic, therefore we were not reassured that unauthorised staff could access the keys and the medication cupboards.
- A small range of eye drops were kept within the clinic. These were supplied by a pharmacist, who answered any queries staff had regarding the drops. We reviewed all the medicines stored within the service and found them all to be in date. Drops that required refrigeration were stored inside a temperature controlled fridge.
- There were no controlled drugs used within the service.
- Local anaesthetic eye drops were administered prior to surgery by the surgeon.

Records

- Medical records were kept electronically and surgical records were kept in a paper format. The paper records were archived off site following surgery. Staff could access the paper records if required. On the day of surgery, all the information from the paper surgical records was recorded on the electronic file, with the exception of the instrument traceability records and the signed patient consent form.
- The service's records policy outlined the requirements of the Data Protection Act 1998 and set out the

Refractive eye surgery

processes for creation, accessing, storage and destruction of patient records. It stated that all records would be retained for eight years, following which they would be securely destroyed.

- We reviewed four patients' records, including consent forms which were on site during our inspection. We saw these were complete and up to date. They included details of the traceability of instruments and all appropriate risk assessments and health questionnaires.
- Following surgery, patients were given a letter detailing the procedure they had undergone and their postoperative medications for them to give to their GP.

Assessing and responding to patient risk

- All patients completed a health questionnaire, which included information about their past medical history. This was in line with National Institute for Health and Care Excellence (NICE) guidance NG45 – Routine preoperative tests for elective surgery. This included consideration of patients' existing medications and checking pregnancy status. The questionnaire also included a request for the patient's GP details.
- Optometrists assessed patients' health in relation to their refractive surgery. This included an assessment of the patient's visual condition, which led to discussions regarding which procedure would be most beneficial for them.
- The clinic used an adapted version of the World Health Organisation's 'Five Steps to Safer Surgery' checklist. This was audited during the quarterly records audit. However, this was not an observational audit. We reviewed four patient records and saw that these were completed. Most patients had both eyes operated on at the same time. However, if only one eye was being operated on, this was marked appropriately, to reduce the risk of wrong site operation.
- Patients were provided with an aftercare advice leaflet prior to leaving the clinic. This included a telephone number for them to call out of hours if they had any concerns. The phone line was routed to the on-call optometrist, who decided whether they needed to call the surgeon out of hours or whether a follow up appointment was needed. This information was also displayed on the service's website.
- Patients were seen postoperatively by optometrists. An emergency support system was in place for urgent cases, where patients needed to be seen by the surgeon

or referred to other services, for example in cases of infection. Optometrists were able to contact the surgeon by telephone for advice. If required, follow up appointments could also be arranged with the surgeon.

- There had been no unplanned transfers of patients from September 2016 to August 2017. If a patient became seriously unwell following surgery, staff would dial 999 to request an ambulance transfer to the nearest NHS hospital.
- The 'assessing patients' needs, promoting and supporting patient choice and independence' policy outlined the reasons some patients were deemed unsuitable for the procedure. This included general health or ocular (eye) health conditions, patients who were unable to consent to the procedure and those whose requests exceeded reasonable expectations. Clinical suitability guidance was also in place and outlined various conditions that excluded patients from admission to the service. This included for example shingles, glaucoma, pacemakers and those with internal defibrillators.

Nursing and medical staffing

- On procedure days the clinic was staffed with one surgeon, one scrub assistant (who could be a nurse or an operating department practitioner), one laser technician, one coordinator and one staff member whose role was to discharge the patient effectively.
- Due to limited activity numbers at the clinic, staff were not based at the clinic, but covered Optical Express clinics across London and the South East England.
- There were no vacancies at the time of our inspection. The service had not used any bank or agency staff from September 2016 to August 2017. If staff called in sick on laser days, the manager attempted to source a colleague from a nearby clinic to cover. If there were no staff available, the list would be cancelled.
- All staff were employed on contracts with Optical Express. Staff did not work under practising privileges.
- An external LPA was used to provide expert advice and guidance. The LPA conducted site visits and risk assessments every three years and either reissued the local rules or validated the existing local rules if there had been no changes. The LPA also visited when any equipment was changed or if there had been any safety incidents, which there had not been.
- The local rules contained the contact information for the LPA, if they needed to be contacted.

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- A certified laser technician was always present during surgery. They undertook the role of the LPS. They ensured that the lasers were calibrated, safety checks were completed and that any laser related incidents were reported appropriately.
- The surgeon who performed laser eye surgery at the clinic held a Certificate in Laser Refractive Surgery. We saw evidence of this in their employment file.

Major incident awareness and training

- The clinic had an Equipment and Mains Service Failure policy which included details of actions to take in the event of an emergency.
- All staff had received fire training and fire drills were undertaken monthly by the external building manager. Due to limited opening hours, the clinic was not always operational or staffed during the fire drills.
- An emergency generator was in place. The manufacturer of the generator stated that the generator would work for one hour. However, in the event of a power outage, the manager told us that staff would only continue operating for up to 15 minutes to finish the eye they were operating on. This was to reduce the likelihood of staff attempting to finish a list if there was a blackout. The generators were tested annually to ensure they were still functional and were checked at the start of every laser day.

Are refractive eye surgery services effective?

Start here...

Evidence-based care and treatment

- Care and treatment was delivered in line with current legislation and nationally recognised evidence-based guidance.
- Optical Express' medical director was a panel member who assisted in developing the Royal College of Ophthalmology guidance in April 2017. They ensured all guidance and policies were in adherence to national guidelines.
- All policies were available in paper format within the clinic. The policies were evidence based and easy to read, and would assist staff who were looking for guidance. The policies reflected best practice and national guidance.

- Patients had their needs assessed in line with best practice, including the National Institute for Health and Care Excellence guidance (NICE) NG45 – Routine preoperative tests for elective surgery. All patients underwent screening and assessment prior to being deemed admissible to the service for laser eye surgery. Patients' medical histories were discussed and appropriate tests were undertaken to help determine which procedure was appropriate. A contraindications list was in use, which outlined various conditions which excluded patients from treatment at the clinic.
- There had been no postoperative infections or episodes of sepsis from September 2016 to August 2017.
- An equality and diversity policy was in place. This outlined the protected characteristics and the difference between direct and indirect discrimination. Staff were aware of the importance of avoiding discrimination and had received training this area. Compliance with this was monitored through the content of complaints.
- Technology and equipment was used to enhance care. Optical Express used anterior segment analysis tomography machines for diagnostic testing. They also used specialist lasers, which were programmable to provide consistent and high quality incisions in the eye.

Pain relief

- Pain levels were managed well within the service. Eye drops were used prior to surgery, to ensure the patient did not feel any pain. Patients confirmed that their pain was well managed.
- Following surgery patients were given eye drops to take home. They were also advised on the types of over-the-counter pain relief medications they could take.

Patient outcomes

- Information about the outcomes of patients' care and treatment was collected and monitored. Patient outcomes were monitored via each surgeon, as opposed to each clinic. The surgeons were then benchmarked against each other. Although there was not a surgeon who was based at the clinic, there was one surgeon who performed all of the procedures at this clinic.
- We reviewed the one surgeon's outcomes that worked at this clinic and saw that their laser vision correction

Refractive eye surgery

score for efficacy was 58 and 50 for safety. The Optical Express expected score was 50 and so the surgeon met this for safety and was better than the expected score for efficacy.

- The surgeon's enhancement (re-treatment) rate was similar to that of the Optical Express average of less than 2%. From September 2016 to August 2017, the service completed 30 re-treatments or enhancements. However, some of these patients had their original surgery some time beforehand and therefore, not all 30 re-treatments were completed within 12 months of the original surgery. The reasons patients had re-treatments were due to regression, which can happen some years after the original surgery, issues regarding the quality of vision and that their desired outcome was not achieved.
- There had been no unplanned returns to theatre immediately following procedures from September 2016 to August 2017.
- The surgeon's complication rate was slightly worse than the Optical Express average; at 0.62% compared to 0.52%. We did not see any evidence that any action was taken as a result of this. However, this information contributed towards the surgeon's yearly appraisal, to ensure that patient outcomes were being monitored for each surgeon.

Competent staff

- Staff's clinical qualifications were recorded in their employment files, where appropriate. Clinical staff could evidence their professional registration, professional indemnity insurance and professional revalidation.
- All staff files we looked at had evidence that they had undergone disclosure and barring service (DBS) checks. This included the date of the check and whether the check had identified any past criminal history.
- Staff files contained employment histories, at least two references and evidence of yearly appraisals.
- Twice yearly personnel audits were completed by the registered manager. This checked that staff had valid professional registration, were not under investigation by their professional regulator and had a valid DBS check.
- Staff attended the core of knowledge training every three years, led by the laser protection advisor.

- Optical Express' corporate responsible officer oversaw the surgeon's continuing professional development. This ensured the surgeon undertook at least 50 hours of professional development a year. This also formed part of their appraisal.
- The surgeon who performed surgery at the clinic held a Royal College of Ophthalmology Certificate in Laser Refractive Surgery. This meant that they were accredited by the Royal College of Ophthalmology as being competent to perform the procedures.
- The laser protection supervisor (LPS) role was carried out by a certified laser technician. They were certified by the laser manufacturers following a week long course in the use of lasers and equipment. All LPS completed a competency assessment prior to being certified. This was reviewed every three years to ensure ongoing competency.
- Staff were encouraged to develop and learn new skills. Laser technicians were given the opportunity to train in intraocular lens exchanges, which were carried out at other Optical Express locations.
- Staff had one-to-one meetings with their line manager. Their line manager was the manager at the clinic where they spent most of their time. Due to the limited activity numbers at the clinic in Northampton, no staff were assigned the clinic as their base clinic, and as such, the registered manager did not hold one-to-one meetings with staff. Staff we spoke with confirmed these meetings occurred and that they were helpful and productive. Staff also confirmed that they received annual appraisals with their line manager.

Multidisciplinary working

- All necessary staff were involved in assessing, planning and delivering people's care and treatment. Treatment was surgeon-led and involved discussions with support staff where required.
- Staff worked together to assess and plan ongoing care and treatment in a timely way when people were due to move between teams or services. Due to the shared electronic records system, staff were able to review patient records from any Optical Express clinic location. This meant that patients could attend for preoperative and follow up appointments at other locations.
- Non-medical staff performed extended roles, such as laser assistants. We saw they had completed training in the core of knowledge of lasers to perform such roles.

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- Due to staff frequently moving between different clinics, team meetings were not held at this clinic. However, the registered manager told us that regional team meetings were held and information was shared with all staff, through email communication.

Access to information

- The electronic medical records were accessible at any Optical Express clinic. This meant staff could review records of all patients who had their surgery elsewhere. The electronic records system was password protected and staff members could access and edit records, depending on their staff grade.
- Extra copies of discharge letters were provided to patients, so that these could be passed onto their GP.
- GPs did not have direct access to the surgeon. However, if necessary, they could call the clinic, speak to an optometrist, and then be referred onto a surgeon if needed.
- The on-call optometrist had a direct contact line to the surgeon. If patients raised concerns about their surgery or health condition out of hours, the on-call optometrist contacted the surgeon, if necessary for advice. The on-call optometrist was available out of hours.

Consent and Mental Capacity Act

- Staff understood the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005. All staff had received training in consent, and evidence of this was in the employment files we reviewed. Staff had also received mental capacity training, as part of their duty of care training. We were told that the surgeon would undertake a mental capacity assessment, if there were concerns about a patient's ability to consent to the procedure. Patients who were deemed to be lacking in mental capacity were not admitted to the service.
- A consent policy was in place. This stated that it was the surgeon's responsibility to ensure patients understood the nature and purpose of their procedure and to ensure the consent form was signed before starting.
- The consent policy was not in line with the Professional Standards for Refractive Surgery (Royal College of Ophthalmologists, April 2017) (professional standards). The service's consent policy stated that they would not undertake same day treatments and that there must be at least three days between their consent appointment and surgery. This was not in line with the Professional

Standards for Refractive Surgery (Royal College of Ophthalmologists, April 2017) (professional standards) guidance which states that there needs to be a seven day cooling off period as a minimum. This is to ensure patients have an adequate period of reflection between them agreeing to undergo surgery and the surgery being performed. However, all the patient records we reviewed had at least seven days between initial appointment and their surgery.

- Consent was not always obtained in line with the service's policy. All patients were required to attend a consent appointment with their surgeon at least three days before surgery. During this appointment the surgeon explained the aim of the procedure, any associated risks and benefits and answer any of the patient's questions. Following this, patients were required to electronically sign their medical record. However, this consent appointment often occurred over the telephone, as opposed to in person. From the four patient records we reviewed, all four had been telephone consent appointments. This was not in line with the service's policy, which stated that at the consent appointments, patients should be examined by the surgeon.
- Consent was confirmed again on the day of surgery by the surgeon, with both the surgeon and patient signing again.
- The various risks and benefits associated with the procedure were outlined in the consent forms. We reviewed four consent forms and found all of these to be completed and signed appropriately.
- Patients were given information about the costs of the procedure at the first consultation. These were outlined by the optometrist. If the prices for the procedure had increased between the first consultation and the surgery occurring, the clinic honoured the original quotation. However, one patient told us that their original quotation was £1000 less than the quotation given by the optometrist. They told us the reason for the increase was not explained well to them; however, they still went ahead with the procedure at the higher price. Another patient told us that the cost of their surgery went down on the day of the procedure. This was because the type of procedure was changed when the surgeon re-reviewed the patient's eye, and decided that the cheaper option was safer for them.

Refractive eye surgery

Are refractive eye surgery services caring?

Compassionate care

- Staff understood and respected patient's personal, cultural, social and religious needs. Any specific needs were identified in the health questionnaire, at the beginning of the process, so that these could be accommodated during the procedure. Staff were respectful and considerate to patients, and ensured they had time to ask questions if needed.
- Patients we spoke with told us that staff were caring and helpful.
- Patient told us that staff was encouraging and supportive to patients. Patient feedback we saw was positive, with patients stating that they received compassionate care. This was in line with National Health and Care Excellence (NICE) guidance QS15 Statement 1 which relates to communication with staff, introductions and understanding of the healthcare team and preferences for sharing information.
- Patients' privacy and dignity was maintained. Consultations occurred in private rooms and doors were closed to ensure patients' privacy.
- Staff understood the importance of maintaining confidentiality. All staff had received information governance training, which covered the principles of confidentiality.
- We reviewed the surgeon's patient outcomes data, which included data on the warmth and friendliness of the surgeon. The surgeon who performed the procedures at the clinic scored 98% overall satisfaction rate, with regards to their warmth and friendliness to patients. It also showed that 94% of patients would recommend the surgeon to their friends and family.

Understanding and involvement of patients and those close to them

- Staff communicated with patients so they understood their care, treatment and condition. Most patients told us that information was given in easy to understand formats. The consent form and terms and conditions were thorough and clearly explained the procedure to patients. Most patients told us they were provided time

at the end of their consultations to ask any questions. However, one patient felt 'bombarded' with information and told us that they did not feel they were able to ask questions.

- Patients were given appropriate information about what they should expect from their refractive laser eye surgery and realistic expectations about risks and outcomes. This was in line with the Royal College of Ophthalmology guidance and NICE QS15 Statement 5.
- Patients were given transparent and accurate information about all costs involved as per CQC Regulation 19. This was completed at consultation stage, so that all patients knew how much it would cost before they had their procedure. Approximate prices were displayed on the service's website. Patients were given a written statement, that included the terms and conditions of the service, as well as details of fees, in advance of having their procedure. Whilst this quotation could change from the initial quotation to the optometrist's quotation, once a written statement was provided this cost was not changed.
- Advertising information was honest and responsible. Although they stated that patients would be given 20:20 vision or their money back, it was made clear in the terms and conditions that they might require enhancement treatment in order to gain 20:20 vision. This was in compliance with the Committee on Advertising Practice.
- Patients had the opportunity to discuss their health beliefs, concerns and preferences during their consultation stage. This allowed them to inform their individualised care, in accordance with NICE guidance QS15 Statement 4.

Emotional support

- Staff understood the impact that a person's care and treatment could have on their wellbeing. Staff were empathetic to patients who were anxious about their surgery and reassured them.
- If patients were anxious, a member of staff would go into theatre with them and hold their hand during the procedure.
- Patients' relatives were invited into the recovery room, so that the patient had their support during the recovery period. This also meant that their relative could be well informed of any postoperative care requirements.

Refractive eye surgery

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

Service planning and delivery to meet the needs of local people

- Service planning and delivery was organised to meet the needs of patients. All patients were pre-planned elective patients, undergoing laser vision correction. This meant that procedure lists were well planned and sufficient staffing numbers were employed to treat all patients.
- The clinic did not offer procedures to patients under 18, those with certain medical conditions, or women who were pregnant. This was specified in the clinical suitability guidance list. This was due to the potential risks of treating these cohorts of patients. These risk factors were checked during the health questionnaire, which were completed with the clinical staff at the initial appointment.
- Optical Express' business servicing team forecasted the number of upcoming procedures and planned the logistics, for example, ensuring adequate staff numbers. The team also allocated staff members to prepare for the laser days. Their duties included ensuring all relevant patient records were ready and appropriate medications ordered.
- The service ensured patients had some flexibility and choice. As the clinic was not open regularly, patients were often unable to have their preoperative appointment or follow up appointments at the clinic in Northampton. However, they were able to choose from any other location, which had regular opening days. This meant the patients were able to choose another clinic location and date that suited them best. However, this also meant that patients saw a variety of different staff which resulted in limited continuity of care.
- The facilities and premises were appropriate for the services that were being delivered.

Access and flow

- The clinic was open approximately one day per month for surgery. This day was not a set day each month, and varied depending on patient demand and staff availability. Surgery lists occurred during normal working hours, and evening lists were not held.

- As surgery lists occurred most months, patients generally had minimal waits for their procedure. If they required treatment before a planned surgery day, they had the option of having their surgery at another Optical Express clinic. We were told that they had no waiting lists within the clinic.
- The most common cause of delayed or cancelled procedures was due to laser breakdowns. We were told that lists were sometimes cancelled due to low numbers of patients, but that these patients would usually be offered surgery on the same day at another clinic. We requested data on the number of delayed procedures at the clinic, but were told this data was not collected. From September 2016 to August 2017 13 procedures were cancelled on the day of surgery. These were due to a variety of reasons, including patients not turning up and eye inflammations. However, other procedures were cancelled from the clinic but rescheduled for the same day, at another clinic location. These were not recorded as cancellations, as the procedures did go ahead, however, in a different location to originally planned.
- One patient told us that when they arrived they were not welcomed or booked in by a staff member. The patient waited in the waiting area for 30 minutes before a staff member approached them and reviewed their paperwork. The patient felt that staff did not know they had arrived prior to this.
- Following surgery, patients were automatically given a 24 hour follow up appointment. This was with an optometrist, at any local Optical Express clinic. It was often not at the Northampton clinic due to the infrequent opening days. Some patients we spoke with were happy about this, as they were able to attend other clinics closer to their home. However, one patient told us they had to drive to three different towns for their initial appointment, their surgery and the 24 hour check-up and 72 hour check-up due to limited opening times. As a result, the patient felt they had accrued a lot of mileage. Another patient told us they were unhappy with having to go outside of Northampton for check-ups and that they were not aware of this prior to booking. However, none of the written complaints we saw were in relation to this.
- After the 24 hour appointment, patients were emailed one reminder to make subsequent follow up appointments. However, if the patient did not book these, the clinic did not pursue this.

Refractive eye surgery

- A central appointments system was used, that was operated by Optical Express' head office. The manager of the clinic could then see what patients were booked in on what days.
- From the patient records we reviewed, all patients had the appropriate cooling off periods as set out in the Professional Standards for Refractive surgery (April 2017) guidance. However, the service's consent policy did not reflect this guidance. Therefore, we could not be assured all patients received the appropriate cooling off period.

Meeting people's individual needs

- Services were planned and delivered to take account of the needs of most people. A lift was in operation and all areas were wheelchair accessible. A disabled toilet was also available for patients.
- A policy was in place which outlined that patients who required translation or interpreting services needed to bring their own interpreter with them. It did not state if this person could be a relative, which is not best practice. Any costs associated with translation were required to be met by the patient. It also stated that if a staff member spoke the patient's language then they could also be used.
- The clinic did not have a hearing loop installed for patients who were hard of hearing. We were told that they would bring a translator with them, if required.
- The service did not treat patients with complex health needs or those living with dementia or a learning disability. Additional needs were identified at the preoperative stage. If staff had queries over a patient's health condition, the patient's GP's opinion was sought to confirm a diagnosis.
- Patient information leaflets were available. These contained information about the procedure and common side effects. However, these were all in English and were not available in other languages.
- The service only offered laser vision correction procedures. Therefore, there was no need for large print leaflets.
- A waiting room, with a water dispenser and magazines, was available for patients.

Learning from complaints and concerns

- A complaints policy was in place. We saw a copy of this policy, which was in date. The policy stated that all complaints would be acknowledged within two working

- days and addressed within 20 working days. The complaints policy also had details of the types of concerns that they should report to CQC. Staff were aware of the policy and understood the guidance.
- Patients we spoke with were unaware of the service's complaints procedure and did not recall being given any information about how to make a complaint.
- The service received three written compliments and 10 written complaints from September 2016 to August 2017. All of these were managed under the service's formal complaints procedure and none of them were upheld.
- We reviewed eight complaint files on inspection and saw these related to patients being unhappy with their visual outcomes (four complaints) and patients being unhappy with the terms and conditions (four complaints). The concerns relating to terms and conditions were mainly regarding patients being unhappy that they had to pay for aftercare appointments after one year, or that they had to pay for enhancement surgery. However, both of these were made clear in the terms and conditions which the patients had signed prior to surgery. All of the complaints were responded to within 20 days of receipt.
- All complaints were investigated by Optical Express' corporate complaints team. The clinic's registered manager was only asked to assist in the investigation if the complaint related to the clinic at a local level, for example, if the complaint had been regarding a particular staff member.
- All complaint files we reviewed explained the outcome appropriately to the patient. All patients were offered subsequent procedures or aftercare if required, although the cost of this was met by the patient.

Are refractive eye surgery services well-led?

Leadership and culture of service

- The clinic was led by the registered manager who was the surgical services manager for 28 Optical Express clinics. There was a clear leadership structure from the clinic up to the corporate level. The registered manager was an ophthalmology nurse by background and had worked for Optical Express since 2003.

Refractive eye surgery

- The registered manager was not always present during surgery days. If they were not on site, the laser technician would undertake the role of laser protection supervisor, and manage all laser risks.
- Staff told us that the registered manager was always contactable by telephone or email and that they were receptive and responsive to any communication. We were told that some staff did not see the registered manager that often, approximately once every six months, depending on what other clinics they also worked at.
- Surgeons were managed by the medical director who reported to the chief executive.
- The registered manager told us that the main challenge within the clinic was scheduling deliveries for when someone was on site, due to the limited opening days during the month. They said that as the clinic was single speciality, there were no specific clinical challenges as staff were familiar with the process and knew what would happen.
- Leaders ensured that employees who were involved in the performance of invasive procedures were given adequate time and support to be educated in good safety practice, to train together as teams and to understand the human factors that underpinned the delivery of safe patient care. This was all covered during their mandatory training and appraisals.
- Staff and teams worked collaboratively together. As the staff all worked together across a number of clinics, they knew each well and had formed positive working practices.
- A system was in place whereby patients were provided with a statement of terms and conditions prior to surgery. This included the amount and method of payment of fees.

Vision and strategy

- There was no specific vision for the clinic in Northampton, but the registered manager told us about the vision for Optical Express corporately. This included expanding the work on intraocular lens (IOL) replacements, as this was becoming the main procedure for the company. The clinic in Northampton did not offer IOL replacement at the time of the inspection due to the limited number of procedures conducted there. The vision for the company was set at the corporate level.

- The registered manager had implemented a local strategy for each financial quarter for the Northampton clinic. This involved ensuring all staff were up to date with their training, ensuring all relevant staff were completing the Care Certificate (a set of standards that health and social care workers stick to in their daily working life) and introducing hand hygiene audits.
- Optical Express had set up the first International Medical Advisory Board (IMAB). This was made up of experienced refractive eye experts, who did not have links to Optical Express. They reviewed all the policies, audits and outcomes against best practice, to ensure that they met the required standard.

Governance, risk management and quality measurement

- Governance frameworks were in place. There were three tiers of governance: a clinical governance committee, which fed into the Medical Advisory Board (MAB) and the International Medical Advisory Board (IMAB). The MAB was led by the medical director and clinical services director. If any areas of concern were identified at the clinical governance committee or MAB, which required escalation this would be fed into the IMAB. The IMAB was made up of independent experts.
- Policies were in place which provided staff with clear guidance and processes to follow. These included topics such as surgical site safety, patient verification, medicines management and incidents and near miss events reporting.
- We reviewed two sets of minutes from the MAB. Topics discussed included the consent process, patient outcomes and patient suitability criteria. These were well documented with clear outcomes to share with wider staff.
- We also reviewed one set of IMAB minutes. This covered the endorsement of the clinical suitability guideline, laser surgery outcomes and the introduction of new professional guidance from the General Medical Council and Royal College of Ophthalmology.
- We reviewed the service's risk register, which had a number of risk assessments underpinning it. The risk register was a corporate document but all the risks on it were relevant to the Northampton clinic. We saw each risk had a named person responsible and a deadline for completion. Examples of risks on the risk register included infections, medicine errors and incorrect data entered into the lasers.

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- The service's risk management policy stated that the risk register should be updated and reviewed on a regular basis, but did not specify how often this should be. The registered manager informed us that the risk register was reviewed annually or when new risks were added.
- The registered manager told us that their main concerns were treating the patients with incorrect data and infection rates. Neither of these had happened in the 12 months preceding our inspection. These were listed on the risk register, with mitigating actions. As a single specialty service, the risks to patients were low and staff were trained and skilled to manage risks at the location.
- The surgeon who operated at the clinic had valid professional indemnity insurance. We saw a copy of this in their employment file. This was also checked by the registered manager during their personnel audits.
- A systematic programme of audits was in place, to monitor the quality of services being provided. These included infection control, records, personnel, hand hygiene and patient satisfaction.

Public and staff engagement

- Patients' views were sought through patient satisfaction surveys. These were completed by patients electronically. Their views were sought at one day

post-surgery, three months and six months post-surgery. The results of these were positive, with 98% of patients stating that they had positive overall satisfaction.

- Staff surveys were not conducted at the time of our inspection. The registered manager told us that there were plans to start a surgical staff survey in the coming months. A rewards scheme was in place to reward staff members or teams for excellent contributions to the company.
- Team meetings within the clinic did not occur. This was because no staff were based at the clinic permanently and the clinic often only opened once a month. However, the regional surgery management team met on a monthly basis and discussed topics including incidents, infection control and complaints. Important findings from this meeting were shared with staff via email.

Innovation improvement and sustainability

- There were no examples of financial pressures compromising patient care.
- Staff were focussed on continually improving the quality of care. Resources were spent in trialling and purchasing new equipment, so that patients got the best outcomes possible.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that medication cupboard keys are stored securely.

Action the provider **SHOULD** take to improve

- The provider should review the incident policy, to ensure that information regarding the deadlines for competing investigations is included.
- The provider should ensure that appropriate arrangements are in place for bariatric patients. Suitable equipment should be provided or patients over a certain weight should be excluded on the clinical suitability guidance.
- The provider should ensure that laser keys are stored securely.

- The provider should draft a mental capacity assessment pro-forma.
- The provider should ensure that all consents for surgery are conducted in person.
- The provider should review the consent policy, to ensure it reflects national guidance on cooling off periods.
- The provider should provide translation and interpreting services.
- The provider should introduce hearing loops within the clinic.
- The provider should obtain information leaflets in languages other than English.
- The provider should develop a local vision for 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
Treatment of disease, disorder or injury	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>Regulation 12 (2) (g) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Safe care and treatment</p> <p>How the regulation was not being met:</p> <p>The medication cupboard keys was not stored securely to prevent unauthorised access to the medication cupboards.</p>

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.