Optical Express, Bristol Clinic

Quality Report

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

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.

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optical Express Bristol Clinic provides laser eye surgery for adults who pay privately for their care and treatment. No NHS funded work is completed at this clinic. Optical Express Bristol Clinic (hereafter known as 'the clinic') is operated by Optical Express (Gyle) Limited (hereafter known as 'Optical Express'). The regulated activities at this location are diagnostic and screening procedures; and treatment of disease, disorder or injury; and surgical procedures.

The clinic is situated on the 9th floor of a multi-occupied office building. The clinic area is shared with an Optical Express optical practice. The service was registered in 2003 and was in two other sites prior to the opening of the clinic in December 2015. The service provides refractive eye laser surgery and intraocular lens surgery for day case adult patients. There are no inpatient facilities. No children are treated at the clinic.

Intraocular lens surgery is carried out using sub-tenon anaesthesia. At this clinic, most patients received intravenous sedation. Refractive eye laser surgery is undertaken using topical anaesthesia. The clinic provides refractive laser eye surgery approximately five days a month and intra-ocular lens surgery approximately eight days a month. On the day of surgery, the patients are treated by a regional surgery team who move between all locations within the South West, dependent on demand at the various locations. The registered manager and two other staff members are based at the Bristol clinic. A separate team of optometrists and patient advisors in the general optometric service see surgery patients for pre-surgery consultations, and aftercare appointments as part of the refractive eye surgery and intraocular lens surgery pathways.

Patients could refer themselves to the clinic for initial consultation. Patients are accepted for surgery if they meet admissions criteria and if the optometrist and surgeon agree that surgery is a viable treatment option.

During the 12 months preceding our inspection, a total of 1187 refractive eye surgery procedures were undertaken and a total of 1313 intraocular lens implant/exchange procedures were undertaken. There were 155 Class 3b laser capsulotomies completed. A Class 3b laser capsulotomy is a non-invasive laser procedure which eliminates the cloudiness that occasionally interferes with a patient's vision after cataract / lens replacement surgery.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 10 May 2018. There was no unannounced inspection.

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

At the time of our inspection, we had a legal duty to regulate refractive eye surgery services, but we did not have a legal duty to rate these services. 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:

- Staff knew how to report incidents and safeguarding concerns. Incidents were investigated thoroughly.
- Staff we spoke with understood their responsibilities under the duty of candour
- The surgery team took steps to reduce risk to patients during surgery. This included use of the World Health organisation safer surgery checklist and the Royal College of Anaesthetists 'Stop before you block' procedures.
- Staff followed protocols for infection prevention and control. We saw that staff washed their hands and cleaned equipment thoroughly. Waste was managed safely.
- Staff followed best practice guidelines when handling medicines including cytotoxic medicines. Medicines were stored securely and medicines stock was managed safely.
- Staff kept comprehensive records about patient care. Records were stored securely.

Summary of findings

- There were systems to ensure that lasers were used safely. The environment was designed and maintained for the use of lasers. Staff were trained to operate lasers. Staff were aware of protocols for safe use of lasers and followed these consistently.
- Patients undergoing laser refractive eye surgery had opportunity for appropriate pre-operative assessment and discussion as set out in the General Medical Council Guidance for doctors who offer cosmetic interventions.
- Staff were supported to maintain up to date clinical skills and competencies. Staff participated in appraisals and competency checks.
- Leaders monitored the treatment outcomes of individual surgeons working at the Bristol clinic and these compared favourably to the averages within the company. Changes to treatment decisions were investigated and learning was shared.
- For intraocular lens surgery, pain was monitored by an anaesthetist who administered sedation as required.
- Staff understood and complied with the Mental Capacity Act. Patient consent was checked at every stage of the patient journey.
- Patients were assessed for their suitability for surgery using current treatment criteria. There were adequate systems for follow up of post-surgery patients.
- Staff used evidence based criteria to assess patient suitability for treatment. There was a clear procedure for obtaining patient consent. There were adequate systems for follow up of post-surgery patients.
- All clinical protocols, directives and patient information were reviewed at the annual medical advisory board meeting.
- Surgeons talked to patients throughout their surgery as recommended in the Royal College of Ophthalmology professional standards for refractive surgery.
- Staff built effective relationships with patients. We observed that staff listened to patients and gave patients time to ask questions. Patients told us they felt comfortable and safe with staff.
- Staff gave patients were appropriate information about what they should expect from refractive eye surgery and realistic expectations about outcomes, in line with guidance from the Royal College of Ophthalmologists.
- The service offered flexibility around appointment times and dates and locations. There was no waiting list for surgery. Surgery was rarely cancelled.
- Treatment rooms and waiting areas were comfortable and spacious and fit for purpose.
- Staff considered the individual needs of patients and these were identified on the patient record.
- Interpreter services were available for patients whose first language was not their first language and for patients who used sign language to communicate.
- Staff told us they felt supported, and valued by their peers and their managers. Staff enjoyed their work. Leaders were well respected and there was a clearly defined leadership structure.
- There were several mechanisms for communication between the senior management team and the staff treating patients.
- Leaders monitored quality and safety through internal audit and investigation of incidents. The surgical services manager had recently recruited a member of staff responsible for monitoring safety in theatres.
- Staff had the information they needed to provide care and treatment. Electronic records could be accessed at any Optical Express clinic.
- Staff told us they felt supported and valued in their work. Leaders were approachable and well respected. Staff felt proud of the service they provided.
- There was a strong mechanism for patient engagement through patient experience survey

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

- Not all staff who assisted the anaesthetists had completed immediate life support training.
- The current practice with regards to marking of the surgical site was not compliant with all relevant guidance including Royal College of Ophthalmologists Theatre Procedures Standards, February 2018. These guidelines state that marking must be performed by the surgeon or a nominated deputy who will be present during the procedure.

Summary of findings

- There was a risk that optometrists were not up to date with safety systems and processes. Optometrists were not required to complete mandatory training in topics such as infection prevention and control, moving and handling, conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety.
- The safety of the Class 3b laser machine could not be assured. The last service date was February 2016.
- Optical Express did not submit data to the Private Healthcare Information Network (PHIN).
- The consent policy did not reflect Royal College of Ophthalmologists 2017 standards for a seven-day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon. In the 12 months preceding our inspection, 25% of surgeon consent appointments were carried out less than seven days prior to the day of treatment. This did not comply with the Royal College of Ophthalmology professional standards for refractive surgery.
- Patient's privacy was compromised because the clinic did not provide patients with lockable storage to store their personal belongings during surgery.
- We were not assured that the service risk register identified and mitigated risks to the service using effective governance processes. Not all risks were identified in a risk assessment, such as the overdue service of the Class 3b laser equipment.
- Not all processes of governance were transparent. We were told about mechanisms for review and oversight of clinical practice and protocols that were in addition to the international medical advisory board. However, we could not be assured of these processes during the 12 months preceding our inspection because these meetings were not recorded or made available to the Care Quality Commission.

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

Amanda Stanford
Deputy Chief Inspector of Hospitals (South)

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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Optical Express Bristol

Services we looked at
Refractive eye surgery;

Summary of this inspection

Background to Optical Express, Bristol Clinic

Optical Express Bristol is operated by Optical Express (Gyle) Limited. The clinic primarily served the communities of the South West. It also accepted patient referrals from outside this area.

The service provided refractive eye surgery for adult patients who paid privately for their care and treatment. No NHS funded work was completed at the clinic. No children were treated at the clinic and staff advised patients not to bring children to the clinic. There were no overnight facilities.

At the time of our inspection, intraocular lens surgery was carried out using sub-tenon anaesthesia and in most cases, intravenous sedation. Refractive laser eye surgery was undertaken using topical anaesthesia. All patient activity was carried out at the clinic premises.

At the time of our inspection, the surgery manager was going through the process of becoming the registered manager and was supported in this role by the surgical services manager. The service had not been inspected previously.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor. The inspection team was overseen by an inspection manager and the Head of Hospital Inspection.

Information about Optical Express, Bristol Clinic

Optical Express –Bristol is situated on the ninth floor of a multi-occupied building in the city centre of Bristol. The clinic is part of a nationwide chain Optical Express (Gyle) Limited that specialises in private refractive laser eye surgery and lens replacement surgery. The clinic was commissioned in 2015.

There were 2500 surgical procedures carried out during the 12 months preceding our inspection. No patients stayed overnight at the facility.

During the inspection, we visited the clinic and spoke with 12 staff and four patients. During our inspection, we reviewed five sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service had not previously been inspected.

In the 12 months preceding our inspection, there had been no never events or serious incidents reported. Never events are serious, largely preventable patient safety incidents, which should not occur if the available preventative measures have been put into place by healthcare providers.

There were three permanent members of staff, including the registered manager, employed in the surgery team at the Optical Express Bristol clinic. All other staff including the surgeon, registered nurses, operating department practitioners, optometrists and patient advisors were part of a regional team. The accountable officer for controlled drugs (CDs) was the surgical services manager.

Services provided at the clinic under service level agreement:

Clinical and non-clinical waste removal

Decontamination

Laser protection service

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 termination of pregnancy, cosmetic surgery service, refractive eye surgery, dialysis, and hyperbaric oxygen therapy services where these services are provided as an independent healthcare single speciality service.

We found the following areas of good practice:

- Staff knew how to report incidents and safeguarding concerns. Incidents were investigated thoroughly.
- Staff we spoke with understood their responsibilities under the duty of candour
- The surgery team took steps to reduce risk to patients during surgery. This included use of the World Health Organisation safer surgery checklist and the Royal College of Anaesthetists 'Stop before you block' procedures.
- Staff followed protocols for infection prevention and control. We saw that staff washed their hands and cleaned equipment thoroughly. Waste was managed safely.
- Staff kept comprehensive records about patient care. Records were stored securely.
- There were systems to ensure that lasers were used safely. The environment was designed and maintained for the use of lasers. Staff were trained to operate lasers. Staff were aware of protocols for safe use of lasers and followed these consistently.
- Staff followed best practice guidelines when handling medicines including cytotoxic medicines. Medicines were stored securely and medicines stock was managed safely.
- Patients were assessed for their suitability for surgery using current treatment criteria. There were adequate systems for follow up of post-surgery patients.

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

- The safety of the Class 3b laser could not be assured because the routine service was 15 months overdue.
- Not all staff who assisted the anaesthetists had completed immediate life support training.
- The current practice with regards to marking of the surgical site was not compliant with all relevant guidance including Royal College of Ophthalmologists Theatre Procedures Standards 2018. These guidelines state that marking must be performed by the surgeon or a nominated deputy who will be present during the procedure.

Summary of this inspection

- There was a risk that optometrists were not up to date with safety systems and processes. Optometrists were not required to complete mandatory training in topics such as infection prevention and control, moving and handling, conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety.

Are services effective?

We found the following areas of good practice:

- Optical Express had a medical advisory board. Members reviewed treatment protocols to ensure these were based on current evidence.
- Patients undergoing laser refractive eye surgery had opportunity for appropriate pre-operative assessment and discussion as set out in the General Medical Council Guidance for doctors who offer cosmetic interventions.
- Staff were supported to maintain up to date clinical skills and competencies. Staff participated in appraisals and competency checks.
- Leaders monitored the treatment outcomes of individual surgeons working at the Bristol clinic and these compared favourably to the averages within the company. Changes to treatment decisions were investigated and learning was shared.
- For intraocular lens surgery, pain was monitored by an anaesthetist who administered sedation as required
- Staff understood and complied with the Mental Capacity Act (2005). Patient consent was checked at every stage of the patient journey.

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

- The consent policy did not reflect Royal College of Ophthalmologists 2017standards for a 7-day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon. Surgeons at the Bristol clinic completed 25% of consent appointments less than seven days prior to the day of treatment.
- Optical Express did not contribute to the Private Healthcare Information Network (PHIN)

Are services caring?

We found the following areas of good practice:

- Surgeons talked to patients throughout their surgery as recommended in the Royal College of Ophthalmology professional standards for refractive surgery.

Summary of this inspection

- Staff built effective relationships with patients. We observed that staff listened to patients and gave patients time to ask questions. Patients told us they felt comfortable and safe with staff.
- Staff gave patients information about what they should expect from refractive eye surgery and realistic expectations about outcomes, in line with guidance from the Royal College of Ophthalmologists.

Are services responsive?

We found the following areas of good practice:

- The service offered flexibility around appointment times and dates and locations. There was no waiting list for surgery. Surgery was rarely cancelled.
- Treatment rooms and waiting areas were comfortable and spacious and fit for purpose.
- Staff considered the individual needs of patients and these were identified on the patient record.
- Interpreter services were available for patients whose first language was not their first language and for patients who used sign language to communicate.
- Complaints were investigated promptly.

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

- Patient's privacy was compromised because the clinic did not provide patients with lockable storage to store their personal belongings during surgery.

Are services well-led?

We found the following areas of good practice:

- There was a clearly defined leadership structure.
- There were several mechanisms for communication between the senior management team and the staff treating patients.
- Leaders monitored safety through a programme of internal audit.
- Staff had the information they needed to provide care and treatment. Electronic records could be accessed at any Optical Express clinic.
- Staff told us they felt supported and valued in their work. Leaders were approachable and well respected. Staff felt proud of the service they provided.
- There was a strong mechanism for patient engagement through patient experience survey

Summary of this inspection

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

- We were not assured that the service risk register identified and mitigated risks to the service using effective governance processes. Not all risks were identified in a risk assessment, such as the overdue service of the Class 3b laser equipment.
- The processes of governance were not transparent. We were told about mechanisms for review and oversight of clinical practice and protocols. However, we could not be assured of these processes during the 12 months preceding our inspection because some of these meetings were not recorded or made available to the Care Quality Commission.

Detailed findings from this inspection

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Mandatory training

- In the 12 months before our inspection, all permanent staff employed in the regional surgery team had completed mandatory training in systems and practices designed to keep patients safe. Staff working in the regional surgery team were required to complete an online training package that covered a range of topics including level two children's safeguarding and level two adults safeguarding, conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety, information governance, infection prevention and control, moving and handling. Both surgeons had completed level three safeguarding children training as an optional extra. Bank staff were required to complete the same mandatory training package. Five of the six bank staff had completed their mandatory training in the 12 months preceding our inspection.
- There was a risk that staff were not competent to deliver adequate life-saving care for patients in emergency situations. One of the three staff who assisted the anaesthetists had not completed immediate life support training.The surgical services manager explained there had been difficulties sourcing this training for staff, and going forward they planned for a member of staff to be trained as a trainer. However, a qualified anaesthetist was always available during surgery when sedation was used.
- All other surgery team members were required to complete basic life support training. All five members of staff were compliant with this training.
- Mandatory training requirements for optometrists were different to the surgery team. Optometrists were required to complete an annual refresher training for clinical competencies, plus training in the following key topics: safeguarding vulnerable adults level two, safeguarding children level two, information governance. All optometrists working on the surgery pathway at the Bristol Clinic were compliant with these mandatory training requirements.
- However, optometrists were not required to complete training in conflict resolution, consent, duty of care, equality and diversity, fire safety, health and safety, infection prevention and control, moving and handling. Optometrists' knowledge of safe systems was dependent upon reading Optical Express clinical directives such as the professional standards directive and following guidance issued by the College of Optometrists such as for infection prevention and control.

Safeguarding

- There were systems and processes to keep patients safe immediately following their operation. The surgeon was responsible for post-operative care. The optometry team completed follow up care and could access medical input as required.
- There were systems to protect vulnerable adults. There was a safeguarding policy and this policy conformed to intercollegiate guidance. All staff in the regional surgery team were trained in safeguarding vulnerable adult's level one and level two, plus safeguarding children level one and level two. The surgeons were trained in safeguarding children level three although this was not a mandatory requirement.
- All staff we spoke with understood their responsibility to recognise and report safeguarding concerns and knew where to go for further advice if a safeguarding concern arose. The registered manager was the safeguarding lead. There had been no safeguarding incidents reported during the twelve months preceding our inspection.
- The leaders of the service promoted safety in their recruitment practices and ongoing checks. Staff

suitability for working in the clinic was established at recruitment and monitored thereafter. We checked a variety of staff files and saw that all relevant documents were available such as evidence of identification, professional registration and qualifications. We saw that all staff disclosure and barring checks had been completed within the three years preceding our inspection in accordance with the company policy.

Cleanliness, infection control and hygiene

- Effective systems were in place to prevent and protect patients from a healthcare-associated infection. There had been no reports of healthcare acquired infection detected post-surgery during the twelve months preceding our inspection.
- There were systems to ensure that the environment and equipment used for patient care were clean. Staff followed cleaning schedules and used checklists to evidence that treatment areas were thoroughly cleaned at the end of each day of surgery and then deep cleaned once per month. Treatment areas were visibly clean and uncluttered. We observed that staff followed infection control protocols regarding the cleaning of diagnostic equipment between patient uses.
- We saw that staff followed protocols for infection prevention and control. Protocols reflected the relevant elements of the National Institute for Health and Care Excellence (NICE) guidance regarding surgical site infection. Staff wore disposable clothing including gloves, masks, hats and aprons.
- Staff used effective hand hygiene techniques. Staff washed their hands thoroughly in accordance with NICE quality standard QS61 Infection Prevention and Control. Hand hygiene audits in the surgery team were completed regularly and these showed that effective hand hygiene measures were used by staff. All staff were involved in the audit process by auditing each other during unannounced 20-minute observations of clinical practice. Results were consistently very positive.
- Waste was managed according to best practice, segregated and stored in containers in a locked room whilst awaiting collection. There was a current service level agreement with a private contractor for the collection of clinical waste. For intraocular lens surgery, decontamination of surgical instruments was carried out in accordance with Health Technical Memorandum (HTM) 01-01 'Management and decontamination of surgical instruments (medical devices) used in acute care'. All surgical instruments used for laser refractive surgery were disposable.
- The laser treatment room complied with Royal College of Ophthalmology Ophthalmic Services Guidance (2013). Laser refractive surgery was performed in an operating theatre with an airflow system that minimised the spread of airborne infection. Intraocular refractive surgery was performed within a standard ophthalmic operating theatre. Humidity conditions in the operating theatre were maintained consistently within the range for safe operation of equipment specified by the manufacturers of the lasers being used. Staff recorded a log of humidity conditions and this was checked as part of the clinic audit. The air handling system was validated in February 2018. Microbiology and air particle testing occurred in November 2017 with satisfactory results.
- Clinical staff we spoke with understood the importance of identifying sepsis and taking prompt action when required. Sepsis is a life-threatening illness caused by the body's response to an infection. Optical express had a sepsis awareness protocol for staff in line with NICE guideline NG51 Sepsis Recognition Diagnosis and Early Management. This protocol included identification of risk factors and symptoms and referred staff to use the NICE algorithm if a situation arose where they suspected a patient had sepsis.

Environment and equipment

- There were systems to ensure that equipment used in intra-ocular lens surgery and refractive laser eye surgery was safe to operate on the day of surgery. Before surgery started, the laser technician set up and calibrated the equipment according to the manufacturer's instructions and then repeated this process regularly throughout the day of surgery. This process produced data which was checked by the laser technician against expected ranges to monitor for any discrepancies. The laser technician emailed the manufacturers engineer at the end of every treatment day with this data.
- Resuscitation equipment was available and readily accessible. Staff checked this equipment prior to every surgical list for safety and completeness.
- Surgical equipment used for refractive eye laser surgery and intraocular lens surgery procedures had been serviced within the twelve months preceding our

inspection. However, the safety of the Class 3b laser machine could not be assured because the last service date was February 2016. This non-invasive laser machine was used to remedy symptoms of vision cloudiness experienced by some patients after intraocular lens surgery.

- There were recording systems that allowed details of specific implants and equipment to be provided rapidly to the Medicines and Healthcare Products Regulatory Agency when needed. Theatre staff attached the packaging with unique identification label to the patient's paper record.
- There was an up to date laser safety policy available for staff which followed Health and Safety Executive guidance on Control of Artificial Optical Radiation 2010. The laser protection advisor carried out a site visit and risk assessment every three years or when new equipment was installed or if a safety incident occurred. The most recent risk assessment was in June 2016 and no further actions were identified to mitigate the risks of the laser equipment. The laser protection advisor was responsible for revalidating the protocols that staff followed in the laser treatment environment (local rules). At the time of our inspection all staff knew where to find the local rules and had signed to say they had read the latest version.
- There were systems to ensure that laser safety protocols were followed during surgical procedures. The registered manager was the laser protection supervisor with overall responsibility for the safety and security of the lasers. The laser equipment was operated only by authorised users as identified in the local rules.
- The treatment area was set up to mitigate the safety risks associated with laser treatment and complied with guidance issued by the Medicines and Healthcare Products Regulatory Agency. The laser controlled area was clearly defined. Illuminated warning notices were clearly visible. There was a key pad securing entrance to the operating theatre. Laser safety of the clinic environment was assessed as part of the regular clinic audit completed monthly.
- There were no facilities for overnight stay and no recovery facilities with level two capacity for patients who were slow to recover from the effects of sedation or who experienced medical problems during sedation, as recommended by the Royal College of Anaesthetists 2015. However, in the event of a patient experiencing an adverse reaction to an anaesthetic, the team could undertake detailed patient observation. The anaesthetist could provide one to one care, including full monitoring, advanced airway resuscitation and immediate access to appropriate medicines. During the 12 months preceding our inspection, there had been no incidents of patients requiring these facilities at this location.

Assessing and responding to patient risk

- The team thoroughly assessed the level of risk for each patient to ensure their suitability for treatment. Prior to the day of surgery, patients completed a health and lifestyle questionnaire and optometrists conducted a thorough examination of the patient's visual and lifestyle needs. The optometrist and patient discussed any risk factors such as the existence of diabetic retinopathy or high blood pressure. Some risk factors resulted in the patient being excluded for surgery, for example, pregnancy.
- When surgeons made decisions to treat patients, they followed a detailed protocol based on best practice and research evidence. This protocol required staff to consider permanent conditions such as thin corneas, temporary conditions such as breast feeding, and systemic conditions such as epilepsy, depression, cancer or diabetes. In certain situations, for example if a patient had a history of epilepsy, the surgeon advised patients they would need a letter from their GP to confirm their suitability for surgery.
- Patient risk was reviewed on the day of their surgery. The pre-operative nurse verified all the details of the previously identified risks and checked the patients pulse rate, temperature, respiration rate, and blood pressure to ensure that no further risks had arisen since the previous consultation.
- Patients did not receive an assessment of venous thromboembolism and bleeding risk on admission or 24 hours after their surgery. However, patients who were taking blood thinning medicine were required to have an International Normalised Ratio (INR) test completed by their GP before surgery. This test is used to monitor how well the blood-thinning medicine is working. If the test result was outside of expected parameters, the patient's surgery was postponed.
- The anaesthetist adhered to National Patient Safety Agency/ Royal College of Anaesthetists 'Stop before you block' protocols. These aim to reduce the incidence of

patients receiving nerve blocks for the wrong side of their body. The team checked which eye was to be operated on prior to the local anaesthetic being administered.

- When the surgery team carried out refractive eye surgery, they followed systems for completing verbal checks during surgery as recommended by the Royal College of Ophthalmologists standards for refractive eye surgery. The team marked the surgical site, stated what refractive outcome was planned, stated what lens model and power was required and confirmed the correct lens implant was present in theatre. When the surgery team carried out intraocular lens surgery, they completed the five steps to safer surgery World Health Organisation checklist.
- Staff completed several checks to verify the location of the surgery site. However, the specific process for marking of the surgical site was not consistent with all professional guidelines. The surgical site marking was completed by the optometrist, who was not present in theatre during the procedure. This did not comply with the guidelines of the Royal College of Ophthalmologists Theatre Procedures Standards, February 2018 which state that if a nominated deputy completes the marking, that deputy should be present for the duration of the surgical procedure.
- We saw that all stages of the safer surgery checklist were included in the surgery process. All team members were present at the pre-surgery briefing. We saw that measures had been taken to encourage optometrist attendance at the post-surgery de-briefing.
- Staff took precautions to mitigate the risk of complications during eye surgery. Staff monitored patients receiving intravenous sedation using recommended equipment such as pulse oximetry and non-invasive blood pressure monitoring. Intravenous access was available throughout the procedure. An echocardiogram machine and resuscitation equipment was available for use when required. Staff used a recognised system for monitoring the deteriorating patient. This was the National Early Warning System (NEWS).
- There was a clear and regularly tested pathway to enable the patient to receive appropriate advanced medical care. If an emergency occurred during surgery, the surgeon was present in theatre throughout the surgical procedure and the anaesthetist was available when sedation was used. The surgery team knew what to do if a patient collapsed. The Optical Express protocol stipulated that staff were to telephone for an ambulance in the event of a cardiac arrest. This scenario was practised every three months. The most recent simulation had highlighted the need to identify appropriate parking for the ambulance outside of the clinic building and to keep the building management team informed of developments.
- Staff took precautions to mitigate the risk of complications following eye surgery. Patients were carefully monitored to check for any sign of inflammation, irritation or infection post-surgery. The team gave patients an aftercare advice leaflet that included telephone numbers to call if they had concerns or queries post-surgery. The optometrist routinely reviewed patients the day after their surgery and then again at regular intervals until discharge. The optometrists told us they felt comfortable to contact the surgery team with any concerns identified post operatively. Optometrists could also contact the clinical services team for advice.
- After-care arrangements included access to specialist medical input if required. Post-operative follows up appointments were scheduled for the morning to allow time for staff to arrange suitable urgent medical follow up for patients if the need arose. There was an emergency support system for urgent cases where the clinical services team co-ordinated care between the surgeon and optometrist and co-ordinated external referrals to another consultant or laboratory services when required.
- There had been two incidents when a patient was required to return to the operating theatre unexpectedly. One of these patients required the lens to be repositioned; the other patient required the corneal flap to be repositioned. There were no lasting negative effects from these additional procedures.

Nurse staffing

- There were sufficient staff to meet patients' needs. Managers at Optical Express used a staffing tool that had been approved by their medical advisory board. This tool calculated the number of staff and roles required for each surgery list according to the tasks to be undertaken. Staffing numbers and skill mix complied with the Royal College of Ophthalmology guidance on staffing in ophthalmic theatres.

- There were no surgery team shift changes during the surgery day.
- In the surgery team, there were three members of staff permanently employed based at the Bristol location; this was the registered manager plus a nurse and an operating department practitioner. All other staff present in the surgery team on treatment days were made up of a combination of the remaining two permanent members of staff based elsewhere in the region plus seven bank staff.
- There was an effective system for engaging staff at short notice from other clinics to cover sickness or annual leave. Staff absence was escalated to a scheduling team at the central office who could access the staff database for the region. This database included permanent members of staff in the south west surgery team as well as long established 'bank' staff that were frequently and routinely included on the surgery staffing lists. Cover was always provided for staff absences.
- There were systems to ensure that staff travelling between different bases were familiar with safety processes. All protocols were standardised throughout the company and staff felt at ease travelling to other sites to assist with surgery in their role. Staff were familiar with the teams in other sites and identified no concerns with this pattern of work. The laser protection advisor was available to all staff by telephone if required during normal working hours.

Medical staffing

- Patients received care from experienced and appropriately qualified medical staff. There were no staff working under practising privileges at the clinic. There were two surgeons directly employed by Optical Express who completed all surgical procedures plus pre-surgery consent consultations and follow up consultations as required. Both surgeons were on the General Medical Council specialist register in Ophthalmology.
- Intravenous sedation was administered by the anaesthetist who was employed by an agency. Local anaesthetic blocks were performed by the anaesthetist.
- There was a service level agreement for the laser protection service. A laser protection advisor visited every three years to complete a risk assessment. Clinic staff could telephone the laser protection advisor for advice when required.
- In an emergency, medical staffing was available. The surgeon was present throughout the surgical procedure. The anaesthetist was available in an adjoining room whenever a patient had sedation for the surgical procedure. If a patient required further medical input, for example if the patient had a cardiac arrest, staff used the resuscitation equipment available on site and called for an ambulance to take the patient to the emergency department of a nearby hospital.

Records

- There were safe systems for storing records. Electronic records were password protected and paper records were stored in filing cabinets in a locked filing room. No paper records were left unattended at the time of our inspection. On the day of treatment, the information from the paper record was entered onto the electronic file. At the end of surgery, staff securely packaged paper records and an optical express courier visited twice daily to transport the records to the external archive facility. The archivist confirmed receipt of all listed records by email.
- There were systems to ensure that staff followed best practice with regards to record keeping. Patient documentation was audited every three months by the surgical services manager. This audit had not identified any recurring concerns for the Bristol clinic during the twelve months preceding our inspection. The registered manager audited record keeping as part of the monthly clinic audit. No concerns were identified through this process. The clinical services team audited documentation as part of the review of complex cases. We saw that staff in the clinical services team emailed optometrists individually to provide feedback on specific records which did not meet the required standard.
- Patient records were completed in accordance with the General Medical Council Guidance for doctors who offer cosmetic surgery. We reviewed five sets of patient records. We saw that records contained patient identification, relevant assessments and consent documents as well as details of the surgery undertaken and medicines prescribed.
- Records were maintained each time a laser was operated. We saw that staff inputted a contemporaneous record of laser operations for every patient. This aspect of laser safety was audited as part

of the clinic audit completed monthly by the registered manager. Completion of this assessment was audited as part of the records audit every three months. No notable concerns were identified by this audit process.
- Staff shared details of the surgery with the patient's GP when patients gave permission for them to do so. Patients could choose whether to give permission for the clinic to contact their GP regarding the treatment they received at the clinic. If necessary staff asked patients to contact their GP directly when further clinical information was required, such as international normalized ratio (INR) results for patients taking blood thinning medication. The treatment pathway was suspended pending receipt of the relevant information. After treatment, staff gave each patient relevant information to share with their GP if they chose to do so.

Medicines

- There were effective systems for the management of medicines. There was a current and comprehensive policy for the management of medicines which served as a guideline for staff to follow. The policy included the ordering, receipt, prescribing, administering, dispensing, storing and disposal of medicines, emergency medicines, reporting of drug errors and adverse reactions plus the training and competency of staff.
- There had been no reported medicines incidents during the 12 months preceding our inspection. Medicines management was audited as part of the clinic audit completed by the registered manager every month. No notable concerns had been identified as part of this audit process.
- Staff stored medicines safely and securely within locked cabinets or fridges. Staff monitored and recorded the temperature of fridges using thermometers that identified minimum and maximum temperature ranges. There were clear instructions for staff to follow in the event of temperature recordings not being within expected ranges.
- We checked five patient records and saw that staff clearly documented patient's allergies in the prescribing document.
- There was an emergency stock of medicines available containing treatment for anaphylactic shock, diabetic coma, adrenaline, aspirin, antihistamines, a spare inhaler for asthmatic patients and portable oxygen for patients feeling feint. These medicines were within their expiry dates.
- Nurses participated in the dispensing of eye drops. The medicines policy included instructions for safe dispensing. None of the medicines being dispensed required re-constitution. All dispensing was checked by a second member of staff to mitigate risk of error. Nursing competency checks included safe dispensing methods.
- The use of cytotoxic medicines was well managed. There was a policy and procedure to guide staff. Risks associated with the use of this medicine were identified within a risk assessment and actions were taken to protect the safety of patients and staff. For example, the surgeon took responsibility for prescribing the cytotoxic medicines and these were ordered as a pre-prepared solution specifically for each patient as required. These medicines were stored in secure, rigid containers in a fridge. These medicines were collected in sealed purple cytotoxic waste bins by the waste contractors. There was no spillage kit for cytotoxic waste but the policy clearly outlined the procedure for staff to follow in the event of spillage.

Incidents

- There had been no serious incidents and no never events during the 12 months preceding our inspection. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers.
- Staff in the surgery team and the optometry team understood their responsibilities to raise concerns and knew how to record safety incidents. This included the need to report suspected or actual ocular injury to their employer and to the laser protection advisor. There were four incidents reported at the Bristol clinic during the twelve months preceding our inspection.
- All incidents in the surgery team were investigated by the surgical services manager. There were no themes evident from the four incidents reported during the 12 months prior to our inspection. This process included checking the onward patient pathway to ascertain if any harm or detriment to treatment resulted from the incident. There had been no incidents of suspected or actual ocular injury reported.
- The surgical services manager demonstrated awareness of potential triggers for a duty of candour notification where applicable. All staff we spoke with were clear

regarding their responsibilities for duty of candour. There was a duty of candour policy in place since 2015. 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. There had been no incidents that met the threshold for the duty of candour in either the surgery team or optometry team.

- Staff told us that learning was identified and shared with the regional surgery team following the investigation of incidents. We saw that it was normal practice for learning from incidents to be shared at the pre-surgery briefing. There was evidence that incidents were discussed at team meetings and learning was shared. For example, following an incident of surgical equipment failure, the minutes showed that this had been discussed and action taken to ensure the serial number of failed equipment was logged prior to returning the item to the manufacturer.
- Incidents reported by the optometry team were investigated centrally by the clinical services team. Two types of optometry incidents were routinely reported. Firstly, when the surgeon recommended a treatment option that was not the option recommended by the optometrist, this was reported and investigated and individual learning was fed back to the optometrist by email.
- Secondly, when patients presented at the Bristol clinic with post-surgery complications, these were investigated by the clinical services team. Due to the nature of the business, it was unrealistic to expect the service to track whether patients presented at other healthcare facilities for treatment of infection following surgery at the Bristol clinic.
- Optometrists used a grading system to classify these complications. Optometrists reported patient complications to the clinical services team who provided advice and guidance regarding the most effective way to treat these patients. Part of this clinical review also involved an audit of the patient pathway by the clinical services team in conjunction with the medical director and the clinical services director.
- If an optometrist identified that a further surgical procedure might be needed to rectify an unresolved complication, the clinical services director, medical director and operating surgeon reviewed the optometrist recommendation. Optometrists and surgeons discussed learning from clinical cases at a three-monthly regional face to face meeting that included presentation of actual complex case studies.
- The surgical services manager reviewed all National Patient Safety Alerts (NPSA) and forwarded these to staff when appropriate. Every three months the surgical services manager sent a summary of alerts that included a breakdown of their relevance to the clinic. For example, the regional surgery team were required to be extra vigilant regarding the use of the manual resuscitation system following the release of a medical device alert.

Major Incident awareness

- The service used a variety of methods to monitor safety. The surgical services manager evaluated all incidents reported, checked staff competencies and audited compliance with safety policies. At a local level, the laser technician monitored the safety of laser equipment used in intraocular lens surgery and refractive laser eye surgery by carrying out system checks on surgery days.
- Patient safety was maintained if surgical equipment failed. Intra-ocular lens surgery and refractive laser eye surgery did not proceed if laser equipment was not functioning or did not calibrate successfully. Laser machines cut off automatically if the data inputted by the laser technician was out of the expected range. Laser technicians contacted experts in the clinical services team for immediate advice over the telephone and had the option of contacting the manufacturer if a problem could not be resolved. Patients were offered surgery at alternative clinic locations or alternative surgery dates.
- Laser treatment was not compromised if power failed mid-treatment. Laser equipment was fitted with an uninterruptible power supply sufficient to complete a surgical procedure, as recommended by the Royal College of Ophthalmologists 2017. There was a policy to guide staff in the event of mains service failure. Those patients whose surgery had not started would be re-scheduled for another surgery date. Post-operative care would be rescheduled at an alternative clinic.
- The service did not benchmark safety performance of the Bristol Clinic in comparison to other clinics. The safety performance of individual surgeons was benchmarked across the company.

Refractive eye surgery

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Staff followed evidence based protocols for treatment. Optical Express had an international medical advisory board (IMAB) made up of international refractive surgery experts. They met annually over several days to consider new research evidence, technologies and guidelines for best practice such as the Royal College of Ophthalmology Standards for refractive surgery. The IMAB used this evidence together with the Optical Express outcomes data to review the clinical protocols of the company. For example, the suitability guidance and treatment criteria clinicians used to make decisions to treat patients.
- Patients had their needs assessed and their care planned and delivered in line with evidence based guidance and standards. All surgeons and heads of department plus the medical director and the clinical services director were members of the medical advisory board (MAB). This was an open meeting for discussion of the IMAB recommendations during which changes were agreed to treatment criteria or protocols or decisions made to introduce new technology.
- The medical advisory board set standards for all surgeons and optometrists. These standards were in line with national guidance such as NICE guidance on photorefractive surgery, Royal College of Ophthalmology Standards for Laser Refractive Surgery and Royal College of Surgeons' Professional Standards for Cosmetic Surgery.
- The service complied with NICE Interventional Procedures Guidance IPG164 Photorefractive (laser) surgery for the correction of refractive errors. For example, patients understood the potential benefits and risks of their surgical procedure by watching an information video. This was then followed up during consent discussions with the optometrist and surgeon.
- Staff ensured that patients undergoing laser refractive eye surgery had opportunity for appropriate pre-operative assessment and discussion as set out in the General Medical Council Guidance for doctors who offer cosmetic interventions.

Nutrition and hydration

- Staff gave patients appropriate advice regarding what to eat and drink prior to their surgery.
- Staff gave patients hot or cold drinks and biscuits following their surgery

Pain relief

- The clinic ensured that patients were given adequate pain relief. Dependent upon the type of surgery, the team used either topical or sub tenon anaesthesia to ensure that patients did not experience pain during surgery.
- The team could monitor the patient's pain throughout the procedure because patients were fully conscious and responsive.
- Staff informed patients about the expected level of pain during and after the surgery. Nurses advised patients how to manage their pain after surgery by taking their preferred choice of simple analgesia.

Patient outcomes

- Optical Express used data to monitor the efficacy and safety of treatment. Outcome data was collected for every treatment undertaken including long term follow up. Optical Express compared their outcomes with the data in the National Ophthalmic Database. This comparison provided a means of benchmarking the treatment outcomes of individual surgeons.
- The management team closely monitored the individual performance of surgeons who worked at the Bristol clinic. An annual audit of the individual surgeon's outcomes was made available to the registered manager. These included for example total number of treatments, mean age and gender, pre-operative measurements of the eye, treatment types, one-month post treatment distance vision for different types of vision correction, one-month post treatment refractive predictability, attempted versus achieved results, efficacy, safety, surgeon safety and efficacy over time, estimated enhancement rate and complications.
- Specific data for the treatment outcomes obtained at the Bristol clinic was not available because Optical Express monitored outcomes according to individual surgeons rather than locations. The outcomes data for the surgeons operating at the Bristol clinic were similar to the outcomes data for other surgeons working for Optical Express.
- At a corporate level, there were systems to ensure that clinicians made safe and effective decisions around

patient care. Quality and compliance officers completed checks of every patient record two days prior to surgery. All action points raised from these checks were emailed to the registered manager to action.

- If a patient presented for surgery and on examination, the surgeon disagreed with the clinical recommendation of the optometrist, this resulted in the surgeon completing a 'non-treatment form'. This triggered a review by the clinical services director who examined the clinical reasoning of both the optometrist and surgeon. Any learning from this review was shared with the relevant clinician. If an optometrist graded a patient with a complication post-surgery, this triggered a review of the patient journey by the clinical services team in conjunction with the medical director and the clinical services director.
- The average rate of complications for treatments carried out in Optical Express clinics was 1%. The rate of complications for the surgeons who worked at the Bristol clinic was lower (better) than the average for Optical Express.

Competent staff

- There were systems to ensure staff in the surgery team were competent to carry out their role. Four of the five permanent staff working in the South West regional team had completed an appraisal during the 12 months preceding our inspection. The remaining appraisal was on hold to enable a new manager to complete this as a training exercise. The surgical services manager checked the skills competencies of all staff in the surgery team every three years. This included competencies to administer cytotoxic medicines.
- The competence of surgeons was assured before they were permitted to perform eye surgery independently. The medical director and clinical services director completed the induction of all surgeons. This process included detailed information about the procedures; clinical suitability guidance; policies and procedures; diary and patient management systems; protocols and pathways. Surgeons then shadowed the medical director or a senior surgeon and attended training with the laser manufacturer which included a period of supervised practice. The surgeon was required to undertake a number of procedures under the supervision of the medical director or senior surgeon following their training before they were entered onto the list of authorised users. This list was kept under review by the surgical services manager.
- The medical director monitored the ongoing competence of surgeons by their clinical outcomes, which were benchmarked within the company. The provider ensured they had opportunity to complete adequate continuing professional development for the purposes of revalidation. Both surgeons held evidence of an established refractive surgery practice. Surgeons were required to provide evidence of their annual appraisal and this was available for both surgeons who worked at the Bristol location.
- All staff operating laser equipment were trained in this role. All staff completed the laser core of knowledge training day. The laser technician was certified by the laser manufacturer following a one-week course in the use of the lasers and associated equipment. Laser technicians participated in a review of their competencies every three years. Optical Express employed senior refractive trainers who carried out the laser competency assessments locally and supported technicians and laser protection supervisors to ensure they remained skilled.
- The clinical competencies of optometrists were up to date. Regional optometry development managers were responsible for inducting, training, developing, supporting and completing the appraisals of optometrists. Competencies of the optometry team were reviewed annually during the appraisal process. All optometrists working at the Bristol location had received an appraisal in the twelve months preceding our inspection.
- Optometrists who treated eye surgery patients were trained to complete the additional clinical tasks of the surgery pathway, including the management of post-operative side effects and complications of eye surgery. These optometrists participated in a two-week training course that included an introduction to clinical governance processes, the electronic record system, and the patient pathway, the interpretation of diagnostic instruments plus practical observations of clinical practice.

Multidisciplinary working

- Multidisciplinary working outside of the team was dependent upon patient choice. At their initial

consultation, patients were encouraged to give consent to sharing of information with their GP. For those patients who consented, a treatment summary was automatically generated by the electronic records system and sent to the GP when the final appointment was recorded by the clinician. All patients were given a copy of their treatment summary on discharge.
- For some high-risk patients, the team insisted that patients asked their GP for a letter confirming their health status prior to surgery going ahead.

Seven-day services

- The clinic did not operate a seven-day service.

Health promotion

- The clinic provided a service for refractive eye laser surgery and intraocular lens surgery only. These services did not include general health promotion based upon the national priorities to improve the health of the population.
- Staff empowered patients to manage their own health and to take responsibility for their aftercare. Staff advised patients how they could help to achieve the best outcome during the procedure, as recommended in the Royal College of Ophthalmology standards for refractive eye surgery. Staff advised patients how to look after their eyes in the weeks following surgery to get the best outcomes for their surgery. Staff encouraged patients to attend regular vision check-ups post-surgery.
- Nurses supported patients to be independent by teaching them to administer their own medicines following surgery.

Consent and Mental Capacity Act

- Staff understood and complied with the Mental Capacity Act 2005. All staff in the surgery team had completed a mandatory training module on consent which included information on the Mental Capacity Act 2005. Only patients who could give informed consent were accepted for surgery. Patients who were requesting surgery received a pre-operative assessment and thorough discussion of their needs with both the optometrist and the surgeon. Staff gave detailed verbal and written information about all risks, benefits, realistic outcomes and costs of treatments. Patients were offered a range of options for treatment as alternatives to refractive eye surgery. Staff showed patients a video that explained the recommended surgery
- Staff ensured that patients continued to give informed consent as they progressed along the surgery pathway. Patients were given opportunities to change their mind. There were no time limited deals offered. Staff gave patients information to take home to read including written information about treatment options and a paper copy of the consent form. The printed consent form clearly explained the risks of using cytotoxic medicines in refractive eye surgery. Patient advisors, optometrists, surgeons and nursing staff all checked patients consent at every stage of the assessment and treatment process. Patients were offered translation services if they did not understand English.
- Staff ensured that patients had capacity to give consent for surgical procedures. Assessment of capacity to consent began with the patient's self-assessment in the health questionnaire. This asked patients to declare any mental health conditions that affected their ability to understand. During the initial consultation, the optometrist assessed the patients understanding of the limitations and benefits of treatment, and if any doubts regarding capacity were noted, the patient was steered toward a less invasive treatment option such as corrective eye wear. Any concerns that arose from the health questionnaire or from the optometrist's assessment triggered a letter to the patients GP. Surgeons made the final decision whether a patient had the mental capacity to consent to treatment. This assessment was recorded in the patient's electronic record.
- The consent process was completed by the surgeon; patients were given a choice of either face to face or over the telephone consultation. High risk categories of patients were excluded from telephone consultations. During the six months preceding our inspection, 69% of consent consultations were carried out over the telephone.
- The Optical Express consent policy did not follow guidelines published by the Royal College of Ophthalmology. Potential patients were given a minimum of three days 'cooling off' period between agreeing to go ahead with the procedure and surgery being performed. The Royal College of Ophthalmology recommends a minimum cooling off period of seven days between the procedure recommendation and

surgery. In exceptional circumstances, where a one-week cooling off period is impractical, the reasons for this should be agreed with the patient and documented in the medical record.

- During the six months preceding our inspection, Optical Express data showed 25% of surgeon consent appointments were carried out less than seven days prior to the day of treatment. The surgical services manager explained that Optical Express were in the process of changing the electronic system. The amended version would ensure that staff could only book consent appointments more than seven days prior to surgery.

Are refractive eye surgery services caring?

Compassionate care

- Staff respected the identity and dignity of patients. Staff used eye contact when speaking to patients. We observed that staff introduced themselves to the patient. Staff communicated with patients in a respectful and considerate manner. During consultations, staff explained the reasons for asking for personal information.
- Surgeons talked with patients during surgery, explaining to patients what sensations they were likely to experience during surgery. This complied with the Royal College of Ophthalmology professional standards for refractive surgery.

Emotional support

- When patients expressed anxiety regarding their surgery or tests, staff in the optometry team were kind and patient, and gave verbal reassurance.
- Staff gave extra time to patients with emotional needs. If appropriate for the patient, a staff member was allocated to sit with the patient during surgery to hold their hand. Patients could request a chaperone for any consultation as per the company policy.

Understanding and involvement of patients and those close to them

- Staff supported patients to understand relevant treatment options including benefits, risks and potential consequences in order to make informed choices. We observed face-to face consultations and saw that staff gave patients ample time to ask questions. Patients told us they felt comfortable asking questions and staff tried wherever possible to make them feel at ease.
- At various stages of the treatment journey, we observed staff patiently explaining written information and checking patients understanding, for example, prior to consent, during the consultation process, and during the medicines talk.
- We saw that staff gave patients written information about what to expect during surgery. Following their pre-operative optometrist assessment, the optometrists gave patients a written report that included details of their eye health, prescription and diagnostics, the recommended treatment, surgeon details and full cost of treatment.

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

Service delivery to meet the needs of local people

- The facilities and premises were designed and maintained for the service delivered. The clinic was easily accessible from the town centre and close to public transport links. Waiting areas were comfortable. Treatment areas were spacious. Treatment rooms were arranged to facilitate ease of patient movement along the surgery pathway.
- The team tried, wherever possible to provide continuity of care. For example, a patient would be seen by the same surgeon and the same optometrist throughout their patient journey. The need for continuity was identified in a clinical directive.
- The surgeon delegated routine review appointments to the optometrists. The optometrists followed clinical directives to ensure their practice complied with the Royal College of Ophthalmologists professional standards.

Meeting people's individual needs

- Staff were considerate of patient's individual needs. Following the patient's initial consultation, staff in the optometry service used the free text section on the patient's electronic medical record to flag any additional

requirements to the surgery team. On the day of our inspection we observed that staff were sensitive to the needs of a patient with hearing difficulties. There was a portable hearing loop available.

- Some adjustments were made to ensure that people with impaired mobility were given equal access to care and treatment. We saw that a patient with back pain was offered an alternative method of surgery which meant that they were not required to lie completely flat and still. This was discussed in advance at the pre-surgery team briefing.
- Some reasonable adjustments had been made to ensure that language was not a barrier to treatment for patients whose first language was not English. An external interpreter service was available for patients whose first language was not English and for patients who used British sign language as a means of communication. Patients were not required to pay for the cost of this service.
- Some adjustments were made for patients with eyesight difficulties. Some written patient information was available in large font, such as the laser surgery terms and conditions document, the reposition, removal and/or replacement of an ophthalmic device informed consent document and the reflection period addendum informed consent document. The aftercare information leaflet included photographs to aid understanding.

Access and flow

- Access to the service was timely and flexible. There was no waiting list for refractive eye surgery. Patients were offered an appointment on the next planned surgical list.
- Staff at the Bristol clinic were flexible with appointment times to meet the needs of patients who had far to travel. If the surgery dates at the Bristol clinic were not convenient, dates at other clinics nationwide were offered. The option of telephone appointment with the surgeon for the consent process was popular with patients who told us they were pleased to reduce their time spent travelling to appointments.
- The rate of cancellations of surgery was low at 7%. Reasons for cancellations were varied including patient choice, equipment failure, clinical changes or complications.
- The team tried to minimise the time that patients spent in clinic on their day of treatment. Patient arrival times were staggered to coincide with their allotted surgery time. Patients were encouraged to go for a walk in the city centre if their surgery start time was delayed. Patients we spoke with told us they had waited longer than expected on the day of their surgery. However, the subjective results of the patient experience questionnaire completed during the 12 months preceding our inspection indicated that patients at the Bristol clinic felt they had spent less time waiting than the average time indicated on this survey. The clinic did not objectively monitor the length of time that each patient waited on the day of their surgery.

Learning from complaints and concerns

- Complaints were investigated by the clinical services team. There were seven complaints received by the Bristol clinic during the 12 months preceding our inspection. Neither of these complaints were upheld by Optical Express. The surgical services manager identified themes from complaints. Most complaints related to patients being dissatisfied with their visual outcome following surgery or the charges for enhancement procedures. Patients were kept informed regarding the outcome of these investigations.
- Teams learned from complaints and shared this learning with other teams. For example, when a patient was dissatisfied with their surgery experience, this was communicated to the optometry store manager to ensure that staff adopted a sensitive approach to the patient on their follow up appointment.

Are refractive eye surgery services well-led?

Leadership

- There were clearly defined systems of leadership for all staff working at the clinic. Clinical leadership of the surgery pathway was divided between two separate clinical governance structures and centrally supported by the clinical services team. The link between both leadership structures was the clinical services director and the medical director. All staff we spoke to were clear how the leadership structure worked.
- There was strong clinical leadership of the surgery team, provided by the surgical services manager who was responsible for all the surgery teams nationwide. The surgical services manager was supported in this role by the clinical services team, the medical director and

clinical services director. The registered manager was responsible for day to day coordination of the clinic. This person was new in post and the surgical services manager was supporting them whilst they became familiar with the requirements of the role.

- Clinical leadership of the optometrists was provided by a regional optometry development manager who had oversight of the training and development and completed optometrist appraisals. The optometry development manager was supported in this role by the clinical services team and the medical director.
- Clinical leadership of the surgeons was the responsibility of the medical director and the clinical services director. They were supported in this role by the medical advisory board who were guided by the international medical advisory board.
- Leaders had identified challenges to the quality of the service, such as the need for theatre protocols to become embedded. The leadership team had appointed to a new role created to lead safety initiatives within theatres. The intention was for this member of staff to play a key role in monitoring the safety of surgery through observation and real-time interactions with teams. The plan was for this staff member to initially focus on embedding the world health organisation safer surgery checklist within all surgery teams. Staff in the surgery had participated in a development workshop which encouraged good safety practice within theatres.
- We saw that leaders were visible and approachable. Staff from both teams told us they had confidence and trust in the leadership team, and described the surgical services manager as 'knowledgeable' and 'responsive'.

Vision and strategy

- There was a vision and mission statement for the company. The mission was to grow and develop the network of clinics globally and provide the highest quality science based technology, superior products and services that enhance people's lives. This was to be achieved by fostering a work environment that values and rewards integrity, respect and performance. Some staff were familiar with the values. However, these values were not developed in collaboration with staff, people who use the services, or external partners.
- The strategy for the Bristol clinic was determined at a corporate level. The strategy was not available as a written document for the inspection and we were not able to consider progress against the delivery of the strategy or to evaluate how robust or realistic this strategy was. However, we were told the plan was to introduce bilateral surgery procedures and this was due to commence in the next 2-3 months. The service had also appointed a new refractive eye laser surgery manager lead based in Cardiff who would also provide leadership for the Bristol clinic.
- The leadership had taken account of the Royal College of Ophthalmology Professional Standards for Refractive Surgery. Leaders had made amendments to the protocols around consent, specifically the requirement for a seven day 'cooling off' period' in order to align with best practice.

Culture

- All staff told us they felt respected, supported and valued. All staff told us they were proud of the service they provided for patients and proud to work for the company. Staff participated in appraisals. We saw there were opportunities for career development as staff were promoted to more senior roles within the company. Members of staff told us they could access advice and guidance when they needed to.
- The culture of the service was focused on working together to provide the best possible care for patients. The patient experience was very important to the team.
- In surgery briefings, we observed a non-hierarchical structure where staff of all grades could speak up. During theatre we saw that staff worked together in a cooperative and appreciative way.
- In the minutes of local team meetings, we saw that when staff raised concerns, these were addressed. For example, in February the team had raised a security issue regarding workmen cutting through the clinic to access toilets on the floor below. The surgical services manager supported staff to speak directly to the workmen and building manager and advised staff how to escalate this further if necessary.
- Leaders took a personal interest in the safety and well-being of staff. At this location, there had been no reason for leaders to take action regarding behaviour that was inconsistent with the values of the company.

Governance

- There were three levels of clinical governance forum for the reviewing of surgical ophthalmic procedures.
- There was an independent medical advisory board (IMAB) that consisted of experts in the field of

ophthalmic surgery. We saw the latest minutes of the IMAB dated April 2018. This forum met once a year to review surgical ophthalmic procedures in line with the latest evidence base for treatment including clinical research, published guidelines, and Optical Express data. This group also reviewed all clinical directives and information given to patients.

- There was a medical advisory board (MAB) that met once per year. We were told that members of this forum discussed the recommendations of the IMAB and considered how policies and protocols might need to be reviewed or amended. However, we could not be assured of this process because the latest minutes of the MAB submitted as part of the inspection process were dated September 2015.
- The surgical services manager participated in a monthly clinical governance committee teleconference. This forum consisted of the medical director, the responsible officer, the refractive operations manager, the clinical director and the surgical services manager. The surgical services manager told us this meeting was a forum to raise location specific issues and trends identified across locations in the surgery and optometry teams, for example, from incidents or audits and to address safety or quality concerns raised by teams. However, we could not be assured of this process because the clinical governance committee teleconference had not been recorded since April 2017.
- Staff were informed of changes to clinical protocols by a clinical directive that was communicated by email twice a week for three consecutive weeks. Staff were required to respond to the clinical services team within one week to confirm that they had read, understood and intended to comply with the contents of the directives.
- There were systems to provide operational management of staff when working at the Bristol clinic. The optometry store manager was responsible for the routine operational management of the optometry team who carried out pre-surgery consultations and post-surgery follow ups in the optometry store. The surgery manager was responsible for routine operational management of the regional surgery staff when they were working at the Exeter clinic and the smooth running of the clinic that day.
- The safety and quality of the patient journey was monitored effectively. There was a central clinical services team responsible for the monitoring of various aspects of clinical governance across the entire patient pathway. This included specific members of staff who looked at complaints management, cancellations, the governance of optometrists, changes in policies and processes. All policies and procedures for the laser surgery service were reviewed during the 12 months preceding our inspection.
- The two surgeons who performed surgery at the Bristol clinic were on the General Medical Council Specialist Register in Ophthalmology and held current indemnity insurance. Surgeons were not permitted to invite visiting surgeons into the theatre.

Managing risks, issues and performance

- The registered manager was supervised by the surgical services manager who was part of the senior leadership team, which included the medical director. In this sense, the registered manager had a direct route to and from the senior decision makers of the organisation.
- We were told that the surgical services manager escalated concerns at the clinical governance committee and informed the registered manager of the outcomes of these discussions. However, we could not be assured of this process because the clinical governance committee teleconference had not been recorded since April 2017.
- Leaders used internal audit processes to monitor staff compliance with safety protocols. The registered manager repeated a clinic audit every month. This included infection control, decontamination, air handling, incident and complaints management, patient satisfaction, record keeping, personnel, maintenance of equipment, personnel, emergency equipment, medicines management, laser safety, quality management and health and safety.
- The registered manager reported the results of these audits to the surgical services manager, who monitored compliance and checked results to identify trends across locations. We checked the last three audits and saw that only minor issues were identified with no recurrent themes or trends. Action plans were recorded and all identified actions were completed.
- The surgical services manager took action to manage surgical risks. For example, low levels of legionella had been detected during water safety checks. To address this, staff were reminded about the water flushing protocol and the pipes were lagged to reduce heat transfer

- The local risk register was a collection of risk assessments rather than a live tool to monitor current risks to patient care or service delivery. In most circumstances where risk to the health and safety of staff or patients was identified, such as needle stick injury or power failure during treatment, the surgical services manager completed a risk assessment and identified ways to reduce or manage the risk. Staff signed to say that they had read the risk assessment and understood the required actions to take. For example, risk assessments for the Control of Substances hazardous to health (COSHH) were completed in March 2018. All hazardous substances were stored in non-patient areas in rooms secured by key pad.
- However, the surgical services manager was aware of other live risks to patient care that were not risk assessed or recorded on the risk register. These included the lack of availability of external training for immediate life support and the delayed routine maintenance of the Class 3b laser. The lack of availability of external training for immediate life support was being addressed. The intention was for the new theatre lead to be trained to act as 'second facilitator' for these courses. However, the delayed routine maintenance of the Class 3b laser was not identified on the regular clinic audit, had not been risk assessed and was not actively mitigated.
- We were told that financial processes and data regarding current and future performance were monitored at a corporate level by the senior management team. However, the service did not provide evidence of senior management meetings so we could not be assured of these processes.

Managing information

- Staff had the information they needed to provide care and treatment to patients. All information was accessible to the surgery team in paper or electronic format. Prior to the surgery date, the clinical services team checked the electronic files of all patients scheduled to attend the clinic. This was to ensure that all necessary documentation and pre-surgical actions had been completed, for example, GP letter received if necessary.
- The system for storing individual patient records was accessible to staff who needed this information. The clinic used a password protected electronic patient record system. Different grades of staff could view, access and add records which were appropriate to their role at any of the Optical Express locations. The electronic record included details of any unexpected events occurring during surgery. The optometrist could access both the paper copy and the electronic record during their initial aftercare appointment.
- Data management was monitored at a corporate level. There had been no incidents related to data security at this location during the 12 months preceding this inspection.

Engagement

- The service proactively sought and acted upon the views and experiences of patients. Patients routinely completed the patient experience questionnaire after their initial consultation, 24 hours following their surgery and three months following surgery.
- Results of the 2017 patient experience questionnaire showed patients gave positive feedback about their experience at the clinic. All patients said the surgery team made them feel at ease, that staff explained the post-operative eye drop regime and aftercare process clearly and effectively, and that patients were satisfied with the warmth and friendliness of the surgeon. On most parameters, patients at the Bristol clinic scored their levels of satisfaction with their vision higher (better) than the average score for Optical Express. For intraocular lens surgery, 100% of patients at the Bristol clinic indicated they would recommend vision corrective surgery to their friends and relatives. For refractive laser eye surgery, this score was 99%. This was better than the average score companywide.
- At a corporate level, a range of strategies were used to foster goodwill and commitment from staff. All staff were invited to an annual event hosted by the chief executive. Once a month staff received an electronic magazine. Every week the chief executive communicated to staff by email. Once a week, staff could nominate a colleague who had shown exceptional commitment to their work, and winners received generous prizes.
- Local staff engagement in the surgery team was proactive. Staff in the regional surgery team were invited to attend monthly team meetings. One member of the surgical services management team joined staff at this

meeting. Managers encouraged staff to raise concerns and contribute ideas for improvement. For example, staff decided that a sign for the disabled toilet would be beneficial.

- There were no forums where staff or patients or patient representatives were involved in shaping the planning and delivery of services and/or the shaping of the culture of the organisation.

Learning, continuous improvement and innovation

- Patient advisors scanned all patients who were assessed for refractive eye surgery using a diagnostic technology that produced a three-dimensional map of each eye. The laser followed this personalised 'map' to allow treatment to be custom-fitted to the exact specification of each eye with microscopic accuracy.
- There had been no internal or external reviews of the service at this location during the 12 months preceding our inspection

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Ensure that all laser equipment is regularly serviced according to manufacturer's instructions.
- Records must be maintained in relation to the management of the service. Records should demonstrate when the quality and safety of the service is assessed, monitored or improved.

Action the provider SHOULD take to improve

- The consent policy should reflect Royal College of Ophthalmologists 2017 for a seven-day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The clinic should consider setting up forums where staff or patients or patient representatives can be involved in shaping the planning and delivery of services and/or the shaping of the culture of the organisation.
- The clinic should provide lockable storage for patients to store their personal belongings during their surgery
- The risk register should be an accurate reflection of the risks to the service.
- In accordance with the Royal College of Anaesthetists 'Guidelines for the Provision of Anaesthesia Services (GPAS) Guidelines for the Provision of Ophthalmic Anaesthesia Services' 2018, all members of clinical staff working within the recovery area should be certified immediate-life-support providers and mandatory training should be provided.
- The provider should review the mandatory training offered to optometrists to ensure that this reflects the requirement for staff to have up to date knowledge of safety systems and processes, i.e. that persons providing care or treatment have the skills to do so safely; persons employed by the service provider in the provision of a regulated activity must receive such appropriate support and training to enable them to carry out the duties they are employed to perform
- The provider should ensure that current practice with regards to the surgical site marking is compliant with all relevant clinical and professional guidelines.

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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment All premises and equipment used by the service provider must be (e) Properly maintained. The routine service of the Class 3b laser was overdue by 15 months.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must enable the registered person, in particular, to- Assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity d) maintain securely such other records as are necessary to be kept in relation to- (ii) the management of the regulated activity The clinical governance committee meetings had not been recorded since April 2017. The most recent minutes of the Medical Advisory Board were September 2015.

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.