

Optical Express - Bluewater 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

Overall summary

Optical Express Bluewater Clinic is operated by Optical Express Limited. Optical Express is a nationwide company providing general optometric services. The service provides refractive eye surgery for adults only, aged 18 years and above. The clinic is based on the ground floor within Bluewater shopping complex.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 24 November 2017 and an unannounced visit to the clinic on 8 December 2017.

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

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

Services we do not rate

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

We found the following areas of good practice:

- There were systems to record and manage incidents. Incidents were investigated and learnings were shared across the business to prevent recurrence.
- We observed a positive approach to completion of the safe surgery checklist in line with the world health organisation (WHO) 'Five steps to safer surgery'. On two separate occasions we observed the checks being made and all staff were present at the time and engaged with the checking process.
- There were good laser safety arrangements. Staff were trained in line with recommendations and evidence of this was kept on their personnel files. Laser machines were maintained in line with manufacturer's guidance and records of equipment maintenance were kept up to date.

Summary of findings

- There was sufficient staff with the skills and experience to manage patients' care and treatment. The staff worked well together to deliver the service.
- There was a programme of mandatory training. Staff were up to date with this training. All staff had received an appraisal and this formed part of their personnel development plan. This meant staff had the skills and knowledge to do their jobs.
- Patient records were accessible to staff, records were completed fully and were managed securely.
- Patients received care in line with national standards and guidelines. There were systems to measure patient's and surgeon outcomes. Results were shared and compared across the business.
- Staff treated patients in a caring and respectful way. Staff understood the anxiety of patients and were supportive and patients gave positive feedback about the service. There was a good system to capture patient feedback which was shared with staff.
- The service was planned and delivered to meet the needs of the patient. Patient preference was taken into account when delivering care.
- Complaints were managed in line with corporate policy. Learnings from complaints were shared locally and across the business.
- There was a clear organisational structure with clarity of roles and line management. Staff knew who

their line manager was and managers were seen to be approachable and supportive. There was a vision and mission statement that was visible at the clinic which all staff were aware of.

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

- The consent policy should reflect the Royal College of Ophthalmologist 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Flooring in the back corridor had some small breaks in the surface and sinks in the toilets and dirty utility area were corroded and might present an infection risk. This risk was not identified in the local risk register.
- Patient information leaflets were not available in different languages and there was no formal access to translation services or an interpreter.
- There were no systems to formally capture staff feedback.

Following this inspection, we told the provider that it should make improvements, even though a regulation had not been breached, to help the service improve.

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Refractive eye surgery

Rating

Summary of each main service

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-Bluewater Clinic

Services we looked at;

Refractive eye surgery

Summary of this inspection

Background to Optical Express - Bluewater Clinic

Optical Express Bluewater Clinic is operated by Optical Express Limited. The clinic opened in 2005. The clinic primarily serves the communities of London and South East England. It also accepts patient referrals from outside this area.

The clinic has had the same registered manager in post since 2013.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and another CQC inspector. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection.

Information about Optical Express - Bluewater Clinic

Optical Express Bluewater is registered to provide the following regulated activities.

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

The clinic is based on the ground floor of a shopping complex. Patients are self-referring and self-funded. The clinic provides refractive eye surgery. Ophthalmic surgeons carry out the treatment. The clinic provides the service approximately eight days a month.

During the inspection we visited all areas of the clinic. We spoke with nine staff including registered nurses, technicians, medical staff and managers. We spoke with four patients and one relative. During our inspection, we reviewed three sets of patient records and three staff personnel files. We followed two patients through their treatment.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected once before, and the most recent inspection took place in August 2013 which found that the service was meeting all standards of quality and safety it was inspected against.

Activity

- In the reporting period September 2016 to August 2017 there were 1,740 refractive eye surgery procedures carried out. All these cases were privately funded.

There was not a specific surgeon who was based at the clinic. Surgeons were employed by Optical Express and were allocated to clinics for laser treatment days. Other staff employed by Optical Express would attend the clinic for treatment days including the surgery manager, one registered nurse and two technicians.

Track record on safety (September 2016 to August 2017)

- There were no reported never events.
- One clinical incident of low harm. There were no serious injuries reported.
- There were no incidences of hospital acquired Meticillin-resistant *Staphylococcus aureus* (MRSA), Meticillin-sensitive *Staphylococcus aureus* (MSSA), *Clostridium difficile* (c.diff) or *Escherichia coli* (E-Coli).
- There were 16 complaints received by the clinic.

Services provided at the hospital under service level agreement:

Summary of this inspection

- Clinical and or non-clinical waste removal
- Cytotoxic drugs service
- Laser protection service
- Maintenance of medical equipment
- Uninterrupted power supply

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate refractive eye surgery.

We found the following areas of good practice.

- There were systems to manage incidents. Incidents were investigated. There was evidence that learnings were shared across the business. This ensured that the risk of recurrence of an incident that occurred at this location or elsewhere in the company was mitigated.
- We observed a positive approach approach to completion of the safe surgery checklist in line with the world health organisation (WHO) 'Five steps to safer surgery'. On two separate occasions we observed the checks being made and all staff were present at the time and engaged with the checking process.
- There was sufficient levels of staff with the skills and experience to manage patients' care and treatment.
- There was a program of mandatory training to ensure staff had the skills to do their jobs. Staff were up to date with their mandatory training and were given time to complete training.
- There were good laser safety arrangements. Staff were trained in line with national recommendations and evidence of this was kept on their personnel file. Laser machines were serviced regularly and maintained according to manufacturers' guidance. There were accurate maintenance records kept.
- Patient records were completed fully and were accurate. Staff could access records which were managed securely.

However

- Flooring in the back corridor had some small breaks in the surface presenting an infection risk.
- Sinks in the toilets and dirty utility area were corroded and needed attention as they presented a risk of infection.

Are services effective?

We found the following areas of good practice

- Patients received care in line with national standards and guidelines there were systems to measure patient and surgeon outcomes. Outcomes were compared across the service and were in line with other centres.

Summary of this inspection

- There were suitably trained and competent staff to deliver and manage the service. All staff had received an appraisal as part of their development.
- The staff worked well together as a team to deliver care to patients.

However

- Staff sought consent from patients prior to the procedure. The consent policy should reflect the Royal College of Ophthalmologist 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.

Are services caring?

We found the following areas of good practice

- Staff treated patients in a caring and respectful way, addressing them by name and escorting them to appointments and treatments.
- Staff understood the anxiety of the patients waiting for treatment. We observed them being supportive to patients during their treatment.
- Patients said were involved in the planning of their .They gave us gave positive feedback about the service and this was reflected in the provider's patients surveys.

Are services responsive?

We found the following areas of good practice

- There was flexibility in the planning and delivery of the service to meet the needs of the patient. Patient preference about location and time when the treatment was to be undertaken was taken into account.
- Complaints were managed in line with corporate policy. Learnings from complaints were shared with the clinic staff and across the rest of the business.

However

- There was no provision to meet the communications needs for people whose first language was not English. Patient information leaflets were not available in different languages. There was no formal access to translation services or an interpreter.

Are services well-led?

We found the following areas of good practice

Summary of this inspection

- There was a clear organisational structure with clarity of roles and line management. Staff spoke of their managers as being approachable and supportive.
- There was a clear vision and mission statement that staff were aware of. They were displayed around the clinic for patients' information and to remind staff.
- Governance systems supported the service and reviewed patient outcomes. Governance review meetings were held on a regular basis and minutes were shared with staff.
- There was a good system to capture patient feedback which was shared with staff and used to consider improvements.

However

- Local risks relevant to the location were not always reflected in the risk register. For example the small superficial breaks in the back corridor flooring that might present an infection risk, the damaged and incomplete flooring in the storage room were not listed.
- There were no systems to formally capture and record staff feedback. However, there were informal systems which enabled staff views to be taken into account.

Refractive eye surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The service had an incident and near miss policy. This was an Optical Express corporate policy that covered staff responsibilities in reporting and investigating incidents. During our inspection staff were able to explain incident reporting and how they received feedback at their local team or regional meetings.
- Optical Express Bluewater did not report any never events or serious incidents in the last twelve months prior to our inspection. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- We looked at records for the past twelve months prior to the inspection and saw there was one reported incident at Optical Express Bluewater which was of low risk and involved the management of a nervous patient. This incident had been investigated and the learnings about clear communication with patients had been shared with clinical staff.
- All incidents or complaints were collated by the clinical services department at head office and a report of all incidents could be accessed at any time. A serious incident had occurred at another clinic. A root cause analysis was completed and learnings were shared with the staff at Optical Express Bluewater. Staff belonging to the surgical team had signed the incident report to indicate that they had read this.
- The surgical services manager had received training and was responsible for the root cause analysis (RCA)

into any relevant incidents. RCA are investigations to identify why and how safety incidents happen. The manager considered any control measures that needed to be put in place and was responsible for ensuring this was shared across the business. This was evident in the incident we reviewed.

- Information would be shared across the business by use of a surgical services directive that was sent to each location, we saw that staff signed the directive as evidence that it had been read.
- Team briefing involving all staff was undertaken on all treatment days and this included safety issues and learning from incidents. We saw that incidents was a standing agenda item on the quarterly regional team meetings.
- 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 was a corporate duty of candour policy.
- There had been no incidents at the clinic that fitted the criteria for the duty of candour process. Staff we spoke to were able to tell us what the process for duty of candour would be and explained it was to be honest and open about any incidents affecting patients. All ophthalmologists signed a self-declaration of duty of candour agreeing that they will exercise this when necessary and this was stored on their personnel files.

Mandatory training

- The clinic followed the Optical Express staff training, development and appraisal policy which stated that mandatory training for staff consisted of eleven modules delivered online. The training requirement was reviewed every three years. Training included

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infection prevention and control, fire safety, health and safety, moving and handling, safeguarding for adults and children, information governance and conflict resolution. There was guidance on the required frequency of the training.

- Basic life support training was completed annually by all staff. Nursing and support staff were not trained in intermediate or advanced life support as the treatment at the clinic did not include general or local anaesthetic other than the use of eye drops.
- The training matrix available at the service showed that of the four staff allocated to this clinic, two had completed their training and two had recently started in post (within the last two months) and were in the process of completing their training.
- Staff confirmed that they were given time to complete their mandatory training and that the training was well presented.

Safeguarding

- There was an up-to-date safeguarding children and vulnerable adult policy which covered staff responsibilities, types of abuse and action to be taken in case of suspected abuse of patients or visiting children. There was a corporate safeguarding lead providing advice and oversight.
- The clinic had local contact details for the local safeguarding board, police and care quality commission.
- Safeguarding was included in mandatory training. All clinic staff had level two adult safeguarding training and although there were no patients under the age of 18, level two child protection training was undertaken.
- The surgery manager was trained to adult safeguarding level three, who was also the lead for safeguarding at the location and monitored that staff had completed their training.
- Staff spoken to were aware of the safeguarding policy and training but had not had an occasion when they needed to report a concern. No safeguarding concerns were reported to the CQC during the year up to our visit.

Cleanliness, infection control and hygiene

- The location had no incidences of a healthcare acquired infection in the last 12 months prior to our inspection.
- The environment in the treatment and clinical areas was seen to be clean and tidy. Two of the patients spoken to who had completed their treatment described the environment as clean, tidy and functional.
- There was a corporate overview of the infection prevention and control policy that detailed staff responsibilities and how to minimise the risk of infection. There were associated policies on the use of single use items, aseptic technique, traceability and recall. This demonstrated an awareness of hygiene and risk within this specialised service.
- Staff we spoke to confirmed that they had completed their on line training in infection prevention and control and this training was repeated every three years.
- We saw the most recent observational hand hygiene audit. This showed staff were fully compliant with policy and our observation during the inspection was that hand hygiene was carried out appropriately. Staff were bare below the elbow which assisted with enabling good hand hygiene.
- Throughout the clinic there was adequate supplies of hand gel. The guidance "How to hand rub with alcohol based formulation" by the World Health Organization (WHO) dated 2009 was displayed in the clean and dirty utility areas.
- We observed that there was a good supply of personal protective equipment (PPE) such as gloves and these were used appropriately and changed between patients and disposed of correctly. All staff wore disposable scrubs and staff had their hair tied back and wore a disposable theatre cap during patient treatment.
- Staff used disposable, single-use instruments, to eliminate the need for decontamination. Waste bins were operated via hands-free openings. Suitable waste bins were available for sharps and waste. A service level agreement was in place for collection and disposal of clinical waste.

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- Weekly housekeeping cleaning checks were complete and daily cleaning checklist was completed on treatment days. We saw that the monthly cleaning log was completed and signed and dated for the past six months.
- There was a daily surgery checklist completed every treatment day which included, checking all patient areas, ensuring cleaning lists were complete and that adequate scrubs were available for staff. Staff checked the availability and date of stock. During the inspection we checked 12 items of stock and found them to be in date.
- In the room where the laser was being used we saw that the temperature and humidity was continually monitored and recorded, staff explained this was to ensure the optimum function of the laser. There was a fire extinguisher located in this area.
- Water temperatures in the clean and dirty utility areas were checked once a month. There was a range which the temperature should be within and actions to be taken if outside of this range. All checks we reviewed were complete.
- Water flushing was completed in line with the clinic's policy for managing the risk of legionnaire's disease. Legionnaire's disease is a lung infection caused by legionella bacteria which is spread when water supplies become contaminated
- with bacteria which is more likely in larger more complex water systems such as those found in clinics or hospitals. The results for the tests taken at the clinic in the two months prior to our inspection showed no Legionella contamination.
- We observed that sharps management complied with Health and Safety (Sharps Instruments in Healthcare) Regulations 2013. We checked three sharps bin containers and all were clearly labelled to ensure appropriate disposal and traceability. There was information displayed in the main treatment area of actions to be taken in the case of a sharps injury.
- We observed waste to be appropriately segregated and disposed of in accordance with local policy.
- The vinyl flooring in the back corridor which patient's accessed for the toilets was marked but on checking was clean. There were some small superficial breaks in

the flooring surface, so this was not intact and might present an infection risk. This was highlighted to the surgical services manager at the time of the inspection. We did not see this detailed on the local risk register.

- We noted that the sinks in the dirty utility area and toilets were corroded and needed further cleaning or replacement. We did not see this detailed on the local risk register.
- The floor in the clinic store room was not intact with an area of bare concrete. On asking we were told that this was to be repaired. There was no stock on the floor areas. On our return visit the floor had been repaired and was intact.

Environment and equipment

- Patients entered through the main Optical Express shop entrance where the main reception was located. From the main reception patients for consultation and treatment were escorted to the rear of the optical shop. They were directed to a second small reception area which led onto a waiting area specific for patients having treatment. All the treatment and consultation rooms led off the main corridor and were located on the ground floor.
- We looked at all clinical areas including the laser treatment room which had connecting clean and dirty utility areas, surgeon's examination room, discharge room and screening room. These areas were visibly clean, tidy and free from clutter.
- The main treatment area contained two lasers, these were maintained under a contract which provided an annual service, quarterly engineer checks and an emergency call out service.
- There was a maintenance folder which held evidence of service checks made on equipment. For example; we observed there was evidence of annual checks being made on fire extinguishers, three monthly laser servicing and electrical safety testing annually.
- The laser room was visibly clean and tidy and precautions had been taken to meet the requirements of the local laser rules. The control area was clearly defined and with warning lights that were illuminated when the laser was turned on, so staff and patients

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knew not to enter when the laser was in use. The room was accessed with a keypad entry and only clinical staff knew the code. There were no windows in the laser room and reflection hazards were minimised.

- We observed that before each treatment the laser technician performed safety and calibration checks. The machines also had safety warnings and failsafe cut-outs built into the laser software. We observed the checklists had been completed and signed by staff.
- The location had a contract with an external laser protection advisor (LPA) who was responsible for undertaking risk assessments, providing advice and training on laser safety. The LPA had developed the local rules and these were reviewed on a three yearly basis. We saw the current rules were in date, signed by all staff and contained information on responsibilities, control of hazards and risk assessments. Staff were able to tell us the purpose and where to find the local rules.
- The most recent visit by the LPA was in June 2016 and we saw that a full risk assessment had been done of both lasers. Alongside this was a register of authorised operators and support staff.
- After the completion of each patient treatment, all details of the patient, the laser operator and procedure carried out were recorded in the laser register. Records were seen to be completed and legible.
- Staff told us that stock was easy to obtain in the clinic and they have all the resources they needed to do their job.
- We saw there were security measures with all clinical rooms secured with a keypad lock which would prevent non-clinical staff entering the clinical areas and ensured the privacy of patients who were being seen by staff.

Medicines

- The service had a corporate medicines management policy in place. This was up to date and accessible to staff via the organisation's electronic system and a hard copy was available. There was an up to date British National Formulary (BNF) available so staff could access information about any medicines.
- Managers stated that no controlled drugs, injectable sedation or injectable local anaesthetic blocks were used and no cytotoxic medicines were prepared on site. The Ophthalmologist prescribed all medication given, this was predominantly eye drops.
- The registered nurse was responsible for ordering, receiving, recording and storing of medicines. Medicines were ordered from a third party supplier and we saw there was a service level agreement to support this process.
- The medicine policy set out the requirements for training and the completion of competencies for the nurses and technicians. Competencies included identifying the BNF, preparing drops to take home and how to install eye drops. All staff at Optical Express Bluewater had completed medication competencies with managers assessing registered nurses and nurses assessing technicians.
- Two patient discharges were observed and these were carried out in line with the local policy. The registered nurse dispensed the eye drops and checked the drops and prescription with the technician. The technician discussed with the patient the eye drops and aftercare. There was written aftercare instructions which contained pictures to make it clear how eye care was to be managed.
- The service had an up to date mitomycin policy. When mitomycin eye drops were administered we saw there was a consent form which stated that this drug was used off license and there was a risk of systemic absorption. Mitomycin is a cytotoxic drug which means they contain chemicals which are toxic to cells. The preparation used at Optical Express Bluewater was pre-prepared prior to delivery and there was a Control of Substances Hazardous to Health (COSHH) assessment completed. The procedure to follow in the case of spillages was covered in the policy.
- On treatment days, prior to any procedures being carried out, the fridge temperatures were checked and recorded and were seen to be within normal range. There were instructions for what should be done if the temperatures were found to be outside the recommended range.
- The emergency drugs that were kept with the emergency equipment were the type that might be used

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in the case of an anaphylaxis reaction, which is a serious allergic reaction that is rapid in onset and may cause death. These drugs were stored in the clean utility room in a c

- container within a room that had keypad access. We saw that the local medicine policy had risk assessed how the drugs were stored and as these drugs may need to be used quickly they were not stored within a locked cupboard. We saw that the stock of drugs were checked on treatment days.
- All drug alerts were sent to the surgical services manager and there was quarterly distribution of information to staff. The most recent alert to be shared with staff was a recent Royal College of Ophthalmology alert informing staff about the shortage of a particular brand of eye drops.
- The clinic had a medical gas cupboard located away from patient access; all cylinders were stored upright and chained securely.

Records

- The service had an information and records management policy that set out the responsibilities of staff in correct completion, storage and management of all patient records. There was detail of the corporate Caldicott Guardian and information governance lead. At local level, the clinic manager was designated as responsible for the completion and secure storage of all records. All staff attended information governance training.
- The service had an electronic medical record system and a hard copy of patient records. On the day of treatment the information from the hard copy file was also entered onto the electronic file.
- The records were stored in a locked filing cabinet in an office that was secured by a key pad. The hard copy of records was archived off site as soon as possible and a fulltime archivist managed this process.
- We looked at three sets of patient notes and found these to be complete, dated and signed. Records were legible, accurate and up-to-date. Medication charts had any patient allergies documented. Labels including the patient's name and date of birth were on each page.

- A quarterly audit undertaken in October 2017 of ten sets of patient records was completed showed that one set of notes did not have a fully completed safe surgery checklist. There was an action plan to address this. Staff had signed to say this was complete.
- Staff managed patient information securely and computer screens were locked when staff left their work station.
- Discharge information about the procedure and aftercare was given to the patient and they were then able to pass this onto their GPs if they wished to do so.

Assessing and responding to patient risk

- Prior to the patient having laser treatment, patients were assessed for their suitability for treatment. Checks included completion of a health questionnaire and eye examination.
- Patient health questionnaires were reviewed by the ophthalmologist and discussed with the patient when consent was discussed. All patients were seen by the ophthalmologist prior to treatment being undertaken.
- We observed that a team brief was carried out every morning prior to the beginning of treatment. The briefing covered the order of patients for the day and any changes that might be made to that list. Consent completion was checked. Safety checks included checking that all staff had completed basic life support training and recording any current alerts that staff needed to be aware of.
- At the end of the day there was a documented debrief about any concerns. We saw that the briefing sheet was then signed by all staff.
- Staff used an adapted version of the World Health Organisation (WHO) surgical safety and five steps to safer surgery checklist prior to the procedure. On two separate occasions we observed the checks being made and all staff were present at the time and engaged with the checking process. The checklist was fully completed.
- A safe surgery checklist audit was completed quarterly alongside the records audit. The results for October 2107 showed that out of ten sets of notes, one patient record did not have a fully complete WHO checklist; as there was one signature missing. There was an action

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plan to remind all staff that all forms should be fully completed and there was evidence that this was discussed at the team meeting and staff signed the minutes of the meeting.

- We observed that the parameters being set on the laser were checked on three separate occasions against the prescription and before treatment was carried out. These checks were carried out by a minimum of two staff and were signed as complete in the patient records.
- Following the procedure patients were taken to the discharge room, offered refreshments and were encouraged to stay until they felt well enough to go home.
- There was eye wash available for use in the case of any splashes of irritant solutions to patient or staff eyes.
- Before discharge the patient was given a phone number to use out of hours in case they had a query or concern. This information was written on the aftercare advice leaflet which staff went through with the patient before they left the clinic. Patients were told to contact the clinic with general non-urgent queries in working hours.
- The clinic's telephone was manned centrally and passed to the clinical teams in the event of a clinical query. Out of hours, the phone was manned by one of the optometrists who was able to call the operating surgeon out of hours for advice.
- The ophthalmologist was trained in basic life support. The policy in the case of patient collapse was to call 999 and to maintain basic life support until emergency services arrived. Staff were aware where the emergency equipment was stored.
- Emergency equipment was checked at the start of each surgery day and checks were recorded in the emergency checking log and included checking call bells. Equipment consisted of basic airway support, oxygen, a face mask and tubing. There was no access to an automated defibrillator which the staff told us they had been trained to use and was being considered for purchase.

Nursing and medical staffing

- Nursing staff arrangements were dependant on when the clinic opened and this was dependant on patient demand. There were no set days when the clinic opened and staffing was organised centrally as the surgical team worked across the region.
- The organisations central scheduling team managed staff rosters, which meant the clinic had sufficient, suitably qualified staff to cover clinical days. Rosters were allocated one to two months in advance. The surgeon was allocated first and other staff were rostered according to treatment at the clinic.
- The Optical Express Bluewater clinic had a copy of a staffing levels document which specified the number and skill mix of staff for each procedure. The clinic manager explained the minimum staffing levels and the escalation process if staff were unable to work at short notice. For example any shortfalls in staffing would normally be covered by staff from another region.
- There were no staff vacancies at the time of our inspection and the clinic did not use agency staff.
- The operating theatre team comprised: a surgeon, a scrub practitioner and a laser technician. They worked with a pre- and post-operative technician. There was always a registered nurse on duty.
- The clinic manager was the laser protection supervisor (LPS) and was on site when treatment was taking place at the clinic. If the surgery manager was not in the treatment room during the procedure one of the laser technicians, who had undergone training, would be allocated to act as LPS on the day.
- There was one resident surgeon who formed part of a regional team covering other clinics nearby. This surgeon had completed the Royal College of Ophthalmology Certificate in Laser Refractive Surgery.

Major incident awareness and training

- We saw that all fire doors were unobstructed and exits were clear. Fire extinguishers were in place and were in date. We saw fire detectors and fire action notices were in place. The fire alarm system was checked weekly.

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- Fire evacuation was organised annually as part of the evacuation process that the Bluewater shopping centre undertook. Evacuation in the case of a bomb alert was also carried out annually.
- There was an uninterrupted power supply system in place to support lasers for at least thirty minutes in the case of an interruption of power and this meant patient treatment could be completed.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- Policies had been developed in line with the Royal College of Ophthalmology Standards for laser refractive eye surgery and the National Institute for Health and Care Excellence (NICE) guidelines in relation to refractive eye surgery. Staff we spoke to were aware that policies and procedures were accessible on the intranet and as a hard copy.
- Suitability guidance and treatment criteria were subject to critical review annually by the International Medical Advisory Board (IMAB). The IMAB comprised of refractive eye experts independent to optical express.
- The medical advisory board reviewed the guidance and treatment at their most recent meeting and staff had access to this guidance through the company website.
- Prior to surgery all tests were carried out in line with the NICE guidelines (NG45) Routine pre-operative tests for elective surgery. Patient's medical history was discussed and appropriate tests and scans were taken to help determine treatment.
- The service followed NICE guidance for photorefractive (laser) surgery for the corrections of refractive errors (IPG64). The surgeon made the appropriate tests and checks pre-treatment and was responsible for ensuring robust consent was obtained. Patients were supplied with information on the potential risks of the treatment and we observed that the ophthalmologist completed this check with the patient.

- Within the clean utility area there was a poster displayed of the 2017 NICE sepsis risk stratification tool so staff would be aware of how they could identify and escalate any concerns.
- Clinical managers carried out a monthly audit to check that infection control and health and safety checks were carried out. There was an action plan to address any areas of non-compliance and when action had been taken to address this it was signed by a staff member to show completion. The most recent audit check for November 2107 was complete.
- Staff told us they were kept up to date with any changes in practice through team or regional meetings or a written directive and there was evidence of a recent directive which all staff had signed.

Pain relief

- Pain relief was administered in the form of anaesthetic eye drops prior to treatment and was documented. We observed that patients were asked if they were in any discomfort during the procedure.
- Pain management was discussed both at the consent process and when the patient was speaking to the surgeon. There was an explanation of what discomfort the patient might experience and how this was best treated.
- There was further discussion and written information following the procedure about the use of anaesthetic eye drops and standard pain relief medication. Patients were given a 24 hour helpline number and advised to contact the service if they had any concerns.

Patient outcomes

- Optical Express had a biostatistician who produced outcome reports and analysis. Consultants were issued with the report annually but could access the data on line at other times. This was demonstrated during the inspection by the surgical services manager by accessing the intranet. Individual ophthalmologist results were used as part of their appraisal process.
- The data collected showed that patient demographics and preferred treatment was recorded. As patients attended follow up appointments a graph of the

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outcomes was recorded at one month, three months and twelve months. This was compared against predicted outcomes that were established when the patient initially attended the service.

- Enhancement procedures carried out by each ophthalmologist was scored and compared with other surgeons. Complication of surgery rates were monitored and compared across the business.
- Each ophthalmologist results were discussed at the Medical Advisory Board (MAB) where any necessary changes to effect and safety were reviewed and recommendations made.
- In the twelve months prior to our inspection no patients had an unplanned return to theatre following refractive eye surgery. There had been no patient transfers out of the clinic in the last 12 months
- The enhancement rate for patients at Optical Express Bluewater clinic showed 26 (eyes) enhancement procedures during the timeframe 01 September 2016 to 31 August 2017 where the primary treatment was undertaken during the previous twelve month timeframe. This was within the 5% occurrence rate that Optical Express expected.
- In the twelve months prior to inspection there were 153 complications, the most common being dry eye within six months of procedure that occurred in 57 eyes. This was in line with results from other clinics. Patient outcome results were discussed and documented at the MAB.
- A print out of the refractive patient experience questionnaire (PEQ) showed that Optical Express Bluewater results were compared with other Optical Express clinics. Results indicated that Bluewater clinic was in line with other clinics except for waiting times and this was being monitored and discussed at the regional meeting.
- At the time of the inspection the organisation did not contribute to the National Ophthalmic Database (NOD).

Competent staff

- Staff had access to the corporate Optical Express staff training, development and appraisal policy. This

contained information on the six week induction to be completed, including orientation, access to policy and procedures and role based training. Laser training requirements were included in the plan.

- The policy also stated the requirement for yearly appraisals, continual professional development, clinical supervision and reflective practice. The policy stated that support would be given to the staff in their revalidation process.
- Records showed that all staff had received an appraisal within the last twelve months. Staff told us that annual reviews were done by their manager and during this process they were able to discuss their training needs. One member of staff told us they had received support to complete their nurse registration revalidation.
- Staff told us there were opportunities to retain any specialist skills and learn new skills. Training needs were identified during the appraisal process. Laser training certificates for all staff were kept in their personnel files and showed that all staff had received core knowledge training for laser safety which was repeated every three years.
- We spoke to a new member of staff who spoke positively about the mentor support they had while completing their induction.
- Clinical staff completed role specific competencies, for example, clinical staff had completed medicine competencies relevant for their role and records of this training were kept on their personnel file.
- We looked at the training records for one ophthalmologist working at the clinic and saw an appraisal was completed annually by the medical director. Patient feedback and any legal enquiries were retained in their file.
- The medical director completed the appraisals for ophthalmologists employed by Optical Express. When the ophthalmologist had an NHS practice, a copy of their most recent appraisal was kept on file. Evidence of revalidation was in the file. We checked two staff personnel files and they contained a record of induction, mandatory and competence training.
- The surgery manager was the laser protection supervisor. Their personnel file held a copy of their

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most recent training for this role and we saw they had completed training and were certificated as competent for the laser protection supervisor role. They were subject to three yearly competency reviews to assess their skills and their knowledge of guidance.

Multidisciplinary working

- We observed good multi-disciplinary working between all staff at the clinic. Staff told us they worked well together as a team and each member of staff was aware of their role within the team.
- Monthly team meeting minutes showed that all members of the surgical team attended. The purpose of the meeting was to support team working and share learnings across the disciplines. Feedback from the regional meetings was discussed at team meetings.
- Staff worked at other branches of Optical Express which demonstrated flexibility and consistency. Staff told us they enjoyed the variety and that they all worked well together as a team.

Access to information

- We looked at how staff accessed patient information and observed hard copies of the patient record was available on the day of treatment but was archived soon afterwards.
- Electronic patient records were password protected but staff had access to specific parts of the pathway dependent on their role. If a patient attended another branch of Optical Express for treatment or follow up, staff were able to access their electronic file.

Consent and Mental Capacity Act

- There was a corporate consent policy dated September 2017 which detailed staff responsibility in gaining valid consent. This stated the surgeon's responsibility in gaining consent and assessing capacity of the patient. The consent policy should reflect the Royal College of Ophthalmologist 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- Staff described the consent process as multi-layered. Often the optometrist was the first member of staff to discuss the procedure with the patient and gave them relevant procedural information, a consent form and a

document detailing terms and conditions which set out the costs of the procedure. The patient then viewed a video of the risks and benefits of laser treatment and signed to say they had seen this.

- The surgeon saw or telephoned the patient to talk them through the procedure and to discuss consent. Staff told us this would be carried out seven days following initial consultation allowing the patient time to consider options before deciding to proceed.
- On the day of treatment we observed on two occasions the surgeon meeting the patient prior to treatment, verbal information was given again about the procedure including risks and benefits, there was an opportunity for the patient to ask any questions, the patient then signed an electronic consent.
- Staff had undergone Duty of Care training which contained information about consent and the Mental Capacity Act (2005). Staff were able to explain the process of consent and the assessment of capacity.
- In the three sets of patient records we reviewed it was recorded that patients had received procedural information, received consent information and the consent form was complete.

Are refractive eye surgery services caring?

Compassionate care

- We observed that staff at the clinic treated patients in a professional and caring way. Staff introduced themselves and escorted patients to their consultation or treatment.
- The service had individual consultation and assessment rooms, which enabled staff and patients to have private discussions.
- There were notices informing patients that they could ask for a chaperone for their consultation if they wished.
- We observed two surgical procedures. The surgeon explained the procedure in non-technical way that the patient understood including what to expect during

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the procedure and afterwards time was given for any questions to be asked. We observed that during the procedure the patient was reassured and checks were made that they were comfortable.

- Thank you cards were on display in waiting room with positive patient feedback including comments on the caring attitude of the staff.
- Patient feedback was collected at various times during their treatment. The surgery experience questionnaire was completed twenty four hours post treatment. Each month the patient feedback results were provided to the clinic manager. The results were benchmarked against the company average.
- Patient satisfaction results for the last six months were displayed in the reception area which showed 99% of patients would recommend the service to a friend and 99% achieved better vision.

Understanding and involvement of patients and those close to them

- During a patient consultation we observed the patient's questions were answered and the benefits and risks of procedure were explained. Explanations were not rushed and patient understanding was checked at regular intervals.
- Staff told us that they positively encouraged patients to bring a relative or friend with them. We observed that the accompanying person also had their questions answered. Aftercare was discussed pre-operatively with patients and relatives to ensure appropriate caring arrangements were in place. This reflected patient centred care and that patient individual needs were taken into consideration.
- On two occasions we observed a staff member going through the discharge procedure. Staff were smiling, calm and reassuring. The explanation of the procedure was thorough. The aftercare information also contained photos to simplify the explanation. A relative was encouraged to be present and the patient was asked if they had any questions.
- One patient who had a consultation described a good service. They were given sufficient information to know what to expect and commented that "every question has been answered".

Emotional support

- Staff demonstrated in the way they spoke to patients that they understand that some patients were very anxious. They were able to explain how they would reassure patients.
- We observed two procedures and during treatment we observed that one staff member was responsible for supporting the patient by talking to them. Following the procedure both patients told us that they found this very reassuring.
- We observed a member of staff helping a patient who had questions about the health questionnaire and consent, the staff member sat down and took time to explain both documents to the patient.
- The clinic provided clear information on pricing for refractive eye surgery. Following surgery patients were given written information on how to care for the eye post procedure. Staff were seen to check that patients understood the information they were given.
- When booking a patient in for treatment, care was taken to promote the patients right of choice including where to have the procedure done.

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

Service planning and delivery to meet the needs of local people

- The service was designed to provide refractive (laser) eye surgery for adults, from across London and the south east. It also accepted patients from outside of this area. All appointments and treatments were pre-planned. The Optical Express corporate website gave information on how services could be accessed.
- The optometrist carried out consultations for refractive eye surgery working with the Optical Express clinical suitability guidance document which supported an initial screening to assess if the patient was suitable for a refractive procedure.
- The patient received an information pack which contained information about the procedure, the way

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to give consent and a terms and conditions documents. This included information on who to contact for more information and the complaint procedure.

- If more complex surgery was required this could be carried out at another Optical Express clinic, taking into account patient's preference.
- Staff told us that if a specific date for treatment was required and could not be accommodated at Optical Express Bluewater the patient was able to attend another site. The aim was to meet the patient needs in a flexible and timely way.
- Every Monday, operational meetings were held to discuss the planning and delivery of services for all the optical express locations.

Access and flow

- Patients were able to access the service by self-referral without a GP or optician's referral.
- There was no waiting list for treatment and in the previous twelve months prior to inspection there were no cancelled procedures for a non-clinical reason.
- Treatment days were organised in response to patient demand and in an average month there would be between six to nine treatments sessions organised.
- Any missed appointments were followed up with a phone call or email and rescheduled as soon as possible.
- If the patient experienced any complications they would be asked to attend so they could be seen by a consultant.
- On discharge the patient received information about the central help line that would advise on any actions to be taken and direct the patient where to get an appointment if required.
- We spoke to four patients over the course of our inspection and all commented that staff were welcoming and reassuring. They commented that there was no waiting around and described the process as very efficient, they added that the staff were informative and the process was well explained and staff took time to ensure they understood what to expect.

Meeting people's individual needs

- Staff told us that at initial consultation they would assess the patient to identify any specific individual needs. Any patients with complex needs such as dementia or learning disabilities were likely not to be seen as suitable for treatment at the clinic; each case would be assessed on an individual basis.
- As all services were located on the ground floor and there was good access for patients with limited mobility or using a wheelchair. Staff told us that patients who required assistance could be accommodated as generally areas were large enough for wheel chair access.
- Toilets were located close to the waiting area and there were designated ladies and gentleman facilities. There was one toilet appropriate for patients with a disability.
- The waiting room was of an adequate size with plenty of seating for patients and their relatives. Two of the patients we spoke to told us the waiting room was comfortable and there was access to hot and cold drinks, magazines and information leaflets.
- Staff told us that that they ask patients with communication restrictions, this could be a hearing, language or literacy issue to bring someone with them for every appointment.
- The pre-treatment information contained a clear explanation of what patients could expect during surgery and was in line with the Royal College of Ophthalmologist Professional Standards for Refractive Surgery (April 2017).
- However, all patient information and consent forms were only available in English and there was no access to translation services or an interpreter. Patients were asked to bring a relative or friend with them which is not best practice as staff need to be assured that translation presents information in an objective and appropriate way.
- The reception and waiting area was clean and tidy, with television, magazines and chocolates. Patients told us that they thought this was a comfortable area.

Learning from complaints and concerns

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- The service had a corporate complaints policy which provided guidance on the management of verbal and written complaints. This included how complaints should be responded to and timescales for acknowledgement and response.
- The patient's consent form and terms and conditions document contained information on how to make a complaint. We observed a notice at reception with a summary of the complaints process, for example who to raise the complaint with. There was information on how to contact the CQC.
- If a verbal complaint was made the clinic manager told us they would try to resolve the issue as soon as possible. If complaints could not be resolved locally, the central services department would manage and had access to a solicitor if required.
- The patient's electronic file was updated with any complaint details and this was visible to the clinic manager who was able to monitor progress.
- For the twelve month period prior to the inspection, September 2016 to August 2017 there were 16 complaints. Complaints were graded according to severity and reason. Themes included terms and conditions (four) and quality of vision outcome (four).
- Written complaints were managed in line with policy by the clinical services department who would acknowledge the complaint within two working days, co-ordinate investigations and reply to the complainant. A full reply to the complaint was to be completed within 20 working days. The clinic manager would monitor the progress of the complaint and act on any lessons learnt at a local level.
- Lessons learnt were shared with clinic staff, for example one complaint was investigated and demonstrated a failure by medical staff to contact a patient in a timely way when they had rung the clinic for advice. The outcome showed the medical director had addressed this directly with the member of staff. The complaint and outcomes was circulated to the staff at Optical Express Bluewater and we saw that staff signed the directive to demonstrate they had read this.

Are refractive eye surgery services well-led?

Leadership and culture of service

- Optical Express is owned by an individual who fulfils the role of Chief Executive Officer (CEO). This role is supported by optometry directors, operations director and the clinical services team which consisted of the refractive operation manager, surgical services manager and location surgery manager.
- The surgery manager is the registered manager at Optical Express Bluewater clinic and their line manager is the surgical services manager.
- Staff we spoke to were aware of the corporate management structure and were clear who they reported to within the structure. Staff told us that managers were visible, approachable and supportive.
- Ophthalmologists were managed by the medical director who reported directly to the CEO.
- Staff we spoke to told us that the surgical team worked well together and that was why a majority of the staff had worked as part of the team for several years. Staff were most proud of being patient centred in their work and told us they would not change anything.
- They described a good work environment and some staff were able to work flexibly which worked well with their personal circumstances. All staff were happy with the working arrangements of rotating to work at other clinics nearby. The surgery manager worked with the same team at other clinics and therefore staff had consistency in their leadership.
- We observed that advertising information was honest and complied with the guidance from the Committee of Advertising practice and Royal College of Ophthalmologist standards published in 2017. Patients received a statement which included terms and conditions and that information was clear and detailed covering amendments to treatment, exclusions, cancellations and details on the complaints policy.

Vision and strategy

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- Staff we spoke to told us that the vision was to grow the business and be the best provider of eye care. On all computers there was a vision and mission statement which stated the vision was to lead in global elective and healthcare industry through using the most advanced technologies and by working with leaders in the healthcare industry.
- The vision, mission and statement about the contributions of the teams was clearly displayed in the reception areas and staff understood these statements to be relevant to their service and care of the patient.
- The service set up the first International medical advisory board. The board was made up of experienced refractive eye experts with no link to Optical Express. The board met annually to review the organisations data and clinical protocols.
- We reviewed the minutes of the most recent surgeons' meeting held on 23 November 2017. This forum discussed clinical and patient outcomes reported and compared results across the clinics. Results of a recent consent audit were discussed and compliance to the audit was seen to be 98%. In addition there was a review of multi-disciplinary working and standards of record keeping.
- There were policies to support governance structures including incident management and information governance. Risk management was explained in the welfare and safety of patients and the management of risk policy. The policy referred to staff training, team meetings and the maintenance of local risk registers and developing a safety culture.
- The risk register was seen to hold practice risk, general environmental or resourcing risk. There was a risk matrix and all risks were scored and there were control measures and actions in place.
- There were separate health and safety risk assessments, for example the safe storage of cables in the treatment rooms where lasers are stored. Actions had been taken to avoid slips trips and falls in this area but it remained on the risk register. However, local risks relevant to the location were not always reflected for example the small superficial breaks in the back corridor flooring that might present an infection risk, the damaged and incomplete flooring in the storage room were not listed.
- In the three staff files we reviewed there was evidence that all required pre-employment checks were completed.

Governance, risk management and quality measurement

- The local lead for governance, risk management and quality measurement was the surgery manager, supported centrally by the surgical services manager and clinical services director, reporting directly to the CEO.
- Three groups make up the governance structure the international medical advisory board (IMAB), medical advisory board (MAB) and the clinical governance group.
- The MAB had a multi-disciplinary membership, senior managers were involved including the clinical services manager. Minutes of this meeting showed review and discussion of the Royal College of Ophthalmologist guidelines, patient outcomes and suitability criteria.
- Staff told us that they receive feedback from the governance meeting either at the regional meeting or through written clinical directives that would detail any learnings, audit results or new processes. The most recent regional surgery team meeting minutes showed discussion of team brief, cleaning standards, patient feedback and health safety. We could not see a review of audits or patient complaints which did not give assurance that there was an overview of these areas.

Public and staff engagement

- The service had a website where information could be found about refractive eye surgery. This information included details about a free consultation, which treatment options might be available and the cost of procedures.
- The website was easy to navigate and included the patient's pathway and testimonies from patients who had completed treatment. Other social media such as twitter was used to promote Optical Express. In addition there was access to research on the website for different types of eye surgery.

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- Optical Express also collated patient feedback which was collected when patient returned for a follow up appointment, twenty four hours post procedure, after one month and after three months and a year. Patients were able to leave feedback at various points of the patient journey either at the clinic or on the website. The level of patient response was just under 40%.
- Although the clinic had not had any feedback from patients that had initiated change, the organisation had reviewed its appointment scheduling as patients had feedback at other clinics that they were anxious if there was a wait between diagnosis, being seen by the consultant and treatment.
- Staff told us they were encouraged to feedback to their line managers any changes that they felt would improve the service.
- There was a staff recognition and reward scheme called 'Wonderful Wednesday'. This scheme would recognise an individual or a team that had delivered good practice. Staff were aware of this scheme.

Innovation improvement and sustainability

- The medical director was one of the eleven members of the refractive surgery standards working group (Royal College of Ophthalmologists) who published the latest guidance 'Professional Standards in refractive surgery' (April 2017).
- The organisation did not conduct staff surveys but the surgical services manager told us there was a pilot survey in progress at another clinic. In addition, the organisation planned to introduce a Freedom to Speak up Guardian, although there was no requirement for it to do so, to enable its staff to raise concerns.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

Action the provider **SHOULD** take to improve

- The consent policy should reflect the Royal College of Ophthalmologist 2017 for a 7 day cooling off period between the initial consent meeting with the surgeon and the final consent by the surgeon.
- The risk register should reflect all local risks, including actions taken to mitigate the risk and a date for review.
- The flooring in the back corridor and the sinks in the toilet and dirty utility room should be risk assessed in line with infection prevention and control guidelines. There should be remedial action taken.
- Patient leaflets should be offered in languages other than English, and there should be formal arrangements for interpretation services.
- The provider should consider how it formally collects staff views and feedback.