

Optimax Laser Eye Clinics - Newcastle

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Optimax Laser Eye Clinics - Newcastle is operated by Optimax Clinics Limited.

The Newcastle clinic is situated near to the Tyne Bridge in Newcastle city centre. The Newcastle clinic was opened in 1996 for the purpose of assessing for, and treatment of, laser refractive eye surgery for patients aged 18 and over.

The clinic facility is situated on the ground floor of a listed building accessed by some stairs from the main street. Facilities include a large open plan reception and seating area, two consultation rooms, an eye testing room (topography room), a private counselling area, a preparation area, a recovery room and the laser room. There is no private parking facility.

For patients requiring assistance to enter the facility, staff provided an access ramp. There were no designated disabled toilet facilities. The facility provided a hearing loop and free hot and cold drinks.

The service provided laser refractive eye surgery and follow-up care following procedures at other Optimax facilities. If a patient required specialist care or surgery not provided at the facility, patients were duly referred to another clinic.

We inspected the laser refractive eye surgery service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 26 October 2017 along with an unannounced visit to the location on 10 November 2017.

We spoke to six members of staff including the medical director/surgeon, the clinic manager, the clinic supervisor, the optometrist, the laser room assistant and administrative staff. We reviewed five sets of patient records (paper and electronic) and spoke to five patients. We observed the care pathway from initial enquiry, pre-consultation, eye examinations, surgical assessment, the laser procedure and aftercare.

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.

Services we do not rate

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

We found the following areas of good practice:

- There was a caring and compassionate patient-centred culture at the Newcastle clinic.
- Services were safe and ensured patients were protected from avoidable harm.
- Care and treatment received by patients was provided by competent staff following national guidance and professional standards.
- Patient outcomes were good and this was reinforced by very positive patient feedback.
- Patients were informed, empowered and understood treatment options available to them along with potential risks and intended benefits of chosen procedures.
- Local leadership and management was effective and there was a strong collaborative team working approach to service provision at the Newcastle clinic.

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

- Medicine training with particular attention to the management of cytotoxic medicines and dispensing requirements.
- Extended role training procedures to ensure those staff remained competent and up to date with best practice and professional guidelines.
- Access for persons living with a disability whilst keeping within the restrictions applied by the listed building status.

Summary of findings

- Governance and assurance processes around risk registers.
- Governance and assurance processes around the updating of Disclosure and Barring Service (DBS) checks.

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

Ellen Armistead

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Optimax Laser Eye Clinics - Newcastle

Services we looked at

Refractive eye surgery

Summary of this inspection

Background to Optimax Laser Eye Clinics - Newcastle

Optimax Laser Eye Clinics - Newcastle was operated by Optimax Clinics Limited. The clinic opened in 1996 as an independent service in Newcastle city centre. The service provided laser refractive eye surgery for patients over the age of 18. The service received patients from the North of England.

The registered manager has been in post at Optimax for twenty years.

The service is registered to provide the regulated activities of diagnostic and screening, surgical procedures and treatment of disease, disorder and injury.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and was overseen by Sandra Sutton, Head of Hospital Inspection (North).

Information about Optimax Laser Eye Clinics - Newcastle

The service was located on the ground floor of a listed building in Newcastle city centre on a busy main road. Access to the clinic is well served by local and regional public transport networks. There are no private parking facilities at the clinic however there were many public car parks within a short walk.

The service received patients from throughout the North of England and was part of Optimax Clinics Limited. All patients were over the age of 18 years, privately funded, self-referring and self-paying for their treatment. The clinic was open Monday to Friday from 8am to 6pm and occasionally on Saturday depending on dates given by the optometrist and demand for Saturday consultations.

Surgery days were planned to meet demand and these tended to occur twice a month. Other clinic days were used for consultations and aftercare. There were no overnight facilities.

Activity:

- In the last 12 months, the service performed 337 laser refractive eye surgery procedures.

Track record on safety:

- No Never events during past 12 months
- No serious incidents or patient safety incidents during past 12 months
- Two formal complaints between June 2016 and June 2017.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- There was a good track record of safety with robust systems in place to ensure patients remained safe.
- Staff used an incident reporting system to raise concerns and shared learning from untoward events.
- All staff had completed mandatory training modules and were aware of safeguarding issues.
- There were good infection prevention and control procedures in place at the Newcastle clinic and audit results showed patients were protected from avoidable harm.
- Equipment checks and laser safety was well managed and records were appropriately maintained.
- Patient records were maintained in line with professional guidelines.
- Staff completed appropriate pre-consultation, surgical consultation, pre-treatment and aftercare safety checks in accordance with professional standards.

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

- Medicines training required review, specifically for those staff involved in the clinical management of cytotoxic medicines and for those staff involved in dispensing.

Are services effective?

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

We found the following areas of good practice:

- Patients had good and effective outcomes underpinned by evidence based care and treatment.
- Patients are fully informed and had expectations managed regarding treatment and aftercare symptoms.
- Staff had the necessary skills and competence to carry out their roles at the Newcastle clinic. All staff had received an appraisal in the previous 12 months.

Summary of this inspection

- There was collaborative team working observed at Newcastle clinic involving surgeons, optometrists, nursing and administrative staff.
- There was a thorough and robust consenting process at each stage of the care pathway. Patients were under no time restraints or pressures to agree to proceed. Patients were fully informed about treatment options, the risks, intended benefits and proposed outcomes of chosen procedures.

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

- The process for extended role training and ensuring on-going competence lacked robustness and required review.

Are services caring?

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

We found the following areas of good practice:

- There was a strong and visible patient centred culture at the Newcastle clinic.
- Staff were highly motivated and determined to deliver a quality patient experience. This was reflected in extremely positive patient feedback.
- Staff provided compassionate and thoughtful care which met the physical and emotional needs of each individual patient.
- Patients were fully supported, empowered and informed in all care decisions and treatment options.

Are services responsive?

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

We found the following areas of good practice:

- Services at Newcastle were organised and developed to meet patient needs.
- Staff worked flexibly to accommodate patient requests.
- We saw examples of adjustments that staff had made to accommodate patients with specific needs.
- Patients were invited to raise concerns and the complaints process was advertised. Staff managed patient queries in a timely manner.

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

Summary of this inspection

- Waiting times were not routinely displayed in the clinic which some patients may have found useful. Patients were informed of any delays to their treatment.
- Access for patients requiring assistance due to a disability, in particular wheelchair users, was restricted due to the building attracting listed status.

Are services well-led?

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

We found the following areas of good practice:

- Leadership, governance and culture was aligned to deliver quality outcomes for the business and for patients.
- There was an organisational vision and strategy which was known by staff.
- Local management was excellent. There was a caring and supportive culture at the Newcastle clinic along with a collectiveness to deliver positive patient experiences.
- Governance processes considered risk, quality and performance.
- There were a number of mechanisms available to patients to engage with the service. These included face to face, written and on-line options.
- There were positive findings in the staff surveys results and this was reinforced in staff feedback during our inspection.

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

- The corporate drafted and locally developed risk registers failed to log specific risks at the Newcastle clinic. There was a lack of evidence around actions taken. These required improvement and needed review.
- Governance and assurance processes to update Disclosure and Barring Service (DBS) checks requires review.

Refractive eye surgery

Safe

Effective

Caring

Responsive

Well-led

Are refractive eye surgery services safe?

Incidents and safety monitoring

- The provider had new policies aligned to incident and safety monitoring. The Adverse Event and Near-Miss Reporting Policy and the Duty of Candour and Being Open Policy were ratified on 1 October 2017 and had recently been circulated to clinics.
- All staff we spoke with were aware of the new policies and confirmed they knew how to report and escalate concerns. Staff reported incidents using the online Clinical Services Adverse Event and Near-Miss Report Form. The reporting template provided staff with guidance on incident classification, severity and likelihood ratings along with risk rating of recurrence. Staff confirmed incidents were sent to the compliance team and to the clinic manager.
- Staff we spoke with understood their responsibility to report incidents and confirmed any feedback or shared learning from wider company incidents would be discussed at team meetings.
- There had been no never events or serious incidents reported at the clinic in the previous 12 months. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There had been no incidents recorded at the clinic in the previous 12 months.
- There had been no reported Duty of Candour notifications made in the previous 12 months. 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.

- The provider had recently ratified a Duty of Candour and Being Open policy and staff were aware of this, and their associated responsibilities.

Mandatory training

- All staff completed a mandatory training programme on appointment.
- Mandatory training for staff included a range of core topics such as fire safety, manual handling, infection prevention and control, equality and diversity, data protection and safeguarding.
- Mandatory training requirements were logged onto the intranet, uploaded onto the Newcastle clinic training matrix and completion was monitored by the clinic manager. The frequency of completion of the core mandatory subjects varied accordingly, annually or biennially.
- We reviewed the Newcastle clinic training matrix, which showed mandatory training requirements, frequency and completion dates. All staff at Newcastle were compliant with all mandatory training core elements.
- The clinic manager confirmed all staff were due to complete medicines training as part of the mandatory modules and this was due for completion later in the year.

Safeguarding

- The provider had a Vulnerable Adult Protection Policy updated in September 2017 which encompassed safeguarding issues. Staff also referred to a Child Protection Policy dated August 2017.
- The local lead for adult and children's safeguarding issues was the clinic manager. There was no national lead for the organisation. The unit manager had completed level three safeguarding training for both adults and children and clinic staff had completed level two adult and children's safeguarding training.
- Staff we spoke to stated they had very little exposure to safeguarding concerns but confirmed they kept up to

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date with mandatory training which included safeguarding. Staff attended an initial two day safeguarding course with the required refresher training completed locally by the designated lead.

- The Newcastle clinic training matrix showed all staff had completed the required safeguarding training commensurate with their role and within the required timeframes.
- Staff stated they would refer all safeguarding concerns to the clinic manager in the first instance or in her absence, to the Director of Operations. The clinic manager detailed local escalation procedures in the event of a concern and had an awareness of the need to refer to local authority leads where required.
- The Newcastle clinic did not provide care to patients under the age of 18 years.
- The service had not reported any safeguarding concerns in the last 12 months and there were no safeguarding issues reported to the Care Quality Commission.
- Staff underwent disclosure and barring service (DBS) checks prior to appointment and these were stored in the respective staff personnel files. We noted one DBS check was completed in 2003. The clinic manager was not aware of any organisational policy or procedure which detailed a frequency for DBS checking or which required the DBS check to be re-verified.

Cleanliness, infection control and hygiene

- The clinic was clean, uncluttered and well-maintained. There was a Cleaning Policy which detailed standard cleaning procedures and cleaning schedules. Staff took pride in ensuring the clinic was maintained to a high standard.
- Staff checked and cleaned the laser room on a daily basis (when the clinic was open). Staff signed the laser room cleaning schedule to confirm this had been completed. There were no dates omitted. Additionally, staff logged temperature and humidity conditions in the laser room to ensure the safe operation of the equipment as specified by the manufacturers. This complied with Royal College guidance (RC Ophthalmology Ophthalmic Services Guidance for Theatres, 2013).
- The provider had an Infection Control Policy and local guidance on infection prevention and control (IPC) best practice.
- Optimax auditors completed an annual infection control audit in May 2017. The audit covered nine IPC key

performance indicators environment, waste disposal, personal protective equipment (PPE), sharps handling, care of equipment, decontamination, hand hygiene, protective clothing and clinical practices. Auditors identified 100% compliance in seven of the nine domains. Overall compliance was 98%.

- The service reported no healthcare acquired infections in the last 12 months.
- We observed staff washing their hands and using personal protective equipment (PPE) appropriately. All bins were hands free and there were handwashing facilities in the clinical areas and toilets.
- Staff complied with aseptic non-touch technique (ANTT) procedures in setting up and during laser treatments.
- The provider had a policy for the safe use and disposal of sharps and a policy for single use surgical instruments. Staff used sharps boxes for the safe disposal of needles and other sharp items. The service used single use items during surgical procedures and these were disposed of accordingly. This waste was collected by an external contractor for safe disposal.
- Staff used disposable equipment therefore surgical instrument decontamination was not required on-site.
- We observed waste to be appropriately segregated and disposed of in accordance with local policy.
- We reviewed the mandatory training matrix which confirmed all staff at Newcastle had completed the requisite IPC training. Staff confirmed they were aware of the infection control policy and where this could be accessed for guidance.

Environment and equipment

- The service was housed in a listed building in Newcastle city centre.
- Clinic facilities included a large open plan reception and seating area, two consultation rooms, an eye testing room (topography room), a private counselling area, a preparation area, a recovery room and the laser room.
- We followed the patient pathway through clinical and non-clinical areas from initial enquiry to aftercare. We found the environment suitable for the service offered and provided.
- In the reception waiting area, there were chairs and settees for patient comfort. There were also magazines and free access to hot and cold drinks. There were no disabled toilets available and some doorway access was not suitable for wheelchair users. The clinic manager advised they were unable to make such internal

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renovations due to the building attracting listed status. Staff supported patients with mobility difficulties when required, for example, to access existing toileting facilities and to manoeuvre through door spaces.

- All clinic staff told us they had sufficient equipment to deliver patient care safely. Clinical areas were observed to contain equipment that was suitable for the assessment, diagnosis, treatment, recovery and aftercare for patients undergoing laser refractive eye surgery.
- We reviewed evidence detailing maintenance checks of all equipment. The service level agreement folder detailed the agreed equipment and maintenance checks provided by internal and external suppliers. This included air conditioning, cleaning contracts, clinical waste, diagnostic testing and electrical testing. Outside the designated agreements, the clinic manager reported any equipment issues, such as repairs or replacement, to the operations team which included maintenance and engineer colleagues.
- Clinical equipment in use and in storage was CE marked to show conformity with European equipment safety standards. This included protective eyewear, disposables and other theatre equipment. We reviewed the service logs, integrity and functionality of equipment on site and found these to be working in accordance with local and manufacturers guidelines.
- Staff checked the emergency equipment on a daily basis (when the clinic was open) and recorded the check in a log book. The emergency equipment included the automated external defibrillator (AED), the battery and power source of the AED, on-site oxygen and first aid boxes. There had been no omissions in the log check.
- The laser room met the national standards for refractive surgery and ophthalmic services (RCOphth Professional Standards for Refractive Surgery and Ophthalmic Services Guidance for Theatres, 2013).
- The Newcastle clinic adhered to Medicines and Healthcare products Regulatory Agency (MHRA) guidance on the safe use of lasers (2015).
- The clinic had two laser protection supervisors (LPS) with at least one being on duty and present during treatments. All clinic staff had attended core knowledge training and laser specific training commensurate with their role. Staff confirmed they knew whom to contact if they had any concerns about the safety of the laser equipment.

- The maintenance, checking and management of the clinic lasers were directed by the Local Rules which were reviewed and updated every three years by the laser protection adviser (LPA). The LPS completed calibrations, self-tests and gas readings in accordance with Local Rules. The alignment tests, calibration tests and focimeter readings (film test and spot check) were checked by the LPS and the surgeon prior to any treatments. These readings were printed, signed and logged onto Optic (the provider database) and the patient record.
- The laser room design accommodated ducted pre-filter stages for the ceiling mounted high efficiency particulate air (HEPA) filter. The HEPA filter supported the theatre ventilation system by removing odours and unwanted airborne particles. This was checked and changed three times a year.
- The exterior doors to the laser room displayed controlled area warning signs.
- There was an old CCTV and security system fitted internally by the provider. These were no longer in use.

Medicines

- The provider had a number of policies aligned to medicines Medicines Policy, Policy and Procedure for Safe Use of Cytotoxic Drugs and Policy for Prescribing, Dispensing, Administering Medication. The latter was a new policy ratified in September 2017.
- We found all medicines stored safely within lockable cupboards and/or fridges where appropriate. Access to the medicines was limited to the clinic manager or the clinic supervisor who held the master keys. The key holder logged the keys in and out each day to record accountability.
- Staff recorded fridge temperatures on a daily basis (when the clinic was open) to ensure the safety and efficacy of medications requiring storage at specific temperatures was maintained. Staff reported any temperature ranges outside the safe upper and lower limits to the maintenance team.
- The cytotoxic drugs policy detailed risk and protocols involved in the handling and use of cytotoxic medications. Cytotoxic eye drops were used to reduce recurrence of unwanted cell growth following laser treatment. The eye drops were received by the clinic in a sealed bag. The medicine was in a pre-prepared formula therefore staff did not have to prepare the product for use.

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- Clinic staff did not handle the medicine save to open the package and place the sealed pre-prepared medicine onto a sterile field for the surgeons use. At the Newcastle clinic, it was the responsibility of the surgeon to administer the eye drops which were disposed of immediately after use. These had been used on four occasions during 2017.
- Staff stated they had not received any formal training in the use and handling of cytotoxic medications. However, staff were fully conversant with the policy and the local risk assessment on the use of Mitomycin-c eye drops updated in May 2017. Staff were aware of the safe storage requirements, the procedures to be followed in the event of a spillage and of appropriate disposal. There was a designated cytotoxic/hazardous substances storage cupboard in the clinic and staff had access to a cytotoxic spill kit.
- Medications prescribed by the surgeon for patients to take home were dispensed on site by the clinic manager or the clinic supervisor. These medications were labelled in accordance with Medicines and Healthcare products Regulatory Agency (MHRA) guidelines and included the name of the medicine, the dose and administration instructions including route and frequency. The label also included patient name, warnings and details on where the medicine was dispensed from. Patients were also provided with patient information leaflets detailing product characteristics about the medicine.
- The dispensed medicine was checked by the dispenser and the surgeon before being given to the patient. The surgeon and/or optometrist also informed the patient what each of the medications were for and administration requirements. Staff confirmed medicine dispensing was not included in the core mandatory training on medicines management. Staff confirmed they followed local policy.
- Staff completed a patient medicine history prior to prescribing and administration of new medicines. This process was completed on initial consultation and updated at subsequent visits and before treatments in the event of a change. Staff asked about current medication use and allergy status. This information was recorded in the patient notes.
- There were no controlled drugs stored and/or administered as part of the services provided at the Newcastle clinic.

Records

- The organisation had an Information Management and Data Protection Policy and a Records Management Policy.
- The service used a combination of paper and electronic records.
- Access to confidential patient information was restricted to staff and held in restricted areas. All paper records were stored in a locked room in the cellar of the building or were kept with the responsible clinician during consultation. Electronic patient information was stored on the provider database which was password restricted. All computer terminals were manned by staff or secured when not in use.
- We reviewed the records of five patients. We noted the electronic record held personal details including pre-consultation assessments, eye examination results, surgery notes and medication records. Paper records contained a health assessment questionnaire, pre-treatment letter, an initial consent process form, agreement and consent form, a pre-treatment letter and a confirmation of consent form. The notes were dated, signed and legible in accordance with professional record keeping standards.
- There was evidence of requisite cooling off period in all records in line with professional standards for refractive surgery.
- The clinic manager completed quarterly documentation audits. We reviewed the data from the last audit completed in October 2017. Ten patient records were audited and compliance against key performance indicators were in line with good recording keeping practices. There were no identified errors or themes.
- The patient information pack provided patients with guidance on how to access their records held by the provider.
- Following treatments, all patients were given a letter detailing the procedure, medications given and post-procedure care. Staff obtained patient consent prior to sending any copy letters to the GP.

Assessing and responding to patient risk

- The provider had a Medical Protocols document which provided guidance to staff at each stage of the care pathway. This covered 14 modules from initial

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consultation to treatment and aftercare. The document also detailed agreements with local hospitals in the event care required escalation to a specialist NHS centre.

- We observed five patient consultations and saw that risks associated with the treatment were clearly outlined and discussed openly with the patient at all stages namely pre-consultation, surgical assessment and treatment day.
- All patients completed a health assessment questionnaire as part of the pre-consultation and this was reviewed with the clinical staff. The health assessment questionnaire was refreshed on each visit in the event of changes which may impact on risk and safety.
- Staff informed patients of treatment options based on the combination of the health assessment questionnaire, eye examination results and surgeon review which were underpinned by professional guidelines.
- Staff completed a safety checklist for each patient on the day of the procedure which was based on the World Health Organisation (WHO) surgical safety checklist. This safety checks were performed by the laser room supervisor and the surgeon. These essentially covered three elements laser machine checks (including self-tests, gas readings and calibrations focimeter, energy thresholds, film test and spot check), cross referencing of treatment plans on treatment screen and laser screens and a patient safety check (which covered a checklist included patient demographics of name, date of birth, postcode, allergies and medications, procedure verification and eyes to which the laser treatment was being received. The clinic manager audited compliance of the surgical safety checklist on a quarterly basis.
- We observed the safety procedures being carried out and checklists being completed for a treatment list, comprising five patients. On all occasions, the checks were completed consistently and thoroughly. We reviewed the documentation after the treatment and found this to be accurately logged in accordance with professional guidelines.
- Staff completed a traceability form alongside the surgical safety checklist which detailed all the equipment used in the laser room including batch numbers in the event of the later complications or a requirement to look back.
- In most cases, patients undergoing laser eye procedures had both eyes treated on a single visit. In the event of one eye being treated, the surgeon marked the eye and this was rechecked prior to the procedure.
- Staff escorted patients to the recovery room, and into the comfortable chair, after the procedure where they were offered a drink. Patients remained in the clinic until a post-treatment review was completed. This included a check to see how the patient was feeling after the procedure, to ensure they could be safely conveyed home and to revisit post-procedure care instructions.
- Staff supplied patients with an emergency contact card for their surgeon which provided 24 hour contact details until routine clinic review. Patients were also informed of clinic opening times should they require advice or guidance before their review appointment slot. All staff made it clear to patients that they could return to the clinic at any time (subject to opening times) should they have any concerns or queries.
- There was always at least one member of staff on duty who had completed basic life support skills and was competent in using emergency equipment. There were no staff members with intermediate or advanced life support certification.
- Staff were aware of escalation procedures in the event of an urgent patient deterioration or an emergency care need. The local Emergency After Care Cover guidelines provided guidance. Additionally, the clinic had links with the local ophthalmology service should a patient require care to be further managed in a hospital setting.
- In the previous 12 months, there had been no unplanned transfer of a patient to another healthcare provider including the local hospital service.

Nursing and medical staffing

- We reviewed the staffing arrangements for the clinic. The clinic employed a registered manager/lead nurse, a clinic supervisor and two patient advisors/treatment technicians. The clinic also accessed a self-employed ophthalmologist and an optometrist to support the pre-consultations and aftercare.
- The clinic adapted staffing needs in accordance with clinic capacity and demand, risk assessments for a particular list and the experience of the staff required. Essentially, this followed a standard approach of a minimum of four members of staff on duty for laser

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treatment days and aftercare. There was also a minimum of two staff members on duty for aftercare and consultations. A member of administrative staff was present in the clinic every day.

- The clinic manager, a registered nurse was on duty on 95% of all treatment days in the previous 12 months. When not on duty, the clinic supervisor supported the consultant in the laser room. The clinic supervisor had completed extended role competencies which allowed assistance, under supervision of the surgeon, in the laser room. The Newcastle clinic was safely staffed to meet patient need.
- The surgeon attended the clinic on an as required basis subject to patient demand. Based on current figures, the surgeon attended fortnightly to complete surgical assessments and laser procedures. The surgeon remained on-site until all patients had safely departed the clinic. Out of hours, the medical director and/or the surgeon could be contacted directly 24 hours a day.
- The registered manager and the clinic supervisor were jointly designated Laser Protection Supervisors (LPS) and were in attendance on all procedure days. Staff at the clinic could refer queries to the Laser Protection Adviser (LPA), who was based off-site, at any stage.
- There was no bank, agency or locum staff used in the clinic in the last 12 months.

Major incident awareness and training

- The provider had a Major Incident Policy and Procedure. This detailed actions to be taken in the event of fire, flood, gas leaks and bomb threats. Staff were aware of the policy and of what steps to take in the event of a local incident.
- The Newcastle clinic had power back-up in the laser room and back-up nitrogen generator.

Are refractive eye surgery services effective?

Evidence-based care and treatment

- The provider had developed policies and procedures, which were developed in line with relevant best practice guidance such as National Institute for Health and Care Excellence (NICE Guidance IPG164 Photorefractive surgery) and The Royal College of Ophthalmologists (2017 RCOphth guidance).

- The provider had a national Medical Advisory Board (MAB), which set standards for surgeons and optometrists across the organisation.
- The provider had developed a number of new policies in October 2017 following learning identified during recent regulatory inspections at other Optimax locations. These policies were underpinned by best practice guidelines to support care and treatment.
- All patients undergoing procedures had their needs assessed and their care planned prior to any treatment. Any treatments offered were based on the clinical need of the patient and were delivered in line with evidence based guidance and professional standards. Where it was assessed that patients were unsuitable for a particular treatment or were more suitable for a treatment provided outside of the services at the Newcastle clinic, Patients were duly advised and signposted accordingly.
- The surgeon was an active member of a number of professional bodies and staff attended regular local, national and international events to ensure they kept up-to-date with best practice and technological advances.

Pain relief

- At all stages of the care pathway, staff asked patients about their symptomatology which included an assessment of pain, discomfort and irritation associated with their eye health.
- Staff answered patient questions and concerns about pain associated with the procedures. Staff were open and honest with their patients. Staff managed patient expectations around potential discomfort during and after the procedure. Staff also provided reassurance during the procedures to alleviate any anxiety.
- In anticipation of procedures and following treatments, staff administered eye drops for pain relief. Patients were provided with a standard pain relief regime following laser procedures. Additionally, patients were informed of non-pharmaceutical measures to reduce irritation and discomfort following treatments.
- Staff provided patients with a 24-hour helpline number to contact if they needed advice on pain relief. Patients were also invited to call or attend the clinic if they had any concerns around pain relief. All patients were given discharge information that if the pain was severe they should go to their local accident and emergency department.

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- We spoke to patients returning for after care appointments. They informed us that they had experienced little or no pain during or after the procedure.

Patient outcomes

- The organisation monitored patient outcomes for each surgeon and by location. Patient outcomes were collated from three main sources namely predicted results (referred to as Patient Forecast), local audit and patient satisfaction surveys.
- The data from all variables associated with patient outcomes were discussed nationally at the Medical Advisory Board (MAB) and these were cascaded to local clinics. This included clinic benchmarking and surgeon/ ophthalmologist outcome data. The clinic manager reviewed outcomes to identify areas of good practice and areas for improvement.
- We reviewed minutes from MAB meetings and noted discussions were held regarding patient expectations and outcomes.
- Of 337 procedures performed at Newcastle in the last 12 months, there were no patients who required an unplanned return to theatre. There were nine patients who required a re-treatment or treatment enhancement. Of these, two required laser top up surgery and seven suffered from natural regression. There were eight patients who suffered minor post procedure complications following their treatment.
- The clinic captured patient outcome data from patient satisfaction surveys. In the Patient Satisfaction Survey 2016, 99.3% of patients reported positive outcomes and recommended the service at Newcastle.
- Patients consistently commented positively about the outcomes of their procedure and we received feedback "best thing I've ever done, it has completely changed my life, I have been given a sense of freedom, and my only regret was not getting it done sooner".

Competent staff

- Staff accessed training provided by the organisation. This included mandatory training modules, job specific training, extended role opportunities, clinical supervision and skills aligned to supporting patients through the care pathway.
- Staff told us they accessed training to meet continuous professional development requirements. This included

accredited face to face sessions for re-registration and revalidation purposes, bespoke certified training for specialist roles such as LPS and access to on-line modules relevant to job roles.

- The clinic manager and the clinic supervisor had completed the requisite core and updated training in their capacity as LPSs to ensure competence in ensuring patient safety during laser treatments. Staff accessed the external LPA for guidance and training as required.
- The clinic supervisor had completed extended role training under the supervision of the clinic manager. The competencies and skills aligned to the extended role were locally drafted and assessed by the clinic manager. Whilst there was evidence of on-going observed and supervised practice, the competency framework and benchmarking standards was not evidence based and lacked accreditation. The training however did develop skills to fulfil some of the laser room procedures under the supervision of the clinic manager and/or the surgeon.
- All clinic staff had received training around the assessment, identification and treatment of sepsis. Staff were aware of the signs and symptoms associated with serious infections and sepsis associated with their work in the laser eye clinic.
- Clinic staff had not received formal training on the safe use of cytotoxic drugs (Mitomycin C) however were familiar with the policy and the local risk assessment which included guidance on safe storage, handling, disposal and steps to take in the event of a spillage.
- The clinic surgeon met the professional standards for refractive eye surgery required from Royal College of Ophthalmologists and was appropriately certificated to perform such procedures. All treatment outcomes were discussed at appraisal and supported revalidation.
- The clinic manager had completed 100% of staff appraisals in the last 12 months. Staff stated appraisals formed the basis of development objectives.
- The clinic manager confirmed poor or inadequate staff performance would be addressed immediately either informally with a 1:1 meeting or via human resources processes. The clinic manager expected high standards and all clinic staff were aware of their requirements of the role.

Multidisciplinary working

- There was a strong and integrated team ethos at the Newcastle clinic.

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- All grades of staff acknowledged their roles and responsibilities. Staff stressed the importance of effective team working to be fundamental to positive patient outcomes and the patient experience.
- The surgeon had overall responsibility for patient care however was fully supported by the clinic team (including the optometrist, the manager, the supervisor and administrative staff). We observed professional and effective communications between staff. There were particularly good relationships between the surgeon and the ophthalmologist.
- The clinic manager held monthly staff meetings. All staff were invited to attend and minutes of the same were held for reference of those unable to attend. The minutes included topics such as audit results, clinic performance, patient feedback and clinical updates.
- The clinic manager dialled into conference calls with other clinic managers and the senior management team. This was a useful platform to share learning, discuss clinical issues and keep up to date with organisational updates.

Access to information

- Staff held patient information on paper records and in the electronic format on the secure provider database.
- Electronic records were accessible across the provider network which allowed remote review by clinical staff if required. Staff confirmed this was helpful when a patient attended the Newcastle clinic for aftercare following a procedure at another Optimax centre.
- Staff at Newcastle clinic ensured timely transfer of patient information between administration staff, clinic staff, ophthalmologist and the surgeon. This ensured an efficient and streamlined flow through the clinic.
- Patient records provided all the necessary clinical details including medicine information. This included clinical updates, details of consultations, after care appointments and any untoward events. Staff confirmed they could upload additional documents relevant to the patient assessment or clinical history where required or on request of the ophthalmologist or surgeon.
- Staff requested patient consent prior to sharing any information. Patients gave consent for copy letters to be shared with their GP. Additionally, the clinic detailed the process for patients should they wish to access their records.

Consent and Mental Capacity Act

- The provider had a Consent Policy which covered consent to patient examination and treatment. This reflected current guidance to ensure patients understood the procedure recommended, alternative treatment options and the intended risks and benefits in order to make informed decisions.
- The consent process was active at all pre-treatment stages. This included an initial consent process form at pre-consultation stage, a consent and agreement form at surgical consultation and a confirmation of consent form completed on treatment day.
- The agreement and consent form was detailed and was provided to the patient after the initial consultation for them to take away and read before the meeting with the consultant. The form invited the patient to initial each section of the form to confirm understanding and agreement. The form covered areas such as treatment options/alternatives; consent; potential complications, specifics for laser types, enhancement surgery potential cytotoxic eye drops treatment, cooling off period, patient declaration and surgeon declaration.
- We reviewed five patient records and found documentation in relation to the consent process to be fully completed and in line with professional standards.
- We attended patient consultations at all stages of the care pathway and observed clinicians spending time with patients answering questions and discussing the elements associated with the consent process. Staff were aware of the consenting process at all stages and knew of the steps to follow. Staff added however that time spent with patients detailing the consent processes varied according to their needs.
- Staff provided patients with informative literature in the welcome pack and on consultations to reinforce the process. Staff also invited patients to return for ad-hoc visits or contact by phone should they have additional questions outside their appointed consultation time. One patient stated how the optometrist had been especially patient with her in addressing all her concerns and questions.
- Staff demonstrated an awareness and understanding of the legal requirements of the Mental Capacity Act 2005 (MCA) and Deprivation of Liberty Safeguards (DoLS). Staff understood how this impacted on the consent and decision making process.
- Staff acknowledged they had limited experience in dealing with such issues due to their patient cohort

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however stated this made them more acutely aware of the processes and how to escalate concerns. Staff stated if they had concerns about a patient's capacity to consent or if there were any safeguarding concerns, they would be immediately discussed with the clinic manager, the optometrist and the surgeon.

- Staff ensured all patients had a minimum of seven days cooling-off period for reflection and to digest all information provided before consenting to treatment. We reviewed five sets of patient records and noted this was adhered to in all cases. Staff confirmed they would not progress with any treatment unless the patient had been subject to the minimum requisite period. Staff ensured patient appointments were diarised to accommodate this window.

Are refractive eye surgery services caring?

Compassionate care

- Staff were passionate about patient care and all commented that this was the single most important role of the service.
- We spoke with five patients during our inspection. All patients we spoke with told us staff were kind, caring, knowledgeable and sensitive. We observed compassionate and professional interactions between patients and staff at all levels.
- Privacy and dignity of patients was maintained at all times. The reception and waiting area was an open environment however consultation rooms were frequently used for private discussion. We observed positive and discreet conversations between staff and patients.
- Patients were invited to complete satisfaction and service surveys on each attendance at the facility. The patient satisfaction survey was a private touch screen questionnaire which allowed patients to describe the results of their treatment and comment about any aspect of the care received. Additionally, patients were asked if they would recommend the service and if they were treated with respect and dignity. In the Patient Satisfaction Survey 2016, 99.3% of patients recommended the service at Newcastle.

- Where patients were repeat attendees, staff had clearly built up a positive and personal rapport with each individual. Staff spoke warmly about their patients and shared their positive outcomes following treatment.
- We reviewed twelve patient comments and testimonies; all were positive about the care and treatment received. Such comments received were "absolutely amazing staff" and "excellent service and care". Patients consistently commented how they would recommend the service to friends and family.
- It was clear from observational care that staff had built friendly, caring and positive relationships with their patients.
- Patients confirmed their privacy and dignity was maintained at all times. Patients were provided with private areas for consultations, a private changing area and a private recovery area after treatments.

Understanding and involvement of patients and those close to them

- Staff invited and welcomed patient family involvement in care. Staff encouraged patients to have support at appointments, in particular on treatments.
- Staff provided written literature to patients to aid their understanding of the treatment options to support care decisions.
- All patients were asked about their hopes and staff provided realistic expectations of the likely outcomes of their surgical procedure. Staff recorded the content of these discussions in the patient notes.
- Patients were encouraged to ask questions about their care and treatment during consultations. We observed staff answering queries and concerns during these meetings.
- Staff took time to revisit and re-explain instructions to patients and their family member about post treatment care. This included medicines regimen, infection prevention, activities to avoid and after care reviews.
- Patients were aware of and informed of all costs associated with the proposed treatment. Staff discussed financial matters in a private consultation area.

Emotional support

- At initial consultation, staff introduced themselves by first name, their role and how they were there to assist. Staff asked patients how they would like to be addressed during their time at the clinic.

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- Staff provided patients with necessary time and information to make care decisions. Staff confirmed patients could take any amount of time necessary and attend any number of pre-consult appointments before consenting.
- Staff provided counselling support to patients where required.
- We observed staff giving reassurance to patients during consultations and at treatments. Two patients we spoke to informed us they were very nervous before the procedures. They stated "I was very anxious but the staff put me at ease" and "I felt reassured and supported".

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

Service planning and delivery to meet the needs of local people

- Optimax Newcastle was opened in 1996 to provide private eye health services to the population of North East England.
- The clinic manager informed us patients could attend any Optimax clinic convenient to them for consultation. Treatments were offered according to the specific services provided at each location.
- Patient appointments were managed locally and centrally by the provider diary team.
- The Newcastle clinic was open five days a week (Monday to Friday) until 6pm however staff informed us they were flexible with appointments to accommodate patient need. This included later appointment slots and weekend opening.

Access and flow

- Patients self-referred to the clinic. Patients enquired to the clinic via on-line enquiry process, via central telephone booking line, directly to the clinic or by attending in person.
- Staff provided patients with an appointment to suit their needs and convenience. Staff advised these could be accommodated at very short notice. Staff confirmed they had appointed patients on the same day as the initial enquiry on patient request. Additionally, patients walked into the clinic and could be seen immediately subject to clinician availability. Staff also offered a courtesy call to patients in advance of their booked appointment as a reminder service.

- The clinic did not formally monitor or advertise waiting times however staff were mindful of patient arrival time and their progress through the clinic. Staff advised waiting times and delays to consultation and/or treatments were minimal.
- Patients we spoke to advised they had not been subject to any delays or cancellations.
- Staff appointed patients for post-treatment appointments and aftercare reviews subject to the treatment received and in line with best practice guidelines. Staff added they invited patients to attend the clinic at any time, when open, should they have concerns or worries post-treatment.
- There were currently no patients on the waiting list for laser refractive eye surgery and there had been no cancellations in the previous 12 months. There had been no unplanned transfers of a patient to another health care provider in the last 12 months.
- Where patients failed to attend or cancelled an appointment, the clinic manager contacted them by telephone in the first instance to see if they could assist in any way and to understand the reasons for non-attendance.

Meeting peoples individual needs

- The clinic was situated in Newcastle city centre with ease of access by car and public transport. The clinic did not provide any private car parking facilities however there were a number of parking locations within walking distance.
- The clinic was housed in a listed building with stair access from the main street. The clinic provided a ramp for those unable to access the clinic using the stairs.
- The clinic had an open plan reception and waiting area with comfortable settees, magazines, information leaflets and access to hot/cold drinks. There were areas for private consultation and discussion. There were toileting facilities on-site however there were no disabled access toilets.
- Staff confirmed they made reasonable adjustments to meet the needs of each individual patient however added that due to the service offered they rarely provided care for vulnerable patient groups, such as those living with dementia or patients with learning disabilities. Staff welcomed family members or friends to attend with patients to provide support and reduce anxiety.

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- Clinic services and treatment options were available to all (over 18 years of age) irrespective of age, disability, gender, gender reassignment, pregnancy (with some clinical considerations), maternity status, race, religion, belief or sexual orientation.
- Information leaflets were available in the clinic. For patients where English was not their first language or for those with visual impairment, staff confirmed they could obtain the same in braille, large print and other languages.
- Where English was not the patients first language, staff confirmed they accessed translation services when required.
- The clinic had a loop system installed in the reception area to support patients with hearing deficit.
- Staff provided patients with a 24 hour helpline number should they have concerns following their treatment and all were invited to contact the clinic if they had any questions, queries or worries.

Learning from complaints and concerns

- The provider had a Complaints and Whistleblowing Policy which underpinned the process for the handling and management of such concerns. The policy defined the severity of complaints and set out a 20 working day timescale for the response to complaints and concerns. The clinic manager was responsible for responding to complaints in the given timescale.
- Staff provided patients with an introductory pack and a handbook which included information on the service, the procedure, the surgeon and the clinic. The guide provided information to patients on how to contact the clinic if they had complaints, concerns or queries.
- Staff provided patient complaint forms at reception and on tables in the waiting area for ease of patient access. There were also comment books in the waiting area for patients to write their views on care and treatment anonymously or otherwise.
- The clinic manager told us patient comments were also reviewed following completion of satisfaction surveys. Where negative or concerning comments were received, they were highlighted to the clinic manager for follow up.
- Staff at Newcastle invited and welcomed patient feedback in order to ensure were delivering best care.

- Staff were able to confirm how they would handle a patient complaint or concern and these tended to flow through the clinic manager. Patient feedback was discussed at clinic meetings.
- The service received two complaints between June 2016 and June 2017 and these related to patient expectations.

Are refractive eye surgery services well-led?

Leadership and culture of service

- There was a clear leadership and staffing structure within Optimax. We were provided with sight of the Eye Hospitals Group Limited structure which detailed lines of accountability and responsibility from Chair, CEO, senior management team (SMT) and operations.
- Locally, the clinic manager had been in post at the Newcastle clinic for 20 years. The manager was supported by a compliance manager and reported to the Director of Operations.
- The clinic manager confirmed the SMT were visible, approachable and often visited the Newcastle clinic. Morale within the clinic was excellent and all staff we spoke with told us they enjoyed their job. Staff spoke positively of the local team working and of the leadership provided by the clinic manager.
- There was a genuinely caring, professional and friendly culture within the clinic. We observed staff proactively engaging with patients on arrival and throughout their stay.
- There was a strong local culture centred on the needs of the patients. All staff recognised the importance of ensuring they delivered a quality service and had no hesitation in voicing opinion and escalating issues in an open and honest manner.

Vision and strategy

- The organisational mission and vision was to be the first choice in the UK for laser and lens surgery procedures by providing the highest quality service to [our] patients.
- All staff we spoke with understood the company goals and objectives.
- The corporate vision, values and strategy had been developed by the senior management team and were adapted to the changing needs of the business, market trends and patient demands.

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- Staff were aware of their role and responsibilities aligned to business objectives. The business detailed their responsibilities to their staff. These included be committed and proud of their work, be recognised for their efforts, feel responsible and accountable for what they do and be well trained and managed.

Governance, risk management and quality measurement

- The provider had a Clinical Governance and Risk Management Policy which referenced corporate, clinical governance and risk management processes.
- The provider had a corporate governance and quality lead which fell in the remit of the Director of Operations and the Compliance Manager.
- Governance and risk was considered in a number of corporate meetings and cascaded locally. These included monthly SMT meetings, quarterly surgeon meetings, quarterly MAB meetings, bi-annual managers meetings, manager conference calls, training events; and local clinic team meetings.
- The organisational framework and the local clinic structure provided clear lines of responsibility which all staff were aware of.
- It was apparent there had been a number of new policies ratified and existing policies reviewed in the three months prior to our inspection. The clinic manager advised the new policies had been developed in response to lessons learnt from regulatory inspections at other Optimax clinics.
- We were provided with sight of the Clinical Services - Risk Register for Newcastle dated May 2017. The clinic manager advised this document had been compiled at corporate level. The same detailed 15 risks, a risk rating and whether or not there was mitigating action. The risks were generic and lacked specific detail for the Newcastle site. For example; one risk was entitled Cables trip/fall and attracted a risk rating of 1. There was no mitigating action aligned to this risk. Additionally, there was no evidence of risk review, actions taken and review of risk status.
- The clinic manager had developed a local risk register dated September 2017 which highlighted more local risk based concerns however this also lacked necessary detail and evidence of review, actions taken and reassessment.

- The provider had a business continuity plan which covered potential risks such as external threats, clinical equipment issues and IT system failure.
- The clinic manager advised key performance measures tended to be focussed on three pillars, namely patient satisfaction, clinical outcomes and financial targets. The latter tended to attract the greatest audience and was discussed in the majority of local and management meetings.
- All staff working under rules or practising privileges had an appropriate level of professional indemnity insurance in place. All staff working in this manner were monitored by the MAB to ensure they met the professional registration requirements of the role and the local candidate requirements.
- We reviewed four staff personnel files. These held evidence of professional qualifications, practising privileges, insurances, references and recruitment checks. We noted DBS checks on all files however one was dated 2003. The company did not have a policy to determine how often DBS checks should be repeated.

Public and staff engagement

- The provider obtained patient views and experiences of the service from a number of sources. This included informal feedback at clinic appointments, patient satisfaction surveys, on-line reviews, patient testimonials and rating websites. The Newcastle clinic also had a bank of former patients of the service who were willing to be contacted by prospective patients to share their experience.
- The provider had a very informative website which provided information on suitability criteria, facts about eye health, treatment options and clinic locations. The site also referred to financial considerations, free initial consultation and after care guarantees. Additionally, staff provided patients with the consultant biography and detail of surgical outcomes to take home following consultation.
- Staff at Newcastle reviewed patient feedback to monitor and improve patient experience and inform patient engagement. Local clinic feedback fed into the national agenda for consideration in service planning and development.

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- Staff took part in the annual staff survey and feedback from this was positive. Staff enjoyed their work at the Newcastle clinic. Staff informed me they had no concerns raising issues with the clinic manager or the SMT.
- Staff enjoyed the clinic annual event which the company funded as a thank you for the work undertaken at Newcastle.

Innovation, improvement and sustainability

- The clinic manager informed us the company planned on introducing a text messaging service as a means to confirm patient appointments and treatment dates.

Outstanding practice and areas for improvement

Outstanding practice

Staff were focussed on providing quality patient care and determined to ensure patient satisfaction. The personal

and professional relationships staff built with patients with relatively limited contact was exceptional. Patients reaffirmed this with their feedback about the staff and the service provided.

Areas for improvement

Action the provider SHOULD take to improve

- The provider should consider reviewing medicines training with specific attention to the management of cytotoxic medicines and dispensing requirements.
- The provider should consider reviewing the robustness of the current extended role training procedures to ensure those staff remain competent and up to date with best practice/professional guidelines.
- The provider should consider if there are any additional reasonable adjustment measures that could be implemented to support access for persons living with a disability.
- The provider should review governance and assurance processes around risk registers.
- The provider should consider reviewing governance and assurance processes around the updating of Disclosure and Barring Service (DBS) checks.