The Medical Eye Clinic

Quality Report

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Date of inspection visit: 13 October 2017 and 20 October 2017
Date of publication: 29/03/2018

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

Ratings

Overall rating for this location	Requires improvement
Are services safe?	Requires improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

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

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

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

Summary of findings

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

Summary of findings

Letter from the Chief Inspector of Hospitals

The Medical Eye Clinic is operated by The Medical Eye Clinic Limited. The clinic has no inpatient beds. Facilities include one operating theatre, a non-invasive laser room, a pre-surgery preparation room and a post-surgery recovery area. Consulting rooms were shared with a separate optometry company that used the same premises as The Medical Eye Clinic.

The clinic treats ophthalmic patients, both private and NHS (via direct contracts with NHS trusts). Types of surgery carried out include: cataract surgery and laser capsulotomy treatment.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 13 October 2017 and an unannounced visit to the clinic on 20 October 2017. We did not inspect the entire pre-surgery consultation process and post surgery follow up care because this was provided as part of a service agreement with a separate organisation.

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 rate

We rated this service as requires improvement overall.

- There were omissions in the safety risk assessments and operational protocols to keep patients safe. The risk assessment and associated guidance around the use of the non-invasive laser was not comprehensive. Expectations regarding the management of controlled drugs were not clearly defined in an operational policy.
- The system for ensuring all members of the surgery team had knowledge of essential safety systems and processes was not robust. The clinic did not have a policy for mandatory training. Minimum requirements for mandatory training were identified for some but not all staff. Leaders did not have clear oversight of the training completed by the clinicians that made up the team on surgery days.
- There were adequate numbers of medical and nursing staff present on surgery days. However, the accountability of all members of the team was not well defined because not all members of the team had an employment contract.
- The practising privileges policy referred to outdated legislation and was not specific regarding the training requirements for this group of staff.
- The service did not contribute data to the Private Healthcare Information Network.
- Staff did not always respect the confidentiality of patients in their care when giving verbal handovers to other members of the team
- There was no system for engagement of foreign language or sign language interpreters should these be required. There was no hearing loop at the clinic.
- The arrangements for governance did not always operate effectively. There had been no recent review of the governance arrangements or the information used to monitor safety performance.
- The senior team did not have clear oversight of all safety procedures. There were some omissions and inaccuracies in the safety reports that were used by the medical advisory committee to monitor safety performance.
- The audit programme did not monitor staff compliance with all relevant safety protocols. For example, the medicines management policy was not regularly audited. There were no hand hygiene audits.
- Not all risks were mitigated within a reasonable time frame, such as completion of staff disclosure and barring checks.

Summary of findings

- Essential policies and protocols were not always current (the practising privileges policy) or comprehensive (the medicines management policy).

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

- Staff were aware of the protocol for reporting incidents. The senior team ensured that actions were taken and lessons were learnt as a result of incidents reported.
- There were systems to minimise the risk of healthcare associated infection. The environment and facilities were visibly clean. Staff adhered to the infection control policy.
- The team consistently followed World Health Organisation guidelines on the use of safer surgery checklists to minimise risk of harm to patients undergoing surgery. Use of the checklist was carefully monitored by the anaesthetist and the lead nurse. It was evident during our inspection that all members of the team respected the importance of using these checklists.
- Medicines were stored securely and at manufacturer recommended temperatures. Patient records were stored securely to maintain patient confidentiality.
- Patient's care and treatment was planned and delivered in line with current evidence-based guidance, standards, best practice and legislation. The senior team discussed research and guidelines in the medical advisory committee. We saw the team adhered to best practice in the use of the safer surgery checklist.
- Accurate and up-to-date information about effectiveness was shared internally and was understood by staff. This was used to improve care and treatment and people's outcomes. Surgical outcomes were closely monitored and regularly compared to published data to benchmark the effectiveness of the treatments.
- There was effective multidisciplinary working across the whole team and educational sessions were offered to optometrists outside the team.
- Patients had comprehensive assessments of their needs. All necessary patient information was accessible to the team. Staff were aware of consent processes and these were based on best practice and current legislation.
- Staff took time to minimise patient's anxiety. Patients were involved and encouraged to be partners in their care and in making decisions. Patients were encouraged to ask questions and staff gave clear and detailed explanations to queries. Patients told us they felt reassured and informed.
- Staff respected the dignity of patients. Staff introduced themselves by name and role and considered the individual preferences of patients.
- The premises and facilities were designed to meet the needs of patients. The theatre and consulting rooms were accessible on ground level.
- The surgery pathway was focussed on individual needs. Patients could choose to see an optometrist in their local area for follow up care.
- Patients were individually assessed for their suitability for treatment taking into account known risk factors.
- Patients did not wait long for their care. There was no waiting list for treatment and clinics ran on time. During our inspection, clinics ran on time.
- Leaders of the service were focussed on the quality of clinical outcomes and the safety of procedures within theatre.
- There was a vision to develop the service that included diversification of surgery procedures offered to patients and more joint working with NHS providers. Feedback from NHS commissioners was positive.
- The service sought the views and experiences of patients and this. Feedback from was consistently positive.
- Leaders were visible and accessible to staff. All staff were proud to deliver patient centred care.

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

Summary of findings

Amanda Stanford
Deputy Chief Inspector of Hospitals (South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	**Requires improvement** 	We rated this service as requires improvement. There were actions that leaders could take to improve how safe and well led the service was. However, the service was good for being effective responsive and caring towards patients.

Summary of findings

Contents

Requires improvement

The Medical Eye Clinic

Services we looked at

Surgery;

Summary of this inspection

Background to The Medical Eye Clinic

The Medical Eye Clinic is operated by The Medical Eye Clinic Limited. The hospital/service opened in 2015. It is a private clinic in Exeter, Devon providing ophthalmic surgery. The clinic primarily serves the communities of Devon. It also accepts patient referrals from outside this area.

We inspected this service on 13 October 2017. We returned for an unannounced inspection visit on 20 October 2017. There had been no previous inspections of this service.

The regulated activities carried out at this location include diagnostic and screening procedures, surgical procedures, treatment of disease and disorder. The hospital has had a registered manager in post since 15 May 2015.

Our inspection team

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

Information about The Medical Eye Clinic

The clinic has one day case unit and is registered to provide the following regulated activities: Diagnostic and screening procedures; surgical procedures and treatment of disease, disorder or injury. The only service provided at the clinic was ophthalmic surgery. All staff employed by the clinic worked at this location.

From April 2016 to March 2017 there had been 619 intraocular cataract surgical operations completed; 594 of these were for NHS funded patients and 25 patients paid privately for their treatment. At the time of our inspection, all patients paid privately for their treatment.

The Medical Eye Clinic had also carried out five laser capsulotomies, one selective laser trabeculoplasty and two procedures to remove stitches. No patients stayed overnight at the clinic during the same reporting period.

During the same reporting period, 460 patients attended for an outpatient appointment, 252 of these were first appointments and 208 were follow up appointments post-surgery. Of these patients, 430 were NHS funded and 30 patients paid privately for their treatment.

During the inspection, we visited the clinic. We spoke with six staff including; registered nurses, reception staff, medical staff, and senior managers. We spoke with four patients and one relative. During our inspection, we reviewed four sets of patient records. One commissioner responded to our request for feedback regarding the delivery of NHS funded contracts for eye surgery.

There were no special reviews or investigations of the hospital ongoing by the Care Quality Commission at any time during the 12 months before this inspection. The clinic had never been inspected by the Care Quality Commission.

The Medical Eye Clinic employed one registered nurse, one receptionist/health care assistant, one centre manager, one business manager. The remainder of the staff were directors and co-owners of the company. Other self-employed nursing staff formed part of the surgery team on the day of surgery only. Three surgeons and one anaesthetist worked at the clinic under practising privileges. The accountable officer for controlled drugs (CDs) was the anaesthetist employed via practising privileges.

Summary of this inspection

During the reporting period April 2016 to March 2017, there had been:

- No Never events;
- No Clinical incidents
- No incidences of hospital acquired methicillin-resistant Staphylococcus aureus (MRSA);
- No incidences of hospital acquired methicillin-sensitive Staphylococcus aureus (MSSA);
- No incidences of hospital acquired Clostridium difficile (c.diff);
- No incidences of hospital acquired E-coli;
- No complaints;
- No other services operated at the facility. No services offered by the clinic were accredited by a national body.

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal;
- Laundry;
- Maintenance of medical equipment.

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?

Requires improvement 

We rated safe as requires improvement because we found the following issues that the service provider needs to improve:

- There were omissions in the safety risk assessments and operational protocols to keep patients safe. The risk assessment and associated guidance around the use of the non-invasive laser was not comprehensive. Not all essential safety checks were completed, such as routine maintenance of the non-invasive laser equipment. Expectations regarding the management and oversight of controlled drugs were not clearly defined in an operational policy.
- The system for ensuring all members of the surgery team had knowledge of essential safety systems and processes was not robust. The clinic did not have a policy for mandatory training. Minimum requirements for mandatory training were identified for some but not all staff. Leaders did not have clear oversight of the training completed by the clinicians that made up the team on surgery days.
- The audit programme did not monitor staff compliance with all relevant safety protocols. For example, the medicines management policy was not regularly audited. There were no hand hygiene audits.
- There were adequate numbers of medical and nursing staff present on surgery days. However, the accountability of all members of the team was not well defined because not all members of the team had an employment contract.

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

- Staff were aware of the protocol for reporting incidents. The senior team ensured that actions were taken and lessons were learnt as results of incidents reported.
- There were systems to minimise the risk of healthcare associated infection. The environment and facilities were visibly clean. Staff adhered to the infection control policy.
- The team consistently followed World Health Organisation guidelines on the use of safer surgery checklists to minimise risk of harm to patients undergoing surgery. Use of the checklist was carefully monitored by the anaesthetist and the lead nurse. It was evident during our inspection that all members of the team respected the importance of using these checklists.

Summary of this inspection

- Medicines were stored securely and at manufacturer recommended temperatures. Patient records were stored securely to maintain patient confidentiality.

Are services effective?

Good

We rated effective as good because we found the following areas of good practice:

- The senior team discussed and implemented best practice in the medical advisory committee. We saw the team adhered to best practice in the use of the safer surgery checklist. Surgical outcomes were closely monitored and regularly compared to published data to benchmark the effectiveness of the treatments.
- There was effective multidisciplinary working across the whole team and educational sessions were offered to optometrists outside the team.
- All necessary patient information was accessible to the team. Staff were aware of consent processes and these were based on best practice and current legislation.

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

- At the time of our inspection, there was no assurance that the mandatory training compliance of staff engaged via practising privileges was being effectively monitored. There were not systems to monitor the accountability and competence of the subcontractors that made up the team on surgery days.

Are services caring?

Good

We rated caring as good because we found the following areas of good practice:

- Staff took time to minimise patient's anxiety. Patients were encouraged to ask questions and staff gave clear and detailed explanations to queries. Patients told us they felt reassured and informed.
- Staff respected the dignity of patients.

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

- Staff did not always respect the confidentiality of patients in their care when giving verbal handovers to other members of the team

Are services responsive?

Good

Summary of this inspection

We rated responsive as good because we found the following areas of good practice:

- The premises and facilities were designed to meet the needs of patients. The surgery pathway was focussed on individual needs. Patients could choose to see an optometrist n their local area for follow up care.
- Patients were individually assessed for their suitability for treatment taking into account known risk factors.
- Patients did not wait long for their care. There was no waiting list for treatment and clinics ran on time. During our inspection, clinics ran on time.
- However we found the following issues that the service provider needs to improve:
- There was no system for engagement of foreign language or sign language interpreters should these be required. There was no hearing loop at the clinic.

Are services well-led?

Requires improvement

We rated well-led as requires improvement because we found the following issues that the service provider needs to improve:

- The senior team did not have clear oversight of all safety procedures. There were some omissions and inaccuracies in the safety reports that were used by the medical advisory committee to monitor safety performance.
- Potential risks were not always mitigated within a reasonable time frame, such as staff disclosure and barring checks. The risk register was not used effectively to monitor and manage risks.
- Essential policies and protocols were not always current (the practising privileges policy) or comprehensive (the medicines management policy).

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

- Leaders of the service were focussed on the quality of clinical outcomes and the safety of procedures within theatre.
- There was a vision to develop the service that included diversification of surgery procedures offered to patients and
- more joint working with NHS providers. Feedback from NHS commissioners was positive. The service sought the views and experiences of patients and this. Feedback from was consistently positive.
- Leaders were visible and accessible to staff. All staff were proud to deliver patient centred care.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Requires improvement	Good	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	Good	Good	Good	Requires improvement	Requires improvement

Requires improvement

Surgery

Safe	Requires improvement
Effective	Good
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are surgery services safe?

Requires improvement

We rated safe as **requires improvement.**

Incidents

- During the 12 months preceding our inspection, there had been no never events, serious injuries or deaths. There had been no incidents that the provider classified as 'critical clinical incidents' affecting patient care.
- There were systems for reporting incidents and staff were familiar with these systems. There was an incident reporting policy that had been reviewed in the 12 months preceding our inspection. The lead nurse logged all incidents during theatre in a book and then completed an incident report at the end of the theatre list. All staff told us they would inform one of the directors at the earliest opportunity if an adverse incident occurred.
- The senior management team were aware of all incidents that had occurred. The lead nurse submitted a report to the medical advisory committee of all incidents that occurred during surgery that required investigation. This would include, for example, malfunction of equipment, short staffing, surgical complications, and wrong patient identifiable data. The nurse report included a summary of the actions taken following an incident.
- Actions were taken following discussion of incidents in this forum. There had been an incident of posterior capsular rupture. This is when the capsular membrane is accidentally perforated during surgery which can lead to severe visual disability and other complications. Following this medical advisory committee developed a theatre protocol for staff to follow in the event of this re-occurring.
- Thorough investigations were completed when a risk of patient harm was identified. For example, minutes of the medical advisory committee meetings showed there had been two patients who had presented with possible toxic anterior segment syndrome (TASS). TASS is an acute severe intraocular inflammation accompanied by diffuse corneal oedema. This was investigated fully, surgery lists were postponed until the outcome of the investigation was known and a full review of procedures completed. No cause was identified.
- Processes were adapted as a result of investigations into these incidents. For example, several identical pieces of re-usable surgical equipment had failed to operate effectively on repeated occasions. This was investigated with the manufacturers of the equipment. As a result of investigations, the team briefing sheet was amended to include a check of which staff member was responsible for 'flushing' these items of equipment prior to sending for decontamination post-surgery.
- The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. There had been no incidents that had met the threshold for duty of candour during the 12 months preceding our inspection. The managing director was aware of the responsibilities of the service under this regulation. There was a duty of candour policy. However, staff had not participated in any duty of candour training.

Requires improvement

Surgery

Clinical Quality Dashboard or equivalent (how does the service monitor safety and use results)

- The service monitored safety performance through the medical advisory committee. The anaesthetist, medical director and lead nurse presented safety reports to this forum every four months. These reports covered staffing information such as registration and training compliance, rates of infection, audits of various checklists including: theatre briefing and debriefing, the cleaning of the theatre and equipment, emergency equipment, theatre air handling, and fire safety. Reports also listed incidents including any clinical incidents such as medical emergencies, drug reactions or unplanned returns to theatre, details of any complications and post-operative adverse events plus refractive outcomes post-surgery,

Cleanliness, infection control and hygiene

- Systems were in place to minimise the risk of healthcare associated infection. The lead nurse reported any incidences of infection to the medical advisory committee in the nurse report. There had been no incidents of infection during the 12 months preceding our inspection.
- Standards of cleanliness in treatment areas were ensured. During our inspection, all areas were visibly clean and tidy. Cleaning schedules were in place that reflected the standards and guidance from the Royal College of Ophthalmology. Some of the cleaning of the floors and walls was undertaken by an external cleaning company. Cleaning of work surfaces and equipment in the theatre was undertaken by the lead nurse. Checklists were completed to evidence that cleaning was completed regularly and consistently. The lead nurse audited completion of these checklists every four months as part of the preparation of the nursing report to the medical advisory committee.
- Cataract surgery was completed within a standard ophthalmic operating theatre environment complete with air handling system to minimise spread of airborne infection. Staff kept a log of temperature and humidity conditions. Temperature and humidity conditions were maintained consistently within the range for safe operation of equipment specified by the manufacturers and recorded on checklists by theatre staff. The lead nurse audited completion of these checklists every four months as part of the preparation of the nursing report to the medical advisory committee.
- We saw that all members of the team routinely washed their hands in accordance with National Institute for Health and Clinical Excellence quality standard QS61Infection Prevention and Control. Staff wore freshly laundered theatre uniform with sleeves ending above the elbow, minimal jewellery and nails were short and visibly clean in accordance with the Medical Eye Clinic infection control policy.
- There was a provider policy for infection control which had been reviewed in the 12 months preceding our inspection. Some elements of this policy were checked every four months by the lead nurse, for example the nurse report to the medical advisory committee included compliance with completion of checklists for cleaning and the monitoring of the air handling unit. However, compliance with the policy was not comprehensively audited, for example there were no hand hygiene audits undertaken.
- Re-usable surgical equipment was decontaminated off-site by an external provider who was accredited by the International Organisation for Standardisation (ISO). This company who had a service level agreement to provide decontamination services.

Environment and equipment

- Staff had the equipment they needed to keep patients safe. Resuscitation equipment was available to the surgery team. This included defibrillator and mask, oxygen, emergency medicines including anaphylaxis kit. This equipment was checked on every treatment day. However, there was no standard operating procedure regarding the use of the resuscitation equipment and emergency medicines.
- Not all equipment had been serviced in the twelve months preceding our inspection. The non-invasive laser equipment was overdue for maintenance by four months. When this was raised during our inspection, the managing director arranged for this to be serviced eight days after our inspection.
- The completion of equipment checklists were reported on by the lead nurse to the medical advisory committee, however we saw that this report was not comprehensive as it did not identify out of date maintenance of the non-invasive laser equipment.

- The clinical environment was designed to meet the needs of the patients attending the clinic. The operating theatre was non-laminar air-flow which optimised the prevention of spread of infection. The design of the environment ensured that high risk areas such as the operating theatre and the non-invasive laser room were not accessible to the public. The non-invasive laser equipment was situated in a lockable room and had an illuminated sign warning patients and staff not to enter.
- Control measures were used to provide a safe working environment for the use of the non-invasive laser. These included provision of personal protective equipment, restricted access to the laser room, and the use of illuminated warning signs. However, the risk assessment and associated guidance for the use of non-invasive laser equipment was not comprehensive. The Control of Artificial Optical Radiation at Work Regulations 2010 identifies the need for clear documentation to describe safe working practices. The Medical Eye Clinic had not produced such guidance. The risk assessment of the medical laser was added during our inspection. This assessment had not involved the specialist expertise of a laser protection advisor and focussed only on the requirement for routine maintenance.
- All surgical equipment could be traced to allow details of specific implants and equipment to be provided rapidly to the Medicines and Healthcare Products Regulatory Agency when required. Theatre staff attached unique identification stickers from every surgical instrument to the patient record. This included details of the lens implants used.

Medicines

- Medicines were stored securely within locked cabinets and at correct temperatures as recommended by manufacturers. Staff gave written information and detailed verbal instructions to patients regarding their medicines to take home.
- The Medical Eye Clinic did not administer sedation to patients. If the preoperative assessment indicated that a patient might require sedation, these patients were referred to the surgeon's own private practice (a separate company and not part of this inspection). No cytotoxic medicines were used at the clinic.
- Controlled drugs were stored on the premises for use by the other separate companies who rented the facilities, staff and equipment. Staff employed by the Medical Eye Clinic had access to the controlled drugs, as surgery lists for the Medical Eye Clinic sometimes included patients for these separate companies at the beginning or end. There was a system to record the use of controlled drugs. Staff completed a log book recording live stock levels, medicines prescribed and administered by the anaesthetist for each patient. This record was legible and contemporaneous and signed by the anaesthetist and the registered nurse attending. The lead nurse checked stock levels against the record as part of the ordering process.
- There was limited oversight of the protocols for the management of medicines. The medicines management policy was not signed, was overdue for review by one month, and had not been audited during the 12 months preceding our inspection. The policy contained no detail regarding the use of emergency medicines or the controlled drugs. We saw no evidence that staff had completed the training recommended in this policy.

Records

- There were systems to protect the security of the electronic patient records. There was an automatic data back-up of electronic patient records. The system that stored electronic patient records was password protected. The system could not be accessed outside of the perimeter of the clinic. Paper patient records were stored securely in locked filing cabinets in an area not accessible to patients.
- There had been no audits of patient records during the 12 months preceding our inspection. We checked four patient records and found that records were complete. However, signatures were not always legible or dated and signature lists were not evident.

Safeguarding

- Permanent clinical staff had current knowledge of safeguarding systems and processes. The registered nurse and the receptionist on permanent contract had participated in safeguarding vulnerable adults training and safeguarding children levels one and two. There had been no safeguarding concerns raised by the team during the 12 months preceding our inspection. At the time of our inspection, the clinic was not aware of the training compliance status of the sub-contractors it used on surgery days.

Mandatory training

- In healthcare settings, staff complete training that is deemed to be mandatory by the provider to ensure those staff were knowledgeable of safe systems of practice in their day to day work. The clinic did not have a clear understanding of which training they deemed to be mandatory for staff engaged via practising privileges or sub-contractors. The clinic did not have a policy for mandatory training. Minimum requirements for mandatory training were identified for some but not all staff.
- Permanent staff employed at the clinic were offered mandatory training in systems and practices designed to keep patients safe. The registered nurse on permanent contract had completed mandatory training within the 12 months preceding our inspection. Subjects covered included health and safety, information governance, fire safety, equality and diversity, infection control, basic life support, moving and handling, safeguarding vulnerable adults, safeguarding children level one and two, dementia and delirium, mental capacity act and deprivation of liberty safeguards. In the administration team, 67% of staff had completed similar training within the 12 months preceding our inspection. One member of this team had been in post for five months and had completed safeguarding vulnerable adults training only.

Assessing and responding to patient risk (theatres, ward care and post-operative care)

- The team assessed patient suitability for surgery on an individual basis. The clinician assessment of suitability was guided by the nursing pre-operative assessment which included a range of high risk indicators such as a poorly dilating pupil, infection, high blood pressure, heart conditions, diabetes, claustrophobia, tremor, confusion. If a patient answered that any of the risk factors were present, this would alert the clinician to the need for more detailed assessment by the optometrist and surgeon. If patients were considered to be at risk of clinical deterioration they were not accepted for treatment.
- The procedure staff should follow in the event of general deterioration in a patient on the day of surgery was not formalised in a standard operating procedure or policy. There was no protocol related to recognition, diagnosis or early management of sepsis as recommended in the guidelines published by the National Institute for Clinical Health and Excellence (NICE). Early warning scores were not used to assess deterioration in patients. However, staff were aware that they should telephone for an ambulance in the event of a patient requiring emergency assistance when attending clinic. The surgeon and anaesthetists were always on site during surgery days and the surgery team were clear that the surgeon or anaesthetist would take charge of the patient's needs in the event of any concern.
- There was a detailed 'safe surgery and interventional procedures' policy which had been reviewed in March 2017. This gave clear instructions applicable to each member of the theatre team. These instructions were compatible with the guidelines issued by the World Health Organisation for completion of the safer surgery checklist for cataract surgery and included reference to team briefing, sign –in to the anaesthetic room, time out, and sign out from theatre and theatre team briefing. Staff compliance with recording of these checks was audited by the lead nurse every month and no omissions were detected during the 12 months preceding our inspection. We observed two surgical operations and saw that staff followed this protocol seamlessly.
- The effective use of the checklists by the team had successfully identified one patient with an incorrectly recorded date of birth in their biometry. This was rectified with patient, and the correct intraocular lens was implanted. The incident was discussed at the medical advisory committee and was identified as an example to highlight the importance of the time out procedure.

Nursing and support staffing

- The accountability of all members of the theatre team was not defined. The clinic employed a small team of permanent staff including one registered nurse, and two administrative staff, i.e. one centre manager and one receptionist, one business manager, and four directors, one of whom was the surgeon responsible for cataract surgery. The remainder of staff attending the patients on surgery days were selected by the surgeon who worked with them at an NHS provider. These team members were not employed permanently by the clinic or by an agency. There was no formal agreement defining their responsibilities as clinicians on the days they worked at the clinic. Following our inspection, these members of the team were given employment contracts.

Requires improvement

Surgery

- On most surgery days, actual staffing levels were reflective of the numbers deemed necessary by the medical advisory committee. There was a minimum requirement of two registered nurses and one health care assistant in the theatre room plus one nurse for the pre-operative area and one for the post-operative area for each day of surgery. Any shortfalls in staffing were reported to the directors in the lead nurse report to the medical advisory committee. We saw that a shortfall had occurred on two occasions during the 12 months preceding our inspection when only two nurses were available in the theatre room.

Medical staffing

- One of the surgeons who cared for Medical Eye Clinic patients was co-owner and medical director of the company. Two more surgeons were engaged via practising privileges to carry out surgery on behalf of the Medical Eye Clinic.

Emergency awareness and training

- There were no formal plans to respond to major incidents other than weekly fire drills. Surgery was not compromised if power failed mid-treatment. Surgical equipment was fitted with an uninterruptible power supply sufficient to complete a surgical procedure.

Are surgery services effective?

Good

We rated effective as **good.**

Evidence-based care and treatment

- Current evidence and best practice were used to develop and deliver treatment. The senior management team discussed research evidence and new clinical guidelines within the medical advisory committee meeting. For example, the minutes of this meeting recorded discussion of treatment tools published by American Society of Cataract and Refractive Surgery for calculation of intraocular lens specifications.
- The medical advisory committee anticipated the implementation of guidance published by the National Institute for Health and Care Excellence (NICE).The minutes of this meeting recorded that the team had discussed the NICE cataract surgery guidelines due to be published at the time of our inspection.
- The team adhered to evidence based guidance by consistently following critical safety steps that minimised the most common avoidable risks endangering the lives and well-being of surgical patients. The team completed the minimum safety checks listed by the Medicines and Healthcare Products Regulatory Agency (MHRA) in the 'safer surgery checklist for cataract surgery' which is adapted from the World Health Organisation (WHO) 'safer surgery checklist'. We saw that the lead nurse ensured these checks were completed at the time of the surgery for every patient. The team followed best practice for the delivery of these checks which were read aloud with the attention of the entire team and recorded simultaneously, as recommended by the World Health Organisation.

Pain relief

- Patients undergoing ophthalmic surgery were treated under local anaesthesia. They were fully conscious and responsive. Staff were able to monitor their pain throughout the procedure. Staff clearly informed patients about the expected level of pain during and after the surgical procedure. Patients told us they did not feel pain during their procedure and they felt informed regarding the best way to manage any post-operative pain.

Nutrition and hydration

- Patients received adequate nutrition and hydration whilst they were attending the clinic for their surgery. Patients were not required to fast prior to surgery. Patients could access water in the waiting room and were offered hot drinks and biscuits following their procedure.

Patient outcomes

- The medical director audited surgical outcomes using information obtained at both the pre and post-operative visits. The medical director compared outcomes data to published data and reported this to the medical advisory board every four months. For example, the rates of surgical complications such as posterior capsule rupture (PCR) and cystoid macular oedema (CMO) were compared to the national average, the visual acuity

outcomes were compared to the Royal College of Ophthalmology National database audit and the refractive outcomes were compared to the Royal College of Ophthalmology target. The senior team explained that these outcomes compared favourably when benchmarked in this way, and we saw this documented in medical advisory committee meeting minutes.

- Data regarding clinical outcomes was not externally verified. The team did not submit data to national audits or to the Private Healthcare Information Network (PHIN).
- There had been no unplanned readmission or unplanned returns to theatre during the 12 months preceding our inspection. Two patients had attended the accident and emergency department of a local acute trust with suspected Toxic Anterior Segment Syndrome (TASS). These incidents were thoroughly investigated and no cause identified.

Competent staff

- The senior team did not maintain clear oversight of the competence of staff engaged via practising privileges or on permanent contract. The practising privileges policy referred to outdated legislation and was not specific regarding the training requirements for this group of staff.
- The system for monitoring the completeness of documentation supplied during the recruitment process was not effective. There were several essential documents missing. Not all staff files contained evidence of good character, qualifications, skills, competence and experience. We checked the staff files of all staff engaged via practising privileges agreement and we found that some of the required documentation detailed in the practising privileges policy was not available at the time of our inspection. For example, none of these staff files contained evidence of employment history or conduct in previous employment. Of the four files we checked, 75% contained evidence of appraisal during the 12 months preceding our inspection and 25% contained evidence of current compliance with mandatory training. However, some checks were consistently completed and evidence retained for staff files. For example, 100% of staff employed via practising privileges had evidence of disclosure and barring check, photographic identification, professional registration and indemnity insurance.
- At our subsequent unannounced inspection further documentation was made available to us and we were reasonably assured that all staff engaged via practising privileges and permanent contract were suitably qualified to carry out their role. All permanent staff employed at the clinic for more than 12 months had participated in an appraisal during the twelve months preceding our inspection. The lead nurse had completed the revalidation process during the 12 months preceding our inspection.
- The service used a collection of registered nurses and health care assistant staff who covered the staffing requirement for the surgery days. The senior team did not have adequate processes in place to ensure the suitability of these team members. These members of staff did not participate in any formal recruitment process and they held no employment contract or working agreement to provide services by which they could be held accountable for the care given. These team members were not required to submit evidence of employment history or conduct in previous employment. There was no policy that covered the oversight of competence of these members of the team. The staff files of these members of the team did not hold evidence of mandatory training compliance or appraisal. One of the four staff files we checked held no evidence of disclosure and barring check or photographic identification.

Multidisciplinary working

- The service was accredited as a continuing education trainer and had provided external training for optometrists approximately 19 months prior to our inspection. These sessions included ‘wet lab’ training where optometrists and ophthalmologists worked together in a simulated surgery exercise. The team hoped to provide more of these sessions.
- We observed the surgical operations of two patients being cared for by the surgical team in the operating theatre. We witnessed clear and respectful communication between all members of the

multidisciplinary team. The whole team was aware of their individual role and the role of the other team members. The combined team approach was entirely focussed on the needs of the patient.
- The pre-operative assessments and post-operative follow up consultations were provided under a service agreement and completed by optometrists working for a separate company housed in the same building as the Medical Eye Clinic. There were clear channels of communication between the staff working for these different organisations.

Access to information

- The systems for managing information were effective. All information needed for the ongoing care of patients was available to staff on the day of surgery and at subsequent post-surgery follow up appointments.
- The service complied with the quality standard published by NICE QS15 'Patient experience in adult NHS services'. Patients experienced coordinated care with clear and accurate information exchange between healthcare professionals. Following the patient's surgery, the teams shared details of attendance and outcomes with GP's in the form of a discharge summary.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff followed guidelines around consent that were based on current legislation and national guidelines. There was an up to date policy for consent that gave detailed instructions to staff regarding the assessment of mental capacity and the process of obtaining consent. The consent process began with the optometrist assessment when patient's treatment options were explained and patients were given a copy of the consent form to take home. Patients saw the surgeon to complete the consent procedure on the day of surgery. This process followed the Medical Eye Clinic policy for consent.
- However, there had been no audit of the consent process during the 12 months preceding our inspection.
- During the 12 months preceding our inspection, the service had not offered surgery to any patient who was unable to give informed consent to treatment.

Are surgery services caring?

Good

We rated caring as **good.**

Compassionate care

- Staff took time to reassure patients. Surgeons talked to patients during surgery and prepared patients for each new sensation that might be experienced, such as fluid running over the eye. This enabled patients to feel involved in the process.
- Staff respected the identity and dignity of patients. All staff in the surgery team introduced themselves to the patient. Staff showed interest in the individuality of patients, for example, asking questions about their occupational history or leisure interests. Staff used eye contact when speaking to patients and used humour to reduce anxiety.
- However, staff did not always respect the confidentiality of patients in their care. The post-operative recovery area was a small room shared by the patients who had just finished their surgery as well as those patients awaiting collection by their relatives. We observed nurses discussing individual patient's surgery details and post-operative care plans within earshot of other patients.

Understanding and involvement of patients and those close to them

- Staff in the surgery team gave thorough explanations and encouraged patients to ask questions. Surgeons in the surgery team at the Medical Eye Clinic supported patients to understand relevant treatment options including benefits, risks and potential consequences.
- During the pre-assessment consultation we observed the lead nurse addressing the specific queries of individual patients, giving practical assistance such as writing down instructions for a patient with memory difficulties. We did not inspect the entire pre-surgery consultation process because the optometrist assessment was provided by a member of staff working for a different organisation.
- On the day of surgery, nurses in the surgery team supported patients to manage their own recovery pathway. After surgery, patients were made aware of the importance of adhering to the precautions for their type of surgery in order to achieve the best possible outcome

for their vision. Patients were given the option of attending an optometry team close to home for their aftercare. We did not inspect the post-surgery follow up care because this element of the patient journey was provided under a service agreement by optometrists working for a separate organisation

Emotional support

- When patients were anxious, members of the surgery team were sensitive to their needs for reassurance. The patient could choose to have a staff member sit with them during surgery to hold their hand.
- Staff took time to explain what to expect on the day of surgery. Patients could choose to be shown the operating theatre and the surgical equipment prior to surgery.
- Staff engaged with patients during their pre-operative assessments and this helped patients to feel comfortable to ask questions. All patients told us that staff had made them feel at ease.

Are surgery services responsive?

Good

We rated responsive as good.

Service planning and delivery to meet the needs of local people

- The clinic offered some flexibility regarding the choice of dates and locations for pre-operative appointment and for surgery. At the time of our inspection, intraocular lens surgery was offered on three days per calendar month. Patients could choose which month but the date was limited to the designated surgery day. Patients could choose to see an optometrist in their local area for their post-operative follow up consultations.
- The facilities and premises met the needs of the service that was delivered. Waiting areas and treatment rooms were situated on the ground floor with ample parking available for patients. Treatment rooms were spacious and well maintained.
- The service had undertaken two contracts for NHS providers. These contracts were set up to alleviate pressure on NHS waiting lists. For one of these contracts, the Medical Eye Clinic altered several of its usual practices in order to adapt to the specific needs of the patients attending and to fulfil the requirements of the commissioning agencies. For example, a one stop clinic was offered that combined optometrist assessment, consent procedure and surgery in one day.
- A local acute trust commissioned The Medical Eye Clinic to deliver cataract surgery for patients in the Dorset area as part of an initiative to reduce waiting lists for treatment. The feedback from the commissioners of this contract was positive and stressed the quality and responsiveness of the service provided.

Access and flow

- Patients followed a surgical pathway. Patients were referred onto the surgical pathway by an optician. At their initial consultation, patients were seen by the lead nurse from the Medical Eye Clinic and an optometrist from a separate organisation located in the same premises as The Medical Eye Clinic. At this appointment, the lead nurse conducted a health interview with the patient and completed topography and biometry scans of the patient's eyes which were used to inform the optometrist's assessment and recommendation for the next stage of treatment. The next appointment with the Medical Eye Clinic was the day of treatment.
- The surgical pathway spanned two separate companies located in the same premises. We did not inspect the optometry pre-assessment process as this was not part of the services provided by the Medical Eye Clinic. From time to time, the managing director of the Medical Eye Clinic also carried out the optometrist pre-assessment function. The managing director informed us that the optometrist examined the patient's eyes and assessed their vision and determined what surgical procedure to recommend to the patient, pending surgeon's approval. At this stage, patients were informed regarding the costs of treatment and patients were given a consent form to take away and read.
- We did not inspect the optometry follow up process because this was provided under a service agreement by a separate company. The patient was reviewed by an optometrist approximately four weeks following their surgery. Repeat aftercare appointments were then determined by the optometrist.
- Patients were made aware of the pathway following their eye surgery and if unforeseen complications arose outside of normal working hours they were advised to contact their local emergency department

Requires improvement

Surgery

- Patients could access treatment in a timely way. There was no waiting list for consultation or for surgery.
- There was a system to ensure that patients could access expert advice during normal working hours if they experienced any concerns following their eye surgery. Patients were advised to telephone the optometry service located in the same premises as the clinic. The receptionist covering the optometry service (a Medical Eye Clinic staff member) answered these calls and followed an algorithm to ensure that all relevant information was gathered in order for a clinician to assess the urgency of the situation. The receptionist could access the diaries of all optometrists working that day and send an electronic message to alert a named optometrist to respond to the patients query.
- The team took action to minimise the time that patients spent in clinic on their day of treatment. Patient arrival times were staggered to coincide with their allotted surgery time. This meant there was less time spent waiting in the clinic. During our inspection, clinics ran on time.
- There were a small number of surgical operations (seven) cancelled for non-clinical reasons during the 12 months preceding our inspection. All seven patients were offered another appointment within 28 days of the cancelled appointment.
- There was a system for ensuring that patients who were referred for surgery were suitable for this treatment option. Patients were referred by an optician and then assessed by the nurse and optometrist at the pre-operative consultation following an agreed assessment pathway, which took into account the identified risk factors such as asthma and high blood pressure. The surgeon made the final decision as to the suitability of the patient for surgery.

Meeting people's individual needs

- Some reasonable adjustments were made so that patients with disabilities could use the service on an equal basis to others. For patients with mobility impairment, registered nurses were available to assist patients to transfer in and out of the theatre chair. However, patients were expected to provide their own moving and handling equipment as none was stored at the clinic. For patients with hearing impairment, there was no hearing loop available at the clinic.
- For patients with learning disability or dementia, the clinic made reasonable adjustments on a case by case basis. This included involving carers in discussions and taking extra time for appointments. Patients were only considered as suitable candidates for surgery if they were able to give informed consent for the procedure.
- The service had not made reasonable plans for adjustment in the event of a person requiring foreign language or sign language interpreter. There was no policy regarding the use of interpreters and staff were not aware how to access this resource. However, there had been no requirement to engage a foreign language interpreter or a sign language interpreter during the 12 months preceding our inspection.

Learning from complaints and concerns

- There was a system for dealing with complaints including a current complaints procedure. There were feedback forms available in the clinic reception. The service had not received any complaints since it opened in 2015.

Are surgery services well-led?

Requires improvement

We rated well-led as **requires improvement.**

Vision and strategy for this core service

- The leaders of the service were focussed on the continual development of the service. This included continuation of the focus on the quality of patient outcomes as well as the future diversification of types of surgery offered to include blepharoplasty.
- Leaders were keen to engage more with NHS providers to secure further contracts. The Medical Eye Clinic had successfully completed two NHS contracts during the 12 months preceding our inspection and leaders hoped that future NHS contracts could be agreed.

Governance, risk management and quality measurement (and service overall if this is the main service provided)

- There were systems to monitor the safety of patient care. The lead nurse, anaesthetist and the medical director each submitted a safety report for the medical advisory committee meeting held every four months. We saw that these reports covered a summary of any incidents occurred and actions taken to address risks

arising from incidents. In between meetings, safety briefings were held every day of surgery and any safety issues requiring escalation were brought to the attention of the managing director or the medical director.

- In some circumstances, leaders took prompt and comprehensive action to address safety concerns when they were made aware of these. For example, when faults with surgical equipment were identified, these were swiftly investigated and replacement items made available. However, the minutes of the medical advisory committee meetings recorded that two members of staff were awaiting disclosure and barring checks over a 16 month period December 2015 to April 2017. This was not recorded on the risk assessment document. In December 2015 it was identified that a member of staff required safeguarding training. This was recorded as an outstanding agenda item for two subsequent meetings until it was completed in December 2016.
- The leaders of the service did not have clear oversight of all safety procedures and did not ensure that all essential safety checks were completed. The nurse report to the medical advisory committee included reference to equipment such as the air handling unit, but not to the routine maintenance of equipment used in surgery. The reporting process had not identified a lapse in the service history for the non-invasive laser machine.
- There had been no recent review of the information used to monitor performance. Not all of the information reported to the medical advisory committee was accurate, for example the mandatory training status of staff was falsely reported as compliant.
- Audits were completed but these were not part of an audit schedule based upon risk assessment. Not all relevant audits were completed, for example there had been no audits of documentation, consent, and hand hygiene or medicines management since the clinic opened in 2015.
- The process for monitoring ongoing risks was not robust. The service did not hold a risk register. There was a risk assessment for the service. At the time of our inspection this document did not include any live risks. During our inspection one live risk was added related to the maintenance of the non-invasive laser equipment. This risk was undated, did not identify a specific named person to complete the mitigating action and did not contain a date by when it should be completed. This risk assessment document was not referred to at the medical advisory committee meeting and there was no evidence of the closed risks having been discussed in this forum.
- Not all policies and procedures provided relevant guidance to operational staff. The practising privileges policy referred to outdated legislation such as the Care Standards Act 2000. Not all policies were comprehensive. The medicines management policy did not include reference to the management of controlled drugs. Not all key areas of risk were covered by an operational policy. All policies we checked had been reviewed within the 12 months preceding our inspection. However, the medical advisory committee were not involved in the review or 'signing off' of policies.

Leadership / culture of service related to this core service

- This clinic had a small quantity of employed staff, four in total: a lead nurse, a receptionist/patient care advisor, a centre manager and a business development manager. We spoke with three of these staff and all said they felt supported in their roles.
- The directors of the company were easily accessible and visible to all staff. Two of the directors worked at the clinic in a clinical capacity, the medical director/ nominated individual was a surgeon and the managing director /registered manager was an optometrist. We saw that all grades of staff were encouraged to voice their concerns and the registered manager responded positively.
- Staff told us they felt supported in their roles and valued for the work they did. Staff were proud of the service provided to patients. All staff prioritised patient care as their primary focus.

Public and staff engagement (local and service level if this is the main core service)

- The service proactively sought the views and experiences of patients. A patient satisfaction survey was completed following surgery. From October 2016 to February 2017, results showed an average response rate of 84% and an overall patient satisfaction rate of 100%. However, there was no patient representation on the medical advisory committee.

- Permanent staff told us they felt involved in the company, they were able to raise concerns or make suggestions and were well informed regarding changes to policy or procedure.
- The leadership team engaged effectively with NHS providers. Feedback from commissioners of the NHS contract completed by the Medical Eye Clinic reported that leaders engaged proactively with the commissioning team, maintaining a positive and supportive working relationship and meeting all key performance indicators.

Innovation, improvement and sustainability (local and service level if this is the main core service)

- Leaders responded positively to opportunities for learning. For example, the senior team demonstrated a willingness and commitment to make improvements to the service as a result of our inspection. For example, within three months of our inspection, the nurses working on surgery days were offered employment contracts, one of the directors trained as a laser protection advisor, and a controlled drugs policy was written.
- The medical advisory committee focussed on reported outcomes to make improvements to the service offered. There was a complete audit pathway which enabled the team to identify which refractive constants produced the best outcomes for the type and brand of intraocular lenses used at the Medical Eye Clinic. This allowed the surgery team to constantly review and modify their selection to facilitate improved clinical outcomes for patients.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must take prompt action to address a number of concerns regarding the accountability of those team members providing care on surgery days. This action must address the omissions in the recruitment process.
- The provider must take prompt action to address a number of concerns regarding the oversight of staff training in essential systems and processes to keep patients safe
- The provider must take prompt action to address the lack of comprehensive risk assessment and operational protocols regarding the use of the non-invasive laser equipment.
- The provider must ensure there are systems and processes that are operated effectively to assess, monitor and mitigate the risks relating to health, safety and welfare of patients and staff.
- The provider must ensure that there are adequate policies and protocols that are comprehensive and are written to be compatible with current legislation. Sign-off of policies should be undertaken by the medical advisory committee. These policies should be audited to monitor compliance.

Action the provider SHOULD take to improve

- The provider should ensure that all patients confidentiality is maintained at all stages of the patient journey
- The provider should consider conducting a review of the current governance systems.
- The provider should consider setting up a system of assurance that incorporates an audit schedule and defined areas of responsibility around safety processes.
- The provider should ensure that the processes for accountability for controlled drugs provide clear oversight that is separate from the processes of administration of controlled drugs.
- The provider should contribute relevant data to the Private Healthcare Information Network (PHIN)

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems or processes must be established and operated effectively to ensure compliance with the requirements of this part. Systems and processes must enable the registered person to: -(a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (b) assess monitor and mitigate the risks relating to health, safety and welfare of service users and others The information reported to the medical advisory committee was not consistently accurate or complete. The process for monitoring ongoing risks was not robust. Not all potential risks to patient safety, such as omissions of DBS checks, were mitigated within a reasonable time-frame. Not all policies and procedures provided adequate mitigation of risk in the form of guidance to operational staff.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment {C}(1) {C}Care and treatment must be provided in a safe way for service users. {C}(a) {C}Assessing the risks to health and safety of service users of receiving the care or treatment

This section is primarily information for the provider

Requirement notices

Safety risk assessments were not used consistently to develop effective or comprehensive protocols to keep patients safe. The risk assessment and associated guidance around the use of the non-invasive laser was not adequately comprehensive.

Regulated activity

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

Regulation

Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

(1)Persons employed for the purposes of carrying out a regulated activity must- a) be of good character (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them,

(2)Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in a) paragraph (1)

(3) The following information must be available in relation to each such person employed (a)the information in schedule 3

The provider must ensure there are systems to give assurance of the qualifications, competence, skills, experience, good character of the persons employed at the clinic.

The Medical Eye Clinic did not have a system for monitoring the completeness of documentation supplied during the recruitment process. There were several essential documents missing. Not all staff files contained evidence of good character, qualifications, skills, competence and experience. The accountability of some members of the team was not assured because there was no formal agreement or employment contract for their work at the clinic.