Acuitus Medical Ltd

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

Ratings

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Acuitus Medical Ltd is operated by Acuitus Medical Ltd. The service provides day case cosmetic surgery. Facilities include one operating theatre, an admissions room, a recovery room and one consultation room. There is also a waiting room, toilet and shower.

The service provides cosmetic day surgery. We inspected cosmetic day surgery.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 11 June 2019 (we gave staff 48 hours notice that we were coming to inspect). We last inspected this service in June 2018 when we issued a requirement notice for breach of regulation 12 (safe care and treatment) and regulation 17 (good governance).

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.

The main service provided by this service was cosmetic surgery. Where our findings on surgery – for example, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the surgery service report.

See surgery section for main findings.

Services we rate

The service was previously inspected but not rated.

We found safe was inadequate, effective was required improvement, caring and responsive were good and well led was inadequate. We rated it as **Inadequate** overall.

We found areas of practice that require improvement in services:

- Staff did not always complete and update risk assessments for each patient and remove or minimise risks.
- Patients completed on line pre-operative assessments, but we could not see that staff checked these and acted on any concerns
- The service had enough staff, but they did not all have the right skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Records were not always clear and there were omissions to some records.
- Managers did not always check to make sure staff followed guidance.
- The service did not use clear systems and processes to safely prescribe, administer or record medicines. Medicines were not prescribed or administered in accordance with national guidance.
- The provider did not have robust processes in place to monitor and assess patient outcomes and the quality of the service.
- The service did not always provide care and treatment based on national guidance and evidence-based practice, polices were not consistent and did not contain relevant up to date information.

Summary of findings

- Staff did not monitor the effectiveness of care and treatment. They did not use the findings to make improvements to achieve good outcomes for patients.
- Leaders did not all have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced.
- Although the service had a vision for what it wanted to achieve there was not a clear strategy or plans to turn it into action. Leaders and staff did not always understand and apply them to monitor progress.
- The provider did not have effective systems and processes in place to develop and review policies. Not all policies were reflective of the service and not all policies were adhered to.
- Leaders did not operate effective governance processes, throughout the service and with partner organisations.
- Leaders did not use effective systems to manage performance effectively. They did not identify and escalate relevant risks and issues or identify actions to reduce their impact. They had some plans to cope with unexpected events. It was not clear how often risks were reviewed and completed audits lacked detail.
- Although staff were committed to continually learning and improving services, they did not have a good understanding of quality improvement methods or the skills to use them.

However, we found the following areas of good practice:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff kept records of patients' care and treatment. Records were stored securely and easily available to all staff providing care.
- Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Patients were supported to make informed decisions about their chosen procedures and treatments and were given sensible expectations.
- The service controlled infection risk well. The service used systems to identify and prevent surgical site infections.
- Managers were visible and approachable in the service for patients and staff.
- Leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services.

Following our inspection we took urgent enforcement action.

I am placing this service into special measures. Following this inspection, we sent a letter raising our concerns. In response to our letter, the provider took some immediate actions to address the concerns we raised. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Summary of findings

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

Nigel Acheson

Deputy Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	**Inadequate** 	We rated this service as inadequate overall because it did not manage medicines safely and in line with national guidance, staff did not review all risk assessments and act upon them, records were not well maintained, leaders did not have the skills and ability to run the service and governance processes were not effective. However, feedback from patients was positive. Appointments were scheduled to meet the needs and demands of the patients who required their services.

Summary of findings

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Inadequate

Acuitus Medical Ltd.

Services we looked at
Surgery

Summary of this inspection

Background to Acuitus Medical Ltd

Acuitus Medical Ltd is operated by Acuitus Medical Ltd. The service opened in 2015. It is a private cosmetic service in Watford, Hertfordshire. The service primarily serves the communities of London and the Home Counties. It also accepts patient referrals from outside this area. Services are provided for patients aged over 18 years. It provides a range of cosmetic procedures including rhinoplasty (nose reconstruction), rhytidectomy (facelift), breast augmentation (implants), liposuction (fat removal) and abdominoplasty (tummy tuck). All patients are seen on a day case basis.

The service has had a registered manager in post since 11 June 2015. The short announced comprehensive inspection took place on 11 June 2019.

We regulate cosmetic surgery services and we now have a legal duty to rate them when they are provided as a single specialty service. We highlight good practice and issues that service providers need to improve and take regulatory action as necessary.

The service provides day case cosmetic surgery for adults only. No persons under the age of 18 are seen and/or treated at the service. The service is operational Monday to Friday 9.00am to 8.00pm and Saturdays from 9.00am to 5.30pm.

The service offers services for self-paying clients only.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and second CQC inspector. The inspection team was overseen by Julie Fraser inspection manager and Bernadette Hanney, Head of Hospital Inspection.

Information about Acuitus Medical Ltd

The service has one day case theatre and is registered to provide the following regulated activities:

- Surgical procedures
- Treatment of disease, disorder and injury

During the inspection, we visited the day case theatre, the consultation room the admission room, the recovery room and the decontamination room. We spoke with four staff including the registered manager and clinical director, one administrator and a registered nurse. We spoke with three patients. During our inspection, we reviewed eight sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected three times, once in May 2017 and December 2017. The most recent inspection took place in June 2018. In June 2018 we found that the service was not meeting all standards of quality and safety it was inspected against. This led to two requirement notices being issued for regulation 12 (safe care and treatment) and regulation 17 (good governance).

Activity (March 2018 to February 2019)

- In the reporting period March 2018 to February 2019 There were 664 day case and outpatient episodes of care recorded at the service; of these 246 (37%) were day case discharges and 418 (63%) were outpatient attendances.

There were two surgeons, two anaesthetists employed under practising privileges, two registered nurses and seven other staff. The accountable officer for controlled drugs (CDs) was the registered manager.

Track record on safety

Summary of this inspection

- Zero never events
- The service reported two clinical incidents
- Zero serious injuries
- Zero incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA)
- Zero incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- Zero incidences of hospital acquired Clostridium difficile (c.diff)
- Zero incidences of hospital acquired E-Coli
- The service had received two complaints from March 2018 to February 2019

No other services operated within the location.

Services accredited by a national body:

- Clinical and or non-clinical waste removal
- Interpreting services
- Maintenance of medical equipment
- Decontamination of 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?

The service was previously inspected but not rated

Inadequate

We rated it as **Inadequate** because:

- Staff did not always complete and update risk assessments for each patient and removed or minimise risks. This meant that opportunities to prevent or minimise harm were missed.
- Patients completed on line pre-operative assessments, but we could not see that staff checked these and acted on any concerns.
- The service had enough staff, but they did not all have the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Records were not always clear and there were omissions to some records.
- Managers did not always check to make sure staff followed guidance.
- The service did not use clear systems and processes to safely prescribe, administer or record medicines which put people at risk. Medicines were not prescribed or administered in accordance with national guidance.

We found the following areas of good practice:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff kept records of patients' care and treatment. Records were stored securely and easily available to all staff providing care.

Are services effective?

The service was previously inspected but not rated

Requires improvement

We rated it as **Requires improvement** because:

- Managers did not always check to make sure staff followed guidance.
- Staff assessment processes were not robust.
- Although there were policies in place some were out of date and there were several different formats.
- Some audits were carried out, but these were not detailed and did not contain clear action plans. We did not see any evidence that lessons had been learnt or shared from audits

Summary of this inspection

We found the following areas of good practice:

- Staff gave patients enough food and drink to meet their needs.
- Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Are services caring?

The service was previously inspected but not rated

Good

We rated it as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Are services responsive?

The service was previously inspected but not rated

Good

We rated it as **Good** because:

- The service planned and provided care in a way that met the needs of local people and the communities served. The services provided reflected the needs of the population served.
- The service was inclusive and took account of patients' individual needs and preferences.
- People could access the service when they needed it and received the right care promptly.
- It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

Are services well-led?

The service was previously inspected but not rated

Inadequate

We rated it as **Inadequate** because:

Summary of this inspection

- Leaders did not all have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced.
- Although the service had a vision for what it wanted to achieve there was not a clear strategy or plans to turn it into action. Leaders and staff did not always understand and apply them to monitor progress.
- Leaders did not operate effective governance processes, throughout the service and with partner organisations.
- Leaders did not use effective systems to manage performance effectively. They did not identify and escalate relevant risks and issues or identify actions to reduce their impact. They had some plans to cope with unexpected events. It was not clear how often risks were reviewed and completed audits lacked detail.
- Although staff were committed to continually learning and improving services, they did not have a good understanding of quality improvement methods or the skills to use them.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Inadequate

Surgery

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

Are surgery services safe?

Inadequate

The service was not previously rated

We rated it as **inadequate.**

Mandatory training

The service provided mandatory training in key skills to all staff. However, the process for monitoring and recording the training was not robust.

- Staff received mandatory training in safety systems, processes and practices. Training was mostly provided via e-learning modules, with face-to-face sessions for basic life support training. Staff within the service understood their responsibility to complete mandatory training.
- There was some evidence that staff had completed mandatory training modules including infection prevention and control, fire, complaints, health and safety, information governance, safeguarding vulnerable adults and chaperone training. Specific training for clinical staff included anaphylaxis, specialised equipment training and operating room protocols. However, the system to ensure staff had undertaken training was not robust. There was no obvious oversight of consultant's mandatory training.
- Managers had introduced a training tracker to monitor compliance with mandatory training. This was an improvement from our previous inspection in June 2018. The training tracker recorded that training had been completed but it was not fully up to date and did not include a date for review. Review date information was held in the staff members personal record together with training certificates. Managers planned to introduce a training calendar to monitor compliance on a quarterly basis.

Safeguarding

Not all staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse but did not all know how to apply it.

- There were processes and practices in place to safeguard adults from avoidable harm, abuse and neglect that reflected relevant legislation and local requirements. The service's safeguarding policy was in-date and accessible to staff via the intranet. This policy referred to adults and included details of who to contact if staff had any concerns about an adult. Although the service did not see children, the safeguarding policy referred to ensuring that the needs of children were met if any concerns were raised through consultation with a patient. There were clear processes to follow in the event of a safeguarding concern.
- The registered manager was the designated safeguarding lead for vulnerable adults. The registered manager was trained to level two.
- Eight staff had received adult safeguarding training on how to recognise and report abuse at level two. However, three staff were due to complete training in March 2019, this had not been recorded as completed. One member of staff had received additional online training about female genital mutilation (FGM).

However, staff were not all clear about what constituted a safeguarding concern, for example the use of antidepressant medications was identified as a safeguarding concern.

- There had been no safeguarding concerns raised to CQC in the reporting period from March 2018 to February 2019.
- The service had an up to date chaperone policy. Six members of staff, including administrative staff had attended chaperone training. Three staff members were due to complete this in March 2019; however, the training tracker was not updated to indicate that training had been completed. Notices were displayed throughout the service advising patients that a chaperone was available on request.
- Safety was promoted in recruitment procedures and ongoing employment checks. Staff had Disclosure and Barring Service (DBS) checks carried out at the level appropriate to their role. We saw that staff had up to date DBS certificates. However, the requirement for DBS checks was not referred to in the practising privileges policy.

Cleanliness, infection control and hygiene

The service controlled infection risk well. The service used systems to identify and prevent surgical site infections. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

- Standards of cleanliness and hygiene were generally maintained. We saw that there were cleaning schedules in place and that these were completed. Environmental cleanliness audits for January to March 2019 demonstrated that areas were checked regularly for standards of cleanliness. The operating theatre was cleaned after each procedure. A cleaner attended three times a week for all areas.
- The service used single patient use surgical instruments and had done so since the last inspection in 2018. During this inspection the registered manager confirmed that the service continued to use single use instruments. The decontamination of equipment was outsourced to another service. This eliminated the risk of cross patient contamination from re-used medical equipment.
- The service had an up to date infection prevention and control policy. We saw that the five moments of hand hygiene notices and “bare below the elbows” signs were evident. We saw evidence of personal protective equipment (PPE), gloves and hand gel. There was no clinical activity on the day of our inspection and we were unable to observe hand washing in line with national guidance(NICE Infection prevention and control: QS61, quality statement 3 April 2014). Hand hygiene audits were carried out monthly and 100% compliance was demonstrated between January and March 2019. However, we saw one member of clinical staff wearing false nails. We raised this at the time of our inspection. The service did not have a uniform policy.
- Appropriate theatre attire was available for staff when they carried out procedures. The service used disposable clinical wear (commonly referred to as “scrubs”) for intra-operative procedures. Designated theatre shoes were available for staff to wear in the procedure room. This was in line with best practice (Association for Perioperative Practice Theatre Attire 2011). The e-nurse handbook contained a theatre attire poster (Standards and Recommendations for Safe perioperative practice Sept 2011) but no other uniform policy.
- The storage area for intravenous (IV) fluids, sterile instruments and consumables was clean and tidy. There were no sealed boxes stored on the floor. This was an improvement from our last inspection in June 2018 when some sealed boxes were stored on the floor and could be damaged if a flood occurred. However, intravenous fluids were not locked away and were accessible to all staff.
- The temperature in the storage area was checked on a daily basis and records we reviewed confirmed this.
- Patients were screened for MRSA (antibiotic resistant bacteria) in line with national guidance (Department of Health Implementation of modified admission MRSA screening guidance for NHS (2014). The pre-operative risk assessment form included patient history for MRSA. There had been no incidents of MRSA from January 2018 to December 2018.
- Patients were provided with written information about pre-operative skin preparation before their surgery. Staff checked with patients that they had used the

pre-operative skin preparation when they were admitted for surgery. There were notices for patients and relatives displayed with information about reducing the risk of surgical site infections.

Environment and equipment

The facilities and premises were well maintained. However, the service was not consistent with the maintenance of equipment to maintain patient safety. Staff managed clinical waste well.

- The premises were well maintained and had suitable facilities for the cosmetic surgeries and consultations provided.
- All electrical items were electronically tested. A service level agreement was in place between the service and an external maintenance provider. They attended the service annually to service and safety test the electrical equipment. However, we were unable to see the service dates on electrical equipment in theatre.
- Most consumables checked were in date, however we found one box of haemoglobin test cards that were out of date. This meant that staff could not be assured that results were accurate.
- Staff told us that the contents of the resuscitation trolley were checked weekly as dictated by the audit schedule. The resuscitation policy stated that the resuscitation equipment must be checked when there was clinical activity. The resuscitation trolley was checked as part of the pre-operative World Health Organisation (WHO) Surgical Safety Checklist. However, the resuscitation trolley was not tamper evident. This meant that there was a risk that items could be used and not replaced. Resuscitation council guidelines were clearly displayed.
- We found that some flammable items were not stored in line with the control of substances hazardous to health (COSHH) guidelines. This guidance recommends that potentially hazardous chemicals are stored in a COSHH cabinet. We raised this during our inspection and staff took immediate action to lock flammable items in a COSHH cabinet.
- Sharps bins were generally labelled and stored appropriately. However, we saw that one sharps bin was overfilled.
- Toilet and shower facilities were available for patients. However, there was no call bell system available for patients in case of an emergency occurring, or a patient requiring assistance in the bathroom.
- There was a service level agreement in place for the collection of clinical waste. This ensured the safe collection, handling and disposal of any clinical waste.
- There were processes in place for providing feedback on product failure to the Medicines and Healthcare Products Regulatory Agency (MHRA). Details of products used on each patient such as the lot number (an identification number assigned to a particular quantity or lot of material from a single manufacturer), was recorded and stored in the patient record.
- Monthly environmental audits were undertaken. We saw that actions were taken immediately if there were areas of non-compliance.
- Fire safety equipment was fit for purpose and was in date. This included fire extinguishers, fire blanket, alarm system, heat and smoke detectors, and emergency lighting. All staff had received fire training. The fire extinguishers were checked monthly and a fire alarm test was done weekly. One staff member had received fire marshal training. A practice drill had taken place two months before our inspection. However, there were no details or attendees, or actions taken.

Assessing and responding to patient risk

Staff did not always complete and update risk assessments for each patient and remove or minimise risks. Patients completed on line pre-operative assessments, but we could not see that staff checked these and acted on any concerns. Opportunities to prevent or minimise harm were missed.

- There were policies in place detailing what action should be taken if a patient deteriorated and required transfer. However, the deteriorating patient policy was focussed on the measurement of the National Early Warning Score (NEWS). Managers told us that they were planning to implement training to manage an emergency transfer. Staff were able to describe what they would do if a patient required immediate transfer. This involved dialling 999 and requesting an ambulance transfer. No patients treated at the service had required transfer to the local acute NHS provider.

- The service carried out cosmetic procedures that could be performed under local anaesthesia or intravenous sedation. There was an agreement with the local acute NHS hospital for the transfer of patients if they required a higher level of care.
- Patients seen at the service were generally fit and healthy. The service had a sepsis policy. Electronic sepsis training was provided but was not recorded on the training tracker system. We were not assured that the service had effective systems, oversight and training for the identification and treatment of sepsis. The electronic handbook referred to the NEWS observations that would be taken if a patient deteriorated during a procedure but not to any further actions. There was no reference to the management of a patient who was unwell post procedure and who disclosed symptoms during post operative support telephone calls.
- Pre-operative consultations for cosmetic surgery included a risk assessment of the patient's suitability for the procedure, such as their medical history, general health, age, existing diseases or disorders, medications and other planned procedures. Patients completed a preoperative questionnaire on line and returned it to the service. We could not see evidence in five out of eight records that these had been reviewed and were not assured that all health risk factors would be identified. We raised this with managers who took immediate action to amend the form to include a signature of the health professional who had reviewed the forms.
- Although the service undertook risk assessments including the NEWS to identify a deteriorating patient and venous thrombo-embolism (VTE) they were not using the most up to date version of the NEWS. We found that the NEWS and VTE assessments were mainly carried out accurately. This meant that staff were assessing and documenting patient risks.
- Some patients had observations recorded before, during and after surgery. We reviewed eight sets of patient records and saw that two patients observations were not fully recorded. We were not assured that all patients observations were taken or recorded correctly. This meant that there was a risk that staff may not recognise or respond appropriately if the patients health deteriorated.
- There were arrangements in place to ensure patient safety checks were made prior to, during and after surgical procedures were completed. This was in line with national recommendations (National Patient Safety Agency (NPSA) Patient Safety Alert: WHO Surgical Safety Checklist January 2009). This was an improvement from our last inspection. A team brief was carried out prior to each operating list, however, the team brief check list stated only that "everyone must be present" and did not identify which roles these were. There was no record of any discussions held or potential risk factors, this meant that we were not assured that any issues of concern were clearly identified. We raised this with managers during our inspection and they immediately revised the check list to include full details of those present and their role.
- The admissions policy stated that patients should be escorted home by a responsible adult following a procedure undertaken under intravenous sedation. All patients had to have access to a telephone in case they needed to contact someone for follow up advice or treatment. We saw that one patient had requested a taxi to take them home which was not in line with the policy. Managers told us that the patient was accompanied by a staff member. We did not see evidence of this discussion in the patient record. We were not assured that safe discharge arrangements had been communicated to the patient. Staff told us that this had been discussed at a recent meeting and surgeons would only operate if the patient had an escort home.
- Not all discharge summaries contained full details of medications prescribed and these were not clearly recorded in the patient record. Therefore, we were not assured that all risks to patients receiving medication had been considered, for example if the patients received the correct instructions about the medications, how long to take it and the exact dosage. We raised this with managers. Following our inspection, documentation was amended to include all these details.
- During surgical procedures there were three to four staff in the operating theatre. These included the surgeon, anaesthetist and a registered nurse and the registered manager. Occasionally there was a second nurse. The anaesthetists and two surgeons had advanced life support (ALS) training, the nurse had immediate life

support (ILS) and was booked for ALS training in October 2019. The registered manager had ALS training which was in date and due for review in October 2019. The service had appropriate monitoring equipment which included capnography equipment which assesses ventilation for patients undergoing sedation. This was in accordance with The Association for Perioperative Practice (AfPP) - Leading Perioperative Excellence (December 2018).

- Patients were contacted by staff post operatively for up to 14 days to review their condition and answer any questions that they had.
- The service had an admission policy which set out the criteria for the selection and admission of patients to the service. The American Society of Anaesthesiologists (ASA) classification of physical health was used to assess a patients' suitability for treatment at the service. Most patients had an ASA score of one. This meant they were completely healthy and fit for surgery. Occasionally, the surgeon would operate on a patient with an ASA score of two. This meant the patient had a mild systemic disease, which was well-controlled and had no functional limitations. The exclusion criteria for treatment at the service included patients with a body mass index of more than 35 (obese), active treatment for cancer, a history of myocardial infarction (MI) within the last 12 months or venous thromboembolism (VTE), a condition in which a blood clot forms in a vein.
- Psychologically vulnerable patients were identified and referred for appropriate psychological assessment (Royal College of Surgeons Professional Standards for Cosmetic Surgery 2016). Staff were prompted on the pre-operative assessment template to ask patients if they had a history of mental illness. Following the pre-operative consultation, the surgeon would only write to the patient's GP advising them of the planned procedure if there was any concern raised. Manager's told us that some patients did not want their GP to be made aware of their procedures.
- We saw that a white board was used for swab and needle counts in the procedure room. This meant it was clear to both the surgeon and scrub nurse the number of swabs and needles that had been used. Staff told us that these were counted for completeness by the surgeon and scrub nurse at the end of each procedure.
- All patients seen at the service had consultant-led care. There was access to consultant medical input the whole time a patient was in the service. The anaesthetist remained in the service until all patients had been discharged.
- At the initial consultation and again on discharge, patients were given the surgeon's personal mobile number and the service telephone number for any questions or concerns they had. Patients had direct access the surgeon for 48 hours following their procedure.
- The service had one emergency call bell in the recovery area in case of an emergency, this sounded throughout the building. There was no recorded testing of this so the service had no assurance that it was working. The nurse and the surgeon each had access to a "walkie talkie". Patients were not left unattended in the recovery area.
- The service had a major haemorrhage pack. This was checked weekly. We saw that all items were in date and available.

Nursing and support staffing

The service had enough staff but they did not all have the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

- One permanent full time member of nursing staff was employed. One bank nurse was employed and used when needed. We saw that staffing levels were sufficient, with each patient attended to by the cosmetic surgeon and a registered nurse. However, the registered manager reported that the service experienced difficulty in recruiting nursing staff. This was not recorded on the risk register.
- Staff had an initial induction to the service, an electronic handbook with policies and processes was provided with some specific clinical training in addition to mandatory training. For example, the registered manager provided some training about pre-operative assessment. The service did not have a formal competency booklet or assessment process, therefore we were not assured that learning was embedded.
- The nurses were assessed as competent in all clinical activities, for example scrub technique, by the registered

manager. We were not provided with any evidence of competencies to demonstrate the nursing staff's capability of working in a cosmetic and theatre environment, or method of assessment of competence. We could not be assured staff competencies were being adequately monitored and were not assured that all staff had the required competencies to keep patients safe. Managers told us that staff exposure to procedures was increased gradually and they would progress to more complex tasks as they became more experienced.

- A health care assistant was due to commence employment. No agency staff were used by the service.
- Seven non-clinical staff were employed, including the registered manager and commercial director.
- No procedures had been cancelled due to inadequate staffing.

Medical staffing

The service had enough medical staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix and gave locum staff a full induction.

- There were four medical staff worked under practising privileges with a fifth due to start.
- Four of the medical practitioners holding practising privileges for cosmetic surgery were on the General Medical Council (GMC) specialist register for plastic surgery. The service had a practising privileges policy however this was not dated so we could not be assured that this had been reviewed to ensure the most up to date information was included. It was a requirement of the practising privileges policy that the surgeon was contactable for 48 hours following surgery and lived within one hour of the service.
- As all patients attended the service as a day-case or outpatient, there were no handovers or shift changes. The surgeon and anaesthetist remained in the service until all patients were discharged.

Records

Staff kept records of patients' care and treatment. Records were, stored securely and easily available to all staff providing care. However, records were not always clear and there were omissions to some records.

- The service had two record keeping systems in place. Patient's pre and post-operative records were stored in an electronic record format. This meant that all consultants, service and clerical staff had access to the record. A written paper record of the patient's procedure was maintained. We found that not all conversations were recorded. Three online records were seen, there was only evidence of a discussion with the patient about post-operative pain, sickness or medication in one record. This meant that it was difficult to follow the complete patient pathway in the record and to be sure that follow up conversations included discussions about any symptoms. This meant we could not be sure that patients were being discharged from the service with adequate information to keep them safe.
- During our last inspection in June 2018 we noted that not all entries within the records were dated and signed to ensure a complete and comprehensive patient record. During this inspection we reviewed eight records and saw that there were still some omissions to records, for example there was no documentation about the dispensing of some medications, there were no recorded signatories on some check lists and not all entries had names and dates of every page.
- Pre-operative assessments were recorded and stored in the patient's paper record. They included next of kin and GP details, past medical history, allergies, medication taken and details of actions to take before the clinical procedure. However, these forms were not signed as having been reviewed by clinical staff. We were not assured that for example, any allergies or current medication were identified. This meant we could not be assured that any contraindications to patent safety would always be assessed and recognised. We raised this with managers who reviewed the pre-operative assessment form and amended it to include details of medications used. A section was added for staff signatures clarifying that they had reviewed the assessment and documented any findings and actions taken.
- Monthly record keeping audits were undertaken. These were limited and did not contain details of the numbers

of records audited, and if omissions were found, how many records this affected or clear action plans. Following our inspection managers took action to review all documentation and met with staff to discuss accurate record keeping procedures. Managers sent us minutes of meetings held after our inspection in June 2019 which confirmed this. The registered manager planned to monitor compliance by reviewing every patient record daily and would then audit records on a monthly basis.

- The service reported that 0% of patients were seen in the outpatient's service without relevant medical records being available. Some patients were seen in a different location, managers said that records were made in the online system and could be accessed from anywhere. Paper medical records were rarely taken off site. If records were removed from the service they were carried in a sealed bag by a responsible person, usually the surgeon. This was recorded on the risk register. The service had an up to date medical records policy, but it did not refer to records being taken from the premises.
- Access to electronic records was protected with individual log-ins and passwords, which all staff employed by the service or who had practising privileges were given. We saw that terminals were locked when not in use. Paper records were stored securely in locked filing cabinets. Keys were stored in a dedicated key safe and only clinical staff had access to the key safe.
- Patients were given a discharge summary and information, which included details of the surgery performed, postoperative advice, contact numbers and follow-up appointments. Patients were asked for their consent to share information with their GP. All patients who consented had GP letters sent, detailing consultations and procedures performed. Patients who did not consent were given a copy of their discharge summary.
- Records were organised in a way that allowed identification of patients who had been treated with a particular device or medicine in the event of product safety concerns or regulatory enquiries. This was in line with national guidance (RCS Professional Standards for Cosmetic Surgery (April 2016)).

Medicines

The service did not use clear systems and processes to safely prescribe, administer, record and store medicines.

- During our last inspection in June 2018 we found that not all records relating to the administration of medication included a date or time. Records did not state what the volume was or what the rate of delivery should be. During this inspection we found that not all medicines were prescribed or dispensed in line with national guidance. For example, we found that some medicines prescribed did not indicate the route of administration, dose or length of time to be administered for. This meant that patients were at risk of taking the incorrect dose of medication. We raised this as a serious concern with the provider during and immediately after our inspection.
- We saw that some medicines had been administered to patients without a clear prescription being written and a medicine had been recorded as given but it was unclear in the records if allergy status or significant medical history had been reviewed. We were not assured that the patient's allergy status had been reviewed as there was no recording in the record to indicate a review. This was not in accordance with Nursing and Midwifery Council NMC Professional Guidance on the Administration of Medicines in Healthcare Settings January 2019), GMC Good Practice in prescribing and managing medicines and devices 2013) or Royal Pharmaceutical Society (RPS) and Royal College of Nursing (RCN) – Professional Guidance on the Administration of Medication in Healthcare Settings January 2019).
- There were pre-printed labels for pre-packed medicines. However, the antibiotic label did not state how long to take the medicine for. We saw that an antibiotic had been prescribed without stating the duration for which it should be taken. The risk to patients was that the medicine could be taken for either too long or too short a period of time or at incorrect intervals than clinically indicated.
- The service did not have processes in place to track and trace "to take out" medicines (TTO's).TTO's were prescribed by the doctor and dispensed by a nurse but not checked in accordance with national guidance. There was no record maintained of what was dispensed. There was inconsistent instruction provided to patients

on how to take their medicine which could have an adverse effect on their health and recovery if not taken correctly. This meant that we were not assured that all patients received the correct medicines with the correct dosage instructions as this information was not clearly documented in the patient record and there was no system to monitor medicines that were dispensed. We raised these serious concerns with managers during and immediately after our inspection. They took immediate action to address the concerns and took the decision to cease dispensing TTO's for all new patients. Patients would be issued with a private prescription to collect their medicine from a registered pharmacy before their procedure. Managers told us they were arranging a service level agreement (SLA) with local pharmacies. This meant that the service would no longer have any dispensing responsibilities. Medicine prescribing and administration record keeping processes were reviewed and amended to ensure they met with national guidance and mandatory medicines management training was being provided for all medical and nursing staff within two weeks.

- The service had a medicine policy; however, this contained the names of staff rather than the role and included the name of a member of staff as an authorised handler of controlled drugs (CD's) (medicines subject to additional security measures), who was no longer employed by the service. The policy included the arrangements in place for the ordering, receiving, storage and prescribing of medicines.
- The service had an antibiotic policy which identified antibiotics used for specific procedures.
- CD's were checked for administration by two members of registered staff. The controlled drug book was checked and correct. A weekly check was made of CD's, this was undertaken by one member of staff. This was not in line with best practice for example if the CD stock was inaccurate the nurse checking the stock had no witness during the checks. Therefore, we were not assured that the provider had effective systems and processes in place for checking controlled drugs in accordance with the Misuse of Drugs Regulations 2001.
- Medicines were stored securely in locked cupboards in the procedure room. When clinical staff were on site, they were responsible for the safe custody of the medicine's keys. The practice manager also had access to these keys. Keys were stored in a key safe.
- There were processes in place to check medicines to ensure sufficient stock and that medicines were in date. All medicines checked were within their expiry date.
- Medicine fridges were locked and fridge temperatures were checked daily. We saw that the fridge temperatures were within the normal range. However, it was not indicated on the check list the actions to take if the fridge temperature was out of range. Staff told us that they would turn off the fridge and if it was still out of range they would dispose of the medicines.
- Intravenous fluids were not locked away, this meant that all staff had access to them.
- An oxygen cylinder was in date but there was no sign to state that oxygen was stored there.
- Emergency medicines were not kept in a tamper-evident resuscitation kit bag. This was not in line with national guidance (Resuscitation Council (UK) Statement: Keeping resuscitation drugs locked away (November 2016).

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.

- The service had an up to date incident reporting policy in place.
- There were arrangements in place for reviewing and investigating safety and safeguarding incidents and events when things went wrong. An incident form was used to record all incidents or accidents that occurred within the service. The form included patient details, the date, time and description of the incident or accident, who it was reported to, action taken by staff, learning outcomes and changes to practice. We reviewed two

incident reports and saw that learning outcomes were identified and changes to practice were made, when indicated. We saw that actions were taken to add relevant questions to the pre-operative assessment form. Incidents were a standard agenda item at the nurses meetings but not the clinical meetings.

- From March 2018 to February 2019 the service reported two incidents. We did not see evidence of grading of clinical incidents.
- There had been no never events reported during the period from March 2018 to February 2019. 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.
- Patients who used the service were told when something went wrong, given an apology and informed of any actions taken as a result. Staff were aware of their responsibilities with regards to the duty of candour. 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, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. None of the incidents reported met the threshold for the duty of candour.

Safety Thermometer (or equivalent)

The service used monitoring results well to improve safety. Staff collected safety information and shared it with staff, patients and visitors.

- The service monitored patient safety information such as unplanned emergencies, complication and infection rates, and re-admission rates within 30 days of the original procedure. From January 2018 to December 2018, the service reported zero unplanned emergencies, unplanned returns to theatre, unplanned transfers, complications and infection rates, and re-admissions.
- For the same period, the service reported zero incidents of hospital-acquired venous thromboembolism (a deep vein blood clot) or pulmonary embolism (PE) (a blood clot in the lungs). The service did not monitor the incidence of pressure ulcers. Patients who attended the service underwent outpatient or minor day-case procedures. This meant there was a very low risk of patients acquiring a pressure ulcer, VTE or PE while having treatment.

Are surgery services effective?

Requires improvement

The service was not previously rated

We rated it as **requires improvement.**

Evidence-based care and treatment

The service did not always provide care and treatment based on national guidance and evidence-based practice, polices were not consistent and did not contain relevant up to date information. Managers did not check to make sure staff followed guidance. Staff protected the rights of patients subject to the Mental Health Act 1983.

- Although there were some policies to ensure safe practice was followed, these were inconsistent in their presentation as there were several different formats. This meant that they were not standardised which could lead to confusion. Not all policies were referenced or dated so we could not be sure that staff had access to the most up to date information. For example, the medicines management policy identified staff members by name rather than their role in the organisation, one named person no longer worked for the organisation. Policies could be accessed by all staff through the shared drive, staff we spoke to knew how to access policies.
- Not all policies were in place, up to date or followed guidance from the National Institute for Health and Care Excellence (NICE). For example, the National Early Warning Score (NEWS) was in place to monitor acutely ill patients but did not follow the latest NICE clinical guidance CG50, which had been revised to identify subtle changes in a patient's physiological condition. This meant that staff may not be alerted to early signs of

a patients deteriorating condition. There was no policy for pre-operative fasting, however, there was basic information provided in the pre-operative health assessment form.

- The provider carried out some clinical audits to monitor consistency of practice. These included perioperative medical records documentation, medication, resuscitation, hand hygiene and environmental audits. The audit tools were limited in detail this meant that it was not clear what was actually being audited. For example, the medication audit required a yes or no answer to three questions about stock levels, storage and expiry dates. There was no information sought about whether prescriptions were written or administered in line with national guidance, whether they were recorded accurately or whether there were action plans to address errors or omissions. Similarly, the medical records audit did not include the numbers of records audited, there was no reference to the electronic element of the record, any omissions to the record or whether all entries had been signed and dated. Findings from some audits were not widely shared within the service. We did not see any evidence in minutes of the clinical meeting with consultants nor the team meeting with nurses that audits, results or learning were discussed. Audit was not recorded as a standard agenda item. We could not be assured that learning from audits were identified, taken forward or implemented.
- Approaches to patient assessment for suitability for proposed surgery were disjointed. There were not robust systems or procedures in place to assess patients fitness for surgery. Patients saw the consultant pre-operatively at the initial consultation appointment. The surgeon considered each patient's medical history, general health, mental health concerns and history of previous cosmetic surgery before any surgery was performed. The expected outcome was identified and discussed with each patient before treatment and was reviewed postoperatively. This was in line with professional standards (RCS Professional Standards for Cosmetic Surgery April 2016). However, patients also completed an on line pre-operative health questionnaire. There was no record that staff reviewed and discussed the pre-assessment form before surgery to identify any potential contra-indications. We were not assured that there were effective assessment systems in place to keep patients safe.
- From patient records we reviewed, staff and patient's we spoke with, we found cosmetic surgery was managed in line with professional and expert guidance (Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016).
- Patients were supported to be as fit as possible for surgery. For example, patients were advised to stop, or at least reduce, smoking and alcohol intake before and following surgery. They were also told what they could eat and drink before their surgery, which was in line with national guidance.
- Patients were told who they should contact if they had any concerns following their surgery. All patients received the direct mobile number of the surgeon after their procedure. This was a direct access number for the first 48 hours after the procedure
- On the day of surgery, women of childbearing potential were asked if there was any possibility they could be pregnant. Pregnancy tests were carried out with the patient's consent, where indicated. This was in line with national guidance (National Institute for Health and Care Excellence (NICE) NICE guideline [NG45]: Routine preoperative tests for elective surgery (April 2016)).

Nutrition and hydration

Staff gave patients enough food and drink to meet their needs and improve their health. The service made adjustments for patients' religious, cultural and other needs.

- Patients were advised not to eat solid food for six hours preoperatively and not to have clear fluids for two hours pre-operatively. This was checked against the admissions check list.
- Patients nutrition and hydration needs were met. Patients were offered a choice of two different types of sandwiches, toast and biscuits and hot or cold drinks following their procedure.
- Patients were routinely monitored for nausea and vomiting during and following their procedure.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.

- Pain was assessed and managed well. The minor surgical procedures carried out at the service were performed under local anaesthesia or conscious sedation. No patients were given general anaesthesia.
- Pain was regularly assessed both during and following surgery, until the patient was discharged from the service. Staff told us they asked patients if they were comfortable and pain free when carrying out procedures. Patient's told us that they were offered pain relief as necessary. All patients were given pain relief medication to take home with them following their surgery, unless contraindicated. Staff told us each patient was followed up the next day with a telephone call to check their well-being and whether they were in any pain. Only one in three of electronic records we reviewed had evidence of a discussion about pain.
- The service did not audit pain relief. Pain scores were recorded on the NEWSs. Patient records confirmed that pain relief had been given. Patients were contacted by service staff on a daily basis for 14 days postoperatively, patients were asked about any pain during this call.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment. They did not use the findings to make improvements to achieve good outcomes for patients.

- The service did not participate in any national or local audits to review patient outcomes. Managers told us that PROMS (patient related outcome measures) data was collected on selected procedures and were discussed at monthly clinical meetings. This was in line with RCS (Royal College of Surgeons) standards. However, we did not see evidence of discussions about PROMS in clinical meeting minutes or how information was used to improve patient care.
- The service had updated its admission policy and patient selection process to ensure that only those patients who were most suited to the procedure were offered surgery. Patients were offered several consultations before a procedure to ensure they had sufficient time to prepare and make a final decision to proceed. Following procedures, patients were offered after care telephone calls to ensure they were satisfied with the outcome. If not remedial action would be taken.
- From March 2018 to February 2019, there were no unplanned readmissions within 28 days of discharge, no unplanned returns to theatre and no surgical site infections.
- Managers referred to the private healthcare information network (PHIN) website to compare outcomes with other providers. The registered manager collected the demographic and procedural data from online scheduling software on a periodic basis and submitted this.

Competent staff

The service made sure some staff were competent for their roles, but this was not always evidenced. Managers carried out staff appraisals and held supervision meetings with them to provide support and development. However, the assessment processes were not robust.

- The consultant surgeons were skilled, competent and experienced to perform the treatments and procedures they provided. They performed plastic and cosmetic surgery procedures for the NHS. The four consultants were on the General Medical Council (GMC) Specialist Register. The Specialist Register was introduced on 1 January 1997. Since then doctors must be on the Specialist Register to take up any appointment as a consultant in the NHS.
- There was an up-to-date policy in place for the granting and reviewing of practising privileges. The documents required before practising privileges were granted included evidence of private medical insurance cover, immunisation status, appraisal records, Disclosure and Barring Service (DBS) check, and two references. DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable. We saw these were up to date in the records we reviewed. Managers told us that if there were concerns about a consultant's practice it would be identified through the appraisal process

undertaken by the main employer and that this was a contractual obligation. If such concerns existed concerns would be investigated and action taken as appropriate.

- The service had an induction programme for new staff. We saw that this was documented and included orientation to the building, to systems and processes and management organisation. Nursing staff were supernumerary for their first two weeks, managers told us that they gradually increased their exposure to procedures and the activities they undertook. We did not see this documented.
- Staff had access to electronic workbooks which contained some general information and some procedures and policies. However, this information lacked detail. There were no competency booklets for staff to guide and support their learning and development within a cosmetic and theatre environment.
- Managers did not consistently ensure staff were competent for their roles. Staff competency was not assessed robustly. There were no assessment frameworks in place to demonstrate and ensure that learning and development had taken place. Training sessions were delivered and included for example, information about airways management, anaesthesia and pre-assessment. However there was no evidence of assessment of practice. This meant that we were not assured that all staff were competent for these roles. The registered manager assessed clinical practice but was not practising clinically.
- We reviewed three staff records including a consultant, nurse and clerical staff. We saw evidence of DBS checks, GMC and Nursing Midwifery Council registration, two references and appraisal.
- From March 2018 to February 2019 100% of staff had received an appraisal within the last year. The appraisal process was an opportunity for staff to identify learning and development needs. Staff told us that they had identified learning needs during their appraisal and these had been addressed.
- We saw that six out of 11 staff had undergone chaperone training, this included clerical staff. A further four staff were due to complete this in March 2019, the training tracker had not been updated to record if this had happened. All staff who acted as chaperones had received and disclosure and barring service check.
- Clerical staff were given additional training to support the delivery of safe and effective care. For example, they had received training about some of the procedures undertaken at the service so that they could answer some of the patient's initial questions.
- The service had a policy for clinical supervision. Staff were expected to access clinical supervision six to eight weekly. There was no documented information in the electronic handbook nor processes to identify who the clinical supervisor was or how they were allocated. The policy stated that the supervisee was responsible for the maintenance of records. We were not assured that any issues addressed through clinical supervision were clearly identified and acted upon if necessary.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

- The team worked well together to provide patient care. Staff told us they worked closely together to ensure patients received person-centred care and support.
- Treatment provided was consultant-led. All team members were aware of who had overall responsibility for each patient's care.
- Relevant information was shared between the service and the patient's GP. If patients consented, the surgeon wrote to their GP following the consultation. They informed them of the planned procedure and asked whether there were any contraindications. A discharge summary was sent to the patient's GP postoperatively if the patient consented. This included details of the surgery performed and any implants used, where appropriate.
- The surgeon would involve mental health services when indicated. They had links with a psychologist, who they would refer patients to if they felt this was needed. They would also write to the patient's GP if they had any concerns about a patient's mental health.

Seven-day services

The service was not open seven days a week. However, systems were in place to provide support to patients if required

- The service was open six days a week. From Monday to Friday 9am to 8pm and Saturday 9.00-5.30pm.
- The service only undertook planned surgery with operating lists organised in advance.
- Patients were given their consultants mobile telephone number and had direct access to the consultant for 48 hours post operatively. Patients were contacted every day for 14 days following surgery to ensure they did not have any concerns

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

- The smoking status and alcohol intake of patients was recorded at the initial consultation. Patients were advised to stop smoking for two weeks before and after surgery. This was to reduce the risk of any complications and help promote healing.
- Patients were asked about the use of any recreational drugs and vitamin or herbal supplements when they completed their online pre-operative assessment form, however this was not always reviewed?
- Patients were sent written information to provide them with pre and post-operative information, for example advising them to use a pre-operative skin wash to reduce the risk of post-operative infection and to bring a post-operative garment, if advised, to support the wound healing process.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health. They used agreed personalised measures that limit patients' liberty.

- Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. No patients were seen at the service who lacked capacity. Managers told us that if there were any concerns about a patient's capacity to consent, they would not perform cosmetic surgery without seeking further information from the patient's GP.
- Patients were referred to a psychologist if there were any concerns about their mental health or emotional well-being. The service had links with a psychologist to whom they could refer patients as necessary. There were no referrals to the psychologist in any of the records we reviewed.
- The service had an up to date consent policy. The surgeon who obtained the consent was be the surgeon who carried out the procedure.
- Staff understood their responsibilities regarding consent. The consultant surgeon offered patients a minimum of two consultations before they carried out any surgery, however they could see the surgeon as often as they needed to. They explained the expected outcomes and ensured the patient understood these and any potential risks before agreeing to go ahead with surgery. We saw detailed preoperative information, which included managing expectations, risks and potential complications of surgery.
- Consent was obtained in line with national standards (Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016). Consent was obtained in a two-stage process. Most patients undergoing cosmetic surgery waited a minimum of two weeks between consultation and surgery.
- Patients signed a cooling off letter if they signed their consent within 14 days of seeing the consultant. We did not see any cooling off letters in the patient records that we reviewed.
- We reviewed eight patient records and found consent forms were fully completed, signed and dated by the patient and the operating surgeon. However, one consent form was dated but did not include the year. The consent forms included details of the planned surgery, intended benefits, potential risks and complications.

Are surgery services caring?

Inadequate

Surgery

Good

The service had not previously been rated.

We rated it as **good.**

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

- The service had a person-centred culture. Staff were motivated and inspired to provide care that was kind and promoted patient's dignity. There was no clinical activity during our inspection, so we were unable to observe care. Following our inspection, we spoke with three patients via telephone. Patients told us that staff were professional, respectful and considerate. Staff introduced themselves to patients and made them aware of their role and responsibilities.
- Patients told us that they were fully involved in decisions about their care and were able to ask questions, felt listened to and that staff were very approachable.
- Patients' privacy and dignity needs were understood and always respected. Where care and treatment required a patient to undress, staff ensured this was done in complete privacy through the provision of a private room, curtains and/or screening. Appropriate clothing such as gowns were provided, where necessary. Female patients were examined in the presence of a chaperone, all patients, male and female were offered a chaperone.
- The service sought patient feedback following surgery and contacted patients for 14 days post operatively. Patients were asked to rate their experience as excellent, good or poor. Feedback audits from patients from January to March 2019 demonstrated that 99.8% rated the service as excellent, 0.05% as good and 0.02% as poor. The audits did not identify how many feedback forms were collected.
- Patients told us that "it had been a lovely experience", they were "very grateful" and "it was a very good experience".

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

- Staff understood the impact that a person's care and treatment could have on their wellbeing. Staff were empathetic to patients who were anxious about their surgery. They took the time to reassure them. One patient told us they "saw the surgeon two or three times and could see again if necessary".
- Patients were given appropriate and timely support and information. All patients were given the surgeon's personal mobile number, who they could contact if they had any concerns or questions.
- The service had links with a psychologist who they could refer patients to, if they had any concerns about their emotional wellbeing.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

- Staff communicated with people so that they understood their care, treatment and any advice given. Patients told us they felt involved in their care and had received the information they needed to understand their treatment. Patients told us that they had time to consider their surgery and that the risks and benefits were clearly explained
- There were appropriate and sensitive discussions about the cost of treatment. Patients were advised of the cost of their planned treatment at the booking stage. This information was also sent by email, so that patients were fully aware of their planned treatment costs.
- The service only performed surgery under local anaesthetic and deep sedation. Patients who underwent deep sedation were informed that they needed to have an escort home. This meant patients were empowered to be independent and manage their own health very quickly after surgery.

Are surgery services responsive?

Inadequate

Surgery

Good

The service had not previously been rated.

We rated it as **good.**

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. The services provided reflected the needs of the population served.

- A range of cosmetic treatments and procedures were available at the service. The most common surgeries performed were liposuction, tummy tucks, and aesthetic breast augmentation. Procedures were available for men and women. The surgeons had the experience, skills and expertise to carry out the procedures and treatments provided at the service.
- All consultations and postoperative checks were carried out by the operating surgeon. This ensured patients received continuity of care.
- The facilities and premises were appropriate for the services delivered. There was a small waiting area on the ground floor, one consultation/treatment room, one procedure room and one recovery room. This was sufficient for the number of patients who attended the service. There was adequate seating for patients and visitors.
- The service was located near to the motorway network and was situated on an industrial estate. The website included directions to the service. There was limited parking for patients and their relatives immediately outside the service, however there was other parking availability in the complex.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences.

- There were arrangements in place for patients who required translation services. The service used a local interpreting and translation service as needed. However, staff told us that family members or friends were also sometimes used as interpreters, this was not best practice. We were not assured that all questions and answers were interpreted accurately. For example, medical terminology, possible risks, complications and benefits may not be accurately translated and understood.
- All leaflets were written in English, staff told us that these could be translated if necessary.
- All patients attending the service were required to be independently mobile. There was a wheelchair available for patients who had undergone surgery. If patients were not suitable for a day case setting, one of the surgeons had practising privileges at another medical facility and arrangements were made for the patient to have the procedure there. There were no facilities available for patients who were hard of hearing.
- Arrangements were in place for ensuring psychiatric support where necessary. The registered manager referred patients to a psychologist if they were concerned about their mental health and wellbeing.
- There was a drinks fridge available for patients and their companions.
- We saw that suggestions for improvement were included in the patient feedback audits. For example, patients had requested dedicated parking and a quicker follow up.
- Patients told us that "it had been a lovely experience", they were "very grateful" and they were "very happy".

Access and flow

People could access the service when they needed it and received the right care promptly.

- Patients had timely access to consultations, treatment and after care. Most patients undergoing cosmetic surgery waited a minimum of two weeks between consultation and procedure. This 'cooling off' period was in line with national recommendations (Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016).
- The appointment system was easy to use and supported people to access appointments. Patients could arrange an appointment by phone or make an enquiry through the service's website. The on-line enquiry form was easy to use.

- Patients could access care and treatment at a time that suited them. Evening and weekend appointments were available, which facilitated flexibility and promoted patient choice. The service was open on Saturdays from 9.00 am to 5.30pm. Weekday appointments were available up to 8pm.
- Appointments and treatments were only cancelled or delayed at the request of the patient. From March 2018 to February 2019 there had been no cancelled procedures.
- Theatre times were scheduled according to activity levels. There were three to four procedures undertaken each week. Only one patient was seen or received treatment at the service at any one time.
- Waiting times from consultation to procedure were audited in the patient feedback questionnaire. The data was collected and reviewed monthly. Audit data provided from December 2018 to February 2019 demonstrated that 92% of 26 patients who responded were happy with the waiting time. The patients we spoke with said they had timely access to treatment. Patients told us they were able to arrange an appointment for their procedure around other commitments.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them but did not share lessons learned with all staff. The service included patients in the investigation of their complaint.

- The service had a complaints procedure in place, although this was due for review. The medical director was responsible for managing the complaints process. Complaints could be made to any member of staff or the medical director either verbally or in writing. If a patient wished to make a complaint while they were in the service, staff would attempt to resolve the issue immediately. Managers sent a written response in reply to a written complaint within three working days or within five days if the complaint could be investigated and responded to fully within this time. Otherwise, the service aimed to provide a full written response to the complaint within 20 working days
- Managers planned to resolve the complaint within 20 days, if this was not achieved, a letter of explanation was issued
- There were processes in place for patients to appeal if they were unhappy with the outcome of their complaint. The complaints policy stated that if patients remained dissatisfied with the outcome of their complaint they were advised to escalate to the Citizens Advice.
- The service kept a record of all complaints received. All complaints received were discussed at the clinical meeting. Not all staff we spoke with were aware of complaints received therefore we could not be assured that lessons learned were always shared with staff effectively.
- From March 2018 to February 2019 the service had received two complaints. These related to dissatisfaction with the outcome of surgery, miscommunication about the timing of a follow up appointment and the attitude of the surgeon. We saw the complaints had been responded to in a timely and courteous manner. Actions were taken to resolve the complaints to the patients satisfaction.
- The patients we spoke with knew how to make a complaint or raise concerns. Information on how to make a complaint was publicly displayed in the waiting area.
- In the same reporting period, there were no complaints referred to the ombudsman.

Are surgery services well-led?

Inadequate

The service had not previously been rated.

We rated it as **inadequate.**

Leadership

Leaders did not all have had the skills and abilities to run the service. They did not always understand and manage the priorities and understand the risks the service faced. However, they were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

Inadequate

Surgery

- The management team comprised of the medical director and the commercial director. The medical director was also the owner and registered manager. The registered manager was previously a plastic surgeon. The registered manager did not perform surgery but assisted surgeons during some procedures. The commercial director was responsible for business functionality. The commercial director did not have a health background. They were responsible for, and led on clinical care and service delivery. This meant that leaders within the service did not have an expert view and the clinical ability to run the service. Managers told us that they operated "a flat structure" which empowered staff and elevated their level of responsibility.
- We were not assured that leaders had the skills, knowledge and experience, they needed to ensure the service met patient needs. Leaders did not identify or understand the risks to the service. For example, they did not ensure that all staff were competent for the roles they undertook to ensure patient safety. However, the management team described how they strived to be professional, open and inclusive.
- Leaders did not understand the challenges to quality and sustainability, therefore prior to inspection they had not identified the actions needed to address them. Audit processes were not robust and did not identify areas of concern, for example the auditing and monitoring of safe and effective practice in the management of medicines.
- They had not established suitable and effective policies and procedures to fulfil the requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). For example, polices were not detailed or up to date with the latest guidance and medicines management were not managed in line with national guidance to keep patients safe.
- Staff spoke positively about the leaders of the service, from their direct line manager to the director of the company.

Vision and strategy

The service did not have a clear strategy or plans to turn it into action. Leaders and staff did not always understand and apply them to monitor progress.

- There was no robust strategy for achieving priorities in the service. This meant that there were no detailed, realistic objectives and plans for delivering and sustaining high-quality care.
- The service had a vision and a mission. The vision was "to create a multi-disciplinary service offering both cosmetic surgery and non-surgical treatment options under one roof". The mission was to deliver the best care and attention, focus on innovation and research and to promote a conservative approach to recommending treatment.
- While the staff we spoke with were unable to fully articulate the vision, it was evident they always worked within the ethos of it.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear. The service promoted equality and diversity in daily work and provided opportunities for career development.

- The service had an open and honest culture. Any complaints raised would have an open and honest 'no blame' approach to the investigation. In circumstances where errors had been made, apologies would be offered to the patient and staff would ensure steps were taken to rectify any errors.
- Managers reported that excess layers of management were not required, this speeded up communication, responses and led to a culture that supported openness and fairness. All staff were able to access the management team when needed.
- Staff told us that there was good teamwork within the service across all disciplines.

Governance

Leaders did not operate effective governance processes. Staff at all levels were not clear about their roles and accountabilities. Whilst staff had regular opportunities to meet and discuss the service, they did not learn and take action from the performance of the service.

- Key and critical information did not flow around the service effectively. During our inspection, we found the registered manager did not have checks in place to ensure that high standards of care were always maintained. This included relevant and up to date policies, appropriate risk assessments, appropriate risk register and there was no participation in national audits or benchmarking their services. There was a lack of systematic review of policies, risk assessment and the risk register. This meant that leaders did not have clear oversight of the service.
- Arrangements for governance and performance management were not always effective. There was a lack of an robust governance framework to support the delivery of quality patient care. There was no clear oversight of the day to day working of the service. For example, the service failed to identify risks associated with safe and effective medicines management practices. There was a lack of evidence of assessment of competencies and clinicians did not all follow professional guidance. We raised concerns about medicines management during, and immediately after our inspection. Managers took immediate action to address concerns and change practice.
- There was no process to review key items such as the strategy, values, objectives, plans or the governance framework. This meant that there was no clear oversight of the service, identification of issues or concerns or clear methods to review and improve service delivery to patients.
- Some policies and procedures were out of date. Policies were written in different formats and not all policies were referenced. This meant that staff may not always be following best practice and they were not always easy to follow. We were not assured that there was a robust system of review for procedures and protocols or keep polices up to date with the latest guidance. Some polices, or guidance was not available at all for example fasting guidance for patients.
- Monthly multidisciplinary clinical meetings took place. Minutes of meetings confirmed that practice issues including documentation, the consultation process, risk assessments and complaints were discussed. There was a standard agenda but no terms of reference for the meetings held. During our last inspection in June 2018 staff told us that although monthly team meetings were held, they did not receive minutes from these meetings. During this inspection we saw that minutes were shared with staff on the intranet. If incidents occurred or there were other areas of concern identified, managers called additional clinical meetings to discuss these and to formulate action plans.
- There were processes in place to ensure that equipment was checked and stock levels were maintained. Checklists we reviewed corroborated this. There were also processes in place to ensure that theatre equipment was single use and disposed of safely.
- There were systems in place to review practising privileges. We saw that staff files included up to date details of professional registration, appraisal, DBS checks and training undertaken. Staff working under practising privileges had an appropriate level of professional indemnity insurance in place.

Managing risks, issues and performance

Leaders did not use effective systems to manage performance effectively. They did not identify and escalate relevant risks and issues or identify actions to reduce their impact. They had some plans to cope with unexpected events. It was not clear how often risks were reviewed and completed audits lacked detail.

- A basic risk register was in place dated January and February 2019. This detailed three risks which all related to the opening of a second service at a different site. The risks included a brief description of actions required to minimise the risk, a risk score, and who was responsible for the risk. There were no documented risks relating to this location for example actions to take in the event of a major incident either clinical or non-clinical, a power failure, flood, or staff sickness due to the small number of staff employed. Risks identified on the risk register did not have a date for review. This meant that managers did not have an understanding or oversight of the risks and issues to patients, staff and the service.
- The service had risk assessment policy which had been due for review in March 2019. The policy outlined arrangements for identifying, evaluating and reducing all organisational risks through the completion of suitable and sufficient risk assessments. However, risks found on inspection had not been recognised by

managers. We found that the risk register did not generally reflect the risks within the service. For example, the difficulty in recruiting nursing staff, risks associated with a deteriorating patient, or risks associated with the dispensing of TTO's (to take out medicines) were not recorded on the risk register. No clinical risks or risk associated with patient care were identified on the risk register.

- Managers did not have effective oversight of clinical audit. The programme of internal clinical audits was limited. Audits were not robust, lacked detail, did not clearly identify areas of risk or have clear action plans. The audit process was not discussed at clinical meetings and was not a standing agenda item. This meant that managers did not have full oversight of the service. There were no clear structures and processes in place to ensure the quality of the services and operational processes delivered, or systems to identify where actions should be taken. There was limited learning from audits, learning was not shared efficiently and therefore improvements to practice were not made effectively. Some monthly audits took place including medication, records and environmental audits. However, concerns for practice such as the prescription and administration of medicines not being in line with national guidance or omissions to records had not been identified as a concern. This meant that managers were unaware of the risks to safe patient care and treatment and we were not assured that they could manage performance effectively. We raised this with managers following our inspection and they took action to amend audit tools. Further details of future audits were requested.
- The service did not participate in any national audits to review patient outcomes. We were not assured the service monitored their process or used results to improve patient outcomes.
- Information management systems were in place to protect patients against breaches of confidentiality and to prevent data loss. This included controlled access to paper records in the service.
- Information governance was not included in the mandatory training nor identified on the training tracker. We could not be assured therefore that all staff were aware of the requirements of managing a patient's personal information in accordance with relevant legislation and regulations for example the General Data Protection Regulations (GDPR).

Managing information

The service collected data but did not analyse it or use it well. Staff could find the data they needed, in easily accessible formats, but did not always use it to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were submitted to external organisations as required.

- The service collected Q-PROMs (patient reported outcome) data for all patients who underwent certain cosmetic surgeries such as breast augmentation.
- Staff had access to the organisation's computer systems. They could access policies and resource material.
- All staff we spoke with demonstrated they could locate and access relevant and key records easily and this enabled them to carry out their day to day roles.
- Electronic patient records could be accessed easily but were kept secure to prevent unauthorised access to data. There were arrangements in place to ensure the confidentiality of patient information held electronically. Staff were aware of how to use and store confidential information. During our inspection, we found computer terminals were locked when not in use to prevent unauthorised persons from accessing confidential patient information.
- Data regarding patient outcomes was routinely collected and monitored. The results from patient questionnaires were reviewed and used to improve service provision, where indicated.

Engagement

Leaders and staff engaged with patients, staff, and the public to plan and manage services.

- People's views and experiences were gathered and used to shape and improve services. Patient feedback was sought following surgery. Patients told us that they were fully involved in decisions about their care and were

able to ask questions, felt listened to and that staff were very approachable. Patients could post reviews onto the services website. All patient feedback we saw was positive.

- Patients' feedback was routinely collected and monitored. Detailed questionnaires were sent to patients following surgery which asked patients to rate their experience as poor, good or excellent against 18 measures. These included procedure outcome, cleanliness, information provided by the surgeon, patient involvement in decisions about their care, the approach of staff, answers to questions and follow up procedures. Patients were also asked for any improvement suggestions and if they would recommend the service to a friend. Patient feedback was discussed at clinical meetings. Minutes of meetings confirmed this.
- People considering or deciding to undergo cosmetic surgery were provided with the right information and considerations to help them make the best decision about their choice of procedure and surgeon. Patients told us they received comprehensive information about the surgery they were considering. This included how the procedure was performed, costs, and the risks and complications associated with the procedure.
- Managers provided patients with information about how to raise a complaint. The complaint's procedure was available in the waiting area.
- The service only employed a small number of people. Staff told us that information was shared regularly on an informal basis, as they worked so closely together. They also held regular team meetings. The minutes of meetings we reviewed showed good staff engagement from clinical and support staff.
- There was a website for members of the public to use. This held information regarding the types of procedures offered.

Learning, continuous improvement and innovation

Although staff were committed to continually learning and improving services. They did not have a good understanding of quality improvement methods or the skills to use them.

- Whilst staff responded promptly to both our verbal and subsequent letter detailing our serious concerns, they had not recognised the concerns themselves. There was overall lack of awareness from both the manager and clinical staff on standards of practice required to provide a safe and sustainable service.

Concerns included:

- Lack of clarity about how often risks were reviewed and ensuring a robust risk register that was specific for this service.
- The provider did not have robust processes in place to monitor and assess patient outcomes and the quality of the service.
- Record keeping was not robust with omissions to records and lack of detail.
- The prescription and administration of medicines was not in line with national guidance. The service did not use clear systems and processes to safely prescribe, administer or record medicines.
- The provider did not have effective systems and processes in place to develop and review policies. Not all policies were reflective of the service and not all policies were adhered to.
- Leaders did not operate effective governance processes.
- Leaders did not use effective systems to manage performance effectively. They did not identify and escalate relevant risks and issues or identify actions to reduce their impact They had some plans to cope with unexpected events. It was not clear how often risks were reviewed and completed audits lacked detail.
- While there was a limited programme of clinical and internal audit in place, we found completed audits lacked detailed and we could not see evidence how outcomes and learning was shared.
- Varied arrangements were in place for patients who required interpreting services.

The service had addressed some of the concerns raised at our previous inspection. These included:

- Meetings were minuted and minutes were shared with all staff electronically.
- Equipment was well maintained. All electrical equipment was serviced and safety tested annually.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure the proper and safe management of medicines. Staff responsible for the management and administration of medicines must be suitably trained and competent and this should be kept under review. Regulation 12(2) (g).
- The provider must ensure that all patient risk assessments are carried out, fully documented and do all that is reasonably practical to mitigate risks to service users. Regulation 12(1) (a), (b).
- The provider must take prompt action to ensure effective processes for governance and risk management of the service. They must ensure a system is in place to assess, monitor, manage and mitigate patient risks. Regulation 17 Good governance (1) (2)(a)(b)(d).
- The provider must ensure that written policies are evidenced based, reflect current national guidance, are up to date and are written in the same format.
- The provider must ensure that they maintain secure, accurate, complete and contemporaneous records in respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided; Regulation 17(2)(c).
- The provider must ensure there are robust audit programmes with clear action plans in place to measure patient outcomes. Regulation 17 Good governance (1)(a).
- The provider must ensure they maintain an effective risk register

Action the provider SHOULD take to improve

- The provider should ensure that the mandatory training tracker is kept up to date
- The provider should ensure that staff have a clear understanding of safeguarding concerns
- The provider should ensure that all staff details are maintained during fire evacuation drills
- The provider should ensure that robust assessment processes are in place for new staff
- The provider should ensure that all intravenous fluids are stored securely
- The provider should ensure that the resuscitation trolley is tamper proofed and checked before procedures
- The provider should ensure that there is an emergency call bell system in the patient toilet and shower facilities
- The provider should ensure that the team brief is fully completed with actions taken and risk factors identified
- The provider should assess and provide evidence of staff competence
- The provider should ensure that they use professional interpreters
- The provider should ensure there are effective governance processes, throughout the service and with partner organisations

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
Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment