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

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Overall summary

Acuitus Medical Ltd is operated by Acuitus Medical Ltd. The service provides day case cosmetic surgery. Facilities include one operating theatre and one consultation room.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 3 May 2017, along with an unannounced visit to the hospital on 17 May 2017.

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

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

Summary of findings

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

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

• Some medication and equipment were out of date.

• Some medications were not stored securely.

• Medication keys were not stored securely.

• There was no record of a second checker or signature during the administration of controlled drugs.

• Controlled drugs were only checked on a monthly basis.

• There was no major haemorrhage pack within the operating room.

• There was no evidence that the operating room's ventilation was compliant with Department of Health Technical Memoranda (03-01) Specialised ventilation for healthcare premises.

• At the time of our inspection, the management team were unaware of their non-compliance with various national standards, including the ventilation system requirements, the checking of the resuscitation trolley and the storage of medications.

• There was no contents checklist for the resuscitation trolley.

• Not all World Health Organisation 'Five Steps to Safer Surgery' checklists were completed fully.

We saw one patient with a history of depression, who was taking antidepressant medication, had cosmetic surgery without evidence of a GP summary or psychiatric evaluation.

• There were no dates on the sharps bins.

• Four out of six staff members employed on practising privileges had no evidence of completing mandatory training.

• Only one of seven employment staff files reviewed had evidence of two written employment references.

• Not all patient safety audits were completed. The results from completed audits were not shared with staff. Not all audits, which identified areas for improvement, had action plans.

• Staff employed on practising privileges did not have documented mandatory training.

• Most policies reviewed had no date of issue.

• Staff told us they did not receive summaries or minutes from team meetings.

• Theatre uniforms were not cleaned in accordance with national guidelines.

• Not all patient observations were recorded in patient records.

• New staff did not have a documented induction.

• The observation charts used to identify and manage a deteriorating patient were not in line with national guidance.

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

• Staff were aware of the duty of candour and could explain how and when this duty would be engaged.

• Records were stored securely.

• Staff were familiar with the process for safeguarding adults.

• A consultant surgeon was present during the entirety of the patient's admission.

• Guidance was followed for recording medical implants.

• All staff had valid disclosure and barring service certificates.

• Staff provided compassionate care to patients.

Patients' dignity and respect was upheld.

• Evening and weekend consultations were available for patients.

• Translation services were available.

• The registered manager was seen as an approachable and visible leader within the service.

Following this inspection, we told the provider that it must take some actions to comply with the regulations

Summary of findings

and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with three requirement notices. Details are at the end of the report.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Location		Start here...
Surgery		• Some medication and equipment were out of date. • Some medications were not stored securely. • There was no major haemorrhage pack within the operating room. • There was no contents checklist for the resuscitation trolley. • Not all World Health Organisation 'Five Steps to Safer Surgery' checklists were completed fully. • There was no evidence that the operating room's ventilation was compliant with Department of Health Technical Memoranda (03-01). • We saw one patient with a history of depression, who was taking antidepressant medication, had cosmetic surgery without evidence of a GP summary or psychiatric evaluation. • Most employees had no evidence of two written employment references. • The risk register was generic and did not include risks personalised to the service. We found risks on inspection that were not reflected within the risk register. • There was a limited audit schedule. This meant the registered manager did not have oversight of patient outcomes and safety measures. • At the time of our inspection, the management team were unaware of their non-compliance with various national standards, including the ventilation system requirements, the checking of the resuscitation trolley and the storage of medications. However: • Records were stored securely. • A consultant surgeon was present during the entirety of the patient's admission. • All anaesthetists, one surgeon and the registered manager had advanced life support training. • Staff provided compassionate care to patients. • Patients' dignity and respect was upheld. • A wide range of procedures were available. • Evening and weekend consultations were available.

Summary of findings

• The registered manager was visible and approachable.
• There was an open culture.

Summary of findings

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Acuitus Medical Ltd

Services we looked at
Cosmetic 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 hospital in Watford, Hertfordshire. The hospital 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 between 18 and 65 years old. It provides a range of cosmetic procedures including rhinoplasty (nose reconstruction), rhytidectomy (facelift), breast augmentation (implants), breast reduction, liposuction (fat removal) and abdominoplasty (tummy tuck). All patients are seen on a day case basis.

The hospital has had a registered manager in post since 11 June 2015. The announced inspection occurred on 3 May 2017, with an unannounced inspection on 17 May 2017.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, a CQC inspection manager, and a specialist advisor with expertise in cosmetic surgery. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

Information about Acuitus Medical Ltd

The hospital has one day case theatre and one consultation room. It is registered to provide the following regulated activities:

• Surgical procedures

• Treatment, disease, disorder and injury

During the inspection, we visited the operation room and consultation room. We spoke with six staff including the registered manager, two surgeons, two administrators and the practice manager. We spoke with one patient who was present during the inspection. We also received six 'tell us about your care' comment cards, which patients had completed prior to our inspection. During our inspection, we reviewed seven sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC.

Activity (July 2016 to April 2017)

• In the reporting period, 624 patients were seen.

• In the reporting period, 122 procedures were performed.

• These were all privately funded.

Four surgeons and two anaesthetists worked at the hospital under practising privileges. The accountable officer for controlled drugs (CDs) was the registered manager.

Track record on safety

- No never events

- No clinical incidents

- No serious injuries

- No incidences of hospital acquired MRSA bacteraemia

- No incidences of hospital acquired Meticillin-sensitive Staphylococcus aureus (MSSA) bacteraemia

- No incidences of hospital acquired Clostridium difficile (c.difficile)

- No incidences of hospital acquired Escherichia coli (E-Coli) bacteraemia

- No complaints

Summary of this inspection

Services provided at the hospital under service level agreement:

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

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We do not currently have a legal duty to rate cosmetic surgery services.

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

• Some medication and equipment were out of date.

• Some medications were not stored securely.

• Medication keys were not stored securely.

• There was no record of a second checker during the administration of controlled drugs.

• Controlled drugs were only checked on a monthly basis.

• There was no major haemorrhage pack within the operating room.

• There was no evidence that the operating room's ventilation was compliant with Department of Health Technical Memoranda (03-01).

• There was no contents checklist for the resuscitation trolley.

• The observation charts used to identify and manage a deteriorating patient were not in line with guidance.

• We saw one patient with a history of depression, who was taking antidepressant medication, had cosmetic surgery without evidence of a GP summary or psychiatric evaluation.

• Not all World Health Organisation 'Five Steps to Safer Surgery' checklists were completed fully.

• Four out of six staff members employed on practising privileges had no evidence of completing mandatory training.

• There were no dates on the sharps bins.

• Not all patient safety audits were completed. The results from audits that were done were not shared with staff. Not all audits, which identified areas for improvement, had action plans.

• There was no service level agreement in place with the local NHS trust for the transfer of a deteriorating patient.

• Staff employed on practising privileges did not have documented mandatory training.

• Theatre uniforms were not cleaned in accordance with guidelines.

• Not all patient observations were recorded in patient records.

Summary of this inspection

• New staff did not have a documented induction.

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

• Staff were aware of the duty of candour and could explain how and when this duty would be discharged.

• Records were stored securely.

• Staff were familiar with the process for safeguarding adults.

• A consultant surgeon was present during the entirety of the patient's admission.

Are services effective?

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

• Only one of seven employment files reviewed had evidence of two written employment references.

• Most policies reviewed had no date of issue.

• Fasting guidance was not in line with best practice.

• Patient outcomes were not collected.

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

• Anaesthesia protocols were in line with guidance.

• Adequate pain relief was given to patients.

• All anaesthetists, one surgeon and the registered manager had advanced life support training.

Are services caring?

We found the following areas of good practice:

• Staff provided compassionate care to patients.

• Patients' dignity and respect was upheld.

• Confidentiality was maintained.

• Patient feedback was very positive.

• Patients were advised of all possible costs before surgery took place.

Are services responsive?

We found the following areas of good practice:

• A wide range of procedures were available.

• Evening and weekend consultations were available.

• Arrangements were in place to gain access to translators, if needed.

Summary of this inspection

• Reasonable adjustments were made for patients with physical disabilities.

• A policy was in place for managing complaints.

Are services well-led?

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

• At the time of our inspection, the management team were unaware of their non-compliance with various national standards, including the ventilation system requirements, the checking of the resuscitation trolley and the storage of medications.

• There was no set vision or values for the service. Staff were unaware of any corporate vision or values.

• The risk register was generic and did not include risks personalised to the service. We found risks on inspection that were not reflected within the risk register.

• There was a limited audit schedule. This meant the registered manager did not have oversight of patient outcomes and safety measures.

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

• The registered manager was visible and approachable.

• There was an open culture.

• Patient and staff feedback was sought.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	N/A	N/A	N/A	N/A

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

Incidents

- Staff generally understood their responsibilities to raise concerns, to record clinical safety incidents, concerns and near misses, and to report them internally and externally. Staff provided examples of clinical incidents they would report, for example, falls or medication errors. There had been no recorded incidents or never events in the reporting period from April 2016 to March 2017. Never events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. However, on inspection we found one case where a patient had their surgery done within the two week cooling off period. This should have been reported as an incident, but had not been recorded as such.
- An incident reporting template was available electronically and staff were aware of this. Staff were aware of the types of events that would constitute incidents, for example, falls. We were told a process was in place to investigate incidents if and when they arose. Incidents would be investigated by the registered manager, with an initial response to the patient within 24 hours and a full investigation completed within three days. However, there was no incident management policy in place, at the time of inspection. As such, there was no evidence that a process was in place to investigate and manage incidents. When we returned on our unannounced inspection we saw an incident policy had been created. This reflected guidance and included information on the reporting of injuries, diseases and dangerous occurrences regulations (RIDDOR). A framework was in place to grade incidents depending on severity, with details of appropriate actions to take.
- The service had not set specific safety goals. As such, performance against safety goals was not monitored.
- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations is the regulation that introduced the statutory 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. Staff were familiar with the duty of candour and were able to provide examples of when this would be required.
- Staff assured us that patients would be told if they were affected by something that went wrong, would be given an apology and informed of any actions taken as a result. As there had not been any incidents during the reporting period, we were unable to see this in practice.
- Surgical site infection rates were monitored. The results provided by the service indicated there had been no surgical site infections since the service began in July 2015.
- We were told lessons would be learnt and shared through monthly meetings. We reviewed two sets of minutes and saw never events and near misses were a standing agenda item. However, staff told us that team meetings were informal, across an open plan office, and that they did not get told about any potential incidents or near misses during these meetings.

Clinical Quality Dashboard or equivalent

- The service did not use a clinical quality dashboard. As all patients were day case, and there were no inpatients, there was a very low risk of patients acquiring pressure ulcers whilst at the service.
- We were told that all patients were assessed for venous thromboembolism (VTE) on admission. VTEs are blood clots that can form in a vein and have the potential to cause severe harm to patients. We reviewed six patient records. Of these, two had no evidence of a VTE assessment being completed. At the time of our inspection, compliance with VTE assessments was not audited. As such, we could not be assured whether VTE assessments were routinely completed for all patients. We were told auditing VTE assessment forms would begin in May 2017.

Cleanliness, infection control and hygiene

- The operating room and consultation room were visibly clean and tidy. An infection prevention and control policy was in place; however, this had been due for update in May 2015, with no evidence of the policy being reviewed.
- Staff adhered to being 'arms bare below the elbow' and used personal protective equipment, such as gloves and aprons, appropriately. The flooring in the patient facing areas was well maintained and was non-slip. Hand sanitising gel was available and used by staff.
- Staff decontaminated their hands before and after episodes of care, in line with National Institute for Health and Care Excellence (NICE) guidance QS61 Statement 3. At the time of our inspection, there was no clinical hand wash basin in the consultation room. Department of Health Guidelines 2013 HBN009 state that clinical hand wash basins should be available and used between patient contact. There was a small kitchenette located next to the consultation room. We were told this sink was used by staff to decontaminate their hands. This was not in line with best practice. However, we were assured that the kitchenette area was no longer used for food preparation and, as such, the risk of cross contamination was lowered.
- We observed a postoperative consultation and saw the surgeon wash their hands in the kitchenette sink before and after patient contact. Hand sanitising gel was used appropriately and gloves were worn when touching the patient.
- Hazardous cleaning chemicals were not stored on site. These were brought in by external contractors during weekly deep cleans. The deep cleans were overseen by the registered manager, to ensure standards of cleanliness were adhered to. We saw a cleaning checklist in place, which confirmed daily cleaning by staff and the deep cleans by the external contractors, had been completed and checked by another staff member.
- Patients were not routinely screened for MRSA and clostridium difficile. These are infections that have the capability of causing harm to patients. This was compliant with Department of Health 2014 guidance for day case patients. Patients completed risk assessments, to identify if they were high risk for being carriers of MRSA or Clostridium difficile. Patients who were deemed high risk were given screening. If a patient screened positively for MRSA they would be ineligible for admission and they would be advised to inform their GP. Patients with a previous history of MRSA were not eligible for admission to the service.
- The service ran a monthly audit regarding infection control. This covered patient washing, hair removal, skin disinfection, prophylactic antibiotics, warming intravenous and infiltration fluids, perioperative warming, maintaining asepsis, wound management and surveillance of surgical site infections. This was in line with NICE guideline CG 74. The results of these showed mainly compliance with best practice. Areas of concern identified by the audit included documenting patient washing within the preoperative checklist and documenting patient temperatures every 15 minutes during theatre and every 30 minutes during recovery. At the time of our inspection, there was no action plan in place to meet these areas of concern. Plans were in place for action plans to be formulated at the next clinical governance meeting.
- The service used single use surgical instruments, which were used for one patient and then disposed. Therefore, there was no need for decontamination procedures.
- Staff wore shoe covers when entering the operating room. This was not in accordance with best practice, as evidenced in research by the Hospital Infection Society 2002. We raised this with the registered manager during our inspection.

Surgery

- During the announced inspection, staff laundered their own scrubs at home, as there were no laundry facilities on site and the service did not have an agreement with an external contractor. This is not recommended by the Association of Perioperative Practice 2011 as this does not ensure items are washed at the correct temperature, or that items do not become contaminated between washing and the next use. When we returned on our unannounced inspection we saw that this practice had stopped, and all scrubs and linens were single use only. The infection control policy was updated to reflect this.
- The management team were unable to provide evidence that the operating theatre had been commissioned and was compliant with Health Technical Memorandum (HTM) 03-01 Specialist ventilation for healthcare premises. This is required to ensure that there are sufficient air changes within the operating room environment, to minimise the risk of avoidable harm. We raised this as a concern and the decision was taken by management to stop all surgical cases until reassurance could be given. Sufficient information was not provided to demonstrate compliance with HTM 03-01. Acuitus Medical were in the process of building a new theatre which was due to be completed in June 2017 and the senior manager reassured us that this would be commissioned and fully compliant with HTM 03-01 prior to use.

Environment and equipment

- We found out of date equipment within the operating room and consultation room. We found two endotracheal tubes (a tube placed into the windpipe through the mouth to maintain breathing in an emergency), eight boxes of dressings, one box of cannulas (a thin tube inserted into a vein or body cavity to administer medication, drain off fluid or insert a surgical instrument), two boxes of sutures (stitches), a large pack of disposable forceps (an instrument used to hold objects during operations) and a skin marking pen. We escalated this with the registered manager who provided assurances that all out-of-date equipment had been disposed of. Furthermore, plans were in place for a policy to be created to prevent this reoccurring. During the unannounced inspection we found that all medication and equipment was in date.
- The facilities and premises were well maintained. At the time of our inspection development work was ongoing to create a new theatre, a decontamination suite and separate recovery area. During this transitional time, the original buildings were still being used, and these were maintained appropriately. Areas where building work was ongoing were securely separated from patient facing areas to ensure safety of patients and staff.
- Electrical equipment was used in accordance with manufacturing instructions and was well maintained. An electronic database was used to keep a log of equipment which had been electrically safety tested. Some newer pieces of equipment, purchased in December 2016 had not been electrically safety tested. However, guidance from the Health and Safety Executive states 'new equipment should be supplied in a safe condition and not require a formal portable appliance inspection or test. However, a simple visual check is recommended to verify the item is not damaged'. None of the new pieces of equipment we saw, which had not been safety tested, were visibly damaged.
- Processes were in place to report any product failures to the Medicines and Healthcare Products Regulatory Agency (MHRA). The registered manager had signed up for the 'yellow card scheme' whereby they could report any side effects to medicines, medical device adverse incidents or defective or counterfeit medicines. At the time of our inspection, there had been no reports to the MHRA.
- Arrangements were in place for the management of waste and clinical specimens. A contract was in place with an external contractor who provided an on demand clinical waste removal service. This included both hard waste, for example, sharps and soft waste, for example, gauze. However, on inspection we found sharps bins without dates of issue. Sharps bins should have dates of issue so that staff know when these need to be destroyed, per s.5 of the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. On our unannounced inspection, we saw that all sharps bins had been dated. The sharps policy had been amended to include the requirement to ensure all sharps bins were dated, sealed appropriately and handled safely.
- The service did not carry out bariatric surgery. The admission criteria specified only patients with a body mass index of less than 35 would be admitted for surgery. As such, bariatric equipment was not required.

- The resuscitation trolley in the operating room was not set out in accordance with the Resuscitation Council UK guidelines. The resuscitation trolley within the operating room did not follow an organised format, and had equipment and medications mixed together within the drawers. We were told that the resuscitation trolley was checked daily by the registered manager, and saw an electronic spread sheet in support of this. However, there was no contents checklist for the resuscitation trolley. This made it difficult to tell if the full inventory was present and the daily checks therefore relied upon the checker's memory of the items that were supposed to be there. On our unannounced inspection we saw that the resuscitation trolley had been rearranged, in accordance with Resuscitation Council UK guidelines. A contents checklist was in place, so staff checking the trolley could be assured of its contents.
- There was no major haemorrhage trolley or pack available within the operating room. We were told that in the event of a patient haemorrhaging (suffering a large bleed), staff would get equipment from cupboards within the operation room, such as sutures and swabs. This was not in line with the National Patient Safety Agency 2007 Rapid Response, which states that emergency equipment should be readily available and checked daily and prior to procedures being carried out, to avoid time delays. This was rectified by the time of our unannounced inspection. A pack had been put in place, with a red lid for easy identification. This was checked weekly for expiry dates.

Medicines

- Arrangements for managing medicines were not robust. Medications were not all stored securely, within locked cupboards, in accordance with the Royal Pharmaceutical Council of Great Britain guidelines. We found medications, including intravenous medications and resuscitation medications, on unsecure trolleys in both the operating room and consultation room. We also found out of date medications; one box of omeprazole (used for indigestion and acid reflux) and two boxes of saline ampules. We escalated this immediately to the registered manager, who assured us all out of date medication had been disposed of. At our unannounced inspection we saw all medication was stored securely and in date. An emergency drugs kit had been made, which contained all medications needed in an emergency, including adrenaline, aspirin, glucagon (treats low blood sugar and those with anaphylaxis), midazolam (used for sedation) and salbutamol (opens the airways). This was in a sealed pack, with expiry dates clearly noted on the outside.
- Medications requiring refrigeration were kept within a locked fridge. Fridge temperatures were checked daily by the registered manager to ensure they were in acceptable limits.
- Medication keys were not always kept securely. There were two keys for the controlled drugs cupboard. We were told that one key was kept on the registered manager's person and that the other was hidden in a secret location, so that it could not be found in the event of a break in. We were told only the registered manager knew this location. During our inspection, we found a key to the controlled drugs cupboard within the general medication cupboard. This was contrary to Department of Health guidance, which states that controlled drugs keys need to be kept securely inside a locked key cupboard.
- The keys for the general medication cupboard were stored inside the records trolley, which was not in line with best practice. This meant the keys were accessible to non-registered staff, for example, the administrative staff. This was not in accordance with guidance, which states only registered staff should have access to medicine keys. We escalated this with the registered manager, who told us they would buy a secure key cupboard. When we returned on our unannounced visit, we saw a secure keypad box had been installed. This held all medication keys and the controlled drugs key. Only the registered manager knew the code for the box.
- The drawing up and administering of controlled drugs needs to be overseen by two clinicians, with both clinicians signing the controlled drugs book, in accordance with NICE guideline NG46. This is due to additional checks that are required, due to the potential for controlled drugs to be misused. Within the service, the drawing up and administering of controlled drugs was overseen by two clinicians; the registered manager and the anaesthetist. However, the anaesthetist did not sign the controlled book to document the second check. This was identified internally during a controlled drugs audit in April 2017; however, the practice had not been rectified by the time of our inspection. We raised

this with the registered manager, who told us that two signatures would be obtained in future. During the unannounced inspection, we could not check if this had been implemented, as there had not been any patients since we raised this concern.

- On our announced inspection controlled drugs checks were conducted monthly. We raised this as a concern, as this meant that if any controlled drugs were to go missing, it could possibly not be identified for one month. This meant it would be very difficult to ascertain how, when or who took the controlled drugs. On our unannounced visit we saw that controlled drugs were now being checked daily, with an electronic log kept of the checks.
- The service had a Home Office licence for the management and storage of their controlled drugs. At the time of our inspection this was being reviewed to see whether the service required this.
- The service had denaturing kits to ensure controlled drugs were made safe to dispose of. Denaturing of controlled drugs typically involves physically mixing the medicines with a binding matrix to make the material physically irretrievable in the waste chain. The resultant material is classified, described and disposed of as a waste medicine. This was in line with the Environment Agency guidelines.
- The service had a contract with a pharmaceutical wholesaler, which dispensed medications on a same day delivery service.
- We reviewed seven medicine charts and saw that allergies were documented, where applicable.
- Antibiotics were administered orally and intravenously, in accordance with the service's antibiotic policy.

Records

- Patient's individual care records were not always accurate, complete and up to date. We reviewed 15 records and found that observations were not always documented. Out of the 15 records we looked at, eight records had missing observations. Omissions were also found in the VTE assessments, as noted above, and in the World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist, which will be discussed later in the report, under the heading 'assessing and responding to patient risk'. This was not in line with recommendation 12 of the Department of Health Review of Regulation of Cosmetic Interventions 2013.
- We also found that the initial consultation form did not ask for a date or signature, and as such, these were often not dated.
- All records we reviewed were legible and had evidence of preoperative assessment. For patients who had received an implant, records showed that details of the implant were documented in the records and recorded on the implant registry.
- Records were stored securely in a lockable cabinet within the office area of the service.
- The majority of records were paper based, although an electronic system was also in use. The electronic system could be used when surgeons were consulting with patients at other locations. The electronic record system was through an encrypted cloud service, with each surgeon having an individual login to access the system. When paper records were made, the individual surgeons had responsibility for ensuring that a copy was given to the registered manager, so they could be integrated into the main clinical record. This was a requirement of the surgeons' practising privilege agreements.

Safeguarding

- Systems, processes and practices to minimise the risk of harm had been identified and put in place. All staff employed directly by Acuitus Medical Limited had evidence of receiving safeguarding adults level 2 training. A safeguarding policy was in place, which documented the types of abuse staff should be aware of and details on what to do in case of a safeguarding concern. The number for the local safeguarding adults board was highlighted, as was CQC's details. However, the safeguarding policy did not have a date of issue or expected revision, nor version control. This meant we were unable to see if this policy had been reviewed and updated.
- There was no evidence that all staff employed on practising privileges had safeguarding adults level 2 training. We reviewed six employment files for staff on practising privileges. One staff member had safeguarding level 2 training, which was in date. One

staff member had training, which had expired in November 2016. The four remaining staff members had no evidence of safeguarding training. We raised this at the time of our inspection and on the unannounced inspection, we found that the registered manager had requested that all staff complete the training and provide evidence of this.

- Staff we spoke with were familiar with the safeguarding process and told us they felt comfortable doing so if necessary. We were told there had not been any safeguarding concerns raised since the service opened. Staff were familiar with female genital mutilation and told us they would report any concerns to the safeguarding team.

Mandatory training

- Staff who were employed directly by Acuitus received effective mandatory training. This covered topics including information governance, fire safety, infection control, lone working, handling violence and aggression, complaints, the reporting of injuries, diseases and dangerous occurrences regulations (RIDDOR) and control of substances hazardous to health (COSHH).
- For staff employed on practising privilege agreements there was limited evidence that they had completed mandatory training. The registered manager told us that most mandatory training was completed at their NHS employment, that they had oversight of staff training and would identify any gaps which the service needed to meet. When we reviewed the training files for staff members on practising privileges, four out of the six staff members had no evidence of any mandatory training. Therefore, the registered manager did not have oversight of what mandatory training they had completed elsewhere, and what training may be outstanding. A fifth staff member had evidence of mandatory training; however, they had all expired in November 2016.
- A sepsis policy was in place and all surgeons had received training in this. This was in line with NICE guidance NG51.

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

- An admission policy was in place, which outlined the eligibility criteria for patients. The American Society of Anaesthesiologists (ASA) score is an assessment criteria to ascertain whether a patient is fit for surgery. Only patients with an ASA1 (a normal, healthy patient) or ASA2 (a patient with mild systemic disease) score were admitted. Patients with a higher ASA score were not permitted due to the heightened risk of surgery. Other patients, including those with severe hypertension (high blood pressure), patients who had previously received organ transplants and patients with a history of VTE were excluded from admission.
- Some risk assessments were carried out for patients who used services and risk management plans developed in line with national guidance. We saw evidence that all patients underwent a telephone questionnaire, which identified potential areas of risk, as well as a preoperative risk assessment at the consultation. These covered patients' past medical history, previous operations and current medications.
- We did find that there were omissions in assessing VTE for all patients on admission, as discussed previously in the report. We also reviewed seven sets of patient notes and saw that not all WHO 'Five Steps to Safer Surgery' checklists were completed. WHO checklists are surgical safety checklists that should be completed before and after surgery occurs, to reduce the risk of errors. One patient record did not have a checklist, which meant there was no evidence the checklist had been considered and completed. Two further patient checklists had not been signed and one checklist was not dated. The service did not audit completion of WHO checklists at the time of our inspection.
- We were told that all patients had a physical and psychiatric assessment at their preoperative consultation, and that this was part of the admission policy. On review of the notes, we saw that patients' past medical histories were reviewed. The registered manager informed us if a patient on antidepressants or other similar medication requested cosmetic surgery, the service would obtain a GP summary to ensure that the patient was psychologically fit for surgery. However, on review of medical records we found a patient who was taking antidepressants who had had two cosmetic procedures performed, without evidence of a GP summary or further psychological risk assessment. We also spoke with a patient who told us they had depression due to body image. They told us their GP

was not contacted, and their cosmetic surgery went ahead without any psychological evaluation. This was not in line with the Royal College of Surgeons' Professional Standards for Cosmetic Surgery 2016. We were told that if GP summaries highlighted any area for concern, patients would be referred for a cosmetic procedures screening questionnaire (which can help identify if a patient has body dysmorphic disorder). There had been no referrals at the time of our inspection.

- The service had not implemented a nationally recognised process for identifying a deteriorating patient, with appropriate escalation responses, such as the national early warning system (NEWS). Surgeons told us this was not needed as NEWS charts were used to help nurses identify when to seek medical advice, and that this was not required as the whole process was consultant led. However, this is not the only purpose of NEWS charts. NEWS charts are also used to score physiological measurements to monitor and identify if a patient's condition deteriorates.
- The service used a modified recovery sheet, where we were told observations were recorded every 15 minutes, until the patient was awake, alert and had been to the toilet. However, on review of patient records, we found four out of seven records had observations missing. The recovery sheet did not follow the format of a NEWS chart, with no scoring to identify if a patient condition deteriorated. This did not comply with NICE guidance CG50. During our unannounced inspection, we were told that plans were in place to begin using NEWS charts. This was evidenced in the service's policy on managing the deteriorating patient. Any patient scoring over a seven would be transferred to the local NHS acute trust.
- The service ensured there was access to consultant medical input the whole time a patient was admitted. The consultant surgeon and the registered manager (a surgical fellow) remained with the patient until discharged. As all patients were day-case and had local anaesthetic, most patients were discharged within two hours of their procedure.
- On discharge, patients were given the office telephone number in case of any concerns following discharge. This number was used as a helpline during office hours. Out of office hours patients were given their surgeon's mobile number to call, as a 24 hour emergency hotline. This was in line with Association of Anaesthetists of Great Britain and Ireland guidance. Before procedures were scheduled, the service ensured that surgeons would be available for the next seven to 10 days, depending on the nature of the procedure, so that they would be available for calls and to review the patient if required.
- A transfer policy was in place in the event of complications requiring a patient to be transferred to an NHS hospital. This policy was not dated. At the time of our announced inspection, there was no service level agreement in place with the local NHS provider to accept transfers. As such, the policy stated that staff should call 999. This was not in line with the Independent Healthcare Advisory Services guidance on critical care transfer for patients 2015, which states formal agreements should be in place with local NHS trusts. The policy stated that the surgeon would accompany the patient during the 999 transfer to allow for consultant-to-consultant handover. When we returned on our unannounced inspection we saw that an agreement had been made with the clinical lead at the local NHS acute trust, with details on who to call in the event of a transfer.
- Major cosmetic surgery was undertaken, for example abdominoplasty and large volume liposuction. A postoperative haemorrhage protocol was in place, in case of major or significant blood loss. This stated that consultants would work to control the bleeding whilst calling 999 for an immediate ambulance transfer to the local NHS provider. The service did not store blood on site as it had been decided by the service that the location was not appropriate for blood transfusions, due to its isolation from other healthcare services. Sutures and swabs were available in the event of a major bleed; however, at the time of our announced inspection these were not kept within a contained major haemorrhage pack. This was rectified by the time of our unannounced inspection. There was a landline present within the operation room, as well as a mobile phone, to ensure that staff could easily dial 999.
- Patients were discharged once they had recovered appropriately from their procedure and anaesthesia. They were discharged once a responsible adult had come to collect them from the service.

- The consultant and registered manager always stayed with the patient until they had been discharged. The anaesthetist stayed with the patient until they were physically safe to be discharged and were sitting, talking and had been to the toilet.

Nursing and support staffing

- At the time of our inspection the service did not employ any nurses. The registered manager was in the process of interviewing nurses, who would be employed on practising privileges arrangements.
- Two administrators were employed, along with a non-clinical practice manager, and a finance manager.
- At the time of the inspection, there were no vacancies and no staff had left in the previous 12 months (data from May 2016 to April 2017).
- Agency staff were not used within the service.

Medical staffing

- Staffing levels and skill mix were well planned. Four members of staff were always present when patients received conscious sedation. This included the consultant surgeon, the consultant anaesthetist, the registered manager (who was a clinical fellow but acted as the scrub nurse) and a runner (who was non-clinical). The Academy of Medical Royal Colleges Safe Sedation Practice for Healthcare Procedures 2013 standards states that an appropriately trained individual needs to be present when sedating patients. This individual needs to be separate from the anaesthetist, the surgeon, the scrub nurse or the runner. This individual should not have any tasks or responsibilities, other than to observe the patient during sedation. The service did not employ such an individual to observe patients when undergoing sedation, and all members of staff within the operating room had other roles and responsibilities. This was in breach of the standards.
- If a staff member was unable to attend a procedure, it would be rescheduled. We were told this had happened on two occasions since July 2016.
- No locum or agency staff were used at the service. The service had one anaesthetist on practising privileges, eight anaesthetists on bank and four surgeons on practising privileges.
- New staff brought in on practising privileges were given an induction by the registered manager. However, this was not documented, so we were unable to see evidence of this.
- As all patients were day-case, there were no handovers or shift changes at the service. The consultant surgeon remained with the patient until discharge.

Emergency awareness and training

- Potential risks were taken into account when planning services. The service had a utility failure policy which detailed what staff should do in the event of a water or electricity failure. There was a backup diesel generator in place, in case of electricity failure. A fully charged mobile phone was kept within the operation room, in case landlines failed and they needed to dial 999.
- We were told that fire drills occurred six monthly, however, at the time of our inspection in May 2017, we were told the last drill had been in July 2016.
- Plans were in place to start conducting clinical skills drills in June 2017.

Are surgery services effective?

Evidence-based care and treatment

- Relevant and current evidence-based guidance, standards, best practice and legislation were identified and used to develop how services, care and treatment were delivered. The registered manager was signed up to receive alerts in changes in National Institute for Health and Care Excellence (NICE), so that they would be aware of any changes in best practice. They also subscribed to the Royal College of Surgeon's mailing list, so that they were kept up to date with changes in guidance.
- People generally had their needs assessed and care planned and delivered in line with evidence-based guidance, standards and best practice. Staff followed the Association of Anaesthetists of Great Britain and Ireland anaesthetic protocols when patients received intravenous sedation.
- Patients assessed as being at risk of venous thromboembolism (VTE) were given anti-embolism stockings and compression boots, alongside

medication. VTEs are blood clots that can form in a vein and have the potential to cause severe harm to patients. This was in line with NICE QS3. However, as mentioned above, this was not audited at the time of our inspection and not all patients had evidence of an assessment. It had become a mandatory requirement within the service to assess patients for VTE in December 2016. Plans were in place to start auditing this in May 2017.

- Policies were based on best practice and referenced legislation appropriately. For example, the safeguarding policy referenced the Human Rights Act 1998, and the consent guidance referred to the Mental Capacity Act 2005. However, policies were either not in date or had no date on them, which meant it was unclear how and when they had been or would be reviewed. We escalated this to the registered manager and when we returned on our unannounced inspection we saw that this had been rectified. All policies had been reviewed, with version control, dates of issue and for next review.
- The service did not use care bundles. Care bundles are a set of evidence based interventions that, when used together, significantly improve patient outcomes. For example, a surgical site infection care bundle would include the steps to take to avoid surgical site infections at the preoperative stage (before surgery), the intraoperative stage (during surgery) and postoperative stage (after surgery). Whilst the individual components of the bundle can be used separately, using them together has been shown to improve patient outcomes. We raised this with the registered manager during the inspection and he told us he would review this process.
- Discrimination, including on grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation was avoided when making care and treatment decisions. An equality policy was in place, which outlined the protected characteristics under the Equality Act 2010. All decisions were based on clinical criteria, as opposed to discriminating factors.
- Technology and equipment was used to enhance the delivery of effective care and treatment. Bispectral index monitors were used to monitor brain activity whilst patients were under sedation. Bispectral index monitors allow anaesthetists to tailor the dose of anaesthetic used to the individual patient, by giving access to electroencephalogram information. Electroencephalogram information shows electrical activity in the brain. This ensures patients do not receive too little anaesthesia, therefore, feeling pain, or given too much, which would lead to a longer recovery process. This was compliant with NICE diagnostics guidance DG6.
- The rights of people subject to the Mental Health Act were protected. Any patients detained under the Mental Health Act were not eligible for admission. Staff were aware of what to do, in the event that a patient displayed mental health needs. Processes were in place to contact the duty officer at the local NHS mental health trust.
- Due to the relative infancy of the service, they did not submit to the NICE shared learning database at the time of our inspection.
- Professional guidance was followed regarding the recording and management of medical device implants. Surgeons told us patients who received implants had details included in the Breast and Cosmetic Implant Registry. The notes we reviewed supported this.
- Preoperative tests were managed in accordance with NICE guidance CG3. Past medical histories were taken to identify any ongoing or previous medication history. Women were asked whether they could be pregnant, and pregnancy tests were available onsite, if a woman thought this could be a possibility. We observed a postoperative appointment and saw NICE standard QS49 was complied with, in regards to checking wounds and advising patients on dressing care.
- Patients were supported to be as fit as possible for surgery. For example, patients were asked about their smoking habits and advised this could affect their outcomes.
- We were told that if any psychiatric concerns were raised as a result of the past medical history, they would request a GP summary. If this raised further concerns, patients would be asked to complete a cosmetic procedures screening questionnaire (which can help identify if a patient has body dysmorphic disorder). If concerns still remained patients would be asked to complete a psychiatric review.

- The service had adapted guidance on quality standards for sepsis screening and management. A thorough sepsis policy was in place, which detailed the actions to be taken in the event of suspected sepsis.

Pain relief

- Pain was managed well. Patients had surgery under local anaesthetic, with additional sedation where needed. No patients were given general anaesthetic within the service.
- Patients were given analgesia (pain relief) to take home with them following their discharge, along with advice on how often to take them. Consultants were available to speak to patients after discharge, if they had any concerns about their pain levels.
- Audits into pain relief provision were not conducted at the time of our inspection.
- The service did not participate in the Anaesthesia Clinical Services Accreditation scheme. Anaesthesia Clinical Services Accreditation is a voluntary scheme for NHS and independent sector organisations that offers quality improvement through peer review.

Nutrition and hydration

- We were not assured that people's nutrition and hydration needs were being assessed and met correctly. Information given to patients before their surgery told them to fast (withhold) food for six hours and drink for two hours, however, we saw patients were fasting for longer than this. We saw one patient had not eaten or drank for 12 hours before surgery, and was in theatre for 3.5 hours. There was no evidence in the notes that this patient had been given intravenous fluids during their surgery, which meant it appeared they had not had any water for over 15 hours. This did not comply with the national guidance on fasting The Association of Anaesthetists of Great Britain and Ireland 2010, Pre-operative Assessment and Patient Preparation.
- We were told patients were offered beverages and biscuits once their procedure had finished.
- A prevention of nausea and vomiting protocol was in place, to reduce the risk of patients feeling sick after surgery. Patients were given oral medications before surgery to prevent sickness.

Patient outcomes

- Information about the clinical outcomes of people's care and treatment was not routinely collected and monitored. The service did not collect Q-PROMS (patient reported outcome measures) at the time of our inspection. Completion of PROMs, pre- and post-operatively, allows for a patient's own measurement of their health and health-related quality of life, and how this has been changed by the surgical intervention. PROMs are distinct from more general measures of satisfaction and experience, being procedure-specific, validated, and constructed to reduce bias effects.
- Patient satisfaction surveys were completed, between two to six weeks following the operation. Of the forms we saw, these showed positive feedback, with all patients happy with the outcome of their procedure.
- The revision rate for the service (when patients want their procedure to be done again, due to being unhappy with the outcome) was 3%. This is better than the national average of 5%.
- The service did not benchmark their outcomes to other services. As such, we were unable to see how they compared to similar services.
- Surgeons were aware some audits were conducted by the service, but were unaware of any outcomes or actions arising as a result of these.
- At the time of our inspection, the registered manager was in the process of setting up an account with the Private Healthcare Information Network (PHIN), so data could be submitted in accordance with the legal requirements set by the Competition and Markets Authority. We were told that due to the relatively small volume of patients, the service was waiting to build up another three months of data, which they would then submit. PHIN became a legal requirement in September 2016.
- The service reported that there had been no readmissions to theatre. This meant that there had been no occasions where a patient began to recover, faced complications, and then required the surgeons to operate again.

Competent staff

- Staff generally had the right qualifications, skills, knowledge and experience to do their job; however, this

was not always clearly recorded. Four members of staff on practising privileges had no evidence of any mandatory training on record. Therefore, we were unable to see if they had completed the necessary training for their role. The registered manager told us they checked staff competencies on a monthly basis. However, we were not reassured of this process, given that many staff did not have competencies recorded.

- Only one member of staff, out of seven files reviewed, had two written employment references. Four surgeons had one written reference on file. At our unannounced inspection the registered manager told us that verbal requests had been made to the staff to supply two written references.
- All staff working in a clinical capacity had evidence of their clinical qualifications. Furthermore, all the anaesthetists, one surgeon and the registered manager had completed advanced life support training.
- All staff had valid disclosure and barring service certificates.
- Learning needs of staff were identified in a yearly appraisal. Staff employed under practising privileges had their appraisal at their main employer. The registered manager obtained a copy of this. All staff employed directly by the service had an in-house appraisal. The registered manager had an independent appraisal that was in date.
- Staff were provided extra training where necessary. For example, we saw one staff member had received chaperoning training so that they could chaperone patients when required. Moreover, the practice manager had been trained in perioperative care and could act as a runner during procedures.
- All the clinical staff who were employed on practising privileges had successfully revalidated with the General Medical Council (GMC). Revalidation is the process by which all licensed doctors are required to demonstrate on a regular basis that they are up to date and fit to practise in their chosen field and able to provide a good level of care.
- At the time of our inspection, the registered manager assisted in every operation undertaken. As such, all staff were subject to continuous clinical supervision by the registered manager.
- Consultant surgeons only carried out surgery they were skilled, competent and experienced to perform. All surgeons performed similar operations in the NHS, or in other private practices. All surgeons had a list of their scope of practice, which they were not allowed to operate outside of. Surgeons did not bring in any external first assistants or advanced scrub practitioners. External first assistants or advanced scrub practitioners are registered practitioners who provide assistance under the supervision of the surgeon. They do not perform any surgical intervention. Their roles include assisting with patients' positioning, skin preparation and use of suction.
- Of the four surgeons who had practising privileges at the service, three were on the GMC specialist register. Entry on the GMC specialist register is a requirement for any doctor who wishes to undertake a consultant post within the NHS. We were told the fourth surgeon was working towards this. The registered manager also assured us that they were encouraging surgeons to apply for certification with the Royal College of Surgeons (RCS). Certification is voluntary, but the RCS expect all eligible surgeons who carry out cosmetic surgery in the private sector to certify to demonstrate high professional and clinical standards in their area of practice.
- We saw evidence that the registered manager regularly reviewed the GMC register, to check that no conditions had been placed on the medical staff's fitness to practise.
- The registered manager reviewed practising privileges yearly. We were told this process would involve checking the staff member's curriculum vitae, references, disclosure and barring service certificate, occupational health record and an informal interview. Given the infancy of the service, this process had not yet been undertaken. One of the surgeons on practising privileges was also appointed as a surgical advisor, who would assist the registered manager if any concerns arose.
- Arrangements were in place to make sure that local healthcare providers were informed in cases where a staff member is suspended from duty. The requirement for staff to inform the service if they had been suspended elsewhere was written into their practising privileges. If this was breached, the staff member's practising privileges would be revoked.

Surgery

Multidisciplinary working

- All necessary staff were involved in assessing, planning and delivering people's care and treatment. Treatment was consultant-led and involved discussions with the anaesthetist and registered manager where required.
- The team worked well together, providing cohesive care to patients. There were positive working relationships between the administrative team and the clinical team, with staff working together well.

Access to information

- All the information needed to deliver effective care and treatment was available to relevant staff in a timely and accessible way. Records were a mixture of electronic and paper based notes, however, the systems were well integrated and staff were familiar with the process.
- The service asked all patients for their consent to share information with their GP regarding the procedure and any implant, if relevant. However, we were told most patients refused to consent to information sharing with their GP regarding their cosmetic procedures. In these instances, extra copies of the discharge summary would be given to the patient, and they would be advised to forward a copy to their GP.
- Details of implants were kept on file. Patients received a warranty card for their implant(s), which included tracking details. The same tracking details were also kept on the patient record, on the discharge sheet and inputted into the implant registry.
- A system was in place to ensure that medical records generated by staff holding practising privileges were available to all staff. It was written into their practising privileges that any paper based records had to be scanned and a copy incorporated into the main medical notes. Electronic records could be seen immediately, with staff having individual log-ins to access the system.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Staff understood the relevant consent and decision making requirements of legislation and guidance, including the Mental Capacity Act 2005.
- A two-stage consent process was in place at the service. When patients were booked for surgery patients were given a leaflet which contained all the relevant risks and benefits of the proposed procedure. The risks and benefits were also discussed during the preoperative consultation. Consent was formally taken on the day of surgery. Patients signed the consent form for surgery and also consented to photographs, where relevant. Consent was always taken by the surgeon.
- On all patient records we reviewed, we saw completed consent forms.
- Patients were supported to make decisions by being given realistic expectations about the outcome of their surgery. The letters which discussed the risks and benefits were checked by the registered manager to ensure all language was objective and quantifiable. This meant the patient would have impartial information to make the decision. Staff were available, either at preoperative consultations, or for telephone consultations, if patients wished to discuss the procedure further.
- If there were any concerns regarding a patient's mental capacity to consent to treatment, they would be referred for a GP review. Patients suffering from a medical condition that included psychosis were not eligible for admission, due to concerns about their ability to provide valid consent.
- At the time of our inspection, completion of consent forms was not audited.
- The RCS Professional Standards for Cosmetic Surgery sets out the requirement for a two-week cooling off period, between deciding to have cosmetic surgery and the procedure taking place. The two-week wait was discussed at preoperative consultations with patients and was highlighted on the email quotation. Two surgeons we spoke with during the inspection told us they always observed the two-week period. The registered manager told us of one occasion whereby the patient insisted on the operation occurring during this period. This was not reported as an incident. On this occasion, the patient signed an extra disclaimer, accepting that the procedure was going ahead against the service's advice. However, when we reviewed patient records we saw a patient who had their surgery within 11 days of initial consultation, without evidence of an extra disclaimer.

Surgery

Are surgery services caring?

Compassionate care

- Staff understood and respected people's personal, cultural, social and religious needs, and took these into account. Patients were asked during their preoperative consultation whether they had any special requirements due to cultural or religious reasons. Patients were asked whether they would prefer a chaperone to be present during consultations, to ensure patients felt comfortable.
- Staff took the time to interact with patients and gave them the opportunity to ask questions. We observed a postoperative consultation and saw that the surgeon spoke in a respectful and considerate manner to the patient.
- Staff were encouraging, sensitive and supportive to patients and their relatives. Patients told us staff were understanding and sympathetic towards them. This was in line with National Health and Care Excellence (NICE) guideline QS15 Statement 1.
- Patients' privacy and dignity was always respected. Patients got changed or undressed behind curtains. Chaperones were offered for consultations, especially when the patient was the opposite gender to the consultant. All external doors and windows were opaque, so that people outside were unable to see in. Consent was taken for photographs or videos to be taken of the patients before and after surgery. These were only used for teaching purposes, or to share with prospective patients, if consent was obtained.
- Confidentiality was maintained in the service. Patients who called the service were not given any information until they had confirmed their name, date of birth and address. All correspondence was sent through email, so that letters could not be opened by anyone other than the named recipient. Phone numbers were taken of relatives who would be picking up patients following their procedures. These were stored on the preoperative consultation form. If a relative called for progress on their family member, the number would be crosschecked against the number on file. If the two numbers did not correlate, staff would not provide any information, but call back on the number on file. This was in line with NICE guidance QS13 Statement 13.
- As all patients were treated under local anaesthetic people were mobile and independent soon after surgery.
- We reviewed copies of patient satisfaction surveys. These were overwhelmingly positive, with patients remarking 'my experience was amazing' and staff were 'very transparent and professional.'
- We also received six 'tell us about your care' cards. Within these, patients told us that staff 'make you feel very welcome', 'have been excellent' and 'the staff were attentive and reassuring'.

Understanding and involvement of patients and those close to them

- Staff communicated with patients so that they understood their care, treatment and condition. Information was given in easy to understand formats. Time was given at the end of the postoperative consultations if the patient wanted to ask any further questions.
- Staff recognised when patients needed additional support. They encouraged relatives to stay in during consultations if patients wanted this and during the preoperative stage if patients were feeling anxious.
- Patients were advised at the initial consultation stage of all possible costs that would be incurred. This was also sent by email, so that patients were fully aware of the cost implications. A six month warranty was written into the contract between the patient and surgeon. If any further surgical work was required in this time frame, only the anaesthetist's fees would be applicable.
- Patients were told of all possible risks and benefits of the procedure they were proposing to undertake. Realistic expectations were set, so that they understood what the outcome would be. This was in line with NICE guidance QS15 Statement 5.

Emotional support

- 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 and reassured them.
- A system was in place whereby if patients consented, they could be given contact details of other patients who had undergone the same procedure. This allowed them to form bonds and get first-hand experience of the types of outcomes available.
- Due to the types of anaesthesia and short recovery times, patient were empowered to be independent and manage their own health very quickly after the operation.

Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- Information about the needs of the local population was used to inform how services were planned and delivered. The procedures offered were in line with the skill set of the surgeons who had practising privileges at the service. We were told that if there was an increased demand for a procedure which was not currently offered, the service would look into expanding their workforce, to be able to offer the procedure.
- The services provided reflected the needs of the population. The majority of procedures carried out were liposuction, due to local demand. A wide range of procedures were available, for example, rhinoplasty (nose reconstruction), rhytidectomy (facelift), breast augmentation (implants), breast reduction, liposuction (fat removal) and abdominoplasty (tummy tuck). Procedures were available for men and women. Specific procedures available for men included gynaecomastia (male breast reduction), pectoral implants and abdominal etching (contoured abdomen or 'six pack').
- Evening and weekend consultation appointments were offered to patients to provide flexibility and choice. Most postoperative checks were completed by the operating surgeon. This provided continuity of care. If this was not possible, another surgeon or the registered manager conducted them.
- The facilities and premises were appropriate for the services that were planned and delivered. Patients were admitted to the consultation room, where consent, marking and photographs took place. Patients would then walk into the operating room, which was adjacent. Following the procedure, patients would recover in the operating room, until they were able to walk back to the consultation room.

Access and flow

- Patients had timely access from initial consultation to procedure, and after care. From records we reviewed, we saw that most patients were operated on within one month. All patients undergoing cosmetic surgery are advised to wait a minimum of two weeks between consultation and procedure, as a 'cooling off' period.
- Patients could generally access the service at a time that suited them, once the surgeon's and anaesthetist's availability had been confirmed. The registered manager confirmed that between July 2016 and April 2017, there had been four occasions when appointments had to be rescheduled, due to changes in the medical staff's availability. These patients were then rescheduled within seven days.
- An appointments system was in use at the service. We spoke with the administration team who told us this was easy to navigate.
- Services ran on time. Only one patient was at the service at any one time, therefore, delays were rare.

Meeting people's individual needs

- Services were planned and delivered to take account of the needs of different people. Same day translation services were available through a contracted service. Several staff members were also multilingual and were able to communicate with patients in multiple languages, if required.
- Patients living with dementia were not eligible for admission for cosmetic surgery. This was determined during the telephone questionnaire to assess patients' suitability.

- Reasonable adjustments were made so that disabled people could access and use services on an equal basis to others. A hearing loop system was in place for patients with hearing impediments. All doors were widened to allow wheelchair access.
- Arrangements were in place for ensuring psychiatric support where necessary. If patients reported any symptoms of psychosis following surgery, they would be reviewed in case this was an indicator for sepsis. If there was no physiological cause for the psychosis they would be referred to the local NHS mental health trust. There was no service level agreement in place with the local NHS mental health trust, however, the registered manager had the appropriate contact details to make a referral.

Learning from complaints and concerns

- Patients knew how to make a complaint or raise concerns. Information on how to make a complaint was included in the paperwork given to patients prior to their procedure. There was also a section in the patient feedback form, which allowed patients to raise a complaint if necessary.
- The service reported they had received no complaints since July 2016. The registered manager told us he had received three concerns between July 2016 and April 2017. These were low level issues which were investigated by the registered manager and resolved within 48 hours. These were not classified as complaints.
- A complaints policy was in place. This was undated. This outlined the two stage process for local resolution of complaints. All complaints would be acknowledged within three working days and investigated by the registered manager within 20 working days. Details were included within the policy for appealing a complaint outcome, as well as contact details for CQC.
- We were told that lessons learnt from complaints would be shared at team meetings. We saw that complaints were a standing item on the agenda at the monthly board meetings.

Are surgery services well-led?

Leadership / culture of service related to this core service

- The registered manager led the service. Their background was in general surgery. One of the consultant surgeons who had practising privileges was also the surgical advisor. The registered manager performed many roles within the service. These included overall management, scrub nurse, daily cleaner and auditor. We had some concerns about the amount of duties the registered manager held and how they would be able to discharge all of these duties to the correct standard. We raised this with the registered manager during our inspection who told us they would be recruiting additional staff, including nurses, as the activity had increased.
- Due to the small nature of the service the registered manager was very visible. They were present during every surgical procedure. All staff we spoke with said they were approachable and accessible. However, the management team had not taken reasonable practicable action to ensure that all national standards had been adhered to. Examples included the safe management of medicines and controlled drugs, checking the resuscitation trolley and compliant theatre ventilation systems. We raised these concerns during our inspection; however, the management team were unaware of their non-compliance with these standards.
- All staff we spoke with told us there was an open culture within the service and that they enjoyed working there. They said it was important to share best practice and staff were encouraged to ask for help. Staff felt valued and respected and worked well together.
- There was an emphasis on the safety and wellbeing of staff. Staff reported no lone working within the service.
- Staff worked collaboratively and shared responsibility in delivering good quality care. All staff were aware of their role in the patient experience and were committed to ensuring patients had a positive experience.
- The service ensured that all marketing was honest and responsible and complied with guidance from the Committee on Advertising Practice. They did not offer

any two-for-one deals to entice patients and ensured all advertising was objective. There were no targets in place for the number of procedures to do in a year; therefore, staff felt there was no pressure to bring in work.

- A system was in place to ensure people using the service were provided with a statement that included the terms and conditions and the services being provided and the amount and method of payment of fees. This information was provided by email, after the preoperative appointment with the patient. The applicable fees were explained to patients, and included all possible charges. The service was approved by the Financial Conduct Authority as an introducer. This meant they were allowed them to put patients in touch with financing organisations.
- Leaders understood the challenges to good quality care and could identify the actions needed to address them. For example, the registered manager told us the main challenges were correct patient selection, competent staff and safety assessments. As such, there was regular engagement with patients, a staff were being courage to apply for Royal College of Surgeons (RCS) certification and monthly audits were due to be implemented from June 2017 for infection control, venous thromboembolism and the World Health Organisation 'Five Steps to Safer Surgery'.

Vision and strategy for this core service

- The registered manager told us the vision for the service was to provide high quality, safe, surgeon-led care, leading to robust patient outcomes. However, the service did not have a vision statement in place at the time of our inspection and these were not displayed on the website. When we spoke with staff they were unfamiliar with the vision.
- The registered manager told us the service's values were integrity, quality, corroboration and safety. Staff were unaware of these values and they had not been formalised into a value statement. The registered manager told us the vision and values had been process driven and developed over time.
- The service had begun to make arrangements to ensure surgical cosmetic procedures were coded in accordance with SNOMED_CT. SNOMED_CT is an electronic form of coding procedures. It ensures that information is consistent across health settings. At the time of our inspection the majority of records were paper based. The registered manager was in discussions with vendors to digitise records and introduce coding.

Governance, risk management and quality measurement

- A newly formed governance framework was in place within the service. Monthly clinical governance meetings had started in January 2017. We reviewed the summaries of two meetings and saw there were standing agenda items, including surgical site infection surveillance, Medical and Healthcare Products Regulatory Agency (MHRA) alerts, complaints, never events and near misses, and quality improvement activities. The summary from the March 2017 meeting showed plans were being put in place to introduce Q-PROMS (patient reported outcome measures) for liposuction, abdominoplasty (tummy tuck) and breast augmentation (implants).
- Staff were clear about their roles and understood what they were accountable for. All procedures were surgeon led and the surgeon took overall responsibility for the patient.
- A risk register was in place, however, it was generic and had not been personalised to the risks for the service. We found risks during the inspection, for example, ongoing building work, a lack of a haemorrhage trolley and controlled drugs not having a second signature, which were not included on the risk register. At the time of the inspection the registered manager had identified the lack of a second signature when administering controlled drugs. This had been identified by internal audit. However, this had not been rectified, nor added to the risk register. There were no dates when the risks had been added, nor dates for when the risks would be mitigated by. There was no name assigned to each risk, to indicate the risk owner. During the inspection, we were told the registered manager owned all the risks. The registered manager told us the risk register was reviewed during the monthly clinical governance meetings; however, there was no evidence of this. On our unannounced inspection, we saw the risk register had been updated to include relevant risks, for example the ongoing building work. There were dates for when these had been added and when they would be removed.

- There was some alignment between the recorded risks on the risk register, and what the registered manager told us was on their 'worry list'. For example, the registered manager told us one worry was regarding the suitability of staff. This was on the risk register with controls and mitigating actions in place. However, other risks identified by the registered manager, such as financial health and the lack of critical care facilities, were not on the risk register.
- Risks regarding the management of medication and equipment were on the risk register. Controls and mitigating actions, such as checking all medications daily for expiry date, were listed. However, these controls and mitigating actions were not robust as we found out of date items during the inspection.
- There was a holistic understanding of performance. This integrated financial health, safety and quality. The registered manager showed enthusiasm for continuing to build the service, and making improvements accordingly.
- There was not a comprehensive assurance system in place to monitor and improve performance. There was a limited audit schedule in place, with audits not being carried out for areas such as Q-PROMS, venous thromboembolism (VTE), World Health Organisation (WHO) 'Five Steps to Safer Surgery' checklist or record completion. This meant the registered manager could not be assured of the service's performance in these areas.
- All cosmetic surgery was monitored and reviewed by the registered manager. The registered manager was present during all procedures and, therefore, had oversight of all operations.
- External first assistants were not brought into the service for procedures. External first assistants or advanced scrub practitioners are registered practitioners who provide assistance under the supervision of the surgeon. They do not perform any surgical intervention. Their roles include assisting with patients' positioning, skin preparation and use of suction. Therefore, checks required by Schedule 3 of the Health and Social Care Act 2008 (Regulated Activity) Regulations 2014 were not applicable.
- All staff given practising privileges had professional indemnity insurance in place. This was checked when practising privileges were granted and renewed. We saw these were filed within the staff member's employment record. All were in date.
- All surgeons at the service carried out the same types of procedures in their other NHS and private work. As such, these types of cosmetic procedures were included in their annual appraisals.

Public and staff engagement

- Patients' views and experiences were gathered through patient satisfaction questionnaires. Plans were in place to start patient forums, once the service had treated more patients. All patient feedback we saw was very positive about the service.
- Staff felt engaged and that their views were taken on-board in relation to planning services and shaping the culture. We saw that certain products were brought in, for example, wound closure strips, at the request of a surgeon. The administrative staff told us their views were taken into account when planning the expansion of the premises, specifically in regards to the kitchen facilities.
- The registered manager and all staff understood the value of staff raising concerns. Administrative staff told us they would escalate concerns to the registered manager, if they felt that a patient was being given incorrect information by the surgeon.

Innovation, improvement and sustainability

- The registered manager had encouraged all surgeons to apply for certification with the Royal College of Surgeons. Certification is voluntary, but the RCS expect all eligible surgeons who want to carry out cosmetic surgery in the private sector to certify so they can demonstrate high professional and clinical standards in their area of practice. At the time of our inspection, surgeons were working towards this.
- The registered manager submitted that the service's method of anaesthesia; using own local anaesthetic with minimal sedation, was an innovative approach to cosmetic surgery. Patients were able to communicate during their surgery, their airways were preserved, and their recovery time much shorter than if they had received a general anaesthetic.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that all patients are risk assessed for venous thromboembolism.
- The provider must ensure that their observation charts and management of deteriorating patients is in line with NICE guidance CG50.
- The provider must ensure that all medicines, including medication keys, are stored securely.
- The provider must ensure that the operating room is fully commissioned and compliant with HTM 03-01.
- The provider must ensure that staffing levels and responsibilities are compliant with the Academy of Medical Royal Colleges Safe Sedation Practice for Healthcare Procedures 2013 when sedating patients.
- The provider must ensure that patient safety audits are completed, including venous thromboembolism and Q-PROMS, and outcomes are shared with staff. Where areas for improvement are identified, action plans must be completed.
- The provider must ensure that all World Health Organisation 'Five Steps to Safer Surgery' checklists are completed.
- The registered manager must ensure that data is submitted to the Private Healthcare Information Network.
- The registered manager must ensure all aspects of care and treatment, including ventilation systems, the management of medications, major haemorrhage packs, the management of resuscitation trolleys, the management of sharps bins and the cleaning of theatre uniforms are in line with national standards.
- The provider must ensure that all staff employed on practising privileges have documented mandatory training, including safeguarding training, and evidence of employment references.

Action the provider SHOULD take to improve

- The provider should ensure that all incidents are recorded appropriately.
- The provider should ensure that the risk register is kept up to date and discussed at clinical governance meetings.
- The provider should ensure that staff receive minutes or summaries from team meetings.
- The provider should ensure that all observations are undertaken and recorded in patient records.
- The provider should ensure that all new staff have a documented induction.
- The provider should ensure that all patients who have a history of mental health receive a psychological assessment prior to proceeding with their cosmetic surgery.
- The provider should ensure that patients complete the two week cooling off period between consultation and the procedure being performed.

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
Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment **Regulation 12 (2) (a)(c)(d)(g) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Safe care and treatment** How the regulation was not being met: Not all patients were risk assessed for venous thromboembolism. Not all World Health Organisation 'Five Steps to Safer Surgery' checklists were completed. The observation charts and management of deteriorating patients was not in line with NICE guidance CG50. Medicines and medication keys, were not always stored securely. There was no evidence that the operating room was fully commissioned and compliant with HTM 03-01. Staffing levels and responsibilities were not compliant with the Academy of Medical Royal Colleges Safe Sedation Practice for Healthcare Procedures 2013 when sedating patients.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Regulation 17 (1)(2)(a)(b) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Good governance**

This section is primarily information for the provider

Requirement notices

How the regulation was not being met:

Not all patient safety audits were completed, including venous thromboembolism and Q-PROMS, and outcomes of audits were not always shared with staff. Where areas for improvement were identified, action plans were not always completed.

Data was not submitted to the Private Healthcare Information Network.

Not all aspects of care and treatment, including ventilation systems, the management of medications, major haemorrhage packs, the management of resuscitation trolleys, the management of sharps bins and the cleaning of theatre uniforms were in line with national standards.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed **Regulation 19 (1)(2) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Fit and proper persons employed**

How the regulation was not being met:

Not all staff, including those on practising privileges, had documented mandatory training, including safeguarding training, and evidence of employment references.