Be Cosmetic Clinics

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?	

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

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

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

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Services we do not rate

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:

- Incident reporting was not consistent. Some staff were aware of incidents and others were not. This made it difficult for the service and staff to take learning from issues that had arisen and change practice.
- The 'theatres' were in fact minor treatment rooms and were not suitable for some of the procedures that were taking place. There were no air changes within these treatment rooms increasing the risk of infection.
- Decontamination of reuseable instruments was not following guidlines. The provider was not able to identify if an instrument was sterile after it had been through the decontamination process.
- Mandatory training was not taking place consistently. Some staff were not aware of the training that they should have undertaken as a minimum requirement for their role.
- There was no induction process in place for new staff or doctors.
- The granting of practicing privileges did not follow the providers policy and thereforerequired checks on doctors were not taking place.
- The service did not use the World Health Organisation (WHO) checklist, therefore this was a risk to patients.
- Patients were not screaned for Methicillin-Resistant Staphylococcus Aureus (MRSA) prior to invasive procedures.
- The service did not follow national guidelines, for example (National Institute For Health and Clinical Excellence) NICE guidelines on medications or the World Health Organisation (WHO) surgical checklist ; they also did not follow their own company policy.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements. We wrote to the provider stating that we were considering taking urgent action to protect patients from harm. Following our letter the provider voluntarily agreed to only undertake injectable and hair transplant procedures. Details are at the end of the report. We are monitoring this service closely and will re inspect at the appropriate time.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Overall summary

BE Cosmetic Clinics Limited is operated by Surgimed Clinic Limited. Facilities include three treatment rooms and a consulting office. The service has no overnight beds.

The service provides elective cosmetic surgery. We inspected surgery at this service.

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection on 14 and 15 March 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

Summary of findings

needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

The main service provided by this hospital was hair transplants. This involved removing single hairs from a location on the body and transplanted onto the head or face (in the case of a beard).

During our inspection we found that the provider was undertaking hair transplants, abdominoplasty, mini abdominoplasty, breast lifts and gynaecomastia.

The service carried out 444 procedures from October 2015 to September 2016. This was broken down into 330 hair restoration surgery, 109 liposuction, four scar revision and one mini abdominoplasty .

We had concerns with the regulated activities carried out at this service. We informed the provider about our concerns and they voluntarily suspended all their regulated activites except for hair transplants and injectable procedures.

Summary of findings

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Summary of this inspection

Background to Be Cosmetic Clinics

This service was established for the provision of elective cosmetic procedures. The main procedure carried out was hair transplant, although others included abdominoplasty, mini abdominoplasty, breast lifts and gynaecomastia.

The provider was registered to provide the following regulated activities with the CQC.

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

At the time of the inspection, the service had a CQC registered manager.

Our inspection team

The inspection team comprised an inspection manager, two inspectors and two specialist advisors with experience in cosmetic and plastic surgery, as well as extensive operating theatre experience.

Why we carried out this inspection

We inspected this service as part of our ongoing comprehensive independent provider inspection programme.

How we carried out this inspection

To fully understand the experience of people who use services, we always ask the following five questions of every service and provider:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

Before the inspection visit, we reviewed information that we held about the location and sought feedback from patients thorough patient experience feedback cards.

We inspected all three treatment rooms at the location and the equipment used to carry out procedures.

Information about Be Cosmetic Clinics

The hospital has no wards or in-patients beds. It is registered to provide the following regulated activities:

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

During the inspection, we visited all three treatment rooms and the consultation office. We spoke with five staff including; health care assistants, doctors and senior managers. We spoke with three patients. We also

Summary of this inspection

received 20 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed ten 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 services first inspection since registration with CQC.

Activity (November 2015 to September 2016)

- In the reporting period November 2015 to September 2016 There were 444day case episodes of care recorded at BE Cosmetic Clinics Limited. All cases were self funded.

One anaesthetist and six physicians worked at the hospital under practising privileges. Two care assistants and one receptionist worked at the service, as well as having its own bank staff. The accountable officer for controlled drugs (CDs) was the registered manager.

Track record on safety

- No Never events had been reported
- No Clinical incidents no harm, no low harm, no moderate harm, no severe harm, no death
- No serious injuries

No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),

No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)

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

No incidences of hospital acquired E-Coli

Four complaints for non clinical issues.

Services accredited by a national body:

- British Association of Body Sculpting (BABS)

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Pathology and histology

What people who use the service say

We spoke to some patients during the inspection and received comments cards from others. The feedback from the comment cards was mainly positive, although not all patients we spoke with where pleased with the service provided; this included dissatisfaction with aftercare due to lack of communication.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

The service was not clear with their incident reporting. We were aware that non clinical incidents had occurred, however the registered manager was unable to show how they had learned from incidents.

There were some infection prevention and control issues identified at the service and this was brought to the attention of the registered manager. Instruments with multiple uses were not decontaminated or sterilised appropriately and in line with the providers policy.

The service had operating theatres that were not suitable for their purpose as they were designed as minor treatment rooms; these treatment rooms had no air changes for infection control purposes.

The service did not use the WHO checklist to ensure the safety patients undergoing procedures. Electronic patient records were not available to staff when the internet server was not working. This was a cause for concern.

The service did not screen patients for MRSA prior to a procedure. This put other patients at risk. There was a lack of intra operative monitoring for patients undergoing a procedure; this was a risk to patients as the doctor would have been unable to identify early warning signals that the patient may be unwell due to the procedure.

Mandatory training was not up to date. Some doctors carrying out procedures did not have a basic life support certificate which was a risk to patients, should a patient suffer a cardiac arrest.

Are services effective?

During the course of our inspection we found that the service was not adhering to NICE guidelines, AAGBI guidelines or other national guidelines as set out by regulatory and professional organisations. We also found that the service did not follow its own policies and procedures, therefore this put the patient at risk.

Audits were not routinely completed by the provider. This did not allow the service to benchmark against other services, therefore the registered manager could not make changes to improve the service based on factual information.

There was no induction for new members of staff joining the service. The staff were taught by those in a similar role whilst during the course of their employment.

Summary of this inspection

When a patient consents to a procedure, there should be a two week cooling off period given. This allows the individual time to reflect on the information provided. The majority of patient records we reviewed showed that most patients consented to their treatment on the day of the procedure, therefore no cooling off period was available. We also found that there was no provision for psychiatric assessment prior to any procedure. The service relied upon the patient to self refer to their GP.

Are services caring?

The service actively encouraged the patient to take a relative or friend with them to their appointments and their procedure. This was to provide emotional support to the patient.

There were no clinical nurse specialists available to offer support to the patient, however the provider utilised (health care assistants) HCAs to speak with the patient and offer support.

There were no counselling services provided to patients or their relatives at this service.

Are services responsive?

The patient was asked for consent prior to their GP being contacted. We were told, in the majority of cases that patients do not consent to this.

The service did not provide translation or interpretation services for their patients. They relied on the relative or friend accompanying the patient to communicate on their behalf. This is not good practice as there was no assurance that the patient had appropriate and accurate information conveyed to them.

There were no provisions for patients with learning difficulties or dementia. There were no private facilities for patients or their relatives/ friends whilst they were waiting/ having a procedure. Those accompanying the patient had to wait in reception.

One of the patients we spoke with said that they were not completely happy with their surgical outcomes. They found it very frustrating and difficult to get in touch with the registered manager in order to rectify the situation. Although the provider sited an independent third party within their policy document for patients that were unhappy with the outcome of their complaints, patients were not made aware of this service.

Are services well-led?

There was a lack of governance within this service. Doctors were granted practicing privileges based on very little information and checks. This was contrary to the providers policy.

Summary of this inspection

We asked the registered manager to provide minutes from governance meetings, however they were not able to produce these.

We found a number of risks during our inspection that were not recorded on the service providers risk register. This was a concern. Risks need to be monitored and managed on a regular basis to ensure the safety of all concerned.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

The main service provided by this hospital was a hair transplant.

Incidents

- The service reported no Never Events during the period October 2015 and September 2016. 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.
- No Serious Incidents (SI's) were reported during the period October 2015 and September 2016.
- There were four non clinical incidents during the period October 2015 and September 2016. The provider said that these were discussed at the staff meeting and changes were made to practices to rectify situations for future patients, however staff informed us that incidents were not discussed at these meetings. We were told that there were no formal minuted meetings to confirm this.
- We were not assured that all incidents were reported. We were told about a clinical incident that occurred shortly before our inspection. A faulty piece of resuscitation equipment (Ambubag) was found by the anaesthetist during their equipment checks. There was no spare ambubag available. The service rectified this situation by ensuring they ordered two pieces of equipment for future usage so that there was always a spare, if required. However, we were concerned that the procedure was carried out despite the ambubag not being available in case of emergency. This incident was recorded within the accident/incident book and noted as 'resolved'. This incident was recorded as a near miss as the provider stated they had to operate on the patient without this piece of resuscitation equipment.
- The service did not hold mortality and morbidity meetings. There were on occasion brief discussions held between two senior doctors and the registered manager as part of other business meetings. There was no evidence to suggest meetings occurred at regular intervals. This informal meeting did not include the anaesthetist. Due to the nature of the cosmetic surgery undertaken by this provider being low risk, it was likely that these meetings would have been held as an exception rather than as a normal occurrence.
- 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.
- Some of the doctors that operated on behalf of the provider under practicing privileges were aware of the duty of candour, however not all doctors understood their duty under this legislation. Other members of staff within the team were unaware of the duty of candour.

Clinical Quality Dashboard or equivalent

- This provider was a day case only service. They had no inpatients and had never needed a patient to stay in over night. They did not carry out venous thromboembolism assessments or falls assessments
- The service did not monitor surgical site infection (SSI) rates. Since the inspection, we have been informed by the service that they have introduced a register to record SSI's, however we have not seen evidence of this.
- The service had a sepsis policy, although not all staff were aware of this.

Cleanliness, infection control and hygiene

Surgery

- All the patients attending the service were day cases. The service did not have a ward.
- There were three treatment rooms classed as operating theatres by the provider. We were concerned with the definition and use of these operating theatres due to the procedures that were carried out within them. There were two treatment rooms where hair transplant surgery took place (Theatre 2 and Theatre 3). There was also a third treatment room (Theatre 1) that was considered to be an operating theatre but it did not have all facilities such as appropriate ventilation and clean/dirty room to be classed as this. Breast lifts, mini abdominoplasty, abdominoplasty and gynaecomastia took place.
- Within Theatre 1, there was a decontamination room containing an autoclave and an ultrasonic device. There were no provisions within Theatre 1 or the decontamination room for air changes. Air changes are required to circulate the air within the theatre or decontamination room to prevent infection and cross contamination. There was a small air conditioning unit on the wall in Theatre 1.
- The floors were all washable lino and visibly clean.
- Worktops and operating couches were visibly clean and pillows were wrapped in wipeable plastic covering.
- We did find the windows had venitian blinds covering them and these had dust on them. We also found dust on window ledges and the paint within the treatment rooms was flaky in places. This was not appropriate for a sterile operating environment.
- An external cleaning company had been contracted to clean the theatres every day. The contract had started three months prior to the inspection. There had been one deep clean of Theatre 1 when the cleaning company began the contract. The next deep clean was scheduled for three months time (every six months). There was no evidence of daily cleaning schedules in any of the rooms.
- The service had different colour coded cloths, buckets and mops which were used to clean different areas within the clinic to prevent cross contamination and spread of infection.
- We did not see any changing or showering facitlites for staff or patients, however Theatre 2 contained a basin for hair to be washed prior to procedure.
- There was the provision of overshoes for Theatre 1 just prior to entering the room.
- No surgery took place during our inspection, however we were told that doctors wore scrubs during procedures. We were unable to observe antiseptic skin preparation as there were no patients on the premises during our inspection.
- Heating was an issue within the treatment rooms. The building was listed and therefore the service was limited in changes it was able to make. The provider had purchased some portable heaters to be placed within the treatment rooms to make the environment more comfortable for patients and staff alike. Heating for the theatres was provided in the form of a portable heater. One of the heaters we saw on the inspection was dirty.
- We found that there was a fridge within the decontamination room which contained local anaesthetic. The fridge was within the 'dirty' area, whereas it should have been housed with in the clean utility area. This increases the risk of cross contamination.
- We understood that hair transplant was a 'clean' procedure. This meant the environment must be clean but not sterile which is required for more invasive surgery; for example liposuction, mini abdominoplasty, abdonminoplasty, gynaecomastia and breast lifts.
- Legionella water testing took place once per week by a HCA.
- We were informed that fridge temperatures were checked every day although we did not see any evidence of this.
- Personal protective equipment (PPE) was available for doctors to use during procedures.
- There were laminated posters above the sinks in the theatres showing the appropriate technique for handwashing. There was no audit for handwashing.
- There was an infection control policy within Theatre 2. This was on the wall. This policy referred to other documents for further information on other aspects of infection control and other policies relating to this topic.
- The service did not monitor surgical site infections (SSI's) and did not conduct an audit. When we spoke with BE Cosmetic Clinics Limited about SSI's, they were unable to tell us if patients had attended an alternative healthcare provider post surgery, therefore they were unaware as to any complications or infections that had arisen following a procedure.
- The service did not screen patients for Methicillin-Resistant Staphylococcus Aureus (MRSA). They were unable to state if they had conducted a

procedure on a patient with MRSA. We were concerned as invasive procedures had taken place, and there was the likelihood of infection and cross contamination of MRSA from one patient to another. Since the inspection, the provider has contracted an external company to test patients for MRSA prior to procedures taking place. They have confirmed that any patient that tests positive will be placed last on the theatre list, and that the theatre will be deep cleaned following their procedure.

- During our inspection, we were concerned with the in-house decontamination process for instruments used during liposuction procedures. We observed equipment that had been through the in-house decontamination process, however the equipment was stained. There were cannulae that had been through the decontamination process, however the ultrasonic machine that the staff used as part of the process had been broken since February 2017, therefore it was not used. Despite the lack of this vital piece of equipment, decontamination continued.
- It was agreed during the inspection that sterilisation of cannulae in-house was not possible and that this was to be outsourced to a decontamination company. We spoke with the provider regarding decontamination and they were not able to identify or confirm those instruments that had been marked as sterile. This in-house process did not meet Health Technical Memoranda (HTM) guidelines. Following the inspection, we have been informed by the provider that all in-house decontamination has been stopped and will be outsourced to a third party with immediate effect, although we have not yet seen any evidence of this.
- There were handwashing facilities in all of the treatment rooms and this included antiseptic handwash. We were unable to observe handwashing protocols as there were no patients or procedures that took place during the inspection. We were also unable to observe doctors and clinical staff in scrubs, altenative theatre dress or bare below the elbows for the same reason.

Environment and equipment

- Within Theatre 1, there was a fully equipped adult resuscitation trolley. This included medications for anaphylaxis, automated external defibrilator (AED), airways and oxygen, amongst other items. The registered manager stated that he checked the resuscitation trolley himself weekly. We saw evidence that the resuscitation trolley was checked regularly by the provider.
- Be Cosmetic Clinics policy stated that there should be resuscitation equipment in all treatment rooms. We were only able to find this within Theatre 1. There was no oxygen or resuscitation equipment in any of the other treatment rooms.
- No children were seen as patients within the clinics for consultation or treatment.
- The theatres were classed within the providers policy as minor treatment rooms (MTR). They were not designed as conventional theatres and did not contain appropriate equipment for adequate air changes; this was a risks of cross contamination and infection. The ventilation system must conform to HTM 03-01 building regulations and it did not meet these requirements.
- Since the inspection, the service acknowledged the HTM 03-01 building regulations and they have ceased any surgery requiring air changes.
- We were advised by the provider that the anaesthetist supplied all of their own equipment, including drugs and oxygen. We were not able to inspect this equipment or their processes as they were not present on the days of the inspection, and there were no procedures planned.
- The provider was not aware of what equipment the anaesthetist provided themselves or used. He said that he had not checked the equipment to ensure it met guidelines or regulation. The anaesthetist was not present during our inspection, therefore we were unable to observe the equipment or practice.
- During some procedures, the patient had their blood pressure and oxygen saturations measured once, and then again at the end of the procedure. During hair transplant surgery, there was no intra operative monitoring at all. Intra operative observations are used to monitor a patient during a procedure. This is to ensure they do not deteriorate due to a reaction to medications administered or for any other reason associated with the procedure. All observations were carried out by a healthcare assistant or theatre runner.
- Instrumentation used for liposuction was multiple use. This was decontaminated in-house using an ultrasonic machine and an autoclave. After discussion with the provider regarding their decontamination process and procedure, they felt this was unsafe.

Surgery

- Cupboards and worktops were visibly clean and all cupboards had keys and locks. All cupboards were labelled with the contents and there was a locked controlled drug cabinet within Theatre 1.
- We asked if there was a policy for collection and storage of specimens, however the provider said that he dealt with these himself. Specimens were sent out to a third party for investigation. We were not shown any policy for management of specimens.
- We were told that equipment used for hair transplant surgery was single use and disposable. We did not see any evidence of hair transplant equipment being reused.
- Within the treatment rooms, there were appropriately labelled sharps boxes. These were not overfilled and temporary lids were closed.

Medicines

- During our inspection, we found a large store of antibiotics, adrenaline and local anaesthetic. These were kept in locked cupboards within the treatment rooms. There were some controlled drugs that were kept locked away in an appropriate container.
- We were told that antibiotics could be used by some doctors as a prophylactic prior to surgery. Some doctors felt it was appropriate that these were given post operatively. This was normally the case for patients in higher risk groups, for example those with diabetes. The provider stated that the service did not follow National Institute for Health and Care Excellence (NICE) guidelines for antibiotic administration and prescription as the guidelines did not apply to the procedures that they carried out.
- We were informed by doctors that patient allergies were documented on the patient record, although we did not have access to electronic patient records due to the faliling of their intranet systems. We were unable to review this.
- Local anaesthetic was used for hair transplant surgery, breast lifts and VASER liposuction (in the form of tumescent anaesthesia- this form of anaesthesia involves giving the patient an amount of saline combined with local anesthetic and adrenaline).
- All medication that we checked during the inspection was in date, however we found that there was a small amount of single use local anaesthetic within an open vile, stored in the fridge within the dirty utility. We brought this to the attention of the provider and he assured us that this would be dealt with immediately.
- Where controlled drugs had been used during sedation, the provider informed us that the anaesthetist had asked him to countersign the paperwork. We were told that a copy of these notes were stored within the patient records. We failed to find signed copies of medication given by the anaesthetist in patient records.
- There were two oxygen cylinders in Theatre 1, however we did not see any other provision of oxygen for Theatre 2 or 3.

Records

- We saw evidence of completed and up to date risk assessments for the environment, facilities, security, fire safety, PPE, and resuscitation equipment.
- Pre operative assessments were carried out by staff at the service. This process involved the patient being weighed, and blood pressure and oxygen saturations measured. The patient was then taken into the theatre to change (if appropriate).
- No ECG assessments were undertaken by the service at anytime. There was no equipment for this assessment. There was a concern that a patient may have a local anaesthetic (tumescent) which involves large amounts of fluid being given to the patient. An undiagnosed heart or lung condition may require close monitoring under these conditions.
- All medical notes were retained within the patient record and stored on the premises for a maximum of six months; thereafter, the records were collected by a third party for scanning to create an electronic file and for safe and confidential storage.
- Patient notes were recorded and stored via an electronic system, making them available to consultants as and when they were required. During the inspection, the intranet was faulty and therefore we were unable to access or view electronic patient records. There was no alternative system in place for such events.
- We reviewed 10 patient written records and found that the clinical notes were inconsistent and incomplete. We found pre printed consent forms and information leaflets given to the patient prior to consent. We also found that there was a procedure where contolled drugs had been given, however it was unclear as to whether these had been administered by an anaesthetist.

- The patient records showed (only February and March 2017 available due to the electronic records being unavailable) that intra operative monitoring did not take place in the majority of cases, even when the patient had been administered controlled drugs and the equipment was readily available.

Safeguarding

- We were told by the service that all staff had completed safeguarding training. They were unable to tell us the level of training that they had received. Not all staff, including the doctors, were fully aware of safeguarding and not all understood the meaning or relevance to the welfare of the patient.
- The training records provided by the service showed that only three members of staff out of 14 had completed safeguarding training. Furthermore, of the six doctors working at the clinic, including those with practicing privileges, only one had completed their safeguarding training. It was not clear which levels the staff or the doctors had attained.
- The safeguarding lead had not completed any safeguarding training.

Mandatory training

There was no induction training for new members of staff, doctors working under practicing privileges or bank/agency staff.

- All the doctors and members of staff that we spoke with said they had received their mandatory training, however, when we checked their training records, this was not the case.
- Training records provided showed that six out of 14 staff members and four out of six doctors had not completed their infection prevention and control (IPC) training.
- The records also showed that two out of the six doctors working within the clinic did not hold a basic life support (BLS) certificate. This was also the case for the registered nurse. Two members of staff had also not completed this training. The doctors and the nurse also did not hold an intermediate life support certificate (ILS).
- There were no other records to indicate any further training had taken place. This included mental capacity act training and deprevation of liberty training.

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

- We were told by the provider that they did not have a written patient admission criteria.
- The service did not use any form of early warning score system to monitor their patients. The provider was unaware as to the use of these documents in practice.
- Since the inspection, the clinic have informed us that they will implement an intra operative observation monitoring tool. We have not seen evidence of this in use to date.
- The service did not use the World Health Organisation (WHO) checklist or 5 Steps to Safer Surgery. They were not aware of this process and stated that they did not do any form of brief or debrief; they also were very clear that they did not do a swab or equipment count pre or post surgery.
- Since our inspection, the service have sent us a copy of the WHO checklist tool that they have decided to use for every procedure. We have not yet seen evidence to show that this is currently in use.
- There was no policy or process in place for patients that required an urgent provision of blood during or following a procedure at the service.If a patient became unwell during a procedure, the service said they would look for reversible causes of the reaction and resort to basic life support (BLS). They would then call for an ambulance to transport the patient to the nearest emergency department for treatment.
- The service had one doctor who was advanced life support (ALS) trained. All other doctors said they were basic life support trained only, however their training records indicated that this was not the case. The clinic policy stated that doctors must be ALS trained when carrying out procedures. Since the inspection we have been informed by the service that they have found a suitable training course in May 2017. We have not been given evidence or information of either course, date, or the names of staff that will attend.
- There were unofficial agreements with approximately two other private care providers within Harley Street, to enable referral of patients, should they require further medical assistance for a non urgent condition.
- On discharge, the patient was provided with a contact telephone number for out of hours assistance. This telephone line was answered by either the doctor on call or the registered manager. Once the patient had been spoken with, a decision was made if the patient needed to return to the clinic for further examination, treatment or onwards referral to another service.

- The service did not always have the patients medical history records, however if a patient had certain conditions eg diabetes or a heart condition, the provider would ask the GP to provide details.
- The service did not carry out any psychological assessment for patients prior to their surgery, however this is required by the Professional Standards for Cosmetic Practice (Sect 5.2). The provider stated that should they be concerned with the reason that a patient may wish to have a procedure, they would ask the patient to attend their GP for a psychological review. The provider explained that this had happened on one occasion.

Nursing and support staffing

- The provider did not use an acuity tool to decide on the number of staff it required to carry out each procedure safely and effectively. We were told by the provider that they required two health care assistants (HCA's) to conduct procedures in liposuction and hair transplant surgery. This was so that one of the HCA's was his assistant and the other was the theatre runner. We asked what he would do in the event that one of the HCA's was not available, or did not arrive for work. He stated that he would have to cancel and postpone the procedure until he had adequate staffing levels. He said that this had not occurred to date.
- The service did not record their actual staffing against their use of bank staff. The permanent staffing arrangement consisted of an HCA, a nurse (temporary vacancy filled by an HCA) and the registered manager. Other staff were called upon as and when needed; for example hair technicians. We asked how sickness and holidays were covered. We were told that this had not been a problem in the past, however if there was a procedure booked and not enough staff were available, they would telephone to see if they could get replacement staff. If they could not get any other staff, they would cancel the procedure, although this had never happened to date.
- The service used HCAs for pre operative, intra operative and post operative observations, preparation of the treatment rooms prior to surgery, and to clear away post procedure. The HCAs were taught by shadowing the nurse or each other. They had no formal induction or training from the provider. One of the HCAs had completed a HCA course abroad, however they had not received any formal training from the provider. There were no other trained or registered nursing or clinical support staff.
- The nurse was not available during the inspection. We were unable to identify and verify how her competencies had been maintained and updated.

Medical staffing

- Out of hours cover was provided via telephone consultation and if necessary, the doctor would attend the clinic to provide face to face care for the patient. The patient was given a 24 hour mobile telephone number on discharge for any concerns or emergencies that they may encounter following their procedure. This was manned by a doctor or the registered manager.
- If the patient needed to attend the clinic outside of normal working hours for emergency purposes, they had to contact the doctor on call. The doctor on call was able to attend the clinic within one and a half hours of the telephone assessment.

Emergency awareness and training

- The service was able to explain their fire evacuation meeting point in case of emergency. There were no other visible emergency plans. There was no provision of a generator in the case of an electrical failure or power cut. We were told that if there was an electrical failure or water disruption issue, they had telephone numbers of emergency electricians and plumbers that they could call upon, however the timescales were not known for their response.

Are surgery services effective?

Evidence-based care and treatment

- The service did not adhere to NICE guidelines, and they were not aware of the Royal College of Surgeon guidelines or those set out by the World Health Organisation (WHO).
- The provider explained that antibiotic admisitration and provision NICE guidance was not applicable to their service, thus they did not use this or refer to this at all.
- The service did not adhere to all of its own guildines and policies. An example of this was with regard to its practicing privileges agreement and letter of grant policy. Doctors given practicing privileges by BE

Cosmetic Clinics Limited were not Disclosure and Barring Service (DBS) checked by the provider; their experience and their registration status with regulatory bodies was not recorded.

- A further example was the provider stated that he checked the resuscitation trolley medications on a weekly basis. The services policy stated that the resuscitation trolley (equipment and medications) should be checked on a daily basis.
- Specimens retrieved from patients during procedures were sent to a laboratory contracted by the provider for analysis as their local pathology service.
- The service stated that they submitted a yearly audit to The British Assocaition of Body Sculpting (BABS) for complications and patient satisfaction.We requested a copy of this audit, however the service did not provide us with this.
- The provider said that they benchmarked against another clinic carrying out similar procedures. We have not been provided with any evidence of this by the service.
- We were provided with one audit by the provider for the previous12 months. This audit showed that 91 liposuction procedures had taken place. 14 of these cases required some form of revision. There were 370 hair transplant procedures, 26 of these required some form of revision and 42 cases of gynaecomastia surgery, 15 of which either developed a complication or required further treatment.
- We received documents for the service that showed a checklist had been used for January 2017. These checklists recorded various pieces of equipment and areas of the clinic that may require remedial measures; it also showed those areas that were meeting standards as seen by the provider. There was no action plan, timescale or responsible staff member assigned to complete outstanding tasks. No other audits were received.

Pain relief

- We were told by the provider that he would ask the patient if they felt pain during the procedure. We did not see any evidence of post operative pain assessment . Post operatively, patients were told to take paracetamol or prescribed codeine for pain relief, if required.

Nutrition and hydration

- The service did not have wards or an inpatients department. If a patient was at the service for a period of time during treatment, especially hair restoration, the service provided food and refreshments. This is purchased off of the premesis at a local restaurant or food establishment. Staff said this catered for the patients preferences, needs and dietary requirements.
- The provider informed us that there were no procedures carried out under general anaesthetic, therefore there were no starve times prior to a procedure.

Patient outcomes

- The service carried out 444 procedures from October 2015 to September 2016. This was broken down into 330 hair restoration surgery, 109 VASER liposuction, four scar revision and one mini abdominoplasty.
- During October 2015 until September 2016, there were no unplanned returns to theatre post operatively.
- There were no instances of patients transferred to alternative care following treatment with the provider.
- During the same period, there were no unplanned readmissions to theatre post operatively.
- The provider stated that they did not record QPROMS (Questionnaire-Patient Reported Outcome Measures) for their services. We were not provided with any evidence to show the recording of QPROMS.
- The provider did not submit data or engage with the Private Healthcare Information Network (PHIN) with their advertising or marketing.
- Staff were trained 'on the job' by another colleague. There was no induction package for staff and there was no training package in place. Some mandatory training had taken place; this included basic life support and infection prevention and control (IPC) however, no other formal training had been provided. We were told by health care assistants that they had trained each other to take patients blood pressure and oxygen saturation levels.
- The provider had a written policy on practicing priviledges. We were told by doctors that they were asked to provide their certificates and CV along with additional documentation to the provider. The registered manager searched the General Medical Council (GMC) register for the applicant to make sure the doctor was registered.

- The service did not carry out its own DBS checks, but instead relied on the doctor to provide previous evidence of a DBS certificate that was carried out within the previous three years.
- There were no checks on the doctors experience or scope of practice. This meant the service could not be sure doctors were fully competent to carry out the procedures they were undertaking.
- Doctors, including the provider, undertook their appraisals via external colleagues and doctors within their areas of practice, on a yearly basis. This was the requirement set out by the GMC.

Multidisciplinary working

- We saw evidence of multidisciplinary team (MDT) working. For example, during hair transplant surgery, a tricologist was used as well as hair technicians. The doctor carrying out the surgery would lead the procedure, however the tricologist/ technician was able to insert the hair follicle once the doctor had made the incision.
- The provider had a service level agreement (SLA) with another private practice close by. This SLA was to provide overnight accommodation for a patient that may require medical observation or treatment during the night. There was no SLA with a local NHS hospital or ambulance service, statutory or private.

Access to information

- All patient records were handwritten and stored on the premises for a maximum of six months. After this period, patient records were collected by a data storage company and scanned on to an electronic system. The doctors then had access to these records at anytime. During the inspection, we were concerned to find that the internet was not working, therefore the electronic patient records were unobtainable. This was a concern as there were no backup plans for such cases.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The patient records showed that four out of five patients consented to their procedure on the day of surgery. Prior to cosmetic surgery, each patient should be given a two week cooling off period. This was not the case.
- We were informed by the provider that if he was unsure as to the patients psychologial suitability for surgery, he would ask the patient to attend their GP for psychological assessment before agreeing to carry out any surgery. He told us of one case where he had asked a patient to obtain this assessment, however we did not see any evidence of this.

Are surgery services caring?

Compassionate care

- The service did not carry out a Friends and Family test. We were told by the provider that they carried out a patient survey which was part of the report that was sent to BABS. The outcomes were requested, however none were provided. We were not provided with any evidence of the patient survey or any associated results.
- Prior to our inspection we gave the provider comment cards for their patients to complete. All of the comment cards were positive regarding the care that they had received from the service.
- We spoke with three patients, however one of the patients was treated at another BE Cosmetic Clinic location, therefore their comments could not be included within this report. The feedback from the two patients that we spoke with were generally positive, stating that the clinic was clean and the staff were very welcoming and reassuring . It was noted that a patient felt they required another consultation with the service post procedure, however they had difficulties arranging a further appointment with the doctor. They found this frustrating and inconvenient.

Understanding and involvement of patients and those close to them

- Patients were encouraged to take a chaperone or relative with them to the service. If the patients first language was not English, the relative or chaperone was used for translation purposes. The provider said that he felt it was important for someone (relative or friend) to be with the patient for support and assistance following their procedure.

Emotional support

- There were no clinical nurse specialists for cosmetic surgery working with the provider or at the service at the time of the inspection.
- The service did not provide any counselling services to patients at any time.

- Patients had the cost of their procedure explained at the initial consultation.

Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- The clinic provided elective surgery; this was by appointment only. The provider tried to accommodate patient preference by being available to carry out procedures at the weekend if necessary and met patients demands. We were told by staff that it was very rare for them to provide services at the weekend.
- All procedures were carried out on patients between the age range of 18 and 75.

Access and flow

- Patients were referred to the service via a third party provider, word of mouth and via internet advertising for hair transplant surgery .
- We were told by the provider that patients would attend the clinic for an initial consultation. Once this had been completed, the patient would have time to consider the information that they had been provided with, and decide if the procedure met their needs. Once the patient decided to go ahead with the procedure, a deposit was paid and a consent form was sent via email.
- On the day of the procedure, the patient arrived at the clinic and was given pre operative information and their expectations were discussed and agreed. The patient was then taken through the pre operative assessment observations by the HCA. This included having their blood pressure, height and weight recorded. Once the doctor was happy with the results, the surgery took place. At the end of surgery, the patient was allowed to rest within the recovery room prior to final post operative observations being recorded. The patient was then allowed to leave and return home. Follow up for patients was either by visiting the clinic at a specified interval or via telephone conversation.
- If a patient was concerned about their surgical site or felt there was a problem, they were asked to call the clinic. The patient was able to speak with a doctor to get further advice. If the doctor felt that they needed to see the patient, both the doctor and the patient made their way to the clinic for a consultation. The doctor then had the option to re operate on the patient or refer them to another private medical professional for advice or treatment locally.
- We were not shown any evidence of exclusion or inclusion criteria for procedures within the clinic. We were told by the service that they did not have an official document that listed any criteria.
- The majority of patient records that we reviewed showed post operative information had been provided to the patient. We were told that the patients GP was not always informed of the surgery because they did not always give consent. It was made clear that some patients do not wish for anyone, including their GP to be notified that they have had any form of cosmetic surgery. The service respected patients wishes.
- There were three procedures out of the 444 cancelled during the reporting period October 2015 to September 2016. The three cancellations were due to waiting times, medication contraindications and another patient was booked into the wrong clinic.

Meeting people's individual needs

- The service did not have a translation service available at the time of the inspection. We were told that patients that did not speak English were communicated with via their relative or friends. We were informed by the clinic staff that if a patient could not understand information due to a language barrier, hand signals were used instead.
- Since the inspection, we have been told by the service that they have a telephone translation service available to patients. We have not seen evidence of this.
- There were no provisions for patients that suffered with dementia or learning difficulties.
- We found disposable underwear was available for patients to wear during their surgery which protected their dignity.
- There was an office for consultations, a waiting room, and three treatment rooms (one of which was used as a recovery room). There were no wards or private rooms for the patient and their relative to use or wait within, prior to, during or post surgery.

Learning from complaints and concerns

- The service stated that they received three minor complaints within the reporting period. We were not

given full reports on the way that the complaints were dealt with. We were informed that the patients were happy with the outcomes and the complaints were resolved to the patients satisfaction.

- The clinic resolved these complaints by a way of apology or reimbursement of funds. We were told that they discuss complaints at staff meetings so that all staff are aware of any issues. One of the complaints that we were informed about was due to waiting times. A patient was kept waiting and had to have their procedure postponed due to timings. The service took learning from this incident and changed their time management to reflect this.
- A further complaint that the service received was due to the low internet signal that patients received in the treatment rooms. The provider rectified this situation so that the signal was adequate for patient requirements.
- We found patients were not signposted to the Cosmetic Redress Scheme (CRS) in the event of an unresolved or unsatisfactory outcome to a complaint. When we spoke with one of the doctors, he was unaware of the CRS.

Are surgery services well-led?

Vision and strategy for this this core service

- The vision and strategy for this service was to improve and be good at the services they provide and to expand their business. The service have recently acquired a further clinic nationally to bring services to the local private patients.

Governance, risk management and quality measurement

- Governance meetings took place at the service approximately quarterly, during the MAC meeting. We requested minutes of the Governance meetings, however these were not provided.
- Practicing privileges were agreed at the MAC meeting, however the process did not follow the clinic policy. DBS checks were not up to date and only one had been carried out by BE Cosmetic Clinics. We found one DBS check that dated back to 2011 was not up to date.
- We found that the doctors had not kept a log or record of the procedures that they had completed. The purpose for recording their experience,and number of procedures they had carried out, (either by shadowing another colleague or as the lead surgeon), was to prove experience and competence.
- After the inspection, we received notification from the provider that he had suspended a number of doctors with practicing privileges from his clinic, therefore only two doctors remained within the service. We also received a copy of a letter of resignation from one of the doctors as confirmation that he was no longer wishing to practice at the clinic. The doctors that had their practicing privileges removed were unable to satisfy all requirements under the providers practicing privileges policy.
- We saw evidence in staff files to show professional indemnity insurance for all doctors except one. This doctors insurance had expired just before our inspection, however the provider stated that he has seen a renewed document. This information was requested, however we have not been provided with this evidence. Furthermore, one of the doctors had insurance but it is unclear from the records provided as to whether this is still valid and up to date as there was no expire date on the insurance document.
- None of the staff or doctors had contracts in place. Only two staff out of 14 and three out of six doctors had provided one or more references.
- Not all staff and doctors had been given an appraisal. Three out of 14 staff, and two out of six doctors had completed their appraisal.
- Not all staff or doctors had a curriculum vitae (CV) within their records. Four out of 14 staff and one out of six doctors did not have this information available.
- The service had a risk register, however not all the concerns we identified during the inspection were included on this; for example the service did not have a generator in the event of a power failure. We noted that the ultrasonic decontamination machine was not working, however this was recorded on the risk register. During our inspection, a new machine was delivered to replace this.
- The clinic had a Medical Advisory Committee (MAC) which comprised the clinic manager, and two doctors, one of which was the clinic owner. The other doctor on the committee mentored the registered manager during some of his procedures, however this mentor was under conditions from the GMC. MAC meeting minutes were requested but not provided.

- Since the inspection, one of the doctors who sat on the MAC resigned. We have not been notified of a replacement.

Leadership / culture of service related to this core service

- The manager led the service in its entirety. He was the CQC responsible person and registered manager. He was responsible for all of the policies and the point of contact for safeguarding.
- When the registered manager was away on business or unavailable, there was a doctor who had practicing privileges at the clinic that covered for him; this doctor only practiced cosmetic surgery in the form of hair transplants. The registered manager carried out hair transplant surgery and liposuction amongst other procedures.
- The service had contact with other private cosmetic surgery clinics locally and nationally. In general, they were in contact with services where they had granted practicing privileges to their doctors. The registered manager said they used these clinics to benchmark against, however it is unclear as to how they carried out this task; very limited data and auditing took place.

Public and staff engagement

- We spoke to staff and they felt that the provider was approachable and happy to listen to suggestions that they put forward. The employed staff said they were 'happy' working at the service but felt that they would benefit from more staff.
- Staff stated that they attended meetings with the registered manager on a regular basis, however there was no evidence or minutes provided by the service to show this.

Innovation, improvement and sustainability

We were not provided with enough information by the service to be able to comment on their innovations, improvements or sustainability.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must put in place a comprehensive incident reporting system.
- The provider must carry out intraoperative observational monitoring at standard intervals as appropriate.
- The provider must screen patients for MRSA prior to any procedure.
- The provider must make clear on all paperwork, who has prescribed and administered any medication and the records must be kept in full and be fully accessible for review.
- The provider must ensure that all doctors carrying out procedures are ALS trained as per your own policy.
- The provider must use the WHO checklist for all surgical procedures.
- The provider must ensure that all staff have completed their mandatory training.
- The provider must make sure they follow their own policy for granting practicing priviledges.
- The provider must ensure that they safeguard their patients in all circumstances, this includes providing a translation or interpretation service for those that require alternative means of communication.
- The provider must ensure that if they conduct cosmetic surgery, HTM building regualtions must be adhered to. This includes the provision of air changes for invasive procedures. Within your policy document 'Operating Theatres' page 136 paragraph 1.1, 1.2, 1.3, 2.1 and 2.2, you do not adhere to your own policy. This policy states that the 'theatres' are minor treatment rooms (MTR). MTR's are not suitable locations for the surgical procedures that you have undertaken.
- The provider must ensure there is an appropriate changing facility for doctors and patients alike, to ensure privacy and prevent cross contamination.
- The provider must ensure that the theatre is deep cleaned as appropriate, especially when a patient that may pose an infectious risk has been treated within the minor treatment rooms.
- The provider must ensure that the treatment rooms are adequate and meet regulations as set out for thecarrying on of cosmetic surgery.
- The provider must ensure that all equipment that is not single use is sterilised and decontaminated to required standards and stored appropriately.
- The provider must ensure that there is a qualified healthcare professional with the patient at all times during and post procedure.
- The provider must ensure that IPC procedures are followed to prevent cross contamination.
- The provider must ensure that there are formalised governance systems to improve the quality and safety of the service and learn from incidents.
- The provider must ensure all resuscitation equipment and drugs are checked daily and recorded.
- The provider must ensure that there is resuscitation equipment available in each of the treatment rooms as per their own policy.
- The provider must record surgical sight infections and monitor surgical activity to establish areas that required improvement.
- The provider must follow their own company policy document 'The Fundamental Standards of Quality and Safety 2017'.
- The provider must follow NICE, WHO, AAGBI and other regulatory guidelines as appropriate, however if they chose not to comply with these, the provider must be able to appropriately and reasonably justify their actions.
- The provider must ensure staff members are given an induction and are formally trained appropriately for their role. This includes bank and agency staff and doctors.
- The provider must record minutes of governance and MAC meetings.
- The provider must ensure that all doctors or medical professional staff hold relevant insurance for their scope of practice.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment • Doctors had not completed their safeguarding training.

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • Medications had been given to patients during procedures, however it was unclear who had prescribed and administered these. • None of the doctors carrying out procedures were ALS trained. • The WHO checklist or equivalent were not used for procedures. • Patients were at risk as there were two procedures running simulatniously. One of the patients was left with an unqualified health care assistant during their procedure which is unsafe. • Patients were not screened for MRSA or other infectious or contagious diseases.

Regulated activity	Regulation
Surgical procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment • There were no changing facilities for doctors carrying out procedures. There were no changing facilities for patients undergoing surgery. • There were no air changes within the treatment rooms in line with HTM regulations.

This section is primarily information for the provider

Requirement notices

- The treatment rooms were only deep cleaned once every six months
- Equipment was decontaminated and sterilised in-house. This procedure was not robust.
- The 'operating theatres' were not suitable for the procedures being carried out. The environment was unsuitable and this was reflected within the service policy.

Regulated activity	Regulation
Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service did not follow their own policies. • Incident reporting was not complete or accurate. • Not all staff had undergone mandatory training. • Not all checks had been undertaken for doctors applying for practicing privaleges with the service. • There were no formal minuted governance meetings. Therefore there was no way to monitor performance or change. • There was a lack of auditing of surgical procedures and governance.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed • There were no safeguards to check that doctors were working within their scope of practice and were qualified and experienced for the procedures they carried out.