BE Cosmetic Clinics Limited

Quality Report

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

Summary of findings

Letter from the Chief Inspector of Hospitals

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:

- There was insufficient evidence to assure us that the operating theatre was compliant with regulations to ensure a safe clean compliant environment for surgical procedures.
- Legionella checks and the legionella risk assessment were not appropriate for a clinical setting.
- We were not assured that portable appliance testing (PAT) was carried out to a competent standard.
- Record keeping was inconsistent, for example the surgical safety checklist was not always completed and there was no documentation of any post-operative follow-up on any patient record.
- The provider, who was the safeguarding lead did not have in date safeguarding training.
- Audits were not carried out on a regular basis and did not always identify areas of concern or result in an action plan.
- The provider was not following Royal College of Surgeons Professional Standards for Cosmetic Surgery in relation to consent with cosmetic procedures which states there must be a minimum two-week cooling-off period between consultation and consent to surgery.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We served a Warning Notice on the provider setting out the need to make immediate improvements to the service. Details are at the end of the report.

Amanda Stanford
Deputy Chief Inspector of Hospitals

Overall summary

BE Cosmetic Clinics Limited is operated by Surgimed Clinic Limited. Facilities include one theatre, one admission/recovery room, one hair transplant room and a consulting office. The service has no overnight beds.

We previously inspected this service in March 2017 at which time we had serious concerns that the provider was not complying with all the fundamental standards of care. We wrote a formal 'Letter of Concern' to the provider on 22 March 2017 setting out the concerns. Following the letter the provider voluntarily suspended all their regulated activities except for hair transplants, which are a 'clean procedure' and do not require the use of a sterile operating theatre.

We inspected this service using our comprehensive inspection methodology. We carried out an announced follow-up inspection on 22 August 2017 and 14 September 2017. The purpose of this inspection was to check what improvements had been made to the service since our previous inspection.

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

The current service provided by this service was hair transplant since the provider suspended all other services following our inspection in March 2017.

94 hair transplant procedures were carried out between April and August 2017.

Summary of findings

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Background to BE Cosmetic Clinics Limited

BE Cosmetic Clinics Limited is operated by Surgimed Clinic Limited. The service opened in 2015. It is a private clinic in central London. The service primarily serves the communities of the London area. It also accepts patient referrals from outside this area.

The service has had a registered manager in post since May 2015.

Our inspection team

The team that inspected the service in August comprised a CQC lead inspector, two other CQC inspectors, and two specialist advisors with expertise in cosmetic surgery and theatre nursing.

The visit in September, comprised of a CQC lead inspector, one other inspector, the CQC National Professional Advisor for Surgical Specialities and two specialist advisors with expertise in corporate governance, health and safety and building regulations compliance. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Information about BE Cosmetic Clinics Limited

The service 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 the theatre, all three treatment rooms and the consultation office. We spoke with three staff, including a scrub nurse and senior managers. We reviewed 15 sets of patient records during this inspection.

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 second inspection since the service registered with CQC.

Activity (April to August 2017)

In the reporting period April to August 2017, there were 94 day case episodes of care recorded at BE Cosmetic Clinics Limited. All cases were self-funded.

There was a nurse and one health care assistant employed as well as a number of bank staff, and three consultants working under practising privileges. A practice manager oversaw patient bookings and the general day-to-day operation of the service.

Track record on safety

- No Never events had been reported in the service.
- 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

There were no current complaints.

Services accredited by a national body:

- British Association of Body Sculpting (BABS)

Services provided at the hospital under service level agreement:

Summary of this inspection

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

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 were not assured that the recently installed operating theatre provided a safe environment in which sterile surgical procedures could be performed.
- Legionella testing was not carried out in accordance with guidance.
- Electrical safety checks, including electrical appliance safety testing, did not comply with current regulations.
- The registered manager, who was the safeguarding lead, did not have in date safeguarding training.
- Patient records were not always completed with relevant follow-up information.
- There was inconsistent use of the World Health Organisation '5 steps to safer surgery' on patient records.

Are services effective?

- The provider did not routinely complete audits. 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.
- The provider was not following the Royal College of Surgeons Professional Standards for Cosmetic Surgery in relation to a two week cooling off period to enable a patient time to reflect on the information provided.

Are services caring?

- Patients were encouraged to take a family friend or relative with them on the day of their procedure. In the absence of a family friend, the provider would arrange a chaperone on request.

Are services responsive?

- The provider had a contract with a translation service to assist patients whose first language was not English.
- There were no current complaints about the service.

Are services well-led?

- The provider did not ensure that there were effective processes in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others.

Summary of this inspection

- The provider did not demonstrate sufficient understanding of compliance requirements within a hospital or clinical setting.
- We were not assured that the provider had an understanding of the requirements related to the provision of safe surgery.
- The service did not benchmark against other services, therefore the registered manager was unaware of potential changes to improve the service based on factual information.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

The main service provided by this hospital was hair transplant.

Incidents

- The service reported no Never Events during the period April 2017 and August 2017.
- Never events are serious incidents that are entirely preventable as guidance or safety recommendations providing strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers. At our previous inspection in March 2017, we were not assured that all incidents were reported. Since then, the provider's action plan stated that in-house training and re-induction had taken place with all permanent staff. However, there was no record available to confirm which staff had completed this in-house training.
- There was a recently introduced induction pack for all new staff. This included how to report an incident (logged in incident/accident book) but did not give any detail of what an incident was.
- There were no Serious Incidents (SIs) or clinical incidents reported between April 2017 and August 2017.
- The registered manager told us they had introduced mortality and morbidity meetings since the last inspection and one had taken place at the beginning of August 2017. We saw a record of this meeting which was attended by three out of the four practising doctors at the clinic. No mortalities were recorded and discussion took place about one patient who required follow-up treatment. There was no planned date recorded for the next mortality and morbidity meeting.
- The Duty of Candour (DoC) is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The registered manager told us there had been no occasions since the last inspection when the DoC had been applied.

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

- This provider was a day case only service. They had no inpatients and had never needed a patient to stay in overnight. They did not carry out venous thromboembolism assessments or falls assessments.
- At the time of the last inspection, the service did not monitor surgical site infection (SSI) rates. Since then, the registered manager introduced a register to record SSIs. We saw there were none recorded and were told there had been no occurrence since the introduction of the electronic SSI register.
- They also told us they recently contacted all patients on their database (more than 900) and confirmed that none had experienced post-operative infection at their surgical site. There was no written record available to confirm this audit.
- The service had a sepsis policy, but there was no information on view in or around any of the treatment rooms to remind staff of the need to remain aware. We spoke with the registered manager who told us that since the clinic saw patients who were well then sepsis was not an issue.
- They also told us they would recognise if a patient showed signs of sepsis, for example, if they looked hot; however hair transplant patients did not have their temperature recorded at the beginning and end of a procedure. We were not assured by their response that patients who might develop a sepsis would be recognised and treated effectively in the absence of recorded temperatures.

Surgery

- When we returned for the second day of this inspection, we saw evidence that the registered manager and the nurse had completed an on-line training course on sepsis awareness. There was information on sepsis awareness displayed in the treatment rooms.

Cleanliness, infection control and hygiene

- The provider failed to meet the guidance issued by the Department of Health on the prevention and control of infections. The legionella risk assessment was not appropriate for a clinical setting and did not comply with Department of Health guidance.
- There were not reliable systems in place to prevent and protect people from a healthcare-associated infection. The theatre environment was not fit for carrying out sterile surgical procedures and increased the risk of infection to patients.
- The theatre had been redesigned since the last inspection in March 2017. The registered manager told us it was designed as a room within a room, which meant that a completely new structure was built within the existing room.
- However, there was insufficient evidence to assure a safe clean compliant environment for surgical procedures was provided within the operating theatre.
- The ventilation system was not compliant with; Health Technical Memorandum - HTM 03-01 A, HTM03/01 B; HBN 10-02 and Health and Safety at Work etc. Act 1974.
- There was no assurance of compliance with Building Regulations (England and Wales) Approved Document F1 Means of ventilation.
- A recirculation direct expansion (DX) air-conditioning unit was installed. This practice is not recommended by HTM 03-01 due to risks associated with refrigerant gas, cleanliness of recirculated air and adequacy of filters. If installed in operating theatres an enhanced three monthly cleaning and servicing regime is required, there was no evidence of this being undertaken.
- The operating theatre was not designed with an adequate pressure regime. HTM 03-01 requires Day Surgery theatres to achieve positive pressurised air changes that are replaced 15 times per hour (15 ACH). This pressure regime ensures contaminates are safely removed from the most sterile area pushing air out to less sterile areas. From the maintenance records, it was clear the air handling design for this installation was based upon extracting air from the theatre suite.
- From our inspection of the operating suite, it was evident it was negatively pressurised resulting in the natural movement of air from dirty to clean areas. There were sliding doors which allowed the movement of air from all parts of the building into what should be a sterile area.
- We saw comments on a maintenance record that indicated that filters were incorrectly installed on the extract duct.
- The provider was unable to produce suitable records of commissioning in line with the requirements of HTM 03-01. There was no evidence to assure us that the ventilation system had been designed, installed or commissioned by an accredited Healthcare specialist ventilation engineer.
- We were provided with no assurance the operating theatre ventilation was annually inspected and revalidated in line with the requirements of HTM 03-01 to ensure the system was compliant and operating in line with the original design.
- The ceiling within the operating suite was porous and unsealed which meant that dust could migrate into the sterile areas and the ceiling cannot be adequately cleaned.
- The legionella risk assessment did not describe the type of system and did not contain a plan to identify any dead legs (a pipe leading to an outlet through which water flows but the outlet is unused or rarely used). Records of weekly flushing of little used outlets were provided which was compliant with the approved code of practice HSG 274. However, HTM 04/01 recommend twice weekly flushing of little used outlets.
- The recently appointed scrub nurse was in charge of infection, prevention and control (IPC). This was their first experience of being IPC lead. They told us that since this was a new working environment for them, they sought advice from another clinic, which carried out similar procedures.
- Floors were covered with washable lino and were visibly clean. Surfaces also appeared clean.
- There were no disposable curtains in use in the clinical areas. The IPC lead told us all fabric curtains would be replaced as soon as surgical procedures were reinstated.
- The bed in the recovery area had a domestic bed cover, which posed a contamination risk.

Surgery

- We noted at the last inspection that the service did not screen patients for Methicillin-Resistant Staphylococcus Aureus (MRSA). Since then, the provider evidenced that an external company was contracted to test patients for MRSA prior to procedures taking place.
- We saw that the newly designed patient notes included a section where the assessing doctor took the decision to swab for MRSA. We were told that any patient with MRSA or considered to be at risk of carrying would be treated at the end of the surgical list. We also saw a risk assessment template which patients completed and included their previous surgical history, previous history of MRSA and exposure to anyone who had it.
- The service had different colour coded cloths, buckets and mops that were used to clean different areas within the clinic to prevent cross contamination and spread of infection.
- Since the last inspection, the provider had begun a contract with a third party for the supply of single-use instruments for hair transplant procedures.
- Clinical waste bins were stored outside and there was correct segregation of waste.
- The practice manager observed hand-washing techniques in July 2017 for one member of staff and there were no issues identified.
- 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, alternative theatre dress or bare below the elbows for the same reason.

Environment and equipment

- Electrical safety checks, including electrical appliance safety testing, did not comply with current regulations.
- It was noted that whilst the fixed electrical installations were tested, this was not done to an acceptable level as some items were overlooked. This was due in part to the absence of an overall asset register of appliances.
- We were not assured that electrical safety testing was carried out to a competent standard. For example, we found an extension lead which had been safety tested to be in a dangerous condition, which the provider removed from use immediately. We found a two part electrical lead of which only one part had been tested and other items of low voltage were tested despite there being no requirement for this to be done.
- There was no evidence that the bariatric couch in treatment room three and the consultation chair in the provider's office were tested at regular intervals in accordance with the Lifting Operations Lifting Equipment Regulations 1998 (LOLER). The provider was unable to show us any maintenance or insurance policies in relation to these pieces of equipment.
- The provider had installed a fire evacuation chair in the operating suite. However, we saw no evidence that any staff member was trained to operate it safely and effectively.
- The premises had one fire exit, which was through the front door on the ground floor and one route of egress from the upper floors, which was down the main staircase. We noted the fire doors between floor one and two were open and led to a disused fire exit.
- The building in which the service operated was a multiple tenanted building. The provider told us they were unaware of any other risk assessments, which might be held by the landlord or other tenants in the building. This meant they were unaware as to whether these risk assessments would conflict with that of BE Cosmetics.
- The provider submitted a copy of a fire risk assessment carried out by an independent fire safety advisor, who also undertook the provider's portable appliance testing.
- The risk assessment stated there was no gas on the premises, however we saw there were two oxygen cylinders in the operating theatre.
- The fuse boards were last tested in 2010 and should have been retested in 2015; whilst the report stated that this was the responsibility of the provider's landlord, we are unclear what action the provider took to draw this to the attention of the landlord.
- Emergency escape lighting was not periodically maintained (every six months). The fire risk assessment noted that whilst this was the landlord's responsibility, the provider must act on it.
- The risk assessment identified that certain doors are wedged open and recommended that all doors be fitted with guards, which release the door in the event the fire alarm was activated.
- Doors in the refurbished first floor theatre area were assessed as being of a one-hour fire-resisting standard and fire exit signage in the property was compliant.
- The fire assessor confirmed that staff had up to date training in how to call the fire brigade, the use of fire extinguishers, the cause and nature of fire and basic fire prevention.

Surgery

- There was a fully equipped adult resuscitation trolley in theatre. This included medications for anaphylaxis, automated external defibrillator (AED), airways and oxygen. We saw evidence that the provider checked the resuscitation trolley regularly.
- The resuscitation trolley in the hair transplant room did not have any laryngeal mask. This mask is used to create an artificial airway in the event of a medical emergency.
- We saw emergency adrenaline kept in an unlocked drawer; this was not safe practice. However, we brought this to the manager's attention and confirmed this was removed when we returned for the second day of this inspection.
- There was a lockable 'control of substances hazardous to health' (COSHH) storeroom for the safe storage and use of chemicals and cleaning materials.
- The provider told us their electrocardiogram (ECG) machines had not been calibrated within the past two years. When we returned for the second day of this inspection, we saw certificates which confirmed that all machines had been recalibrated.
- There was no requirement for paediatric equipment since no children were seen as patients within the clinics for consultation or treatment.

Medicines

- The provider did not always follow their own medicines policy, which stated that the registered manager would carry out a monthly audit of medicines. We saw that a nursing assistant completed an audit of the medicine register in May and July 2017. We were told there were no other audits available.
- The medicines policy also stated that treating medical practitioners should be responsible for completing the dispensing log (medicine register), to include their signature. The May and July 2017 audits identified that doctors had not been signing the register when they provided medicines. The identified action was that doctors would be asked to sign the register.
- When we returned on the second day of this inspection, we saw that the consultants with practising privileges had failed to sign the register.
- We found not all medicines were kept securely. For example, we found boxes of analgesics, which contained 300 tablets in an unlocked cupboard in the admission/recovery room. We also found antibiotics in an unlocked drawer in a trolley in the consulting room. When we returned for the second day of this inspection, we found the manager had addressed this issue and medicines we saw were stored appropriately.
- There were no controlled drugs kept on the premises, as they were not used for the types of procedures currently carried out. We were told by the clinic manager they allocated drugs to the consultants prior to any procedure and logged all drugs in and out in a drugs register book. We saw that records included batch numbers and expiry dates.
- Local anaesthetic was used for hair transplant surgery. All medication checked was in date.

Records

- The practice manager who was non-clinical carried out an audit of patient records in March 2017. It was not clear how many records were audited or what procedures the patient had undergone. The learning from the audit identified that the new patient notes booklet had improved record keeping. However, the audit stated that doctors 'did not document everything' and 'did not complete all sections' but failed to identify which doctors and what sections were not completed and whether there was a pattern to these omissions.
- A further audit was carried out in August 2017 on 10 records. Issues identified included lack of signatures by patients and doctors and incomplete treatment plans and vital sign recording. The audit also identified that not all patients were given an explanation of their treatment or procedure. This audit did not specify the frequency with which these issues arose and there was no evidence of how they would be addressed.
- We reviewed 15 records of patients who had undergone hair transplant procedures. The provider had redesigned their patient notes since the time of our last inspection. The notes template included intra-operative monitoring and a surgical safety checklist.
- We noted that this surgical safety checklist included sign-in, time out and sign out. It did not replicate that of the World Health Organisation '5 steps to safer surgery' which in addition to the ones followed by the provider, also advised a briefing before sign-in and debriefing after sign out.
- We saw that the checklist was not populated on six of the records we viewed and was incomplete on four.

- GP details were not entered on seven records and there was no documentation of any post-operative follow-up, for example outcomes or complications, on any patient record.

Safeguarding

- At the time of the previous inspection in March 2017, we were not assured that all staff had completed safeguarding training. Since then, the provider submitted a staff training record which showed that all but one member of staff had completed safeguarding training, although we were unable to verify at what level this was. There was a note made by the clinic manager on the staff record that the member of staff who had not completed their safeguarding training could not be booked until they had done so.
- The registered manager told us they were the nominated safeguarding lead. The current staff training record showed their training expired in July 2017.
- The provider's safeguarding policy did not make mention of any legislation or guidance with regards to either children or adults and therefore did not properly identify an 'adult at risk'. The term vulnerable adult, used throughout the policy, is no longer in use. There were no clear procedures in place with regards to making a referral and no details of the safeguarding lead's email and telephone number. The policy included helpline telephone numbers for alcohol and substance misuse, bereavement and emotional needs. However, there were no contact details for the local authority to which concerns of abuse should be reported.
- The policy did not include ways in which staff could recognise or respond to different forms of abuse. There was no reference made to any training which staff should undertake.

Mandatory training

- At the time of our previous inspection in March 2017, there was no induction training for new members of staff, doctors working under practising privileges or bank/agency staff. Since then, the provider had developed an induction pack for newly joined members of staff.
- Mandatory training was introduced, which included infection control, safeguarding and basic life support/ intermediate life support; there was no other mandatory training provided. The training record listed 29 staff, including technicians and doctors.
- Three members of staff had out of date infection control training; they were listed as not bookable until they completed this training. Twenty-eight members of staff had in-date basic life support training; where one had expired, it was noted on the staff list that they could not be booked to work.
- However, concerns raised at the previous inspection included the competency of healthcare assistants (HCAs) to take blood pressure and read oxygen saturation levels. Whilst the provider outlined on their action plan that key competencies for HCAs would be identified and further training offered, they had no programme around this and could not assure us of the contents.

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

- The provider told us that they did not have a written patient admission criteria.
- 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. We noted at the time of our last inspection in March 2017 that the provider did not utilise any tools to monitor signs of the deteriorating patient, for example an early warning score system.
- Since then, the action plan stated that the updated patient notes included intra-operative monitoring which would be recorded throughout procedures.
- However, when we reviewed 10 patient records for those who underwent hair transplant procedures we found that there were no intra-operative observations made on seven of these. One of these records without any observations made was recorded as having a cardiac condition.
- One patient who underwent a seven-hour procedure had just two observations made throughout their whole procedure, despite the potential impact of such a long procedure on their health.
- We reviewed a further five records when we returned for the second day of this inspection, each of which had intra-operative observations recorded.
- The registered manager told us they did not carry out ECGs on hair transplant patients.

Surgery

- The registered manager told us they did not do a swab count pre or post-surgery and did not see the relevance of this in hair transplant procedures where swabs used were very small.
- The provider included a surgical safety checklist in the patient notes template since the time of our last inspection. We noted that this surgical safety checklist included sign-in, time out and sign out. It did not replicate that of the World Health Organisation '5 steps to safer surgery' which, in addition to the ones followed by the provider, also advised a briefing before sign-in and debriefing after sign out.
- The provider's policy stated that practising doctors must be advanced life support (ALS) trained when carrying out procedures and there must be an ALS trained doctor on the premises whilst patients are being treated. We saw the registered manager's certificate, which showed they had completed their ALS in July 2017. However, none of the doctors with practising privileges were currently ALS trained, although we saw one had training booked in March 2018.
- The registered manager acknowledged that there were periods when there was no ALS trained doctor on the premises when patients were treated by other doctors. They told us they were in the process of reviewing this policy so that it would no longer be a requirement for doctors to be ALS trained.

Nursing and support staffing

- The provider employed three full-time staff and the rest of the staff group (26) operated on a self-employed basis. There was currently one nurse and one health care assistant (HCA) listed on the staff group.
- We spoke with the registered manager about levels of support for patients during procedures. They told us the clinic did not book follow up appointments and treatment at the same time.
- The provider told us that there was adequate staffing since the clinic was currently undertaking hair transplant and injectable procedures only.
- We confirmed that the nurse was registered as an adult nurse with the Nursing and Midwifery Council (NMC).

Medical staffing

- At the last inspection, we found that doctors with practising privileges at 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.
- The provider told us they had since suspended some doctors and currently only three had active practising privileges where they had completed appropriate DBS sand other checks to confirm they were fit to practice. We confirmed this to be the case during our inspection.
- The registered manager told us they ensured they were available for telephone contact by the patient following any procedure.
- 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. A doctor or the registered manager serviced this.

Emergency awareness and training

- The provider purchased a back-up generator since the time of our last inspection in March 2017 to mitigate against an electrical failure or power cut. We saw there was a list of telephone numbers of emergency electricians and plumbers that could be called upon when required.
- The theatre and clinic rooms were located over three floors. The lift was out of order on the day of our inspection. The registered manager acknowledged that this affected those patients with restricted mobility and their procedure would have to be deferred until the lift was operational. We were told the lift was likely to be permanently out of service as the landlord said the costs of repair were too high.

Are surgery services effective?

Evidence-based care and treatment

- The provider told us there were no NICE guidelines related to hair transplant. Instead, they considered relevant guidelines such antimicrobial stewardship. They also told us they followed guidelines set by the British Association of Body Sculpting (BABS) and British Association of Hair Restoration Surgery.

Surgery

- We found the service did not adhere to all of its own guidelines and policies at the time of the last inspection in March 2017. At the time of this inspection the provider told us they had commissioned a consultant to rewrite policies to reflect changes made to practice and environment; this work had not yet started.
- The registered manager told us they benchmarked their work against another clinic carrying out similar procedures. They acknowledged that this was an informal process and there was no documentary evidence to substantiate it.
- The registered manager provided us with evidence of peer-to-peer case discussions. These were very brief reports and did not identify any learning points or training needs.
- There was no audit of surgical outcomes done since the time of our last inspection in March 2017.

Pain relief

- We saw that there was no pain measurement tool included on the new patient record forms. The registered manager told us they asked patients during the course of treatment about their pain levels.

Nutrition and hydration

- The service did not have wards or an inpatients department. In cases where a patient was at the service for prolonged periods of time, the service provided food and refreshments bought locally.
- 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 94 procedures from April 2017 to August 2017 with no complications noted.
- There were no unplanned returns to theatre post operatively during the same period.
- There were no instances of patients transferred to alternative care following treatment with the provider.
- The provider stated that they did not record QPROMS (Questionnaire-Patient Reported Outcome Measures) for their services.

Competent staff

- The provider had introduced an induction programme for all new staff since the last inspection in March 2017. We saw a completed induction programme for a recently joined member of staff.
- The provider did not carry out competency assessments on staff. They told us they provided staff with a DVD where there was a need to learn more about how to operate an unfamiliar piece of equipment.
- For example, they showed us a DVD related to a particular procedure, which they provided to a recently joined member of staff. They were unable to show us any formal assessment to assure us that the staff member was competent in that procedure.
- We saw that the registered manager had a recent appraisal with an external appraiser, which was signed off with no concerns recorded.
- There were three doctors with practising privileges at the service. We saw that two of these doctors had an up to date appraisal and one had deferred their appraisal from March 2017 to March 2018 which was recorded as due to ill health.
- The provider told us that practising privileges were reviewed and awarded by their Medical Advisory Committee, which also ensured that all documentation was in order. They also told us there was a peer review process with plastic surgery colleagues from other clinics.

Multidisciplinary working

- The registered manager told us they worked in a multi-disciplinary way with a trichologist and hair technicians. The doctor carrying out the surgery would lead the procedure; however, the trichology technician was able to insert the hair follicle once the doctor had made the incision.

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.
- These records were accessible to doctors when they were in the clinic. During the last inspection in March, electronic records were not accessible due to an IT failure and there were no backup plans for such a situation.
- However, at this inspection, the practice manager told us they had developed a contingency plan with the

company which scanned the records; this involved using an alternate IT method. They also told us that the provider stored patient records off site in a professionally managed secure facility.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The process for seeking consent was not adequately monitored and reviewed to ensure it met legal requirements and followed relevant national guidance. The provider's consent policy did not reference the Royal College of Surgeons Professional Standards for Cosmetic Surgery with regards to consent.
- These standards state that consent must be obtained in a two-stage process with a cooling-off period of at least two weeks between the stages to allow the patient to reflect on the decision. Should this not be possible, good reasons should be recorded in the patient's notes. Information on the procedure should be provided to the patient prior to the signing of the consent form, giving them adequate time to reflect on their decision.
- We found that 11 of the 15 patient records that we reviewed during the inspection showed surgical procedures had been consented to on the day of the procedure. None of the records we reviewed documented whether the appropriate cooling off period had been provided.
- Audits did not enable the provider to identify where quality and/or safety was being compromised or provide the necessary information to respond appropriately.
- An audit of consent forms on 10 patient records in April 2017 identified only that the incorrect ink colour was used on one record and the pricing structure should be included in the patient record. It did not identify whether surgeons had complied with professional standards.
- The provider's policy stated that any person unable to give consent due to mental or impairment physical impairment would be declined treatment.

Are surgery services caring?

Compassionate care

- The service did not carry out a Friends and Family test. The provider told us that patients were encouraged to give feedback and we saw there was a comments box in the waiting room area for that purpose. We were not shown any summary report of comments made but were told of one action taken in response to a patient's comments, which resulted in brighter lighting being installed.
- There were no procedures scheduled on the day of our inspection therefore we did not speak with any patients.

Understanding and involvement of patients and those close to them

- The registered manager told us procedures were scheduled such that the one nurse employed was able to attend at all times.

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.

Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- The clinic provided elective surgery by appointment only. The provider carried out procedures at the weekend if requested. The clinic manager told us they hoped to reduce the frequency of weekend procedures to give staff a complete break.
- All procedures were carried out on patients between the age range of 18 and 75.

Access and Flow

- Initial consultations were done face to face with the provider or via video conference. The patient was given pre-operative information on the day of their procedure and discussed their expectations with the provider.
- At the end of surgery, the patient was allowed to rest in the recovery room prior to discharge. There was an open door policy for patients to contact the clinic at any time and they received a follow-up phone call post-procedure, though we did not see this noted on patient records.
- We were told that the patient's GP was not routinely informed of the surgery as they did not always give consent.

- There were no recorded cancelled procedures during the reporting period April 2017 to August 2017.

Meeting people's individual needs

- The provider told us they ensured there was a female assistant available to support female patients and a chaperone was available upon request.
- Building protection regulations for the building meant that disabled access was limited. The provider told us that if a person with physical disabilities required a service, they would be facilitated at a more accessible clinic where the provider had practising privileges.
- The provider's policy stated that only those patients who were mentally competent and able to give informed consent were offered treatment.
- Since the last inspection, a contract was agreed with a translation service to meet the needs of patients whose first language was not English. We were told this service had not been used to date.

Learning from complaints and concerns

- The provider's complaints policy stated that there should be copy of their complaints procedure on display in the reception area. We did not see this policy visibly displayed during the inspection.
- The provider told us they recently joined the Cosmetic Redress Scheme (CRS), a consumer redress scheme for the cosmetic, aesthetic and beauty industry. This was provided through the British Association of Body Sculpting.
- There were no complaints recorded during the reporting period April 2017 to August 2017.

Are surgery services well-led?

Leadership / culture of service

- The service was led by the registered manager who was also the CQC responsible individual. They were responsible for all of the organisation's governance and they were the nominated safeguarding lead.
- Staff told us the manager was visible and approachable.

Vision and strategy

- The provider did not have a clear written vision and values statement, but told us their vision was to continue to provide quality care and also to improve on their reputation.

Governance, risk management and quality measurement

- The provider failed to ensure that there were effective processes in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others.
- The provider had not fully identified actions needed to address challenges to the quality of the service provided. These included the inadequate theatre and infection control environments.
- We were not assured the provider had sufficient understanding of compliance requirements within a hospital or clinical setting.
- We were not assured the provider had an understanding of the requirements related to the provision of safe surgery.
- The recently restructured theatre was not compliant with applicable acts and standards, which ensured patient safety. Contractors were not monitored to ensure that the work carried out was to the required standard. This included deficiencies noted in the fire risk assessment and portable appliance testing.
- The provider did not routinely complete audits. 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.
- Where audits were carried out, no action plan was recorded or lessons learnt identified. For example, an audit of patient records highlighted a lack of patient and doctor signatures and incomplete treatment plans. The audit did not specify the frequency with which these issues arose and there was no evidence of how they would be addressed.
- We saw no general compliance audits related to safety such as fire door checks or escape routes risk assessments.
- As the nominated safeguarding lead, the provider should be safeguarding trained. However, during the inspection we saw that their safeguarding training certificate had expired in July 2017. We brought this to the manager's attention and after the inspection, they provided confirmation that they had subsequently completed the required training.

Surgery

- The service had contact with other private cosmetic surgery clinics locally and nationally, mainly where the provider had practising privileges. We were told these clinics were used to benchmark against, though there was limited evidence of data collection and auditing.
- Quarterly governance meetings included Medical Advisory Committee, morbidity and mortality and significant events meetings. Recent minutes included an update on new procedures and outcome of a patient records audit.
- Minutes of the significant events meeting recorded that there were no significant events reported in the previous six months.
- At the last inspection, we found that doctors with practising privileges at 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.
- The provider told us they had since removed some doctor's practising privileges. There were currently three doctors with practising privileges at the clinic. We confirmed they had had in date DBS certificates and professional insurance cover.

Public and staff engagement

- Staff told us there were monthly team meetings at which information about the service was shared with them.
- There was a suggestion box in the waiting room where patients could post their comments about the service.

Innovation, improvement and sustainability

- The provider had made structural changes since the time of the last CQC inspection in March 2017. These included a new theatre and redecorated treatment rooms and recovery room.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure the theatre operating area is a safe and sterile environment before any invasive procedures are carried out.
- The provider must ensure legionella testing is carried out to required specifications.
- The provider must ensure that equipment is properly and safely maintained in line with relevant legislation and staff that operate equipment are trained to use it appropriately.
- The provider must ensure that all electrical appliances are passed as safe and fit for purpose.
- The provider must ensure that there are effective processes in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others.
- The provider must ensure their safeguarding policy properly reflects ways in which to reduce or prevent risk of significant harm to 'adults at risk'.
- The provider must ensure they follow Royal College of Surgeons Professional Standards for Cosmetic Surgery guidelines in relation to consent.
- The provider must ensure that there are formalised governance systems to improve the quality and safety of the service.
- The provider must ensure that the organisation's policies are up to date with current legislation and professional standards, and that there are appropriate governance processes in place to ensure they are fit for purpose.

Action the provider SHOULD take to improve

- The provider should ensure patient records are completed to include relevant follow-up information.
- The provider should ensure there is consistent adherence to the World Health Organisation '5 steps to safer surgery'.
- The provider should ensure there are disposable curtains in all clinical areas.
- The provider should ensure that bedding used in the recovery area is appropriate for the clinical environment.
- The provider should ensure that the cupboard, which contained the electrical plant, had appropriate signage.
- The provider should ensure that staff follow the organisation's policies and procedures in respect of recording keeping for medicines administration.
- The provider should ensure they comply with their own policies regarding the level of life support training staff are required to hold.
- The provider should have ways in which to benchmark against other services in order to make changes to improve their service based on factual information.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 15 HSCA 2008 (Regulated Activities) Regulations 2010 Safety and suitability of premises **Why you are failing to comply with this regulation:** **1.** During our inspection of this location on 14 September 2017, we identified that the operating theatre environment was not fit for purpose in line with statutory requirements and national best practice. **a.** You failed to ensure the theatre ventilation system met the required standards set out in the Department of Health's Health Technical Memoranda, 'Heating and ventilation of health sector buildings' (HTM 03-01). For example, to maintain a sterile environment, day surgery theatres are required to operate a positive pressure regime, where the greatest pressure is in the most sterile area cascading out to less sterile areas. During our inspection we observed that the operating suite was negatively pressurised with respect to the common areas of the building resulting in the natural movement of air from dirty to clean areas. **b.** You also failed to ensure ceiling material used in the operating theatre environment met the required standards set out in HTM 03-01. The ceiling material was unsuitable for an operating theatre environment as it was porous and unsealed. For the prevention of dust migration from ceiling voids into the sterile space the ceiling should be secure and sealed. Therefore, as a sterile environment could not be maintained, the theatre environment was not fit for carrying out sterile surgical procedures and increased the risk of infection to patients. **2.** You failed to meet the guidance issued by the Department of Health on the prevention and control of infections. During the inspection, we reviewed your documentation relating to legionella checks and found that you did not comply with HTM 04-01, 'Safe water in

This section is primarily information for the provider

Enforcement actions

healthcare premises'. We found that the legionella risk assessment was not appropriate for a clinical setting and did not comply with Department of Health guidance. The Health and Social Care Act 2008, 'Code of Practice on the prevention and control of infections and related guidance', states that providers should minimise the risk of legionella and other water supply and building related infections by adhering to national guidance.

The legionella risk assessment did not describe the type of system and did not contain a plan to identify any dead legs (a pipe leading to an outlet through which water flows but the outlet is unused or rarely used). HTM 04-01 recommends twice weekly flushing of little used outlets, however your records showed that this took place only once a week. By failing to meet the requirements of this legislation, you are not ensuring that premises and equipment are properly maintained which poses a risk to the health and safety of service users and others including staff.

3. We found that electrical safety checks, including electrical appliance safety testing, did not comply with current regulations. The Electricity at Work Regulations, 1989 require that any electrical equipment that has the potential to cause injury must be maintained in a safe condition. Employers must make sure that their portable electrical appliances are safe and are suitable and used for the purposes intended. During the inspection, we were not assured by the quality of electrical appliance safety testing. You did not keep a record of all appliances that required safety testing and you were unable to provide evidence that all appliances which required testing had been tested. We found an extension lead, which was labelled as being safety tested, to be in poor condition and unsafe for use. We also found a two-part electrical lead of which only one part had been safety tested. By failing to meet the requirements of this legislation, you are not ensuring that premises and equipment are properly maintained which demonstrates a risk to the health and safety of service users and others, including staff.

Regulated activity	Regulation

This section is primarily information for the provider

Enforcement actions

Surgical procedures

Treatment of disease, disorder or injury

Regulation 17 HSCA (RA) Regulations 2014 Good governance

Why you are failing to comply with this regulation:

1. You failed to ensure that there were effective processes in place to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others. We asked to see the provider's risk management documentation and were told by the registered manager that there was no single document, which provided a record of all the services risks and actions taken to mitigate them. During our inspection, we asked the registered manager to provide copies of minutes for any clinical governance meetings and staff team meetings, which had taken place in the previous six months. We received four sets of staff meeting minutes and no minutes of clinical governance meetings were provided. The meeting minutes we saw contained only limited reference to risk management. Although risk assessments for fire, health and safety, legionella and disability access were discussed, these were limited to a brief note that these were to take place at the provider's other registered location. From the information you provided you have not maintained oversight of risks within the service. Therefore, not all risks of harm to service users and others were assessed, monitored and mitigated.

2. You failed to have oversight of the quality and safety of the services provided at the location. Systems and processes to assess, monitor and improve the quality and safety of the service were not fit for purpose. Audits were not carried out on a regular basis. Where audits were carried out, they did not always contain sufficient detail to identify areas of concern or result in an action plan for improvement.

a. For example, we saw that an audit of patient records, carried out in March 2017, lacked detail including the number of records reviewed or what procedures the patients had undergone. The audit stated that doctors

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'did not document everything' and 'did not complete all sections' but failed to identify what sections were incomplete and whether there was a pattern to these omissions.

b. A further records audit carried out in August 2017, highlighted a lack of patient and doctor signatures and incomplete treatment plans. However, the audit did not specify the frequency with which these issues arose and there was no evidence of how these issues would be addressed.

c. An audit of patient consent forms carried out in April 2017, failed to identify whether the Royal College of Surgeons Professional Standards in relation to consent for cosmetic procedures were being followed. These standards state that surgeons should ensure that consent is obtained in a two-stage process with a cooling-off period of at least two weeks between the stages to allow the patient to reflect on the decision. Should this not be possible, good reasons should be recorded in the patient's notes. We found that 11 of the 15 patient records that we reviewed during the inspection showed surgical procedures had been consented to on the day of the procedure. None of the records we reviewed documented whether the appropriate cooling off period had been provided. The audit carried out by the service did not identify whether surgeons had complied with professional standards. Therefore, it was not clear whether professional standards were being followed.

Therefore, systems and processes to assess, monitor and improve the quality and safety of the service were not fit for purpose as they did not enable you to identify where quality and/or safety was being compromised and provide you with necessary information to respond appropriately.

3. We reviewed your organisation's policies and found that many, including policies relating to safeguarding and consent, were not up to date with current

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professional standards, legislation or guidelines. This demonstrated a lack of a robust system to review policies and processes to ensure they remain fit for purpose. For example, we reviewed your organisation's safeguarding policy and found that it was not fit for purpose as it did not meet the requirements of the Care Act (2014). The policy did not mention of any legislation or guidance with regards to either children or adults safeguarding and therefore did not properly identify an 'adult at risk'. There were no clear procedures in place with regards to making a safeguarding referral and the policy did not covered any staff training requirements in safeguarding. Therefore, you did not ensure that robust procedures were in place to protect services users, which meant that people were at risk of harm.

4. As the service's nominated safeguarding lead, the registered manager should be trained in safeguarding adults to a level that allows them to carry out their role. The Statutory Guidance to the Care Act (2014, updated August 2017), states that providers of healthcare should ensure that staff have the necessary competences and that training in place to ensure that they are able to deliver the service in relation to the safeguarding of individuals. However, during the inspection on 14 September 2017, we reviewed the lead's safeguarding training certificate, which did not specify which level of training they had completed and had expired in July 2017. Therefore, at the time of our inspection, the safeguarding lead did not have appropriate training to allow them to competently undertake this role.