

Soul Care Aesthetics Ltd

Soul Care Aesthetics

Inspection report

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Overall summary

Soul Care Aesthetics is operated by Soul Care Aesthetics Ltd. The service sees patients on a day case basis only, therefore no overnight facilities were present. Facilities included five consulting rooms for aesthetic procedures; one of which was designated to be used for cosmetic surgery.

The service provided cosmetic surgery for patients over the age of 18; although did offer non-regulated procedures to young people aged 16 to 18. We inspected surgery as a core service.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 18 January 2018.

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

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

Services we do not rate

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

We found the following areas of good practice:

- Staff used tools to promote safer practice such as the National Early Warning Score (NEWS) system to conduct observations. Therefore, any deterioration in health could be easily identified.
- Staffing levels were appropriate for the procedures being provided. Staff were 100% compliant with mandatory training.
- A cleaning system was embedded; a deep clean was conducted weekly and daily equipment cleans were done. We saw the use of stickers identifying the date of cleaning, and the name of the individual completing the cleaning therefore ensuring dirty equipment was not used.
- Surgical instruments were decontaminated where necessary in line with infection prevention guidelines.
- All surgical patients received a post-surgery consultation approximately one week after their procedure. In addition, follow up appointments were

Summary of findings

offered as part of the overall cost for up to a year. This was to ensure the patient's outcomes were successful and enable early identification of problems.

- Staff followed national standards in line with Professional Standards for Cosmetic Surgeons. Where relevant, National Institute of Health and Care Excellence (NICE) guidelines were also followed.
- A transparent approach was taken to providing information about surgical procedures, including the risks and financial cost of surgery. Therefore, patients were able to give informed consent.
- A flexible approach was taken to enabling patients to choose appointment times to suit them. Although the clinic was shut on Sundays, the staff were open to book appointments for surgical procedures on Sundays if a patient specifically requested this.
- The team who worked at the clinic were a small and cohesive team who engaged in staff and governance meetings.
- Public and patient engagement was actively conducted through social media sites and seeking patient feedback.
- Staff at the clinic were conducting clinical trials in order to develop the service.

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

- Staff were conducting World Health Organisation safer surgery checklists for surgical procedures; however we noted that out of five records, one did not have a checklist. Also not all other checklists were completed fully.
- The service followed Health Technical Memorandum 01-05 'decontamination in primary care dental practices' rather than Health Technical Memorandum (HTM) 01-01 'decontamination of surgical instruments'. Despite not formally following a policy which promoted the use of HTM 01-01 best practice guidelines; the service was following all requirements with the exception of protein testing which was in the process of being set up.

- The service used a portable ventilation system to ensure air was free from contaminants rather than an inbuilt system. This was due to constraints of the current location and was due to be rectified when the service moved premises later in 2018.
- At the time of the inspection, the clinic were not submitting data to the Private Healthcare Information Network (PHIN) as part of legal requirements regulated by the Competition Markets Authority (CMA). However, we acknowledge this is a relatively recent legal requirement with providers being asked to initially submit this data over a five year phase which ends in 2020.
- We saw that medicines were held securely and there was a process of escalation should the fridge temperatures be out of range which was to use the alternative medicines fridge held on the premises. In addition, the ambient room temperature for areas in which medicines were stored was not routinely recorded.
- Although staff had completed safeguarding adults training; training on safeguarding children had not been undertaken by all staff. However, the consultant surgeon and clinic manager had both received training in this area. The safeguarding policy did not include a full list of up to date situations in which patients might experience abuse. For example female genital mutilation.
- The service had a risk register was in place, with one risk recorded. However, we identified other potential risks which may have benefitted from being added to the risk register. For example, the clinical waste bin, although kept locked, was not secure due to not being a designated bin for this purpose.
- Although the service demonstrated a good working relationship with local pharmacists; there was no formal service level agreement.

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

Summary of findings

Action the provider **MUST** take to meet the regulations:

- The provider must ensure that the World Health Organisation safer surgery checklist is appropriately completed for each patient undergoing a surgical procedure.
- The provider must ensure they have a local decontamination policy which follows best practice guidelines 'decontamination of surgical instruments'.

Action the provider **SHOULD** take to improve:

- The provider should ensure all staff have an up to date awareness of child safeguarding.
- The provider should ensure the safeguarding policy contains information regarding all types of abuse such as female genital mutilation, modern slavery and the risk of being radicalised.
- The provider should consider the process of submitting data to the Private Healthcare Information Network (PHIN) by 2020 as part of legal requirements regulated by the Competition Markets Authority (CMA).

- The provider should develop a process by which staff members making entries into the medicine fridge temperature log book can be identified. Also, ambient room temperatures should be routinely recorded as per the medicines policy.
- The provider should ensure all potential risks to the service are recorded on the risk register, and all incidents are recorded in order to enable shared learning and appropriate action plans.
- The provider should address the security of the clinical waste bin.
- The provider should develop a service level agreement with pharmacists to formalise current arrangements.

Heidi Smoult

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- The clinic was visibly clean and infection prevention and control practices were followed. Re-usable equipment was decontaminated as per required standards; and we saw evidence of regular cleaning.
- Patient records were securely stored and completed in such a way as to easily identify important information.
- Clinical staffing levels were sufficient to maintain patient care and safety. Patients were monitored during and post-surgery to ensure any deterioration in vital signs was promptly addressed.
- Staff had completed 100% of mandatory training requirements.
- The clinic had an incident reporting system; incidents were discussed within the team and at governance meetings to share understanding and learning.
- Follow up appointments were offered for up to a year post surgery to monitor healing and results.

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

- The service used the World Health Organisation (WHO) checklist to ensure safer surgery; however, these were not always fully completed and in one case, not completed at all.
- The service followed Health Technical Memorandum 01-05 'decontamination in primary care dental practices' rather than Health Technical Memorandum (HTM) 01-01 'decontamination of surgical instruments'. Despite not formally following a policy which promoted the use of HTM 01-01 best practice guidelines; the service was following all requirements which the exception of protein testing which was in the process of being set up.
- The service used a portable ventilation system to ensure air was free from contaminants rather than an inbuilt system. This was due to constraints of the current location and was due to be rectified when the service moved premises later in 2018.
- Although medicines were securely stored and within date, the ambient room temperature was not routinely recorded.
- The bin used for clinical waste, although kept locked, was not designed for this purpose; therefore could be forced open.
- Although the service did not perform regulated activities on children and young people, under 18 years old, they did enter the clinic area for other services. We saw the clinic manager had completed a joint adult/ children safeguarding module. The safeguarding policy did not include a full list of up to date situations in which patients might experience abuse. For example female genital mutilation.

Are services effective?

We found the following areas of good practice:

- During our inspection, we saw staff adhered to Professional Standards for Cosmetic Surgery and relevant guidelines from the National Institute of Health and Care Excellence (NICE).
 - Pain levels were managed through the use of local anaesthetic. Patients were monitored and debriefs held where it was identified patients were not comfortable in order to promote change.
 - The consultant surgeon monitored outcomes such as surgical revision rate, surgical site infection rate and patient satisfaction on a local level.
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Summary of findings

- Staff were competent to fulfil their roles; specific cosmetic training was provided by the consultant surgeon who was an accredited trainer.
- The consultant surgeon appropriately sought consent from patients. Transparent information, including costs, were given to patients to enable them to make an informed decision.

Are services caring?

We found the following areas of good practice:

- All patients we gathered feedback from spoke positively about the care, dignity and respect received from staff.
- Staff responded professionally towards patient questions and queries and were open to providing further information and clarification upon request.
- Patients told us they had time to ask questions and to fully understand procedures, including the risks and benefits.
- Staff knew patients by name and engaged in conversations with patients; promoting a welcoming feeling to the clinic.

Are services responsive to people's needs?

We found the following areas of good practice:

- Staff were responsive to meet individual needs and were aware of how to adapt services to enable patients with additional needs.
- The clinic was located on the ground floor; and the layout enabled patients with mobility problems to access the facilities.
- The clinic did not offer a seven day service; but a flexible approach to appointments was offered to enable patient choice. Surgical procedures could be undertaken during evenings and at weekends.
- Complaints were dealt with in a timely manner. Patient feedback was used to develop the services provided.

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

- We received patient feedback that reported that on rare occasions appointments were delayed. A reported incident showed on one occasion, appointments had been cancelled.

Are services well-led?

We found the following areas of good practice:

- There was a small team working at the clinic. Staff worked within a positive environment where staff supported each other; and feedback was welcomed.
- Plans were in place to develop the service. For example, larger premises had been bought in order to expand the business in terms of size, and procedures offered to patients.
- Patient engagement was conducted through gaining feedback following each appointment. Patients could provide their views in a variety of ways. Patient feedback was displayed around the clinic.
- The clinic management maintained an active presence on social media therefore engaging with the public.

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

- The service had an active risk register with one risk recorded. However, issues we identified during the course of the inspection were not recorded as a risk, such as the clinical waste bins.

Summary of findings

- Although the service demonstrated a good working relationship with local pharmacists; there was no formal service level agreement.
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Soul Care Aesthetics

Detailed findings

Background to this inspection

Soul Care Aesthetics is operated by Soul Care Aesthetics Ltd. The service was registered with CQC to undertake regulated activities in December 2016; although the company offered non-regulated activities before this. It is a private clinic in Cannock, Staffordshire. The clinic serves the communities of Staffordshire, and accepts patients from outside this area.

The clinic was open on Tuesdays between 10 and 5pm, Thursday and Fridays between 10.30 and 8pm, and Saturdays between 10am and 3pm. The consultant surgeon was also able to offer procedures on Sundays where requested by appointment only.

The service has had a registered manager, who was also the consultant surgeon, in post since December 2016.

The clinic offered surgical cosmetic procedures under local anaesthetic only. These comprised blepharoplasty (removal of excess skin on the upper and/ or lower eyelids), ear lobe surgery, lower face lift, brow lift, platysmaplasty (neck lift) and liposuction.

The clinic also offered other cosmetic procedures. These procedures are not within scope of regulation.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor with expertise in surgery. The inspection team was overseen by Debbie Widdowson, Inspection Manager.

Information about the location

The clinic is registered to provide the following regulated activities:

- Surgical procedures
- Treatment of disease, disorder or injury

In addition to surgical procedures, pre-operative and post-operative consultations were held at the clinic by the consultant surgeon. All surgery was conducted on a day case basis using local anaesthetic. No overnight facilities were available at the clinic. All patient records were stored on site at the clinic.

During the inspection, we visited the clinic, which comprised of a reception area, one surgical procedure room, and four clinic rooms for non-invasive or minimally invasive procedures. We spoke with four staff including the consultant surgeon, the clinic manager, a registered nurse and the receptionist. We spoke with two patients. We also received 22 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed five 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 clinic's first inspection since registration with CQC.

Activity (January to December 2017)

- In the reporting period January to December 2017, there were 110 surgical procedures recorded at the service. All of these were privately funded.
- Of the 110 procedures, 37 were for face or neck lifts, 37 for blepharoplasty (eye lid surgery) and 36 for liposuction.

One consultant surgeon (also the registered manager), two nurses, an operating department practitioner (ODP), a clinic manager, a receptionist and a cleaner worked at the location.

Track record on safety

- No never events
- Four incidents had been reported

Detailed findings

- 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 Escherichia coli (E. Coli)

- Seven complaints

Part of the clinic space was rented by a hair and beauty salon. This service was a separate business and not linked to the provider. The space used by the tenants was separated from the main clinic by an open plan wall area.

Services provided at the hospital under service level agreement:

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

Are services safe?

Our findings

Incidents

- The service had recorded four incidents since commencing regulated activity in December 2016 to the date of our inspection in November 2017. These included patient cancellations, faulty equipment and patient injury. All incidents were recorded as no harm or minimal harm caused to patients. Incidents were discussed within quarterly clinical governance meetings which all staff attended. The incidents reported did not show any themes or trends. Learning from these was discussed with staff.
- Staff we spoke with were aware of the incident reporting procedure and had attended meetings during which incidents had been discussed.
- Data provided by the clinic showed no never events or serious incidents had occurred since registration with CQC. 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 incidents had been reported which required the duty of candour to be carried out. The duty of candour regulation under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 requires health service bodies to act in an open and transparent way with people when things go wrong. Clinical staff were aware of the duty of candour and when it should be used.

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

- The service did not use a clinical quality dashboard. Due to the nature of the procedures offered, the medical criteria to be met pre-procedure and surgical procedures being carried out on a day case basis only; the risk of hospital acquired pressure ulcers or venous thromboembolism (VTE) was minimal.
- We saw that bleeding risks were discussed with patients during the pre-procedure consultation; although formal

risk assessments were not undertaken. The consultant surgeon provided pre-surgery advice to patients to minimise the risk of developing VTE or experiencing unexpected bleeding.

- VTE risk was discussed pre-operatively on the day of surgery.

Cleanliness, infection control and hygiene

- The clinic was visibly clean and tidy. A chair used by patients during surgical procedures had an old stain; but was clean. Staff attached stickers to cleaned equipment, which indicated when the item had been cleaned and by whom.
- Staff conducted a daily clean of all areas and equipment. A professional cleaning company conducted weekly deep cleaning in line with NHS cleaning standards.
- The consultant surgeon was trained in the use of an autoclave for decontaminating re-usable equipment. The surgeon was the only member of the team who used the autoclave. Re-usable equipment was cleaned and re-packaged in line with infection prevention and control standards.
- The service worked towards Health Technical Memorandum (HTM 01-05) 'decontamination in primary care dental practices' rather than Health Technical Memorandum (HTM) 01-01 'decontamination of surgical instruments'. The registered manager reported the reason for this was due to the service more closely replicating primary care dental settings rather than acute hospital settings. Testing of the autoclave was carried out in line with requirements within HTM 01-05 and included daily testing. However; as the service was undertaking procedures which would be provided within a hospital; compliance with HTM 01-01 should be demonstrated.
- Despite not formally following a policy which promoted the use of HTM 01-01 best practice guidelines; the service was following all requirements which the exception of protein testing which was in the process of being set up.
- There was no separate 'clean' and 'dirty' room for the processing and decontamination of equipment; however as generally only one set of equipment was cleaned at a time; the likelihood of cross contamination

Are services safe?

was reduced. The room used for decontamination was directly off the clinic room used for surgical procedures therefore there was no need to transport used surgical devices to other areas. We saw that the service had already purchased some single use equipment such as surgical tools to further reduce the risk of contamination, and was planning for all equipment to be disposable in the future.

- We observed some patient appointments and noted that staff washed their hands before and after direct patient contact and used antibacterial gel. Personal protective equipment such as gloves and gowns were available.
- Hand hygiene audits had been introduced recently and were reviewed by the manager. We requested data regarding the results of these audits; results indicated 100% compliance to hand hygiene with no outstanding actions.
- Staff theatre wear comprised of scrubs for nursing staff and scrubs and disposable theatre gowns for the consultant surgeon. Individual staff took scrubs home for washing. There was no specific policy for washing work uniforms; however clothes were washed as per guidelines for example at 60 degrees.
- Staff did not routinely screen patients for Methicillin-resistant Staphylococcus aureus (MRSA) however risk of patients having this infection was assessed at the point of the preoperative assessment.
- The clinic room used for surgical procedures did not have a fixed ventilation system to manage infection prevention however a portable air conditioning ventilation/heating unit: was used which provided the necessary air exchanges. The registered manager had secured new premises which would be fitted with inbuilt ventilation within the next nine months at the time of inspection.
- Data from the service showed no surgical site infections in the 12 months preceding the inspection. However, three cases of inflammatory swelling were treated with antibiotics as identified following routine follow up appointments.
- Flooring within the clinic treatment room complied with infection prevention and control standards.

Environment and equipment

- The clinic was located on the ground floor of a rented premises; enabling safe access. Patient areas had enough space to enable care to be delivered safely.
- Clinical waste was kept segregated and collected via an external contractor. Clinical waste was stored in a locked bin, although the bin was not specifically designed for this purpose. The bin was not appropriate as it could be forced open easily. The service were aware of this and had plans for an appropriate bin at the new premises within the next 12 months. Clinical waste was collected routinely every two weeks, or more frequently if required. Sharps bins were also emptied at the same time.
- No specimens, for example blood or urine, were collected from patients undergoing surgical procedures.
- Equipment used within surgical procedures was maintained as per manufacturers' guidelines, and equipment was electrical safety tested yearly.
- There was a resuscitation pack located at the premises, and adrenaline was available for anaphylactic shock.
- Although the clinic was located on the ground floor, an evacuation chair was available. Staff explained this was to aid patients who may be feeling unwell in the event of an emergency evacuation.
- The fire alarm system had been checked in November 2017, and fire extinguishers had been serviced within the same month.
- Generally the environment was clear and uncluttered although we noted a potential trip hazard in the clinic manager's office; a rug was not securely fastened to the floor. We highlighted this during the inspection; a solution was provided of taping the unsecured part of the rug to the floor. Although there was no patient access to this room, we saw a number of staff entering and leaving this office to ask questions, check information or collect documents who could be affected by this hazard.
- Cleaning chemicals were all stored appropriately in a locked 'Control of Substances Hazardous to Health' (COSHH) cabinet.
- Rooms containing equipment which could cause harm were securely locked using key pad security.

Are services safe?

- CCTV was in place within the clinic, with recordings being kept for approximately six weeks.

Medicines

- Limited quantities and types of medicines were kept on site at the clinic. These included adrenalin (for liposuction procedures and medical emergencies), local anaesthetic, and antibiotics. These were stored appropriately in a locked cabinet located in the surgical procedure clinic room. Although the ambient temperature was monitored to ensure suitability for patients, this was not recorded with regards to maintaining an appropriate temperature for stored medicines. The key for the medicines cabinet was held by the registered manager.
- Medicines stored within a fridge were temperature checked. However, the temperature log did not contain the signature or initials of the individual completing the check. An escalation process was contained within the medicines policy should the fridge temperature be out of range which was to use the alternative medicines fridge held on the premises.
- The ambient temperature of the room could be identified via a thermometer; however was not routinely recorded. The service medicine policy specified temperature monitoring was to take place; with action to be taken if the room temperature exceeded 25 degrees.
- All medicines we checked were in date.
- We found two large, and three small, infusion bags stored within the medicine cupboard. We noted the large bags contained the name of a previous patient, and the small bags had name tags removed. The manager explained that these had been left over from a patient. Although the fluids were still in date, these would normally be destroyed due to being allocated to a specific patient who no longer required these. However, these had been retained to enable engineers to calibrate equipment, namely the liposuction machine. This was seen to be correct as the engineers attended the clinic on the date of inspection to do so.
- The service had accounts with two pharmacists. One of these pharmacists was also used for advice and guidance regarding medicine management. This was an

informal arrangement with no formalised service level agreement set up. However, examples given demonstrated this was an effective working relationship.

- Medicines were prescribed and recorded appropriately within patient records. If patients required medicines to take home; these were prescribed and dispensed by the consultant surgeon.
- No controlled drugs were kept on site.

Records

- During the inspection, we reviewed five sets of surgical patient records. Risk assessments, consent forms, pre assessment forms, and nursing observation records were all maintained as appropriate to the procedure undertaken.
- However, although all five records related to surgical procedures only four had World Health Organisation (WHO) surgical safety check lists attached. Some WHO checklist sheets were not named or dated therefore if papers were separated from patient record files; it would not be possible to identify which patient the information related to.
- Patient records were kept securely within a lockable cabinet.

Safeguarding

- Staff at the clinic including the consultant surgeon and nurses had completed safeguarding adults level two training. Staff we spoke with were aware of what may constitute a safeguarding risk and how to manage this.
- Children under the age of 18 did not undergo surgical procedures at this service. However, young people between 16 and 18 years old did attend for other services, which did not fall within the scope of registration with CQC. We spoke with staff who told us of the pre-treatment consultation which incorporated questions to ascertain any concerns including child protection concerns.
- The consultant surgeon (also the registered manager) had completed level two safeguarding children training through their alternative employment within the NHS. Other staff at the clinic had not completed child protection training with the exception of the clinic manager who had undertaken a combined training

Are services safe?

session on adults and children safeguarding. We discussed this with the registered manager and clinic manager who acknowledged that staff should have an awareness of child safeguarding due to the presence of under 18 year olds in the clinic. We were told that action would be taken post inspection to remedy this concern.

- Staff we spoke with showed an awareness of safeguarding concerns such as domestic violence; and how this may influence an individual's decision to change their aesthetic appearance.
- The service had a safeguarding policy which covered general safeguarding information and how to report concerns. The policy did not include specific elements such as female genital mutilation (FGM), modern slavery or the risk of being drawn into terrorist activity.

Mandatory training

- We saw within staff records that adherence to mandatory training was 100%.
- Mandatory training included fire safety, infection prevention and control, health and safety and basic life support (BLS).

Assessing and responding to patient risk

- Every patient booking for a surgical procedure was given a pre-operative consultation, which incorporated a medical assessment to identify suitability. All patients undergoing a surgical procedure were assessed as scoring 'one'; 'healthy person' as per the American Society of Anaesthesiologists ('ASA') system for assessing the fitness of patients before surgery.
- The consultant surgeon told us of additional exclusion criteria which would exclude a patient from being offering surgery at the clinic. This included contraindications within the patient's medical history, and any intolerances of local anaesthetic.
- Pre-procedure medical assessments enabled the consultant surgeon to consider any psychiatric needs which may impact upon treatment such as body dysmorphic disorder (BDD; an anxiety disorder relating to body image). Whilst there was not a specific assessment to identify symptoms of relevant psychiatric conditions, the consultant surgeon demonstrated competency in identifying concerns. We were told that if

concerns were flagged; the patient would be declined for invasive and/ or permanent treatment with an explanation provided, and general information given about seeking further support.

- The consultant surgeon clarified any allergies a patient may have during the initial consultation, and again prior to any procedures taking place. If a patient had allergies, these were noted on a whiteboard during their procedure for all staff to be aware.
- The risks and unsuitability of liposuction were explained to patients who were obese. Patients confirmed that alternative, less invasive, options were discussed at the pre-operative consultation.
- The World Health Organisation (WHO) steps to safer surgery was in use during surgical procedures. We looked at five patient records and saw the checklist had been used for four out of five patients. For the four patients where the checklist had been used, staff had not consistently completed the 'sign out' stage; which confirms all appropriate steps have been taken to ensure safety prior to the patient leaving the operating room. In addition; one patient did not have a surgical safety checklist completed at all. We raised this with staff at the time of inspection who acknowledged this was an area to improve. The management team had not yet started auditing this process at the time of inspection.
- Nursing staff carried out National Early Warning Score (NEWS) observations on patients, and recorded this within patient records. In the event of a deteriorating patient, various actions could be taken including contacting the emergency services for an ambulance to the nearest emergency department if required. Three NHS emergency departments were available within a nine mile radius of the clinic. The clinic did not have a service level agreement to transfer ill patients.
- Staff undertook mandatory training in basic life support (BLS) to enable them to provide cardio-pulmonary resuscitation to patients who may require this, whilst waiting for emergency services to arrive.
- Face to face follow up appointments were scheduled for each patient approximately a week after surgery. In addition, each surgical patient was called the day after

Are services safe?

surgery to monitor patient progress. For surgical procedures, the consultant surgeon continued to provide follow up appointments for a year post operation.

- The service did not have a specific policy outlining identifying and treating sepsis. However, the consultant surgeon received training on sepsis via their NHS role.

Nursing and support staffing

- Two nurses and an operating department practitioner (ODP) worked at the clinic. Two nurses worked regular weekly hours, and the ODP provided cover on rare occasions of staff sickness or holiday.
- Staffing levels were sufficient to provide a safe service. Each surgical patient was attended to during surgery by a registered nurse and a consultant surgeon.
- The clinic receptionist and a cleaner supported the services offered to patients. The joint owner of the business was the clinic manager who ran the day to day business.

Medical staffing

- One consultant surgeon, also the registered manager and joint owner of the clinic, provided medical staffing cover on a part time basis, they also had an NHS

contract with a local provider. They attended the clinic on Thursday afternoon and evenings, Friday evenings and Saturday between 9.30am to 3pm on a weekly basis. Occasionally, and by appointment only, surgical procedures were performed on Sundays at patient's requests.

- Patients were able to contact the clinic if they had questions in between procedures and follow up appointments. If the consultant surgeon was absent during clinic opening hours, a nurse on duty was able to provide advice and guidance.
- As all patients were day case patients, there were no handovers required between either nursing or medical staff. The consultant surgeon and nurse remained with the patient until discharge.

Emergency awareness and training

- Staff were provided with mandatory fire safety and health and safety training.
- Due to the clinic being located in a shopping complex; the fire alarm system was inbuilt and not individual to the clinic. Therefore, the clinic were not able to schedule their own testing. However, the fire alarm system had been checked for functionality in November 2017.

Are services effective?

(for example, treatment is effective)

Our findings

Evidence-based care and treatment

- Clinical practice followed professional standards for cosmetic surgeons where applicable. For example, each patient was assessed to determine their medical fitness prior to agreeing to perform surgery. Post-operative follow up appointments also followed Professional Standards for Cosmetic Surgery.
- The consultant attended conferences in line with procedures performed at the clinic.
- Surgery offered at the clinic generally resulted in 'clean wounds'; whereby invasive surgery completed resulted in no sign of infection. Antibiotic prophylaxis (pre or peri-operative antibiotic injection) was used where considered necessary in order to prevent surgical site infections as part of the National Institute of Health and Care Excellence (NICE) clinical guideline 74.
- Prior to surgery, patients were provided advice on maintaining health in order to achieve optimum results. For example, advice was given to patients about medicines and supplements which may cause adverse effects (such as excessive bleeding) and the consequences of this explained.
- The service was not directly contributing data to cosmetic surgery relevant national data banks at the time of the inspection; largely in part due to the infancy of the service. However, the consultant surgeon, as part of their appraisal documentation, was collecting outcome data; this data was also to be used for submission to the Royal College of Surgeons (RCS) as part of an accreditation scheme.
- The service did not participate in the Anaesthesia Clinical Services Accreditation scheme. Anaesthesia Clinical Services Accreditation is a voluntary scheme for NHS and independent sector organisations that offers quality improvement through peer review.

Pain relief

- All patients undergoing surgical procedures received local anaesthetic to manage pain during the procedure. Staff checked patients' pain levels throughout procedures.

- We were told about developments to enable additional peri-operative pain relief should the standard local anaesthetic not be as effective for specific patients. This followed a specific case whereby a patient became visibly uncomfortable despite the local anaesthetic being used as prescribed.
- Post procedure, patients were provided with analgesic to take; and were given a seven day supply to take home. Ongoing pain relief requirements was discussed during the follow up appointment a week following the procedure.

Nutrition and hydration

- As all surgery undertaken at the clinic was conducted under local anaesthetic, no fasting of food and fluids was required.
- Patients were provided with a choice of hot or cold drinks within the clinic. Meals were not provided; all procedures were day case with limited recovery time required.

Patient outcomes

- At the time of the inspection, QPROMs (Patient Reported Outcome Measures for cosmetic procedures) were not collected. However the service was due to start this with the next patient consultation after this inspection. QPROM forms were prepared and ready for use for both a pre-operative and post-operative patient satisfaction rating in various areas as relevant to specific procedures.
- The consultant surgeon offered revisions where necessary and maintained a list of required surgical revisions. Revisions provided up to a year post surgery were included as part of the overall cost of surgery. Data from the service showed that there were 12 cases of minor surgical revisions within the last 12 months, which equated to 9%. This is higher than the national average of 5%. The service were aware that their rate was higher than the national average. They told us this rate was due to offering minor revisions at no extra cost to patients. During our inspection, although this was related to a non-regulated activity, the consultant surgeon actively informed a patient that they would prefer to improve a treatment outcome by offering an

Are services effective?

(for example, treatment is effective)

additional injection at no extra cost. In this example, the patient did not identify any concerns and was happy with the original outcome; however they consented to the improvement as identified by the surgeon.

- The consultant surgeon was undertaking initial clinical trials involving specific aesthetic equipment as supplied by a local pharmacist. Although these clinical trials were exploring the efficacy of non-regulated activities; this was part of an ongoing plan to conduct research into the area of cosmetic medicine and surgery.
- The provider did not submit outcome data, such as surgical site infection rates, to the Private Healthcare Information Network (PHIN) as part of legal requirements regulated by the Competition Markets Authority (CMA). This requirement was identified in 2014 to enable private healthcare customers to have information available to compare and contrast individual procedures provided, and the fees charged for such procedures. However, we acknowledge that private healthcare providers are providing this information over a structured five year period from 2015 to 2020 due to this being a new initiative.

Competent staff

- The consultant surgeon working at the clinic was also the CQC registered manager; and part owner of the business. They were registered on the General Medical Council (GMC) on the specialist register of consultants for cardiothoracic surgery and received yearly appraisals for both his work undertaken within the NHS, and for cosmetic surgery performed at the clinic. These were completed with clinicians competent to undertake medical appraisals, including the responsible officer at the NHS trust where the consultant surgeon worked. The consultant surgeon provided yearly appraisals and clinical supervision to nurses to ensure they were competent to undertake their duties. We looked at two out of three nurse employment records and saw proof of registration and fitness to practice was present.
- Relevant staff had undertaken additional training to perform procedures and/ or provide support functions during operations. For example, administrative staff had been trained to undertake cleaning duties.

Multidisciplinary working

- Internal multidisciplinary working between team members worked to provide effective care to patients. The clinic team was small in staff numbers therefore staff worked very closely with each other.
- Surgical procedures were consultant led, with support from the nursing staff.
- We were told of informal relationships with a local pharmacist and an NHS microbiology team who provided advice and guidance when required. We were provided with examples which highlighted these were effective and supportive relationships.

Access to information

- Patient records were in a paper format. The records for surgical patients were clearly marked for easy identification.
- Patients were asked if they would like their GP to be informed of the surgical procedure to be undertaken. If consent was given; their GP would be informed. However, we were told it was common for patients to decline consent to inform a GP of a cosmetic procedure.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- During the initial consultation for procedures; staff discussed the appropriateness of treatment for the patient and offered alternative, less invasive, options where possible. These options included not having any form of procedure at all.
- Within patient records, staff recorded that a two-week 'cooling off' period was given between initial consultations and any surgical procedure. This is in line with the Professional Standards for Cosmetic Surgery for consent to procedures. We saw within patient comment cards that the risks and benefits of surgical procedures were discussed, in addition to alternative, less invasive, treatments, enabling informed consent.
- We were told that no mental capacity assessments had been required since the opening of the clinic. However, the consultant surgeon had completed training in the Mental Capacity Act at their full time employment within

Are services effective?

(for example, treatment is effective)

the NHS. Clinical staff were aware of what may affect capacity, including specific symptoms arising from psychiatric conditions, and identified how patients were screened for this.

Are services caring?

Our findings

Compassionate care

- Prior to the inspection, 22 comment cards were completed by patients. All cards contained positive comments; specifically highlighted were caring and friendly staff and a welcoming environment. Comments also showed that staff treated patients with privacy and dignity.
- Staff introduced themselves to patients, and made friendly conversation to ensure patients were relaxed and at ease. Staff presented as knowledgeable repeat patients and recalled relevant personal details.
- We saw evidence of patient satisfaction survey results undertaken in December 2017. These further highlighted that staff made efforts to present themselves as courteous and understanding. Staff had displayed this feedback anonymously within the clinic for other patients to see.

Understanding and involvement of patients and those close to them

- We saw, and patients told us, that staff involved patients in decisions about their choice of procedure and any

treatment. We were told that staff provided clear advice regarding the risks and benefits of treatment which enabled patients to arrive at their own choice regarding treatment options.

- Patients told us they were given opportunities to ask questions and to discuss their procedure prior to consenting to this. Patients were encouraged and able to ask questions throughout ongoing consultations.
- The full cost of any procedure was discussed within the initial consultation; this included any follow up consultations and any additional costs which may be incurred.

Emotional support

- If the patient required additional support, particularly following a procedure, this could be facilitated by family members or friends attending the clinic, if requested.
- If a patient was identified as requiring emotional support, they would be signposted to relevant services such as their GP in order to receive treatment. The clinic did not have direct links or pathways to emotional support services.
- Staff provided patients with advice regarding their health both before and following a procedure. This was to promote a patient directed approach to managing health and wellbeing; therefore maximising the chances of a positive recovery experience.

Are services responsive to people's needs?

(for example, to feedback?)

Our findings

Service planning and delivery to meet the needs of local people

- The clinic was open for surgical procedures on Thursday afternoon and evenings, Friday evenings and Saturday between 9.30am to 3pm on a weekly basis. These hours also applied for post procedure follow up appointments. Patients could also book specific procedures on Sundays therefore enabling some flexibility to appointment times. The clinic was also open for non-regulated activities on other week days including Tuesdays and Thursday and Friday mornings.
- The service was responsive to adapting practice to suit patients. For example, clinical trials were being initiated for specific services to identify which equipment would provide the optimum results for patients.

Access and flow

- Patients were able to make appointments to suit their needs. Patients could book appointments through a variety of ways including attending the clinic, telephoning the clinic, booking through the website or through social media. Text message reminders were sent to remind patients to attend. The consultant surgeon was flexible where possible to meet patient choice; and in situations where the consultant surgeon was not immediately available, patients could speak with a registered nurse during clinic opening hours.
- Appointments were booked in such a way that patients could be seen with time taken to provide care and answer questions. Patients told us they did not feel rushed and felt time was taken within appointments.
- Patients were given time between their initial consultation and the surgical procedure to ensure they had time to reflect upon their decision and provide informed consent. This is required as part of the Professional Standards for Cosmetic Surgery.
- Patient comment cards showed that occasionally patient appointments were delayed; generally due to the consultant surgeon being delayed at their alternative place at work. On one occasion, appointments were cancelled for this reason. On these occasions, patients were kept informed of delays and any parking costs were provided.

- Surgical revisions were planned as appointments. The service had not had any patients who required an unplanned return to theatre. If this was required, for a medical emergency; the patient would be referred to the local NHS trust.

Meeting people's individual needs

- Staff tailored patient care to individual needs, taking into account patient choice and circumstances. This was in line with the National Institute of Health and Care Excellence (NICE) quality statements.
- Staff gave examples of where they had worked with patients who had specific needs. For example, patients who had a degree of hearing impairment were still offered the opportunity to be assessed for procedures in line with the Equality Act 2010; but staff would adapt their communication to ensure the patient could receive and understand information presented in order to make an informed decision.
- Patients were addressed by their chosen pronoun and name; therefore taking into account if a patient identified as a gender different to that which they had been born into.
- We were told that all patients seen since the clinic offered surgical procedures were able to communicate to a good level in English; although not all patients spoke English as their first language. Staff told us if a patient who could not speak English requested consultations, this would be facilitated with the use of an interpretation service; although the service did not have a specific contract with an interpretation agency. Staff were aware not to use relatives or friends as an interpreter.
- The clinic was located on the ground floor, and was easily accessible for patients with mobility needs. Patients were able to attend in a wheelchair is required and a larger toilets with facilities for wheelchair users was available.
- A privacy screen was available for use to ensure patients' dignity was respected. Patients undertaking surgical procedures were encouraged to sit in a separate, more private waiting area, in order to maintain privacy.

Are services responsive to people's needs?

(for example, to feedback?)

Learning from complaints and concerns

- Data from the service showed seven complaints had been made between January 2017 and the date of the inspection. Of these; one complaint was still outstanding and was being dealt with through a third party.
- No specific themes were identified within the complaints made by patients. However concerns raised were addressed and learnt from.
- Patients were able to access information on how to make a complaint either whilst at the clinic, or via the website. We saw numerous signs detailing various methods for do so, during our inspection.
- The clinic manager sought patient feedback following every patient contact at the clinic. This feedback was used to inform changes and developments within the service. For example, although not a regulated activity; following patient feedback regarding a non-invasive 'inch loss' procedures; this was discontinued staff identified it was not providing optimum results despite patients still requesting this.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

Our findings

Leadership / culture of service related to this core service

- The consultant surgeon was also the registered manager, although was supported by the clinic manager within this role. Both the clinic manager and consultant surgeon were highly visible within the clinic. Patients were familiar with all staff including management; and we observed positive interactions between staff members and patients.
- We were told, and we saw, that a friendly, open and supportive culture operated within the service. Staff members worked as a team, and socialised outside of work to foster positive relationships.
- The consultant surgeon provided line management to clinical staff including continued professional development. They encouraged an open forum for feedback; and requested team members observe their consultations and procedures in order to develop.
- Patients told us, and we saw, that staff were open and honest when providing initial consultations. Patients reported that they were at times advised to have a less invasive, lower cost, procedure or that they did not require treatment of any kind. Prices were displayed in information booklets, on the company website and listed on social media accounts. This aided the process of transparency for patients.

Vision and strategy for this core service

- The service did not have a specific written vision or set of aims and objectives. However, plans were in place to expand the range of procedures and treatments offered. For example, a new premises had been procured which would allow for expansion within the next 12 months, and the provision of a purpose built surgery area.
- Staff were aware of the forthcoming changes and plans for the business.
- The consultant surgeon was working towards accreditation for cosmetic procedures with the Royal College of Surgeons.

Governance, risk management and quality measurement

- The clinic had been registered for surgical procedures for just over a year at the time of inspection. Effort had been made to ensure governance processes were in place to support the effective management of the clinic. Clinic management were open to continue to develop a well-led approach through feedback and learning.
- Clinical and information (joint) governance meetings were held every three months. We looked at two sets of minutes and saw that all regular staff, with the exception of the cleaner who worked once a week, attended. The cleaner was updated on any relevant actions on their next shift. A variety of topics were discussed including incidents, complaints and business development.
- The service held a risk register, which contained one risk added in September 2017. This risk was regarding the accidental disposal of re-useable equipment. During the inspection we identified areas which may benefit from being on the risk register but were not recorded. For example, the clinical waste bin not being appropriately secured and the risk of the consultant surgeon being delayed at their alternative employment, therefore missing or delaying patient consultations.
- Compliance with Health Technical Memorandums (HTM) were not recorded on the risk register however this was being addressed within plans to relocate to new premises. For example, ventilation was currently managed by a portable machine. Upon relocation, plans were in place to incorporate a built in system.
- The consultant surgeon performed all surgical procedures; therefore was able to maintain oversight of this area of work. Their work was overseen via appraisals and nurse feedback following procedures. Staff we spoke to were aware of the scope of their roles and what tasks they were accountable for.
- The service had initiated a programme of audit to ensure quality was measured. Data from the service showed that at the time of inspection; only hand hygiene audits had been undertaken in the 12 months prior to inspection.

Are services well-led?

(for example, are they well-managed and do senior leaders listen, learn and take appropriate action?)

- We reviewed a sample of policies, such as the medicines management policy and safeguarding policy and found these to be comprehensive, with clear guidance for escalation.
- The service had an informal agreement for pharmacy support from two pharmacists. Examples given showed these relationships worked effectively however a formal service level agreement would make this process more robust.

Public and staff engagement

- Staff engagement was maintained through regular contact with and the visibility of, the management team. All staff, with the exception of cleaning staff who worked one day per week, attended the governance meetings held quarterly; and we were told about staff team meetings which were held in a social environment such as a restaurant. Staff we spoke to spoke positively of the management team; and spoke of an inclusive environment whereby views could be expressed and discussed.
- Staff, including the consultant surgeon, engaged with the public through the use of the company website, and social media business accounts. Social media was regularly updated.

- Patient satisfaction scores and feedback were sought after each appointment. We saw previous results and quotes displayed in patient areas.

Innovation, improvement and sustainability

- The consultant surgeon at the clinic was initiating clinical trials to determine outcome difference between specific equipment. Although the trials underway at the time of our inspection were not related to regulated activity; we were told that future plans including conducting research into cosmetic surgical procedures due to an identified gap within this area of medicine therefore promoting continuous learning
- A new building had been procured with plans to re-locate the business into this within the next 12 months. This would enable expansion of the business and services offered; but also enable management to design patient areas to be fully compliant with relevant standards therefore improving the quality of care.
- The consultant surgeon was also an accredited trainer of cosmetic procedures therefore was able to provide both in house, and external training to staff and practitioners.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures	<p>Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2010 Cleanliness and infection control</p> <p>12.—(1) Care and treatment must be provided in a safe way for service users.</p> <p>(a) assessing the risks to the health and safety of service users of receiving the care or treatment;</p> <p>(b) doing all that is reasonably practicable to mitigate any such risks.</p> <p>We saw that the World Health Organisation (WHO) safer surgery checklist was not consistently completed fully. Out of five patient records checked, one patient did not have a checklist.</p>
Regulated activity	Regulation
Surgical procedures	<p>Regulation 12 HSCA 2008 (Regulated Activities) Regulations 2010 Cleanliness and infection control</p> <p>12(2)(h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated.</p> <p>We saw that the decontamination policy was based upon Health Technical Memorandum 05-01 which is used for decontamination of dental equipment rather than surgical equipment.</p>