Aesthetic Beauty Centre - Newcastle-upon-Tyne

Quality Report

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Date of inspection visit: 27 September 2019, 9 December 2019, and 2 January 2020
Date of publication: 16/03/2020

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

Ratings

Overall rating for this location

Are services safe?	
Are services well-led?	

Overall summary

Aesthetic Beauty Centre – Newcastle-upon-Tyne is operated by Aesthetic Beauty Centre LLP. The service provided a range of surgical and cosmetic procedures under local anaesthetic or sedation to fee paying patients over 18 years old.

The service is situated in a large detached house which has been converted into a clinic, that is wheelchair accessible to ground floor level (but without ramps) and is located conveniently for access to local public transport networks, but also has on street parking. Service users arriving were met by staff and directed to a downstairs reception room and waiting area. Adjacent to this were a consulting room and unisex toilet. On the first floor there was a theatre, pre-theatre room, shower/toilet room, clean and dirty utility, and recovery room, together with a room used by staff as the office.

The service provided a range of surgical and cosmetic procedures under local anaesthetic and/or sedation to fee paying patients over 18 years old.

We inspected this service as a responsive inspection following information we received relating to concerns about patient experience and harm. We carried out a short notice inspection on 27 September 2019. Following this inspection we issued a notice of decision under

Summary of findings

Section 31 of the Health and Social Care Act (2008) imposing conditions to suspend the carrying out of any surgical activity which required local anaesthetic or sedation at this location until 04 January 2020.

At the request of the provider we undertook a further short notice inspection on the 09 December 2019 prior to a tribunal regarding the notice of decision which took place on 16-19 December 2019.

Prior to the conditions expiring, CQC undertook a further inspection on 02 January 2020 to review progress against the concerns raised in the September 2019 inspection. On 06 January 2020 the tribunal decided to further extend the original conditions until 06 April 2020.

To get to the heart of experiences of care and treatment for patients, 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. The three inspections were in response to information received and so does not cover all five key questions. We looked only at those parts of safe and well led that caused concern. We did not consider ratings at these inspections.

Services we rate

We had not previously rated this service which was registered on 1 October 2013. As this was a focussed responsive inspection these inspections looked at specific areas and did not cover the whole domains on key questions. Therefore, we inspected but did not rate the service.

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

- There was limited evidence to show how the provider leadership team assured themselves that doctors employed by and who had practicing privileges had the necessary skills, knowledge and competence to care for patients within the service.
- The recovery environment did not meet infection prevention and control best practice in line with national guidance.
- The ventilation system had not been tested in line with national guidance, therefore we could not be assured the air exchange in the theatre environment was safe and effective.
- The provider had transported contaminated instruments inappropriately and without a licence as dictated by regulations.
- The scrub sink in the theatre was not suitable for a full surgical scrub. In addition scrub observations were undertaken of nursing staff, however, there was no observation of medical staff and their scrub technique.
- Patient risk assessments were not always completed and updated in line with best practice.
- Operation notes were not recorded on appropriate documentation for their purpose.Because of this they were difficult to find and not easily legible.
- We found evidence of inappropriate monitoring in patient records.This meant patients were not always monitored appropriately during procedures, this meant the provider would not be able to and did not identify patient deterioration in a timely manner.
- Policies within the service did not reflect the environment, for example, they mentioned roles which were not in place within the service and the deterioration policy did not identify when the provider would call for emergency services support.
- There was no audit of pre-operative risk assessments to ensure these were thorough and complete.There was an action plan in place to improve the sedation records, however, this did not include pre-assessment or nursing documentation.
- The leadership team were unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations.
- The provision of out of hours care was not robust.We were not assured a patient who required urgent treatment, when the surgeon was operating at other locations would receive care from medical professionals who would have the appropriate skills and competence.

However:

Summary of findings

- The leadership team was reported to be visible and approachable.

Following this inspection, we issued a notice of decision imposing conditions to suspend the carrying out of any surgical activity which require local anaesthetic or sedation at this location until 04 January 2020. On 06 January 2020 the tribunal decided to further extend the original conditions until 06 April 2020. We also 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 which are detailed at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery		At this inspection we rated the service as **Not rated** overall. There was limited evidence to show how the provider leadership team assured themselves that doctors employed by and who had practicing privileges had the necessary skills, knowledge and competence to care for patients within the service. The recovery environment did not meet infection prevention and control best practice in line with national guidance. The ventilation system had not been tested in line with national guidance, therefore we could not be assured the air exchange in the theatre environment was safe and effective. The provider had transported contaminated instruments inappropriately and without a licence as dictated by regulations. The scrub sink in the theatre was not suitable for a full surgical scrub, in addition scrub observations were undertaken of nursing staff, however, there was no observation of medical staff and their scrub technique. Patient risk assessments were not always completed and updated in line with best practice.

Summary of findings

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Services we looked at:
Surgery

Summary of this inspection

Background to Aesthetic Beauty Centre - Newcastle-upon-Tyne

Aesthetic Beauty Centre – Newcastle-upon-Tyne is operated by Aesthetic Beauty Centre LLP. The service provided a range of surgical and cosmetic procedures under local anaesthetic or sedation to fee paying patients over 18 years old. The service primarily served the communities of Newcastle-Upon-Tyne.

The service has had a registered manager and the service is registered for the following regulated activities:

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

However, all the regulated activities above were subject to a condition that the provider must only undertake minor surgical and cosmetic procedures under local anaesthesia or sedation as detailed in its statement of purpose for service users aged 18 or over at this location.

We conducted a short notice focussed responsive inspection on 27 September 2019. There were subsequent inspections on 09 December 2019 and 02 January 2020.

The service also provided cosmetic procedures (such as, removal of small blemishes on the skin) which we do not regulate and so we did not inspect those services.

Our inspection team

The team that inspected the service at each inspection comprised of a CQC inspection manager, lead inspector, additional inspector and specialist advisors. The inspection team was overseen by Sarah Dronsfield, Head of Hospital inspection.

For the inspection of 27 September 2019, the team comprised of an inspection manager, lead inspector and a Specialist advisor (SPA) who was a surgical consultant. Following the inspection, a consultant anaesthetist SPA with an inspection manager reviewed patient records.

At the inspection on 09 December 2019 the team comprised of an inspection manager, lead inspector, medicines inspector and a specialist advisor (SPA) who was a cosmetic surgeon.

At the inspection on 02 January 2020 the team comprised of an inspection manager and two inspectors.

Information about Aesthetic Beauty Centre - Newcastle-upon-Tyne

The service is registered to provide the following regulated activities:

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

The above regulated activities were subject to a condition noted above.

During the inspections, we spoke with seven staff, the two directors who were the registered manager and surgeon, governance lead, care assistant, a secretary, and two receptionists. We were able to speak with one service user but also reviewed written feedback sheets from ten service users and reviewed three service user records. We reviewed staff records in relation to four staff.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

Prior to this there was an unannounced focussed inspection on 12 June 2017 in response to concerns as detailed in that report.

Throughout this report, our findings apply to all the regulated activities, unless expressly stated otherwise,

Summary of this inspection

albeit the prime focus of our inspection was on the activity of surgical procedures. This was so because the other regulated activities were ancillary to that main activity.

Activity – March 2018 to February 2019 (reporting period)

In the reporting period there were:

- A number of surgical procedures broken down as follows:
  - 12 male breast augmentations;
  - 29 hair transplants;
  - 24 fat transfers;
  - 34 liposuction;
  - 10 face and neck lifts;
  - 12 eye lifts;
  - 10 female breast augmentations;
  - Seven tummy tucks.
- One complaint.

The service at the location employed the two directors (who performed other roles as noted above) a secretary, and receptionists, and contracted other staff in, (such as, a theatre nurse or anaesthetist, acting under practising privileges) as necessary. Opening times at the location were at the time of our inspection Mondays, Wednesdays and Fridays. Opening times were displayed on the service's website.

Track record on safety

- Zero service user deaths or never events.
- Zero duty of candour notifications.
- Zero safeguarding referrals.
- Zero incidences of healthcare acquired infections.
- One unplanned urgent transfer of a service user to another health care provider.
- One unplanned return to theatre.
- One cancelled procedure for a non-clinical reason.

Outsourced services

- Pathology for excisions (mole) are dealt with by QE Clinical Pathology Services Gateshead
- Clinical waste is disposed of by a third-party contractor.

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?

Are services safe?

We rated it as **Not rated** because:

There was limited evidence to show how the provider leadership team assured themselves that doctors employed by and who had practicing privileges had the necessary skills, knowledge and competence to care for patients within the service.

The recovery environment did not meet infection prevention and control best practice in line with national guidance.

The ventilation system had not been tested in line with national guidance, therefore we could not be assured the air exchange in the theatre environment was safe and effective.

The provider had transported contaminated instruments inappropriately and without a licence as dictated by regulations.

The scrub sink in the theatre was not suitable for a full surgical scrub, in addition scrub observations were undertaken of nursing staff, however, there was no observation of medical staff and their scrub technique.

Patient risk assessments were not always completed and updated in line with best practice.

We found evidence of inappropriate monitoring in patient records. This meant patients were not always monitored appropriately during procedures, this meant the provider would not be able to and did not identify patient deterioration in a timely manner.

Are services well-led?

We rated it as **Not rated** because

Policies within the service did not reflect working practices, for example, they mentioned roles which were not in place within the service and the deterioration policy did not identify when the provider would call for emergency services support.

There was no audit of pre-operative risk assessments to ensure these were thorough and complete. There was an action plan in place to improve the sedation records, however, this did not include pre assessment, operation notes, or nursing documentation.

Summary of this inspection

The leadership team were unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations.

The provision of out of hours care was not robust. We were not assured a patient who required urgent treatment, when the surgeon was operating at other locations, would receive care from medical professionals who would have the appropriate skills and competence.

However:

The leadership team was reported to be visible and approachable.

Surgery

Safe

Well-led

Are surgery services safe?

Mandatory training

02 January 2020 inspection

We reviewed the mandatory training data and compliance in staff files for staff directly employed at the service and found evidence of training and compliance for the nurses employed by the clinic from their records. However, for doctors employed with practising privileges we found they had not all had full employment checks in line with the fit and proper persons employed requirements. Appraisal records from substantive employers were very brief and some references were missing or provided after employment had commenced. There was a list of mandatory training required for doctors employed by the service and staff files held copies of certificates for some completed courses from their substantive post training records. However, it was not clear to us how the provider was assured medical staff had the skills, knowledge and competencies to care for patients within the service.

Cleanliness, infection control and hygiene

09 December 2019 inspection

During this inspection we noted that not all clinical areas were compliant with relevant infection prevention and control procedures. We found that the sink in the theatre, where clinical staff would undertake a surgical scrub, was small and not compliant with relevant guidance. The surgeon told us they could undertake surgical scrub prior to undertaking operations in the dirty utility area, though when we met with them following the inspection, they contradicted this statement.

The flooring within the recovery environment did not meet Health Building Note 00-09: Infection control in the built environment (2013). The guidance states carpets should not be used in clinical areas. We found the recovery room and landing area were carpeted, we did not see evidence of a local risk assessment or a clearly defined pre-planned and preventative maintenance and cleaning programme.

We found that the cleaning of equipment including the sterilisation of equipment took place within the centre. We had significant concerns in relation to this and whether this met Health Technical Memorandum (HTM 01/01) guidance which is applicable to all providers of health services. Following the onsite inspection, we wrote to the provider under section 64 of the HSCA 2008 to supply us with required information and documentation in relation to infection prevention and control. The provider sent us a policy for the cleaning and disinfection of surgical equipment which had been created on 13 December 2019.

In addition, the provider sent us an infection control policy which had also been written on 12 December 2019 following our request for further information. This policy did include all the relevant areas that would be expected within a policy such as hand hygiene, use of personal protective equipment and environmental cleaning. However, we were not assured that this was embedded in practice and that the provider had systems in place to monitor compliance with this policy.

Within this policy it detailed guidance to staff on the disposal of waste including household waste, clinical waste and sharps. The policy also indicated that an independent waste disposal contractor would be used to dispose of waste from the centre. Therefore, it was not clear the provider had previously had suitable arrangements in place to dispose of waste and whether a contractor had been appointed.

We were provided with an infection control audit dated September 2019. There were a number of the standards that the provider indicated they always met such as hand washing sinks were available in all clinical areas, dressing trolleys were cleaned daily and decontamination policies were in place, plus other standards that they sometimes met. Following the audit, it was not clear if the provider had identified the areas for further improvement and whether detailed plans were in place to support this improvement.

02 January 2020 inspection

At this inspection, we found there was no evidence of a verification test to identify if the ventilation and plant were working effectively in-line with HTM guidance. Therefore,

we could not be assured that air exchange in the theatre environment was working effectively to reduce the risk of infection. When we asked the provider, they were not aware of this and told us they would contact their service contractor to review the system the day after our inspection.

We were not assured decontamination procedures met with HTM guidance.We saw the pathway for decontamination of equipment was not appropriate and did not meet best practice. In, addition there were no washing facilities in the clean utility room which meant the person undertaking the decontamination process was unable to wash their hands appropriately. This meant following the update of the policy in December 2019 the provider was still not aware of how to comply with the relevant guidance to ensure measures had been put in place to reduce the risk of patients being exposed to harm.

During the inspection, we found the steriliser had been used seven times during the suspension period, the provider told us they were undertaking some procedures at their Sunderland location. They also told us that the surgeon was transporting this equipment between sites. The provider did not hold a license to transport contaminated items as the carriage of dangerous goods and use of transportable pressure equipment regulation 2009; which states contaminated equipment must be carried in a locked box. This meant there was unsafe transportation of contaminated items. The provider told us they had made initial enquiries to source an external provider to provide sterilisation of equipment. However, at the time of this inspection this was not in place. Following the inspection, the provider informed us they had a verbal agreement with a local NHS trust, however, this had not been formalised with a contract.

We saw evidence of a quote for a new sink which would enable a full surgical scrub, which was to be placed in the theatre environment. However, the provider clarified this was not where they usually performed their surgical scrub. When reviewing the actual sink where surgical scrub took place this environment was also not appropriate for a surgical scrub. This was further evidence that the provider and registered manager were not fully aware of the actions they needed to take to meet relevant guidance and the regulations.

The registered manager told us they undertook scrub observations as part of infection prevention and control audit activity. However, this only related to nursing staff and did not include medical staff at the centre, and there was no documented evidence of these audits.

We saw evidence of a quote to replace the flooring in the recovery room, landing area and consultation room. At the time of our inspection the work was not scheduled to take place until the provider had confirmation they were able to commence surgical procedures.

Environment and equipment

27 September 2019 inspection

The operating room was located on the first floor of the premises. There was a staircase but no lift.

Following an emergency transfer of a patient by ambulance to the local NHS emergency department, ambulance staff reported it had taken 17 minutes to carry the patient down the staircase from the operating room on the first floor. We were concerned this significantly extended the time it took to transfer the patient to hospital. Ambulance staff and CQC specialist advisors did not find the environment supported safe and efficient transfer of a patient requiring emergency care.

09 December 2019 inspection

When we reviewed the environment and equipment available at the centre we noted that in the waiting room where patients recover post procedure the bed was not a standard hospital bed. We asked the provider if this bed was suitable if the patients deteriorated suddenly and required resuscitation, the surgeon told us they would put patients on the carpeted floor if they required cardio-pulmonary resuscitation. However, there was no moving and handling plan or equipment provided to do this safely.

In addition, there was no oxygen or suction equipment available in the in the recovery room, which meant equipment was not readily available should a patient deteriorate suddenly.

02 January 2020 inspection

At this inspection we found that within the waiting/ recovery room there was now portable oxygen and there was a back board available if a patient should require

resuscitation, and suction was also available on the resuscitation trolley. However, we found that the oxygen cylinder was not stored securely and was at risk of falling, causing damage or injury.

The provider had also obtained a quote for replacement flooring, however there was no indication when the flooring would actually be replaced.

Assessing and responding to service user risk

27 September 2019 inspection

When Aesthetic Beauty Centre first registered with CQC in 2011 there was a condition listed on the certificate of registration which stated that the registered provider must only undertake minor surgical and cosmetic procedures under local anaesthesia or sedation as detailed in the statement of purpose.

During the inspection we asked the registered manager what procedures they undertook at the centre and we asked the surgeon how they categorised the level of procedure. They stated that several procedures were not 'minor' procedures and that they considered those such as breast augmentation or buttock augmentation would be classified as 'intermediate' surgery.

We asked what guidance they used to classify the level of procedure and whether they utilised, for example, the BUPA schedule of procedures. The provider stated they were not aware of this guidance and would benchmark procedures based on depth of the incision, the length of procedure, and also anticipated blood loss.

Following the inspection, CQC sought advice from the CQC national professional advisor (NPA) for surgery about the level of procedures ABC was undertaking. They reviewed information provided by the inspection team about the types of procedures undertaken at the location. For example, gynaecomastia surgery is classified in the BUPA schedule as intermediate, the NPA also spoke with a consultant plastic surgeon who confirmed this procedure would be classified as intermediate.

CQC also reviewed patient information leaflets from professional associations such as the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS). In the patient information leaflet for breast augmentation it indicated that this procedure was a major operation. During the reporting period of March 2018 to February 2019 the centre had undertaken 22 procedures of gynaecomastia and breast augmentation which were classified above a minor procedure, which meant the provider was not complying with the conditions of registration

During our review of patient records we found that patient risk assessments were not always fully completed by medical staff. During our inspection we noted one patient record did not include a documented risk assessment carried out in response to the patient's previous medical history of cancer. There was no indication blood tests were ordered and there were no blood test results in the patient notes which would be usual practice in response to the patient's medical history. In another patient's record there was information from the patients GP about their mental health, however we found no documented evidence in the record that this had been followed up by either medical or nursing staff at the centre.

We reviewed the record of a patient who had had two procedures undertaken at the centre. On both occasions, they were taking a medicine that is generally stopped prior to surgery. For the initial procedure the medicine was stopped prior to surgery but not at the time interval recommended by NICE. Whilst for the second procedure the medicine was not stopped, and the patient suffered an adverse incident during surgery. It was not clear from the medical records why a different approach was used for this medication for both procedures when the past medical history of the patient had not changed between procedures and why the doctor had not followed the NICE guidance

For another patient it was documented in the patient record they had an allergy and during their procedure, a medicine to which they may be sensitive to was administered. Thus posing the risk of anaphylaxis. This was particularly concerning as the patient was administered high levels of this medicine and subsequently suffered an adverse reaction. This was indicative of poor pre-assessment and documentation and there were also discrepancies in the allergy documentation including the safer surgery (WHO) checklist.

Throughout our review of the medical records of three patients who had received sedation for their procedure we found no evidence that appropriate monitoring had been undertaken. This monitoring is routinely used to detect early signs of respiratory depression or loss of airway, this is particularly concerning due to the high levels of sedation

that were used during procedures at the clinic. We found there was inadequate monitoring of patients during procedures and in an environment that was not fully equipped to deal with patient deterioration

We asked the registered manager during the inspection if there was an admission policy for the centre to indicate which patients would be suitable to have procedures at the centre and those where it would be unsuitable. The admission policy was undated stated that the ABC "ensures equitable access to the clinic for patients". On page 3 of the policy it stated in the patient selection notes that they "intend to identify patients' suitability according to clinical, psychological, legal and ethical criteria". However, this document did not specify what these should be or how they would be ascertained. We were not clear from the policy, records or discussions with the provider how they ascertained which patients were suitable or unsuitable to have procedures at this location.

We asked the provider if they had a policy for deterioration or escalation which detailed how the service would deal with a patient who became acutely unwell before, during or after a procedure, initially the provider was not clear what was meant by this. When we clarified this with the provider they produced a document and although the introduction referred to dealing with a medical emergency, this was a business continuity plan should a major service be unavailable and not a plan for dealing with a deteriorating patient.

09 December 2019 inspection

During this inspection, we discussed with the provider the types of procedures they were undertaking at the centre. The provider stated they were "stumped" when they had been asked the classification question at the last inspection in September 2019 and told us: 'I just do what I do'. During our discussions it was not clear to us that the surgeon considered the full range of factors upon which they would base their judgement on and relied on title of the procedure and length of time it takes instead.

When we specifically asked about Brazilian butt lift, as these procedures have one of the highest rates of postoperative complications, the provider told us they had stopped undertaking these procedures a while ago. However, when it was pointed out that one of these procedures was planned to be undertaken in October 2019 prior to the imposition of conditions the provider was unable to provide an explanation for this. When we reviewed the diary, which contained details of consultations and planned procedures there was also another one of these procedures booked in at this location on 30 December 2019. This was also whilst the conditions were in place which prevented any surgical procedures taking place.

The provider told us that following the incident in March 2019 with involving a medicine they had reflected on this incident and had revised their policy. When we asked to see this policy the provider told us this had not yet been written but was planned. This meant the provider had not updated their policies and procedures which had been identified in their significant event analysis report in the nine months since the incident. It also meant there had been a delay in putting in place systems and processes to support staff and reduce the risk to patients which meant patients were still exposed to the risk of harm.

A new admission policy was being drafted and we were told by the provider this now included relevant inclusion and exclusion criteria.

02 January 2020 inspection

We reviewed the admission, patient selection and exclusion policy dated 27 December 2019, we saw this included patient exclusion criteria and stated, "patients who due to their medical history, their clinical, psychological, legal and ethical circumstances will not be offered treatment or admission." The recommendations from the significant event analysis were not specifically mentioned in the policy or cross referenced to the planned anticoagulation policy.

We saw the management of the deteriorating patient escalation policy dated 06 December 2019, however, this policy did not reflect the patients and services provided by Aesthetic Beauty Centre. We saw the policy made reference to the national early warning score (NEWS), however, there was no reference to clarify what NEWS score would prompt the provider to call emergency services for support.

Medical staffing

27 September 2019 inspection

The surgeon was registered with General Medical Council (GMC) with a licence to practice; and was registered on the GP register, although the doctor was not on the Specialist Register. It was not clear during this inspection the extent of

the doctor's experience, skills and knowledge in surgery to enable them to proficiently perform the procedures undertaken at ABC. In addition, the doctor had conditions on their professional registration with GMC which included supervision of their practice.

We reviewed the requirements for cosmetic surgeons as outlined in the Royal College of Surgeons Professional Standards for Cosmetic Surgery. It states that surgeons who perform cosmetic surgery should 'be certified in the area of cosmetic surgery in which they practise'. Cosmetic surgery certification requires surgeons to be on the GMC specialist register in a relevant surgical specialty and to meet a series of criteria that demonstrate 'appropriate training'. In addition, we checked the British Association of Plastic Reconstruction and Aesthetic Surgeons who reiterated this position and requirements.

The centre employed two consultant anaesthetists under practising privileges. The term "practising privileges" refers to medical practitioners not directly employed by the provider, but who have been approved to practice there. Both anaesthetists were substantively employed within an NHS hospital trust.

09 December 2019 inspection

During this inspection the surgeon explained that they had "Grandfather rights" which were acquired rights usually granted when there had been a change in requirements for a qualification to practice that would affect those doctors currently practising in that area. The surgeon explained this was why they were not on the specialist register as a surgeon. They told us about their experience and showed us their training records to indicate they had undertaken courses and had experience within the field of cosmetic surgery. Whilst we were told this we have not seen any documentation from the provider or GMC that would confirm this position.

The provider had updated the 'considering cosmetic surgery' guide for patients to reflect the surgeon's lack of registration with BAPRAS, to state they were not a cosmetic surgeon, and outlined their qualifications. The guide now stated the doctor was fully trained in the procedures even though they were not identified as a surgeon on BAPRAS or on the GMC specialist register. This meant there was no ambiguity about their experience or qualifications.

At this inspection we found one sedation record completed by a third anaesthetist who was not previously known to the inspection team. We had understood from our previous inspection that there were only two consultant anaesthetists working under practising privileges for this provider and it was not clear if this anaesthetist had been granted practising privileges. We saw no documented evidence of this,

02 January 2020 inspection

During this inspection we asked the registered manager if the anaesthetist had been granted practising privileges and they told us this doctor had stepped in at the last minute when the scheduled anaesthetist could not attend. The third anaesthetist was a colleague the surgeon had worked with before. There were no records regarding this and staff could not explain why the correct process had not been followed, only that they could not cancel the procedure at short notice.

Records

27 September 2019 inspection

We reviewed five patient records at this inspection as these were the only records available at the centre on the day of inspection. We found significant gaps in written documentation within patient records and they were not fully completed.

In particular, there was very little documented evidence of full risk assessments being carried out for all patients undergoing surgical procedures. The pre-printed forms were comprehensive and posed several questions pertinent to patients' past medical history, tests required and carried out, current medicines and psychiatric health. However, we found minimal patient assessment information was completed and the medical staff explained they discussed with patients any risks verbally. We did note consent had been completed in all the records we reviewed.

09 December 2019 inspection

We saw lists with procedures planned for dates in the future. However, there were only two sets of notes available for inspectors to review on the day of the inspection. The surgeon told us they had implemented a new consultation document which had not been in place at the last inspection. However, in the records we reviewed of those patients who were due to undergo procedures between September 2019 and December 2019, we did not find evidence to demonstrate this documentation had been

used in practice. We found one pre-assessment consultation had taken place and the consent form had been signed in February 2019 but this had not been revisited before the procedure was due to take place. However, a nursing pre-assessment appointment had been made for the week before the procedure was diarised.

02 January 2020 inspection

Between September to December 2019, the provider was still seeing patients for consultations and pre-assessment prior to procedures. Once again, there were very few records available for review by inspectors. Despite CQC raising concerns with the provider following the September 2019 inspection we found no improvement in the completion of the records. Staff told us the doctor had detailed discussions with patients, but the documentation of these discussions were "not their strong point."

There was no evidence the provider had undertaken a retrospective audit of the complete patient records to review the standard of record keeping and whether this was in line with professional requirements or to the level required in the regulations.

The consultant anaesthetists working at the centre had undertaken an audit of all 31 operation records to identify the quality of the records. For the years 2018-19 it showed that end tidal carbon dioxide monitoring and sedation levels were only documented in 23% of records. There was an associated action plan following the audit which stipulated that all procedures must use end tidal carbon dioxide monitoring, implement a modified Ramsey sedation scale during all procedures (8-point scale), and the sedation record has been amended to prompt the documentation of sedation scores.

The provider had undertaken a limited retrospective audit regarding intravenous fluid administration and they had found in none of 31 records audited that the volume given to the patient was recorded. During the inspection on 2 January 2020 the service produced an audit report in line with national guidance and had developed an action plan to use in the future. We were told this was now included in the audit plan however the provider was unable to produce the audit plan to show this.

Medicines

27 September 2019 inspection

The surgeon explained that not all patients would require sedation for procedures. It was only for those who were too anxious to have the procedures using local anaesthetic alone. Conscious sedation is a type of anaesthesia that makes a patient feel sleepy and relaxed, both physically and mentally; it is sometimes used to keep patients calm during minor, painful or unpleasant procedures.

During the inspection we noted the levels of sedation and sedative drugs administered documented on patient records were high and possibly not indicative of conscious sedation. Following the onsite inspection we undertook a further review of the four patient records to assess the levels of sedation used.

In this review, we had concerns about one patient who had a two-and-a-half-hour procedure under local anaesthetic and conscious sedation. Documented in the records there were significantly high doses of medicines administered during the procedure. The doses were sufficiently high to raise concerns about how responsive the patient was during the procedure and whether they were sedated in line with conscious sedation. There was no documentation within the records to indicate the patient's consciousness level was assessed during the procedure.

For another patient who had a four-and-a-half-hour procedure the sedation used was very high and increased the risk of respiratory depression. The dosage levels also gave us concerns about the consciousness level of the patient and whether they could have been awake and responsive during the procedure. There was no information in the patient records that indicated the patient's consciousness level was assessed during the procedure.

09 December 2019 inspection

During our inspection we asked to review the Home office license for the storage and management of controlled drugs. When the provider showed us the license we noted this had expired on 28 September 2019. The provider was unaware this license had expired which meant that since our September inspection, they were storing controlled drugs without the proper licenses.

We reviewed three patient records and found there were discrepancies between sedation records, patient records and the controlled drugs record book. There were discrepancies found in the total amounts of medicines

administered between the records, crossings out in the controlled drugs record book and amounts the sum of the records recorded as "given" and "wasted" did not match the content of the ampoule.

We spoke with the provider about the length of a procedure for one patient. They told us the first 30 minutes would not be operating time but was time the patient spent with the anaesthetist and the surgeon would only start the operation once the patient was asleep**.** This is not in line with the definition of conscious sedation as the patient should be awake and responsive during the procedure

In the three patient records we reviewed, there were high levels and combinations of medicines administered during the procedures; these procedures had been undertaken prior to the September 2019 inspection. This was indicated by the medicine inspector to be high dosages of these medications.

This was further evidence of the concerns raised at our previous inspection about the use of sedation medicine and how responsive the patient would be during procedures. This also indicated the use of these levels of medicine was more widespread and systemic than just the patients we reviewed in the September 2019 inspection.

02 January 2020 inspection

We found at this inspection the controlled drugs home office license had been renewed. Since the December 2019 inspection the provider had undertaken a retrospective audit of medicines prescribing against anaesthetic records and had identified where the gaps were. We saw the provider had taken action to ensure this was not repeated.

Incidents

27 September 2019 inspection

CQC were notified on 24 September 2019 by the local NHS hospital trust that they had received a patient by emergency transfer from Aesthetic Beauty Centre-Newcastle. We were already aware of a patient who had been transferred in similar circumstances in March 2019. On the basis of this information CQC undertook a focussed responsive inspection.

09 December 2019 inspection

The provider told us there was no anticoagulant policy, but they planned to review this as part of the significant event analysis following the serious incident, we were concerned this incident had happened in March 2019 - this was 9 months ago, and the policy had still not been drafted or changes to practice implemented. This meant that the risks to patients had not been mitigated as there was no clear guidance for staff to follow.

02 January 2020 inspection

At this inspection we reviewed evidence of all of the policies the provider had updated and developed, however, we did not find evidence of an anticoagulation policy. We also found there was no specific exclusion criteria with regard to anticoagulation medicines within the admission policy.

We saw the provider had commissioned an independent review of both significant event analyses, which, identified, nine recommendations. However, the provider had not developed an action plan to address the recommendations of the review.

Are surgery services well-led?

Leadership

The leadership team consisted of the two directors of the business who were also the cosmetic doctor/surgeon and the registered manager. In addition, there were a senior administrator, nurse practitioners and receptionists. Staff we spoke with told us the leadership team were highly visible, open and approachable. Staff said they met regularly with them to discuss service related issues, however, this was not a formal documented discussion.

During all of our inspections, the provider repeatedly asked CQC to tell them what they should do to 'fix' the concerns we identified and told us they 'would do it'.

During this period from September 2019 to January 2020 we were concerned that the provider did not understand their responsibilities as a registered provider in line with the Care Quality Commission (Registration) Regulations 2009, specifically Regulation 4 which highlights that the provider is responsible for carrying on the regulated activity. In addition, the registered manager did not demonstrate that they fully understood their responsibilities in carrying on or managing the regulated activity and that services provided met the standards required in the regulations.

09 December 2019 inspection

Surgery

During the inspection on 27 September 2019 there were concerns identified about the levels of sedation patients had been receiving during the procedures. The cosmetic doctor who was also the centre's surgeon and provider told us they were not responsible for the practises of the anaesthetists however when we asked about the responsibility as the registered provider they struggled to answer this.

Governance

We were not satisfied that the service had appropriate systems to improve service quality and safeguard high standards of care. Where policies and procedures had been written these were not service specific and contained information which was not relevant for this provider or the services they offered.

09 December 2019 inspection

At our previous inspection we found there was a lack of policies and procedures to support staff at the centre. The provider had employed a governance lead to support them to get policies and procedures in place and told us all polices were now in date. Of the policies we reviewed at this inspection we could see no dates on the documents or any indication as to when the policies were due for review or where they had been ratified.

The provider had identified the need to develop new pre-assessment documentation and was in the process of writing this based on a policy from another provider.

At this inspection the provider had written a transfer of critically ill adult patients policy. When we reviewed the policy, we found it did not relate to the service or facilities this provider offered. For example, the policy stated "If the problem is lack of staffed ICU (intensive care unit) beds, ascertain whether any patient can be managed elsewhere in the hospital (decision to be made by ICU/HDU Consultant)." The centre did not offer inpatient facilities and there was no ward or intensive care unit and all patients were day cases only so this was not relevant to the services offered at this location

The policy further stated that "Ventilators must have disconnect and high-pressure alarms and must provide PEEP. Oxygen concentration, inspiratory: expiratory ratio, respiratory rate and tidal volume must all be adjustable. Pressure controlled ventilation, pressure support and CPAP may also be useful in certain cases." The provider did not have ventilators on the premises as all patients who had procedures at this service had either conscious sedation or local anaesthetic, there were not the facilities for planned procedures under general anaesthetic.

We wrote to the provider on 12 December 2019 under Section 64 of the HSCA 2008 and told them they must provide us with required information and documentation in relation to infection prevention and control. The provider sent us a policy for the cleaning and disinfection of surgical equipment which had been written following our inspection on 09 December 2019. This policy detailed how staff would and should clean equipment at the centre to comply where possible with HTM guidance. Within the provider's response they stated, "We are currently arranging outsourcing of sterilisation and decontamination services to comply with latest regulations". However, this HTM guidance was first published in 2013 and updated in 2016 which meant the provider had not kept up to date with best practice or put in place mitigating actions in reducing the risk to patients.

The provider sent minutes of a meeting where health & safety, infection control spot audit report results were discussed on 05 July 2019. There was little detail regarding the actual results and just a broad statement in the summary of results section which stated "The audit identified that the checklists provided are a useful tool to ensure monitoring of checks are performed and recorded. This should ensure that the clinic is a safe, clean environment, operating with well trained and informed staff who are assured of appropriate equipment in the expected location in the event of an emergency." However, this report did not identify the concerns we found at inspection regarding non-compliance with HTM guidance, the lack of policies and procedures, the sterilisation of equipment or that clinical rooms had carpeted flooring.

The learning from this audit was identified as "This audit displays compliance with our statutory requirements and gives evidence as no accidents /incidents have occurred. Patients have benefited from medical professionals performing treatments in a safe environment." Furthermore this demonstrates that the registered provider and registered manager have little insight into relevant guidance and regulations to ensure people receive safe, high quality care.

02 January 2020 inspection

The consultant anaesthetists had undertaken an audit of all 31 operation records to review the quality of the records. For the years 2018-19 it showed that end tidal carbon dioxide monitoring and sedation levels were only documented in 23% of records. There was an associated action plan for the audit which stipulated that "all procedures must use end tidal carbon dioxide monitoring, implement a modified Ramsey sedation scale during all procedures (8-point scale), and the sedation record has been amended to prompt the documentation of sedation scores". Whilst this is a good example of learning from audit and putting actions in place to mitigate this, this was limited to a very small area of practice

The provider told us there was no tolerance for poor documentation, however, there was no audit of clinical records for any other nursing or medical staff in the centre despite poor pre-assessment and documentation in patient records first being identified in the inspection on 27 September 2019.

We reviewed the newly developed patient pathway documentation, which was intended for use from the initial consultation through to final post-operative review. We found this did not reflect the services provided at the centre, in addition were shown separate nursing documentation. We were told documentation audits were planned, however, we were not shown a formal audit plan.

We reviewed policies with the registered manager which had been supplied to CQC following the 09 December 2019 inspection. The transportation of a critically ill adult policy had not been amended and remained the current policy. The registered manager told us this policy had been adopted from another clinic. The policy included references to wards, an intensive care unit and the resident medical officer (RMO) which the provider did not have in this service. When we highlighted this with the registered manager, they could not explain why this detail was included in the policy and acknowledged the lack of relevance to ABC They told us they would review the policy to ensure it pertained to this location.

Within the management of the deteriorating patient escalation policy dated 06 December 2019 we found the policy did not identify at which point (NEWS score) an ambulance would be called. The registered manager acknowledged this and suggested that a NEWS threshold of 3-5 would be the cut off, however, this would need to be discussed within the team. This meant we could not be assured that the provider had robust system and processes in place to manage deteriorating patients.

Following the significant event analysis for the serious incident in March 2019 the provider had commissioned an independent review which had made nine recommendations which included undertaking routine audits, develop explicit inclusion, exclusion criteria and to consider a formal rotation of clinicians across one or more centres of excellence. We found at this inspection the explicit criteria had not been actioned as the admission and exclusion policy was not detailed at present.

We reviewed the medical advisory committee (MAC) minutes for March, May and September 2019. We found there were no terms of reference or definition of quoracy. We found the registered manager and the surgeon were present at all meetings however, there was also a Nurse or anaesthetist present. We were told meetings were usually arranged when staff were attending for theatre lists, which meant all staff employed by or who had practicing privileges had all attended a MAC meeting since March 2019. In addition the minutes we reviewed were focused on the two incidents which had taken place, there was minimal evidence of improvement and discussion.

Managing risks, issues and performance

During our inspection we found there was inadequate monitoring of patients who were being given a combination of agents in high doses with an increased risk of respiratory depression, in an environment that was not fully equipped to deal with patient deterioration.

09 December 2019 inspection

There were no robust out of hours arrangements in place should a patient require medical attention. The surgeon told us they were on call 24 hours a day but if the surgeon was not available (they provided services in other areas of the country) they would contact a surgical colleague to provide adhoc medical advice. The surgeon told us they would ask an orthopaedic surgeon to provide this cover. However it was not clear how the provider ensured these doctors had the skills, knowledge and experience to care for patients who had undergone a cosmetic procedure.

The provider told us they had a service level agreement with an NHS hospital trust that if they required a bed for a

patient the surgeon had admission rights to the hospital. This agreement had been made in 2009 and had not been reviewed since then. The provider had no assurance this agreement was still valid.

We asked the provider how they monitored patient outcomes, we were told the complication rate was monitored but the provider could produce no evidence to support this statement. The provider confirmed they did not monitor surgical site infections. In 2013 the GMC produced good medical practice guidance which all doctors registered with GMC are expected follow, this states doctors should "take part in regular reviews and audits of your work and that of your team, responding constructively to the outcomes, taking steps to address any problems and carrying out further training where necessary." In addition, in 2016 the GMC produced additional guidance for doctors who offered cosmetic interventions. Within this guidance it states that "Doctors should routinely monitor patient outcomes, and audit your practice, reporting at least annual data." Furthermore CQC have also produced guidance which states how providers can meet the regulations of the HSCA, specifically for regulation 17 good governance, it states that "To meet this regulation; providers must have effective governance, including assurance and auditing systems or processes. They must assess, monitor and drive improvement in the quality and safety of the services provided, including the quality of the experience for people using the service."

At this inspection the provider told us there were plans to introduce robust audits but there was no evidence of progress on this since the inspection in 2017 when issues relating to governance were first raised or the September 2019 inspection. This meant the provider was not meeting the requirements of either the HSCA or professional standards as a registered Healthcare professional.

02 January 2020 inspection

At this inspection the provider informed us they had developed an out of hours standard operating procedure (SOP). This SOP identified should a patient experience a complication and was within 50 miles of ABC, the provider would open the centre as long as they were able to get anaesthetic and scrub cover. Should the patient be over 50 miles from the centre the patient would be advised to attend their local accident and emergency department. The surgeon advised they would not undertake any procedure at Aesthetic Beauty Centre for the three days prior to them attending other clinics. Outside of these times the registered manager was available, however, there was not local medical cover available.

There was no provision should a patient be slow to come round following sedation. There were no robust plans or arrangements should a patient require transfer as the provider did not have any provision for patients to stay overnight. The surgeon informed us they had been in contact with colleagues at local NHS trusts to arrange for the transfer of patients if required, however, this had not been formalised through a service level agreement (SLA). The surgeon informed us a SLA was not required as ". other private hospitals don't have this in place for the transfer of patients". However, we are aware this is not the case, this further demonstrates the management team lack a full understanding of the governance and management required of an independent provider.

The provider told us they planned to limit procedures to a maximum time limit which would be 90 minutes with 120 minutes as an exception. Any procedure that would last longer than this was to be undertaken at by the surgeon at another provider location. The conditions of registration for this location stipulate that only minor procedures can be undertaken using sedation or local anaesthetic. The provider told us by reducing the time of procedures this would reduce the amounts of sedation and local anaesthetic required. However, they could not explain how they felt the time limit on procedures would mean that they would comply with these conditions of registration.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Regulation 12

The provider must meet national infection prevention and control best practice guidance.

The provider must have documented evidence of annual ventilation validation of the air flow in the theatre environment

The provider must comply with regulations regarding the transport of contaminated surgical instruments.

The provider must undertake scrub observations, competencies and audits of all staff members who work and scrub in theatre.

The provider must ensure there is robust provision of out of hours care, by professionals who have to right skills knowledge and competence to work in the environment.

The provider must ensure robust policies and procedures which are appropriate to the environment in the event of patient deterioration.

The provider must ensure formal service level agreements are in place in the event a patient require overnight observation.

Regulation 15

The provider must ensure the environment meets the requirements of HTM (01/01) guidance in terms of Infection prevention and control.

Regulation 17

The provider must undertake a retrospective audit of all consultation, admission and nursing records to identify area's of improvement.

The provider must develop an annual audit plan to include but not limited to record keeping, infection prevention control and patient outcomes.

The provider must ensure they are aware of their full responsibilities in meeting the standards required by the HSCA regulations

The provider must ensure all policies and procedures are aligned and appropriate to the environment at the aesthetic beauty centre.

Regulation 19

The provider must ensure all doctors with practicing privileges working at the centre, have the right skills, knowledge and competence to work in the environment.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The recovery environment did not meet infection prevention and control best practice in line with national guidance. The scrub sink in the theatre was not suitable for a full surgical scrub. In addition scrub observations were undertaken of nursing staff, however, there was no observation of medical staff and their scrub technique. The provision of out of hours care was not robust. We were not assured a patient who required urgent treatment, when the surgeon was operating at other locations would receive care from medical professionals who would have the appropriate skills and competence.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment The ventilation system had not been tested in line with national guidance, therefore we could not be assured the air exchange in the theatre environment was safe and effective. The provider had transported contaminated instruments inappropriately and without a licence as dictated by regulations.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Patient risk assessments were not always completed and updated in line with best practice. Operation notes were not recorded on appropriate documentation for their purpose. Because of this they were difficult to find and not easily legible. We found evidence of inappropriate monitoring in patient records. This meant patients were not always monitored appropriately during procedures, this meant the provider would not be able to and did not identify patient deterioration in a timely manner. Policies within the service did not reflect the environment, for example, they mentioned roles which were not in place within the service and the deterioration policy did not identify when the provider would call for emergency services support. There was no audit of pre-operative risk assessments to ensure these were thorough and complete. There was an action plan in place to improve the sedation records, however, this did not include pre-assessment or nursing documentation. The leadership team were unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations.

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed We found evidence of occasions where Doctors had undertaken sessional work without the appropriate prior checks being completed.