

Zenith Cosmetic Clinic

Quality Report

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

Overall summary

Zenith Cosmetic Clinics Limited operates Zenith Cosmetic Clinic and a satellite clinic in London. The clinic provides cosmetic surgery and other cosmetic treatments to people over the age of 18 years.

The clinic does not have in-patient beds, patients are treated on a day surgery basis. Facilities include one operating theatre, a two bedded recovery room for the recovery of patients who undergo general anaesthesia and one treatment room for minor surgical procedures such as mole removal. There are several other treatment rooms within the clinic where a variety of cosmetic treatments are performed.

We inspected the clinic using our comprehensive inspection methodology. We carried out an announced inspection on 10 and 11 October 2016.

Zenith Cosmetic Clinics Limited is registered to provide services in slimming clinics but we did not inspect this regulated activity during this inspection.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well led? Where we have a legal duty to do so we rate service 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 do not currently have a legal duty to rate cosmetic surgery services or the regulated activities they provide but we highlight good practice and issues that service providers need to improve.

We found the following areas of good practice:

- The provider had a system in place for the identification and management of incidents.
- The clinic was visibly clean and had processes in place to reduce the risk of infection.
- Staff and patient records were accurate, complete, legible, up to date and stored securely.
- Staff had attended statutory and mandatory training.
- Patients had a full assessment prior to surgery.
- There were adequate numbers of nursing and medical staff to care for patients.
- Policies, procedures and practice incorporated evidenced based care and treatment.
- Pain management was effective.

Summary of findings

- Patients had access to food and drinks.
 - Staff displayed competencies to carry out their duties, worked well together as a team and had access to the information they needed.
 - Consent processes were effective and patients received enough information to make an informed decision about their procedures.
 - Staff treated patients with care and respect and maintained their dignity at all times.
 - The clinic carried out an annual patient survey and patients surveyed reported high levels of satisfaction.
 - Patients received adequate information throughout their care.
 - Chaperones were available.
 - The date of surgery was planned to suit the patient
 - Admission and discharge procedures were clear and patients were contacted following surgery, seen one week post-surgery and were given emergency phone numbers.
 - The clinic catered for individual patient needs.
 - The provider managed complaints effectively.
 - The clinic had a clear vision and strategy.
 - There was a governance structure and meetings took place.
 - The provider identified risks and documented mitigating actions.
 - The clinic kept a local register of cosmetic implants.
 - There was an effective system in place to ensure that an annual review took place of consultant practicing privileges.
 - Leaders were visible and staff told us they had supportive managers.
 - Systems to monitor deteriorating patients were not used throughout the patient journey.
 - Medicines management procedures were not fully implemented including the lack of an antibiotic formulary for antibiotic prescribing. We found some medicines not stored securely
 - The provider did not have a Home Office licence for the storage of controlled drugs.
 - The theatre doors and the exit door adjacent to the theatre were not secure.
 - Clinical governance meetings were not robust.
 - Governance processes around policies and procedures were not effective.
 - There was no documented evidence of legionella flushing procedures.
 - The provider did not audit staff hand hygiene.
 - The provider had insufficient hand cleansing gel in the theatre and recovery areas.
 - We found open sterile equipment on the resuscitation trolley.
 - The scrubbing sink in theatre did not follow Department of Health best practice guidance HBN26.
 - Pre-operative assessment did not include a psychological risk assessment.
 - The safeguarding policy and staff safeguarding training did not cover female genital mutilation.
 - Pre-operative assessments did not include the Association of Anaesthetists of Great Britain and Ireland's risk assessment.
 - The provider had not implemented the Royal College of Surgeons quality patient reported outcome measures.
 - The provider did not submit data to the private health information network and national breast and cosmetic implant register.
 - Patient documentation did not include a record of a two-week 'cooling off' period post consultation.
 - Capacity to consent was not documented in the pre-operative assessment documentation.
- However, we also found the following issues that the service provider needs to improve:
- The World Health Organisation Safer Surgery checklist was not consistently completed by the appropriate person.

Summary of findings

- Cosmetic surgical procedures were not being coded in line with the systemized nomenclature of medicine clinical term.

Following this inspection, we told the provider that it should take some actions, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North of England)

Summary of findings

Our judgements about each of the main services

Service

Surgery

Rating Summary of each main service

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

Overall surgical services at the clinic kept people safe from avoidable harm although there were some areas we identified for improvement.

Surgical services were effective, but the clinic needs to submit data as required by the NCBIR and PHIN and pre-operative assessment could be improved.

Patients were satisfied with the care and treatment they received.

Care was individualised around patient expectation and patient convenience. However, there were no patient selection criteria in place.

Leaders were visible with good management processes in place but governance processes and meetings were not robust.

Summary of findings

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Location name here

Services we looked at

Surgery

Summary of this inspection

Background to Zenith Cosmetic Clinic

Zenith Cosmetic Clinics Limited operates Zenith Cosmetic Clinic. The clinic opened in 2010. It is a private clinic in Nottingham. The clinic primarily serves the communities of the East Midlands. It also accepts patient referrals from outside this area. The clinic is open between 9am and 6.30pm Monday to Saturday. The theatre is operational for surgical procedures approximately one day per month.

A registered manager has been in post at the clinic since 2010.

The clinic also offers cosmetic procedures such as dermal fillers, slimming services, laser hair removal and cosmetic dentistry. We did not inspect these services.

Zenith cosmetic clinic is registered to provide the following regulated activities:

- Surgical procedures
- Treatment of disease, disorder or injury
- Services in slimming clinics

The hospital's senior management team consists of the clinic director who is also the registered manager supported by the clinic manager and medical director. The medical director is the nominated individual.

Our inspection was part of our ongoing programme of comprehensive independent health care inspections. We inspected the hospital on 10 and 11 October 2016 on an announced visit.

We inspected the core service of surgery, at the Zenith Cosmetic Clinic Nottingham, which also incorporated the consultations patients had with their surgeon prior to and after their operations.

The clinic was last inspected in February 2014 using the old inspection methodology and no significant issues were identified.

Our inspection team

The team that inspected the service comprised Julie Knott CQC lead inspector, one other CQC inspector and a specialist advisor with expertise in plastic surgery

Information about Zenith Cosmetic Clinic

Zenith Cosmetic Clinic Nottingham provides cosmetic surgery for self-funding/self-referred patients. The clinic provides cosmetic surgery and other cosmetic treatments to people over the age of 18 years.

The clinic does not have inpatient beds, patients are treated on a day surgery basis. Facilities at Zenith Cosmetic Clinic include one non laminar flow operating theatre, a two-bedded recovery room for the recovery of patients who undergo general anaesthesia and one treatment room for minor surgical procedures such as mole removal. There are several other treatment rooms

within the clinic where a variety of cosmetic treatments are performed. These treatments do not require registration with the Care Quality Commission (CQC) as such we did not look at these during our inspection.

Surgical procedures carried out at the clinic include breast augmentation (artificial enlargement of the breasts), otoplasty (surgery to restore or enhance the appearance of the ears), rhinoplasty (surgery to straighten the nose), blepharoplasty (surgical repair or reconstruction of the eyelid/s), liposuction, tummy tuck, gastric bands and dimple creation. The clinic only accepts medically fit patients.

Summary of this inspection

During our inspection, we visited the operating theatre. We observed the care of two patients in the recovery area and during operative procedures in theatre. We spoke with 13 staff including medical staff, agency staff, managers, clinical staff and administrative staff; we spoke with two patients. We also received three 'tell us about your care' comment cards, which patients had completed prior to our inspection. During our inspection we reviewed ten sets of patient notes. Before our inspection, we reviewed performance information from and about the service.

Between June 2015 and June 2016, 30 patients underwent an invasive surgical procedure. Our inspection focuses on the care quality experienced by these patients.

Four surgeons and one anaesthetist worked at the clinic under practising privileges. The Clinic employed 0.5 whole time equivalent (WTE) registered nurses, 1.5 WTE operating department practitioners plus receptionists, cosmetic therapists and administrative staff. The officer accountable for controlled drugs (CDs) was a registered nurse.

Track record on safety

- No never events
- Three clinical incidents resulting in no harm
- No serious injuries
- No incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA),
- No incidences of hospital acquired Methicillin-sensitive staphylococcus aureus (MSSA)
- No incidences of hospital acquired Clostridium difficile (c.diff)
- No incidences of hospital acquired E-Coli
- Seven complaints

Services provided at the hospital under service level agreement:

- Clinical and non-clinical waste removal
- Maintenance of medical equipment
- Pathology and histology
- Pharmacy

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

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

We found the following areas of good practice:

- The provider had systems in place for managing incidents.
- The clinic was visibly clean and had processes in place to control infection.
- Staff and patient records were accurate, complete, legible, up to date and stored securely.
- Staff had attended statutory and mandatory training.
- Patients had a full assessment prior to surgery.
- There were adequate numbers of nursing and medical staff to care for patients.

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

- There were no documented legionella flushing procedures. Although the provider told us this took place.
- There were no audits of staff hand hygiene.
- There was a lack of cleansing hand gel in the theatre and recovery areas.
- The theatre door and the doors adjacent were not secure, during inspection we found the exit door unlocked and the theatre door not closed properly.
- There were opened items on the resuscitation trolley even though it was checked regularly.
- The scrubbing sink in theatre did not follow Department of Health best practice guidance HBN26.
- We found some medicines not stored securely.
- The provider did not adhere to Home Office requirements for the management of controlled drugs.
- There was no psychological risk assessment in the pre-operative assessment.
- Application of the WHO Safer Surgery checklist was inconsistent
- Systems to monitor deteriorating patients were not used throughout the patient journey.
- The provider did not submit implant data to the national breast and cosmetic implant register.
- There were no antibiotic formularies in place.
- Staff safeguarding training or procedures did not include information on female genital mutilation.

Summary of this inspection

- The pre-operative assessment did not include the association of anaesthetists grade risk assessment

Are services effective?

We found the following areas of good practice:

- We saw that evidence based care and treatment was incorporated into policies, procedures and practice.
- Anticipatory pain relief was given and pain was managed well, patients had access to food and drinks.
- Staff were competent to carry out their duties, worked well together as a team and had access to the information they needed.
- Consent processes were effective and patients received enough information to make an informed decision about their procedures.

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

- The provider had not implemented the Royal College of Surgeons quality patient reported outcome measures.
- The provider was not submitting data to the private health information network
- A two week 'cooling off' period was not recorded in patient documentation
- Capacity to consent was not documented in the pre-operative assessment documentation

Are services caring?

We found the following areas of good practice:

- Patients were treated with care and respect and their dignity was maintained at all times.
- The clinic carried out an annual patient survey.
- Patients were kept well informed throughout their care.
- Chaperones were available.

Are services responsive?

We found the following areas of good practice:

- Services were planned around individual patients, procedure options and patient expectations were discussed at a pre-surgery consultation.
- Admission and discharge procedures were clear and patients were contacted following surgery, seen one week post-surgery and were given emergency phone numbers
- Individual patient needs were catered for.

Summary of this inspection

- Complaints were managed effectively

Are services well-led?

We found the following areas of good practice:

- The clinic had a clear vision and strategy
- There was a governance structure and meetings took place
- Risks had been identified and mitigating actions had been identified.
- The clinic kept a local register of cosmetic implants.
- The clinic had a documented process for annual review of consultants working at the clinic with practising privileges.
- A comprehensive range of policies and procedures were in place.
- Leaders were visible and staff told us they were well supported by their managers.
- Patients surveyed showed high levels of satisfaction
- The clinic embraced new technologies

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

- Clinical governance structures and meetings were not robust.
- The provider did not submit data to the private health information network
- The provider did not submit implant data to the national breast and cosmetic implant register.
- Policies and procedures did not follow a consistent format and some contained irrelevant information and reference to other organisations.
- Cosmetic surgical procedures were not being coded in line with the ‘
- Leaders did not seem aware of the Royal College of Surgeons developments in standards and practice of cosmetic surgical procedures.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

Incidents

- The clinic reported zero never events.
- The clinic recorded three clinical incidents between July 2015 and June 2016. All of these were no harm incidents. There were zero non-clinical incidents recorded in the same period.
- Staff told us they were aware of the incident reporting process, we saw that incidents had been reported according to procedure and investigation reports detailed any learning and action to be taken.
- There was an effective system in place for the distribution of alerts from the central alerting system in relation to medical equipment. Staff told us about a recent alert they had actioned.
- Mortality and morbidity meetings did not take place but managers told us they would hold extraordinary meetings if necessary and information would be cascaded to staff by e-mail, staff meetings or clinical meetings.
- Staff told us they were aware of the duty of candour and had attended a duty of candour training session.

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

- The clinic did not have a clinical quality dashboard but monitored safety through the clinical governance meeting, audit and review of patient feedback and incidents.

Cleanliness, infection control and hygiene

- The clinic had a yearly legionella risk assessment carried out by a third party company. The results from October 2015 showed that the clinic was legionella free. Staff

told us they regularly flushed all water outlets; however, we did not see documentation to confirm this.

Legionella is a bacterium that causes legionnaires disease; it can flourish in water systems.

- Protective equipment, such as gloves and aprons, was available and we observed staff using this when required.
- We observed staff following guidance when scrubbing, gowning and gloving prior to surgical interventions. This minimised the infection risk.
- We did note that the scrubbing sink was in the corner of the theatre area, which posed challenges to staff. Due to the confined space in theatre, the scrubbing could interfere with surgical set up and circulation. The sink and tap were within a recess that made scrubbing to the elbow difficult without water dripping to the operating theatre floor. Gowns and gloves were setup concurrently with surgical sets using the same platform, which had a potential contamination risk.
- Staff were 'bare below the elbows' which meant their forearms were free from clothing and jewellery to allow effective hand washing.
- Cleansing hand gel was not always visible in the areas we visited, for example, we did not see it at the entrances to recovery, theatre or treatment rooms. We did not see posters displayed encouraging staff and visitors to cleanse their hands. However, we observed staff washing their hands between patients in line with the World Health Organisation's 'five moments for hand hygiene'. Sinks were available in the treatment rooms, recovery and theatre to allow effective hand hygiene.
- The clinic had an infection control policy and we observed staff adhering to this.
- The clinic carried out quarterly infection control audits; we saw the audit for October 2016. Actions had been identified such as the installation of battery operated hand gel dispensers. Infection control was discussed during staff meetings.

Surgery

- Staff hand hygiene was not audited.
- The theatre, recovery area and treatment rooms were visibly clean and tidy.
- Staff said theatres received a “deep clean” the day before any planned surgery. The theatre was also cleaned on the day of surgery and between each patient. Cleaning schedules we reviewed confirmed treatment rooms were cleaned daily.
- The theatre had a suitable air filtration system. We saw evidence the filtration system was regularly maintained, cleaned and tested.
- The clinic reported no incidence of Methicillin-Resistant Staphylococcus Aureus (MRSA), Clostridium Difficile (C. Difficile) or Methicillin-Sensitive Staphylococcus Aureus (MSSA) in the reporting period between July 2015 and June 2016. MRSA, MSSA and C.Difficile are all infections that have the capability of causing harm to patients. MRSA is a type of bacterial infection and is resistant to many antibiotics. MSSA is a type of bacteria in the same family as MRSA but is more easily treated. C.Difficile is a bacterium affecting the digestive system; it often affects people who have been given antibiotics.
- Screening for MRSA took place routinely as part of the pre-operative assessment. Records we reviewed demonstrated this was routine practice.
- The clinic was compliant with National Institute for Health and Care Excellence (NICE), Clinical Guideline 74 Surgical site infections: prevention and treatment, for example changing into surgical scrubs and theatre caps was a requirement of all staff and visitors to theatre, when a procedure had commenced, movement in and out of theatres was restricted. This minimised the infection risk. There were no reported surgical site infections between July 2015 and June 2016.
- We saw staff adhering to procedures in line with national guidance to minimise the risk of infection to patients undergoing surgical procedures, for example, skin preparation and the use of sterile drapes.
- We observed vascular devices being inserted correctly in the sterile theatre area and removed as soon as possible to minimise the risk of infection following NICE guidance.
- Processes and procedures were in place for the management, storage and disposal of general and clinical waste, disposal of sharps such as needles and environmental cleanliness.

- A service level agreement was in place with a local acute trust for the decontamination of reusable medical devices.

Environment and equipment

- Systems were in place to secure access to theatre however, on two occasions during our inspection we found the theatre door unsecured; this meant there was a risk of unauthorised access.
- In addition, the theatre was located on the ground floor adjacent to an unlocked exit door. We escalated these findings to the theatre manager who secured the doors straight away and assured us he would discuss this with staff to make sure it would not happen again.
- The resuscitation equipment had been checked prior to each surgical list and we found emergency equipment had been serviced.
- We found two opened single-use items on the top of the airway trolley, we were unsure how long these had been open, and therefore these items were not suitable for use. We escalated this to a member of the theatre staff at the time of our inspection. All other items were sealed and in date.
- An operating department practitioner (ODP) and anaesthetist checked the anaesthetic machine and equipment prior to each theatre list in line with Association of Anaesthetists of Great Britain and Ireland (AAGBI) guidelines. The anaesthetic machines and equipment were in working order and safe to use. There were records of the anaesthetic machine checks; however, we did not see a recorded check for the 20 September 2016 when the theatre had been in use. We discussed this with the theatre manager, who informed us the wrong date had been recorded in book. The remaining cases in the theatre register correlated to the anaesthetic machine checks carried out.
- There was difficult intubation kit in theatre. This was safe and ready for use in an emergency. Intubation is the placement of a flexible plastic tube into the trachea (windpipe) to maintain an open airway.
- There was no piped oxygen or suction in the theatre and recovery areas, both areas were reliant upon portable oxygen cylinders, which were attached to the recovery trolleys and the anaesthetic machine. We saw a good supply of oxygen was immediately available and appropriately stored.
- Fire-fighting equipment had been maintained and tested.

Surgery

- There was an effective arrangement for a third party company to service and maintain all medical equipment such as vital sign monitoring machines. Vital signs are the most important signs that indicate a body's status such as pulse and blood pressure.
- Random checks of seven pieces of equipment across theatres and recovery showed equipment had been routinely checked for safety. Stickers were present indicating when the next test was due. Equipment checked included infusion pumps, blood pressure and cardiac monitors.
- Theatre staff maintained a register of breast implants; this ensured detail could be quickly provided to the health care product regulator if required. Implants used by the clinic bore the CE mark (the symbol for European conformity) which meant they had approval of the MHRA.
- Intravenous fluids (IV) were mostly stored appropriately; however, we did see two bags of fluid in an unlocked cupboard.
- Although the clinic did use antibiotics they did not have any antibiotic protocols in place.
- We saw records of daily checks of the fridge temperatures which were up to date.
- The clinic carried out a monthly audit of controlled drugs management. We saw the audits for May, June and July 2016 and no issues were identified.
- Medical gases such as oxygen were stored in appropriate storage trolleys or holders.
- The clinic dispensed take home medications for patients following surgery, this included simple painkillers and antibiotics.
- Service level agreements were in place with two local pharmacies for the supply of medicines.

Medicines

- We reviewed the medicines management policy, which at the time of the inspection was missing information in several key areas. We informed managers about the omissions and they subsequently revised the policy appropriately.
- On the day of inspection, we found controlled drugs were checked twice weekly, prior to and at the end of each theatre list. Stock levels of controlled drugs tallied correctly with the controlled drugs register. Controlled drugs are medicines which are stored in a designated cupboard, and their use recorded in a special register. There was a named accountable officer for controlled drugs.
- However, the clinic did not hold a Home Office licence to hold stocks of controlled drugs. We discussed this with the registered manager who took action with their designated pharmacist to destroy the controlled drugs. The registered manager told us in future controlled drugs would be obtained on a named patient basis only by prescription. A Home Office licence is not required for controlled drugs obtained in this way.
- Most medicines were locked in cupboards and the keys were kept in a locked safe; keys were signed in and out of the key safe. However we found calcium and potassium supplement medication stored in an unlocked store cupboard in the basement. This meant there was a risk of unauthorised access.

Records

- We reviewed ten sets of patient records. All were accurate, complete, legible, up to date and stored securely. These held details of all cosmetic procedures performed at the clinic.
- The clinic had comprehensive preoperative documentation which contained risk assessments such as a malnutrition screening tool, deep vein thrombosis risk assessment, pressure area risk assessment, manual handling risk assessment and general health assessment including questions about previous anaesthetics. Patients also completed a health questionnaire prior to their pre-operative assessment. Patients' notes we reviewed showed these risk assessments had been fully completed.
- The clinic had an 'access to medical records policy' which gave clear guidance to staff on what to do if there was a request by anyone other than the patient for access to medical records.
- A new electronic patient record system had been introduced earlier in the year. At the time of our inspection, this was being used in addition to the paper records for information such as appointments and financial information.
- Photographs of the patient were only taken with their permission and stored in the password protected, electronic patient record.
- The clinic did not archive medical records off site but did have a process in anticipation of this being necessary at some point in the future.

Surgery

Safeguarding

- There was a safeguarding policy and procedure, which also included guidance on safeguarding children. The policy included appropriate local contacts for staff to call for example, the child protection national helpline and local child protection team.
- The safeguarding policy did not include information on female genital mutilation (FGM) and staff demonstrated a poor awareness of FGM.
- The medical director was the lead for safeguarding.
- There were no safeguarding concerns reported to CQC between July 2015 and June 2016.
- Eighty three per cent of clinical staff had attended adult and child safeguarding training in the past twelve months. That is five out of six staff. The sixth member of staff was new to the organisation but had attended recent safeguarding training in their previous job.

Mandatory training

- Mandatory training included fire safety, health and safety, infection control, basic life support, safeguarding level one children and adults and first aid at work.
- At the time of our inspection, 13 out of 17 members of staff had attended all mandatory training modules. A rolling programme of training was in place to ensure that all staff had attended all mandatory training modules within the provider's timescales.
- Details of attendance at mandatory training were documented in the three sets of staff notes we reviewed.

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

- The clinic managers told us they did not have a defined list of admission criteria however, they did not accept patients for surgery unless they were medically fit. The preoperative documentation contained risk assessments such as a malnutrition screening tool, deep vein thrombosis risk assessment, pressure area risk assessment, manual handling risk assessment and general health assessment including questions about previous anaesthetics. If there was any concern about a patient's suitability for surgery the pre-operative assessment nurse could contact the anaesthetist for advice.
- The nurse at pre assessment did not assess the American Society of Anaesthesiologists (ASA) grade. This was assessed by the anaesthetist on the day of surgery

therefore, there was the potential that a patient may arrive for surgery and be deemed unfit on the day. The ASA is a system used for assessing the fitness of a patient before surgery and is based on six different levels, with level one being the lowest risk. The hospital only undertook procedures for patients graded as level one.

- There was no formal psychological assessment of the patient but the consultant told us he included this in his overall assessment at the pre surgery consultation. There were no pre surgery consultations on the day we inspected. It is a requirement of the Royal College of Surgeons that this key aspect of consultation identifies any patients who are psychologically vulnerable and they are appropriately referred for assessment.
- The clinic maintained a list of patients who had been deemed unsuitable for treatment; we saw the list which included reasons of a psychological nature.
- The World Health Organisation (WHO) Surgical Safety Checklist was in place; however this was not followed consistently. The checklist is a process recommended by the National Patient Safety Agency for every patient undergoing a surgical procedure. The process involves a number of safety checks before, during and after surgery to avoid errors.
- Of the two theatre episodes we observed the anaesthetist and surgeon did not lead on their respective aspects for either case and there was no clear 'sign-in' procedure for the second case. The provider did not audit the use of the checklist.
- Early warning scores were not used throughout the patient journey and an alternative escalation procedure was not in place. Early warning scores have been developed to enable early recognition of a patient's worsening condition by grading the severity of their condition and prompting nursing staff to get a medical review at specific trigger points. However, recovery staff had direct access to the surgeon and anaesthetist at all times whilst the patient was in the clinic.
- A comprehensive peri-operative document was completed for all patients, which included a further pre-operative checklist, intra operative notes, swabs, sharps and instrument count, recovery and discharge. We saw these completed for the two patients whose surgery we observed.

Surgery

- If there was a medical emergency at the clinic either during or after surgery and this required emergency care the clinic used the 999 service to transfer the patient to the local emergency department. The clinic had a resuscitation and cardiac arrest policy.
- Patients were given 24/7 access to their surgeon and anaesthetist before during and following their procedure. Zenith's clinical director was available as further support in case the surgeon or anaesthetist could not be contacted.
- Discharge of patients took place once they fulfilled the discharge criteria in the peri – operative documentation. Patients were discharged with a full course of medication and dressings if required. All patients received a follow up phone call the day after surgery and an appointment to see the nurse at the clinic after one week.

Nursing and support staffing

- There was one whole time equivalent (wte) theatre manager who was an operating department practitioner (ODP) plus an additional 0.5wte ODP.
- There was also 0.5 wte qualified nurse who carried out the pre-operative assessments, follow up phone calls and post-operative checks.
- Due to the low numbers of operating sessions (approximately one per month), agency and bank staff made up the full operating theatre team when required. The theatre and recovery room were staffed to demand.
- On the day we inspected agency staff included, two recovery nurses, one scrub nurse and one health care assistant.
- We saw there was an effective induction of agency staff to the clinic. Documents we reviewed showed that the induction was comprehensive and included orientation of the building, emergency equipment, paperwork, scrub processes and medication.
- We observed a comprehensive handover to the recovery nurse from the scrub nurse about the patient's procedure.

Medical staffing

- At the time of the inspection the clinic had five consultants working with practising privileges.
- The surgeon and anaesthetist were available before, during and following procedures. The provider's clinical director was available as further support in case the surgeon or anaesthetist could not be contacted.

- We observed a comprehensive handover between the anaesthetist, surgeon and recovery staff to ensure the patients' needs were identified and addressed.
- At the time of our inspection, the clinic was working within the recommendations of the 'Association for Perioperative Practice' with regard to numbers of staff on duty during a standard operating list. During our inspection this comprised of one health care assistant, one operating department practitioner (ODP), a consultant, an anaesthetist, scrub nurse and two recovery staff. The theatre manager was working in a supernumerary capacity on the day of our inspection to support staff.

Emergency awareness and training

- Routine fire drills took place, this allowed staff to rehearse their response in the event of a fire.
- The clinic had a backup generator, which was tested regularly. Prior to our inspection, the generator had undergone an annual service.
- We also saw emergency evacuation plans displayed at fire exits informing staff and patients of where to congregate in the event of an evacuation.

Are surgery services effective?

Evidence-based care and treatment

- Senior managers had limited awareness of the Royal College of Surgeons developments in cosmetic surgery and had not started to implement them.
- Surgery at the clinic was carried out on a day case basis. The delivery of day surgery was consistent with the British Association of Day Surgery (BADS). BADS promotes excellence in day surgery and provides information to patients, relatives, carers, healthcare professionals and members of the association.
- We reviewed a range of policies and procedures and witnessed staff adhering to policy and procedure. The theatre policy contained references to the National Institute for Health and Care Excellence, the Association for Peri Operative Practice, the Association of Operating Department Practitioners, the Association of Anaesthetists of Great Britain and Ireland and the Health and Care Professional Council recommendations for best practice and guidance.

Surgery

- Anti-embolism stockings and intermittent pneumatic compression boots were used during surgery to aid prevention of deep vein thrombosis. Deep vein thromboses are blood clots usually in the deep veins of the leg.
- We saw the 2016 audit and survey schedule. The clinic carried out clinical audits four times per year to analyse patient treatments across a range of minor, major surgical and therapist treatments.
- We saw the results of the 2016 surgical audit; issues arising had been shared with staff at clinical governance meetings and staff meetings.

Pain relief

- The theatre care pathway ensured staff enquired about patients' pain and adequate pain relief was given in a timely manner. We saw the anaesthetist ensuring patient's pain would be controlled before waking from anaesthetic by administering pain relief.
- We observed staff regularly reviewing pain in the recovery area post-surgery. If a patient had pain, they administered pain relief and checked this had the desired effect.
- We observed the use of pain assessment scores in recovery to assess the comfort of patients as part of their routine observations. Records we checked demonstrated staff were identifying the patient's level of pain and evaluating the effects of pain relief on a consistent basis.
- We were unable to discuss pain relief with the patients recovering from surgery on the day of our inspection.

Nutrition and hydration

- Pre admission information for patients gave them clear instructions on fasting times for food and drink prior to surgery. Records showed checks were made to ensure patients had adhered to fasting times before surgery went ahead.
- Staff followed best practice guidance on fasting prior to surgery. For healthy patients who required a general anaesthetic this allowed them to eat up to six hours prior to surgery and to drink water up to two hours before.
- We saw the anaesthetist ensuring any nausea or vomiting the patient may experience post operatively would be controlled before waking from anaesthetic by administering anti sickness medications. Records we reviewed showed this was consistent practice.

- Staff offered and encouraged patients to have a light snack and drink prior to discharge from the clinic.

Patient outcomes

- The clinic did not collect Quality Patient Reported Outcome Measures (Q PROMS) or participate in national audits. Q Proms are recommended by the Royal College of Surgeons and involve the patient completing a pre and post-operative satisfaction survey based on the outcome of the cosmetic surgery. Q PROMS are recommended for the following procedures: abdominoplasty, mammoplasty, blepharoplasty, rhinoplasty, and rhytidectomy.
- The clinic had not been submitting data to the Private Health Information Network (PHIN) in accordance with legal requirements regulated by the Competition and Marketing Authority. The PHIN data is a defined set of performance measures and clinical quality indicators that should be collected from January 2016, submitted from September 2016 for publication April 2017. Following our inspection, the registered manager contacted PHIN and started the process of registration and data submission.
- The clinic reported zero cases of unplanned transfer of a patient to another hospital. There were no unplanned readmission within 28 days of discharge and zero cases of unplanned return to the operating theatre between July 2015 and June 2016.

Competent staff

- A qualified nurse at the clinic was registered with the Nursing and Midwifery Council and was in the process of gathering evidence for the revalidation process.
- There was a practising privileges framework used for consultants wishing to practice at the clinic. The clinic director and clinic manager reviewed the practising privileges annually. If there were any concerns about an individual's performance or revalidation process these would be escalated to the medical director.
- We reviewed all the records of the consultants with practising privileges. We saw evidence of up to date revalidation, annual appraisal, General Medical Council (GMC) registration, indemnity insurance, Disclosure and Barring Service checks (to check if a person has a criminal record) immunisation status and relevant training such as mandatory training and cosmetic procedures. Each consultant with practising privileges also had a responsible officer. A nominated responsible

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officer is a requirement of the General Medical Council revalidation process who provides support with appraisal and revalidation. The consultants had a speciality in either plastic surgery or maxillo facial surgery.

- The consultant we spoke with on the day of inspection was aware of the Royal College of Surgeons certification in cosmetic surgery but had not begun the application process. The certification in cosmetic surgery is one of the new initiatives developed by the Royal College of Surgeons.
- We reviewed three staff records. There was evidence of one to one meetings with managers and annual appraisals. Staff told us they had regular meetings with their managers.
- Each member of staff had a training folder. We saw evidence of relevant and up to date training such as cosmetic procedures and duty of candour.
- The theatre manager had produced a competency document to develop the non-registered staff members such as health care assistants. We saw a copy of the document.
- Medical staff and nurses working at the clinic had basic life support training within the last twelve months. Three of the medical staff had advanced life support training.
- Agency staff recruited to work in the operating theatre had scrub nurse skills and surgical first assistant skills.
- Agency staff recruited to work in the recovery room had advanced life support skills.

Multidisciplinary working

- We observed good multidisciplinary teamwork in the theatre and recovery areas. A team huddle took place at the beginning of the theatre session. Comprehensive patient handovers took place between consultants and recovery staff.
- There were good working relationships with other staff in the clinic for example, between the pre-operative assessment nurse and the consultants.
- Clinic staff delivered all follow up care.

Access to information

- All staff had access to the information they needed to deliver effective care and treatment to patients in a timely manner including test results, risk assessments and medical and nursing records.

- Policies and procedure were stored electronically in a shared folder, which made them easy for staff to access.
- Managers told us if patients needed to be admitted to an acute hospital their notes would accompany them as would clinic nursing staff and if necessary the consultant.
- Communication with the patient's GP only took place with the patient's consent.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- Consent was discussed at the pre-operative assessment. Staff adhered to the consent policy which described making sure the patient had sufficient information to make an informed decision and allowing the patient sufficient time to make the decision as recommended by the Royal College of Surgeons. The cooling off period was not formally documented, but staff told us that patients knew they could change their minds and there was usually a minimum of two weeks between the pre-operative assessment visit and the day of surgery.
- Only the consultant performing the procedure could obtain patient consent and this took place on the day of surgery. We saw consent forms completed correctly in patients' notes.
- Staff we spoke with were aware of the Mental Capacity Act 2005 and Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) orders, however the clinic only accepted low risk, medically fit patients for surgical procedures so patients lacking capacity or with DNACPR orders were not treated at the clinic.
- A member of staff told us mental capacity was assessed at the pre-operative assessment but we did not see evidence of this in the pre-operative checklist.

Are surgery services caring?

Compassionate care

- We observed staff introducing themselves when they first met with the patient and again when they were waking from anaesthesia.
- We observed patients remaining covered in the anaesthetic room, operating theatre and recovery area, this meant staff protected patients' dignity. We observed unconscious patients communicated with by nursing and medical staff in a compassionate manner.

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- We observed staff maintained patients' privacy and dignity by using 'do not enter' signs on the cubicle curtains.
- Patients we spoke with told us they felt cared for and they would recommend the clinic to friends and family.
- In the 2016 patient survey question "how would you rate the respect shown to you by the clinician?" 47 out of 52 patients gave the rating of 'excellent' and the remainder were rated as 'good'.

Understanding and involvement of patients and those close to them

- We heard surgeons discussing treatments with patients. The surgeon answered any questions raised.
- Patients received a written detailed quotation of all costs during the pre-surgery consultation, this included blood tests, dressings, drug and anaesthetic costs. Patients signed to say they understood the costs and the quote was valid for 90 days.
- Staff told us patients and relatives were involved in discharge planning to ensure appropriate post-operative caring arrangements were in place.

Emotional support

- We saw staff providing reassurance for patients who were agitated when waking from anaesthesia. This included a nurse spending time with a patient, explaining what the patient should experience and how staff would help and where they were. Staff reassured the patient that the surgery was over and had gone well.
- We observed patients being offered chaperones when examinations were taking place.

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Are surgery services responsive?

Service planning and delivery to meet the needs of local people

- All patients had a free consultation before any treatment took place. This established the patient's motivation and provided them with a range of options regarding the outcomes they desired. This was followed by a treatment plan which outlined the procedures to be undertaken, how these would take place and how they could give feedback to the provider.
- The clinic operated an appointment only system so staffing could be planned well ahead around the expected workload.
- Although the clinic advertised abdominoplasty and bilateral breast reduction they did not carry out these operations on site but referred the patients to another independent healthcare provider who had in-patient services.

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Access and flow

- The clinic managers told us they did not have a defined list of admission criteria however, they did not accept patients for surgery unless they were medically fit. Pre-operative assessment documentation highlighted patients who were not suitable for surgery at the clinic.
- Following our inspection the clinic submitted a document which listed examples of when patients may not be suitable for cosmetic surgery procedures.
- Patients referred themselves to the clinic and appointment times were made according to their preference.
- Patients were greeted at the clinic by reception staff and were seated in the waiting area until they were called by the nurse or consultant.
- Surgeons discussed dates with patients during their pre surgery consultations; this gave flexibility to the patients for deciding when they wished to have their surgery carried out. Patients were usually admitted for surgery within four weeks of their consultation.
- The clinic reported there were no procedures cancelled for non-clinical reasons between July 2015 and June 2016.
- Following discharge home all patients received a follow up call from the clinic nurse. If the patients were having any problems at this stage, the nurse could arrange for them to be seen by a medical practitioner at the clinic or arrange for the consultant to contact them at home.
- Following a surgical procedure, the clinic nurse saw all patients in the clinic one week post-surgery.

Meeting people's individual needs

- We observed patients being offered chaperones when examinations were taking place. However staff acting as chaperones had not received specific training for this role.
- The pre-operative assessment took into account individual needs in relation to language, vision, hearing, age and disability.
- Staff had access to interpreter services if these were required.
- Wheelchair access was available on the lower ground floor.

Learning from complaints and concerns

- The clinic received seven complaints between July 2015 and June 2016. There were no complaints referred to the Ombudsman or the Independent Healthcare Sector Complaints Adjudication Service (ISCAS).
- The clinic had a fully documented complaints procedure. This policy was displayed visibly in reception and was available on-line. The procedure described how a patient should make a complaint and the levels of escalation. Patients were encouraged to provide feedback at any point during their treatment to the clinician involved or the clinic manager.
- We reviewed one completed complaint. We saw that it was managed in accordance with the complaints policy and there was a full record of the complaint investigation, communications with complainant and the outcome. The clinic had amended a treatment protocol following a complaint and we saw evidence of this.
- Learning from complaints took place as part of individual meetings with members of staff or at their quarterly reviews. Managers told us that wider learning took place at staff meetings, clinical meetings and the clinical governance meeting where complaints were discussed.
- We only saw evidence of complaints being discussed at the August 2016 Clinical governance meeting and the management of complaints discussed at one staff meeting in August 2016.

Are surgery services well-led?

Vision and strategy for this core service

- The clinic's vision was to be the most innovative and patient focussed provider of aesthetic care solutions. Their mission was to assist people gain confidence and self-esteem by improving health, wellbeing and appearance.
- The strategy for the clinic was to provide a holistic consultation service to patients, developing a long-term relationship, allied to a five star patient service.
- The clinic's values were integrity, excellence, innovation and holistic care and we saw staff adhering to these values.
- We also saw a copy of the clinic's business strategy 2016, which described the core business structure and marketing plans.

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- There was a clear vision for the theatre, which included increasing activity and redesigning the environment. Some of the works had been carried out prior to our inspection.
- The provider was not ensuring surgical cosmetic procedures were coded in accordance with SNOMED_CT

Governance, risk management and quality measurement (and service overall if this is the main service provided)

- Managers told us the clinic held a bi monthly clinical governance meeting which was their main platform for discussion about risk management and quality measures. However we could not find evidence that this meeting was taking place bi monthly and agenda items did not always cover risk management and quality measures. The meeting lacked terms of reference.
- The clinic was in the process of registering to provide information to the national breast and cosmetic implant registry (BCIR). The clinic kept a local register of cosmetic implants.
- At the time of our inspection the clinic had not begun to collect data to submit to the private healthcare information network (PHIN). The registered manager was unaware of this, but informed us they would look to collect and submit this data. The PHIN data is a defined set of performance measures and clinical quality indicators, which should have been collected since January 2016 and would be published in April 2017. Following our inspection the registered manager informed us they had been in touch with PHIN and had started the process of registration and data submission.
- All the policies and procedures we reviewed had been updated in the last 12 months. However the format of the policies was not consistent and some contained wording relating to other organisations.
- Risk registers were in place for the clinic. Department leaders we spoke with knew and were seen to be managing risk pertinent to their clinical areas.
- A full risk assessment of clinical areas had recently taken place resulting in several items identified on the risk register. The risks were red, amber green (RAG) rated and action had been identified to mitigate the risks with a review date. We saw that some risk actions had been completed. For example, the introduction of a new theatre register.
- Due to the size of the clinic, it did not hold a medical advisory committee (MAC) meeting. Managers told us

that issues normally discussed at a MAC meeting were discussed at the clinical governance meeting. We did not see any evidence of this in the clinical governance meeting minutes.

- The theatre manager was the health and safety lead. The clinic met the requirements of the Health and Safety Executive by carrying out regular risk assessments and raising staff awareness of their responsibilities in health and safety.
- All consultants had a nominated responsible officer and were assessed for their suitability to work at the clinic using the 'application for medical staff appointment and practising/admitting privileges process. This included, revalidation, annual appraisal, GMC registration, indemnity insurance, Disclosure and Barring Service checks (to check if a person has a criminal record) immunisation status and relevant training such as mandatory training and cosmetic procedures.
- Managers told us service level agreements were in place for example with pharmacy, a local acute hospital for blood tests and waste disposal. The clinic director was responsible for overseeing the service level agreements.

Leadership / culture of service related to this core service

- There were some gaps in the leadership understanding of key areas such as clinical governance, female genital mutilation, PHIN and SNOMED data and the requirements around controlled drugs.
- There was a clear organisational structure and staff were aware of who their manager was and told us they felt supported by their manager.
- The clinical managers had the experience, capacity and capability to lead the service and prioritised safe, high quality compassionate care.
- We saw the blame free culture policy and the equality and diversity policy.

Public and staff engagement

- The clinic did not carry out a staff survey.
- The clinic carried out annual patient satisfaction surveys. In the patient survey for 2016, 87% of questions scored excellent (for example, 'The respect shown to me by this clinician was', 'The clinician's explanations of things to me were') that is 590 out of 676 questions.
- Patients completed three Care Quality Commission comment cards prior to our inspection. All three contained positive feedback about the service.

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Innovation, improvement and sustainability (local and service level if this is the main core service)

- The company was investing significantly in improving the theatre environment. There were plans for building work to create improved first and second stage recovery areas.
- The clinic uses ultrasound-assisted liposuction, techniques.
- Managers demonstrated a lack of awareness about new initiatives in cosmetic surgery practice which limited the opportunity to innovate and improve.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should ensure they keep documented records of legionella flushing.
- The provider should consider auditing personal hand hygiene.
- The provider should consider the placement of hand sanitisers.
- The provider should review the access arrangements in and around theatre to minimise the risk of unauthorised access.
- The provider should ensure the scrubbing sink in theatre meets Department of Health best practice guidance HBN 26.
- The provider should ensure there is an effective system in place for the proper and safe management of medicines, to include local microbiology protocols for the administration of antibiotics.
- The provider should consider how it meets the Home Office standards for the storage of controlled drugs.
- The provider should consider how it meets the Royal College of Surgeons key aspect of consultation guidelines in relation to patient psychological assessment.
- The provider should ensure staff are fully complying with the WHO Safer surgery checklist.
- The provider should introduce a system for monitoring the deteriorating patient.
- The provider should consider how it would submit implant data to the national breast and cosmetic implant register.
- The provider should ensure compliance with the multi-agency practice guidelines for female genital mutilation.
- The provider should ensure they comply with the data collection and submission criteria for the private health information network.
- The provider should ensure practices for gaining patient consent comply with the RCS Professional Standards for Cosmetic Surgery including the requirement for a two-week cooling off period.
- The provider should ensure the frequency, membership, agenda items and terms of reference for the clinical governance meeting, clinical meeting and staff meetings are fit for purpose. .
- The clinic should consider reviewing all policies and procedures for accuracy, format and consistency.
- The clinic should ensure that all policies and procedures are fully embedded into day-to-day practice.