Natural Look 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

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services well-led?	Inadequate

Overall summary

The CQC carried out an urgent inspection at Natural Look Clinic in response to concerning information received.

This included concerns regarding treatment received by a patient including allegations that a patient lost a significant amount of blood during a procedure and there was a significant delay in contacting emergency services.

Further, it was alleged safety measures in place during the COVID-19 pandemic were not compliant with guidance.

Natural Look Clinic is operated by NLK Limited.

The service provides pre-operative assessment and post-operative follow up, including wound care for surgical procedures in cosmetic surgery. On site operative surgical procedures include liposuction and fat transfer, breast augmentation with or without uplift, non-major breast reductions, hair transplant, upper lid blepharoplasty, pinnaplasty, labiaplasty, mini-abdominoplasty/small abdominoplasty and mini-facelift.

Documentation submitted to CQC by the provider stated that all procedures were carried out under local anaesthesia with conscious sedation. Major surgical procedures are carried out at other registered establishments under practising privileges. Although, the service was registered for dental surgical procedures, these were not being carried out at the time of inspection.

We inspected this service using our focused inspection methodology. We carried out a short notice inspection on 12 August 2020.

Summary of findings

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

Our rating of this service went down. We rated it as **Inadequate** overall because:

- Staff did not complete and update risk assessments for each patient and did not remove or minimise risks;
- Staff did not identify and quickly act upon patients at risk of deterioration;
- Staff did not keep detailed records of patients' care and treatment. Records were not clear and up to date;
- The service did not use systems and processes to safely prescribe and administer medicines;
- The service did not manage patient safety incidents well;
- Leaders did not have the skills and abilities to run the service;
- Leaders did not understand and did not manage the priorities and issues the service faced;
- Leaders did not operate effective governance processes throughout the service; and
- Leaders and teams did not use systems to manage performance effectively.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements to help the service improve.

Sarah Dronsfield

Head of Hospital Inspection (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	**Inadequate** 	• Staff did not assess risks to patients well or keep good care records. They did not manage medicines well. The service did not manage safety incidents well and did not learn lessons from them. • Leaders did not run services well using reliable information systems and did not support staff to develop their skills. Staff were not always clear about their roles and accountabilities.

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Background to Natural Look Clinic

Natural Look Clinic is operated by NLK Limited. The service opened in 2013. It is a private hospital in Doncaster, South Yorkshire, providing cosmetic surgery for adults aged 18 years and above.

It primarily serves the communities of South Yorkshire. It also accepts patient referrals from outside this area.

The service has had a registered manager in post since opening; the current registered manager has been in post since 2016 and is the owner of the business and its main surgeon and clinical lead.

Throughout this report 'registered manager' is used to refer to the owner of the business and their wider roles and responsibilities as registered manager, safeguarding lead, clinical lead and main surgeon.

The service is registered with CQC to provide the following regulated activities:

- Diagnostic and screening procedures;
- Services in slimming clinics;
- Surgical procedures; and
- Treatment of disease, disorder or injury.

Our inspection team

The team that inspected the service comprised a CQC inspection manager and a CQC inspector, supported remotely by a CQC inspection team.

The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Information about Natural Look Clinic

The service provides day-case procedures which, according to information submitted by the provider are performed under local anaesthetic and/or conscious sedation. It has an operating theatre, with clean and dirty utility-rooms, and four day-case beds. It does not have facilities for patients to stay overnight; it has an agreement with another local, private hospital, at which its surgeons and anaesthetists have admitting rights, for admission of patients who require overnight monitoring.

During the inspection, we visited the premises, including the theatre and each of the recovery rooms. We spoke with staff, including registered nurses, health care assistants, a cleaner, and the senior manager, who was also the lead clinician and main surgeon. We spoke with two patients and reviewed four sets of patient records.

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

The service had been inspected in November 2019, which found that the service was meeting all standards of quality and safety it was inspected against.

Three surgeons and four anaesthetists worked at the service under practising privileges.

Track record on safety:

- No never events have been reported to CQC;
- No clinical incidents have been reported to CQC;
- No serious injuries have been reported to CQC;
- 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; and

Summary of this inspection

- No complaints.

Services provided at the hospital under service level agreement:

- Clinical and non-clinical waste removal;
- Laundry;
- Maintenance of medical equipment; and
- Decontamination of theatre trays and equipment

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?

Inadequate

Our rating of safe went down. We rated it as **Inadequate** because:

- The service did not make sure everyone completed mandatory training in key skills;
- The service did not use systems to identify and prevent surgical site infections;
- Staff did not always complete and update risk assessments for each patient and remove or minimise risks. Staff did not identify and quickly act upon patients at risk of deterioration;
- The service did not have enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment;
- Staff did not keep detailed records of patients' care and treatment. Records were not always clear, up-to-date, and easily available to all staff providing care;
- The service did not use systems and processes to safely prescribe and administer medicines;
- The service did not manage patient safety incidents well. Managers did not investigate incidents and share lessons learned with the whole team and the wider service; and
- The service did not use monitoring results well to improve safety.

Are services well-led?

Inadequate

Our rating of well-led went down. We rated it as **Inadequate** because:

- Leaders did not have the skills and abilities to run the service. They did not understand and manage the priorities and issues the service faced. They were visible in the service for patients and staff. They did not support staff to develop their skills;
- The service had a vision for what it wanted to achieve but did not have a strategy to turn it into action. Leaders and staff did not understand and know how to apply the vision and monitor progress;
- Leaders did not operate effective governance processes, throughout the service and with partner organisations. Staff were not clear about their roles and accountabilities and did not have regular opportunities to meet, discuss and learn from the performance of the service;

Summary of this inspection

- Leaders and teams did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues and identify actions to reduce their impact.They did not have plans to cope with unexpected events;
- The service did not collect reliable data and analyse it. Data or notifications were not consistently submitted to external organisations as required; and
- Staff did not have a good understanding of quality improvement methods and the skills to use them. Leaders did not encourage innovation and participation in research.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inadequate	N/A	N/A	N/A	Inadequate	Inadequate
Overall	Inadequate	N/A	N/A	N/A	Inadequate	Inadequate

Inadequate

Surgery

Safe	Inadequate
Well-led	Inadequate

Are surgery services safe?

Inadequate

Our rating of safe went down. We rated it as **inadequate.**

Mandatory training

The service did not provide mandatory training in key skills to all staff and did not make sure everyone completed it.

- Following inspection, we were provided with information ('Statutory & Mandatory Training Requirements and Compliance') which showed compliance with additional requirements for nursing staff and operating department practitioners (60% compliance) and surgeons and anaesthetists (100% compliance). Following inspection, we were provided with plans to increase the compliance rate of nursing staff and operating department practitioners.
- We were not assured that all staff were up to date with mandatory training requirements and that the service made sure everyone completed their identified mandatory training.
- The 'Policy for Training and Continuing Professional Development' (Issue date: 1 June 2020) outlined the expectations on staff to participate in ongoing training and continuous professional development (CPD) either through their employment at the service or within their employment in the NHS.
- The policy identified general training (for example, fire safety, infection control, information governance, mental capacity awareness) and specific training for those involved directly in the care of patients (for example, basic life support, advanced life support, consent, sepsis).
- Training and CPD was available through informal and formal internal training sessions, courses arranged with external providers but delivered in-house and courses arranged with external providers which required staff attendance.
- The policy confirmed that all training and CPD was recorded within individual staff files which identified courses attended, those planned and when individual training was needed.

Safeguarding

Staff understood how to protect patients from abuse and work with other agencies to do so. Staff had training on how to recognise and report abuse.

- The registered manager was the nominated safeguarding lead ('Policy for Safeguarding Children' and 'Policy for Safeguarding Adults') who "…will complete level 3 safeguarding training" (section 8.3, both policies).
- We were not assured the registered manager had the appropriate training and competence to carry out this role.
- The service had a 'Policy for Safeguarding Children' and a 'Policy for Safeguarding Adults' (both issue date: 1 June 2020) in place. These aimed to ensure all staff were aware of the definitions of abuse, how to recognise abuse, local safeguarding guidance and reporting procedures to fulfil their role in safeguarding children and adults at risk.
- The 'Policy for Safeguarding Children' confirmed it was not the policy of the service to treat children under the age of 18 years nor to "…encourage children to be brought into the establishment whilst parents or other family members of friends are being treated".
- The policies state that safeguarding concerns must be reported immediately to the safeguarding lead and an incident report form completed, fully documented in the patient record and the safeguarding report form.

- The safeguarding lead decides whether to refer, taking in to account the individual's wishes, capacity to make an informed decision, care and support needs, whether there is a person of trust involved and potential criminal activity.
- Staff had access to the safeguarding policy and procedures and safeguarding training was part of the service's mandatory training programme.
- There were no safeguarding concerns reported to CQC in the twelve months before inspection.

Cleanliness, infection control and hygiene

The service did not control all infection risks.

- The service did not provide evidence of systems in place to identify and prevent surgical site infections. We were not assured that all infection risks to patients were identified and managed.
- The service had an overarching 'Policy for Infection Control' (Issue date: 1 June 2020) and further specific policies (all issue date: 1 June 2020), covering the following:
  - Hand hygiene and Methicillin-resistant Staphylococcus aureus (MRSA);
  - Control and prevention of MRSA;
  - Surgical hand decontamination;
  - Control and prevention of COVID-19; and
  - Isolation.
- We saw the service had systems in place to manage and monitor the prevention and control of infection in relation to Covid-19.
- All patients had their temperatures checked on arrival and were required to complete a standard questionnaire to ensure they had no symptoms related to Covid-19 and had not been in contact with anyone who had a positive diagnosis.
- Personal protective equipment (PPE) was readily available at the entrance to reception, as well as handwashing facilities and sanitising hand gel.
- The specific policy in place included protocols for the pre-operative screening of all patients using throat and nasal swabs. Patients were instructed to self-isolate for two weeks prior to surgery.
- Measures had been taken to ensure that staff on the premises maintained social distancing whenever possible. This included notices displayed on the door of communal rooms detailing the maximum number of people allowed in the room at any time.
- Chairs had been spaced out accordingly, and in the patient waiting area couches had been marked to show patients where to sit to maintain social distancing.
- Posters with instructions on the correct donning and doffing procedures were displayed around the clinic for reference by staff.
- A regular cleaning schedule was in place. Domestic staff cleaned the upstairs rooms including the operating theatre twice a week, according to the surgical lists. Surgical lists were normally held on Mondays and Thursdays and domestic staff cleaned the area on Wednesdays and Fridays.
- Domestic staff we spoke with, told us they worked flexibly and if additional theatre lists were arranged, they would be requested to carry out cleaning on additional days.
- Clinical staff cleaned the theatre area and specialist equipment prior to surgery and between each patient. Domestic staff completed checklists to ensure that all areas were cleaned.
- Surgical instruments were cleaned and sterilised centrally by an external company through a service level agreement. The service used some single use instruments such as scissors.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe.

- We saw the theatre appeared clean, but the operating couch had some small tears in the cover which were covered by tape and the ceiling ventilation cover was very dusty. This did not give assurance that the correct procedures were in place to ensure this risk of surgical site infections was minimised.
- The operating theatre was situated on the first floor of the clinic, with separate clean and dirty room (sluice) facilities attached. There was an emergency evacuation pad on the upstairs landing to aid with the emergency evacuation of patients. The staircase was straight and wide, though steep. Staff told us they had not received training or practised the evacuation of patients in an emergency situation.

- Although there was a ventilation system installed in the clean utility room, staff were not able to explain how this worked. However, the registered manager explained during interview, the system was installed approximately seven years previously, and is similar to those used in intensive therapy units (ITU) and makes the air 99.9% clean.
- The system was serviced annually, and the filters changed. The registered manager provided a service certificate showing the system had last been serviced on 19 September 2019 and the area covered (44 cubic metres) by the unit was subject to appropriate rates of air change (59 maximal times each hour).
- The resuscitation trolley was stored in the clean utility room. A defibrillator and suction equipment were available on the trolley and had last been serviced on 11 March 2020.
- Emergency drugs were supplied through an agreement with the local trust and were stored in a separate container with the expiry date clearly displayed (30 November 2020). Staff checked the trolley prior to surgery, and this was recorded in a diary and signed by staff.
- A supraglottic airway device (airway management in adults with nontraumatic out-of-hospital cardiac arrest) was available if required.
- There were three clinic rooms on the first floor for patients to use before and after surgery. These were spacious and clean.
- There was a recovery room which was used for storage and designated for donning and doffing of PPE. We were told that the patient was now kept in theatre for recovery and allowed more time to do this. Patients go straight from the theatre after recovery, back to their room prior to being discharged.

Assessing and responding to patient risk

Staff did not always complete and update risk assessments for each patient and did not remove or minimise risks. Staff did not identify and quickly act upon patients at risk of deterioration.

- We were not assured the service had adequate protocols and procedures for the management of a deteriorating patient particularly when the level of sedation was unclear.
- At the time of inspection, staff and the registered manager were unable to provide a policy on management and escalation of a deteriorating patient. Through interviews, we were not assured that the risks associated with a deteriorating patient would be recognised and acted upon appropriately.
- Following inspection, the registered manager provided policies on 'Risk Management', 'Policy for Patient Monitoring, Deterioration and Escalation' (2020/21), and a 'Policy for Conscious Sedation' (2020/21). These policies were not relevant to services provided at the service, for example, the types of surgery performed at the clinic were not accurate (reference to ectopic pregnancy) and referred to wards and 'Trust' which are not applicable to this service.
- At the time of inspection, the registered manager was unable to provide a policy for the evacuation of patients from the premises in an emergency or evidence of training and practice for such an event. Staff interviewed confirmed there had not been training or drills on evacuation procedures.
- Although these policies identified the use of the national early warning score (NEWS2) process, and the SBAR (situation, background, assessment and recommendation) system, there was no evidence the service used NEWS or SBAR. Further, the service has not provided evidence of plans to train staff in their use following proposed implementation on 13 August 2020.
- In response to being asked about the management of a deteriorating patient, the registered manager identified subjective exclusion criteria and indicated the responsibility for their management was with the anaesthetist and the ODP.
- Within the 'Patient Monitoring, Deterioration, and Escalation' policy received, the section on 'Inter-Facility Transfer (for Patients who have life-threatening injuries or illnesses) identifies four levels for transfer of patients category 1 - category 4. However, there is no evidence that this assessment tool was used for patients.

Inadequate

Surgery

- During inspection we did not find a clear, documented process for monitoring patients, assessment and escalation when there was a deterioration. Staff we spoke with had no knowledge of a deteriorating patient policy and we could not locate one in the policy folder during inspection.
- Arrangements were not in place in the event of major or significant blood loss during surgery. The service did not have an SLA in place to obtain blood products for transfusion with the local trust. This was confirmed by the trust.
- We found systems and processes were not consistent to ensure correct levels of sedation were applied, for example, not all records reviewed (four) recorded the weight of patients, assessments of how awake a patient was during a procedure, comorbidities, body mass index, blood pressure and pulse rates.
- The pre-anaesthetic consultation in the anaesthetic section of the patient record was blank, except for weight, in all four records reviewed. There was no evidence of anaesthetic pre-assessment prior to the day of surgery in the patient records reviewed.
- We reviewed the providers central register of policies onsite which did not contain a policy for conscious sedation or a policy for the management of the deteriorating patient. Staff we spoke with during the inspection were not aware of these polices and were not able to reference them or locate them.
- Following inspection, the registered manager forwarded a Risk Management Policy (Issue date: 1 June 2020) which identified pre-treatment, intra-treatment and post-treatment risks for patients. Among measures identified to mitigate these were:
  - All patients must be fully assessed and counselled prior to treatment;
  - Any possible contraindications must be fully evaluated as to possible effects on the patient; and
  - All forms and papers must be fully completed and signed by anyone making entries in them, as these form a legal record, which can be referred to, in any subsequent legal action.
- The registered manager also forwarded a 'Policy for Patient Monitoring, Deterioration and Escalation' (2020/21), a 'Policy for Conscious Sedation' (2020/21) and a 'Quick Reference Handbook' (Guidelines for crises in anaesthesia, 2019) after the inspection.
- These identified the use of the national early warning score (NEWS2) process, a clear written monitoring plan, observation taking for adult surgical inpatients, the SBAR (situation, background, assessment and recommendation) system to communicate, levels of sedation, pre-procedure evaluation, monitoring (including exhaled carbon dioxide monitoring), and reversal agents.
- These processes were either not used within the service or not consistently applied. For example, end tidal volume (capnography, exhaled carbon dioxide monitoring) was not monitored during sedation. We were told by a member of staff that end tidal monitoring during sedation was not carried out at this clinic and the clinic did not have a capnograph.
- Staff were aware of the policy for resuscitation and the policy for the treatment of anaphylaxis. We saw copies of these in the policy file onsite.
- The protocol for transfer to the local NHS trust in the event of a cardiac arrest was displayed in the operating theatre as were the anaphylaxis algorithm and the advanced life support flowchart from the Resuscitation Council UK.
- The clinic did not have any overnight facilities. If a patient was not fit for discharge and needed on-going care and treatment, the discharge policy stated that arrangements would be made for the patient to be admitted to a local private hospital.
- However, a member of staff told us that due to Covid-19 the private hospital was not accepting admissions from the clinic. The member of staff did not know what alternative arrangements were in place if this occurred.
- If patients experienced problems out of hours, the service supplied a contact number for patients to contact a member of staff. A patient we spoke with confirmed that they had been supplied with this number following their procedure at the clinic.
- The service used the World Health Organisation (WHO) surgical checklist. We saw this had been completed in the notes reviewed.

- Staff told us that all patients had a pregnancy test prior to surgery taking place.

Nursing and support staffing

The service did not have enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

- During our inspection we saw there were not enough appropriately qualified staff on site to provide the appropriate level of care for patients. The mandatory training compliance rate for nursing staff and operating department practitioners was 60%, following inspection we were provided with plans to increase this level of compliance.
- The service was managed by a registered manager who is also the nominated individual.
- Staff employed included registered nurses, health care assistants, operating department practitioners, and surgeons and anaesthetists working under practise and privilege arrangements. All of whom also worked in a local NHS trust.
- Surgeons brought their preferred teams to the service on theatre days to work with them and care for patients before and after surgery.
- The service also employed administrative staff (one full time and two part time) and one cleaner.

Medical staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

- The registered manager was the main surgeon at the service. He carried out most of the breast augmentation surgery undertaken by the service. Another surgeon attended under practising privileges to carry out more complex cases and a further surgeon attended to carry out liposuction procedures when required.
- Each surgeon used their preferred anaesthetist and surgical team, each member of which worked at the service under practising privileges.
- Surgery usually took place two days each week, and an anaesthetist was always present during surgery.

Records

Staff did not keep detailed records of patients' care and treatment. Records were not clear and up to date.

- Although, record-keeping and documentation audits were carried out quarterly by an independent clinician, we were not assured of the robustness of this process.
- We reviewed four sets of patient records for the service; we found that these were not clear, non-compliant with service policies ('Policy for completion of health records' (2020/21)), illegible and difficult to understand. Records did not always have clear dates, times, and designations of the persons completing the documents.
- From reviewing records, we were unable to confirm the service consistently applied the two-week 'cooling off' period. The 'Professional Standards for Cosmetic Surgery' guidance states that 'Ensure that consent is obtained in a two-stage process with a cooling-off period of at least two weeks between the stages to allow the patient to reflect on the decision…information on the procedure should be received at a different time to the signing of the consent form'.
- 'Operation notes' were pre-populated with standard text. Some patients had additional hand-written comments. These did not always accurately reflect the procedure, for example, one record showed the wrong date, the name of the anaesthetist was incorrect, and it stated there was no drain inserted, minor theatre records contradicted this.
- Patient records did not contain completed NEWS2 assessments, clear written monitoring plans, observation records, or SBAR documentation.
- Further, it was not clear from the records that the levels of sedation used were consistent with the service commitment to using only conscious sedation.
- The Risk Management Policy (Issue date: 1 June 2020) stated "…all patients must be fully assessed and counselled prior to treatment", "...any possible contraindications must be fully evaluated as to possible effects on the patient" and "…all forms and papers must be fully completed and signed by anyone making entries in them".
- The identified process consisted of a first appointment when the medical checklist was completed, discussion,

and measurements and photographs taken; a second appointment when a pre-operative assessment was undertaken and consent obtained, then the procedure was scheduled and performed. Post-operative appointments were scheduled usually a few days later, then after six weeks.

- Patient records reviewed did not contain a fully completed and comprehensive pre-anaesthetic consultation. The anaesthetic section of the patient record was blank, except for weight, in all four records reviewed. There was also no evidence of anaesthetic pre-assessment prior to the day of surgery in the patient records reviewed.
- Patient information and records were stored securely in lockable cabinets, in line with the Data Protection Act 2018.
- A copy of the discharge summary was forwarded to the patient's GP, with the patient's consent.
- Within the 'Patient Monitoring, Deterioration, and Escalation' policy received, the section on 'Inter-Facility Transfer' identifies four levels for transfer of patients, there is no documented evidence that this assessment tool was used for patients.

Medicines

The service did not use systems and processes to safely prescribe and administer medicines.

- During interview the registered manager did not demonstrate a full understanding of the different levels of sedation and how it was applied in the service. This discussion indicated that a higher level of sedation (Royal College of Anaesthetists definitions) was applied at the service than that indicated in the service Statement of Purpose.
- During interview the registered manager stated anaesthetists monitored sedation and not the registered manager, and that they will administer a pectoral block only. The registered manager was unaware of the use of drugs used to reverse sedation in the service.
- Two patients confirmed they had no memory of procedures, inconsistent with defined levels of conscious sedation.
- During the inspection, staff and the registered manager were unable to provide policies on conscious sedation or managing a deteriorating patient. The day after inspection the Registered manager provided policies on 'Conscious sedation' and 'Patient Monitoring, Deterioration, and Escalation'.
- The policy on conscious sedation states '…The Natural Look Clinic…does not currently perform any procedures under 'Deep Sedation' and '…the following data should be recorded at appropriate intervals before, during, and after the procedure - pulse oximetry, response to verbal commands (when practical), pulmonary ventilation (observation, auscultation), exhaled CO2 monitoring (where possible), blood pressure and heart rate at regular intervals'.
- We were not assured the service applied these to each patient.
- The policy described how the service will monitor the patient during the procedure using the 'Ramsey' modified sedation scale which uses a score from 1 (awake) - 8 (unresponsive) to assess the patient's verbal response. In the patient records reviewed there was no evidence that patients were assessed during their procedure using this scale in line with the service policy or best practice.
- The policy described there would be regular communication throughout the procedure, however clinical staff including the surgeon also told us that they did not speak to the patient during procedures.
- The policy states waveform capnography is available for all cases at Natural Look Clinic. In the records reviewed there was no evidence or documentation to confirm end tidal volume carbon dioxide had been monitored and we were told the service did not have a capnograph.
- At the time of inspection, the registered manager was unable to provide a licence issued by the Home Office for the possession and management of controlled drugs and claimed they had been told by CQC he did not need one.
- Although the registered manager stated the service did not use controlled drugs, supplies were found on the premises (for example, Fentanyl, Midazolam).
- It was unclear who was the Accountable Officer for Controlled Drugs; the registered manager stated he had

this role, although the report from our previous inspection (November 2019) states '…the accountable officer for controlled drugs (CDs) was the full-time, administrative staff member'.

- Service level agreements (SLA) were not in place for the provision of blood products from external bodies. A policy for blood management and availability was not provided. The registered manager was unable to locate or recall where SLAs were kept when interviewed.
- The registered manager thought they had an arrangement in place with a local NHS trust for the supply of blood products. The local NHS trust confirmed this was not the case.
- Following inspection, the registered manager provided a 'Policy for Blood Management and Availability' (2020/21). This confirmed '… the registered manager is in discussion with local services for the provision of emergency blood in the event of deterioration' and '… on completion of a service level agreement for emergency blood products, this policy will be updated…'.
- Medicines were stored in the clean utility in locked cabinets. Controlled drugs (CD) were checked daily (on days when surgery was taking place) and this was recorded in a designated CD book.
- A Hypobox (care kit that provides a range of glucose products for use in cases of hypoglycaemia in diabetes patients) and an epinephrine autoinjector (a medical device for injecting a measured dose or doses of epinephrine by means of autoinjector technology) were both available on the resuscitation trolley.
- Staff confirmed medication used for sedation was Propofol, Midazolam and Fentanyl. Flumazenil was available for recovery, if needed, although staff told us they did not use recovery drugs as standard, and it was rare to use them. Oxygen was available and stored securely, within the expiry date.
- Patient Group Direction (PGD), a written instruction for the administration of medicines to groups of patients who may not be individually identified before presentation for treatment, was not used within the service.
- Drugs prescribed for patients to take home were recorded in a book and stored in a locked cabinet until the patient was ready to be discharged.

Incidents

The service did not manage patient safety incidents well.

- During interview, the registered manager explained that during the specific incident raised in the concerning information received they had tried to control the patient's bleeding by applying pressure. Delays had been caused by not getting blood products from the local NHS trust and that the patient had been clinically stable.
- The local NHS trust confirmed there was no SLA was in place for the provision of blood products.
- Staff said there was a debrief following the incident and reflection on what had happened and what could have been done differently. One action was to ensure an SLA was in place for blood products.
- The service had a meeting with the patient after the incident occurred to discuss what had happened, under 'duty of candour' requirements.
- Although, this demonstrates recognition of the seriousness of the incident, no notification has been made to CQC as required by the HSCA regulations. This is not consistent with the service 'Policy for Serious Incident or Never Event Reporting' (Issue date: 1 June 2020). The incident was raised through an anonymous concern.
- Further, very limited evidence of learning from this specific incident or subsequent change in practice has been identified.
- There were no never events reported by the service during the twelve months before inspection. Never events are serious patient-safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death, but neither need have happened for an incident to be a never event.
- There were no serious incidents reported by the service during the twelve months before inspection. Serious

incidents are events in health care where there is potential for learning or the consequences are so significant that they warrant using additional resources to mount a comprehensive response.

- The service had a 24 hour on-call telephone line for problems and issues patients have out of hours. The registered manager and other members of staff are on call at all times.

Are surgery services well-led?

Inadequate

Our rating of well-led went down. We rated it as **inadequate.**

Leadership

Leaders did not have the skills and abilities to run the service. They did not understand and did not manage the priorities and issues the service faced.

- The service was led by the registered manager, who was also owner of the business, its main surgeon and clinical lead. They were responsible for the governance of the service, as well as providing care and treatment to patients. Their management of the service was supported by a full-time member of administrative staff.
- During the inspection, the registered manager was unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations.
- These responsibilities were incumbent across their roles as owner, registered manager, safeguarding lead, main surgeon and lead clinician.
- For example, during inspection the registered manager was unable to:
  - correctly identify arrangements the service had in place for the provision of blood products in an emergency;
  - demonstrate an understanding of the different levels of sedation and describe patient sedation used within the service accurately in accordance with Royal College of Anaesthetists definitions;
  - accurately describe the use of controlled drugs within the service; and
  - provide requested policies on conscious sedation, management of the deteriorating patient and a licence issued by the Home Office for the possession and management of controlled drugs.
- Staff did say the registered manager was visible, approachable, and would listen to their ideas and concerns. They spent time at the service almost every day it was open, even if it was not a clinic or theatre day. Whenever they were not on the premises, they were available by telephone.

Vision and strategy

The service had a vision for what it wanted to achieve.

- The registered manager had previously told us that the service's vision was to provide high-quality and safe services for all patients, by constantly updating surgical skills and introducing increasingly effective techniques. The registered manager had told us that they invested heavily in keeping his own surgical skills up-to-date and refreshed.
- Staff understood the vision to provide high-quality and safe services for patients and were clear that the service's priorities were patient safety and practice improvement through development of techniques and skills.
- The service's stated aim on its website and in its literature was to provide top quality services and advice from trusted and qualified sub-specialised medical professionals.

Culture

Staff were focused on the needs of patients receiving care.

- Staff interviewed on inspection did tell us that there was an open culture and they were comfortable with raising ideas and concerns with the registered manager. They also told us that they felt valued and that they were supported to carry out additional, appropriate training.
- Staff we met with and observed were welcoming, friendly, and helpful. All staff we spoke with were focused on the needs and experience of people using the service.

- All patients were provided with a statement of terms and conditions and the amount and method of payment of fees.
- Although, the service used and audited the World Health Organisation (WHO) surgical checklist, these were not complemented with cultural observations to identify continuous improvements.

Governance

Leaders did not operate effective governance processes throughout the service.

- During inspection, the registered manager was unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations:
  - during interview the registered manager abrogated his responsibility for managing a deteriorating patient by stating he left the care of the patient to a colleague (anaesthetist);
  - patient assessment and clinical records were not always signed and dated appropriately in line with professional standards;
  - on the day of the inspection areas of patient record documentation were not underpinned by policies (for example, conscious sedation, management of the deteriorating patient) and were not implemented across the service;
  - there was confusion and limited awareness of current policies at the time of inspection. Policies provided the day after the inspection were not relevant to services provided (for example, the types of surgery performed at the clinic were not accurate and included reference to ectopic pregnancy). Policies also referred to wards and 'Trust' which are not applicable to this service; and
  - following the serious incident, no notification has been made to CQC as required by the HSCA regulations and contrary to service policy.
- Although, the registered manager granted practising privileges to surgeons, governance arrangements around these was not effective or in line with best practice.
- A review of seven personal files of clinicians granted practising privileges, showed deficiencies in recording inconsistent with the 'Policy for Practising Privileges' (Issue date: 1 June 2020):
  - experience and qualifications, references, identity verification;
  - General Medical Council (GMC) number and evidence of checking the register;
  - medical indemnity insurance;
  - Disclosure and Barring Service (DBS) checks;
  - appraisals and revalidation; and
  - training updates.
- Staff were not clear about where to find and how to follow policies and procedures and did not always understand their responsibilities in respect of these. This was inconsistent with service records showing staff had read and understood policies and procedures.
- The service had a current 'Policy for Clinical Governance' (Issue date: 1 June 2020) in place which provided a structure for governance processes.
- The service had identified the need for a 'Medical Advisory Committee' (Issue date: 1 June 2020) and its role, for example, provision of advice and recommendations to the registered person, review of work carried out by all practitioners with practising privileges. This included the review of deaths, unplanned returns to theatre, unplanned readmissions, transfers to other hospitals and incidents. Following inspection, we were provided with minutes of the committee meeting held on 20 June 2020.
- The registered manager held regular staff meetings to discuss and learn from the performance of the service. Following inspection, we were provided with minutes of the committee meeting held in October and December 2019 and May, June and July 2020.

Managing risks, issues and performance

Leaders and teams did not use systems to manage performance effectively.

- At our previous inspection it was reported the service kept a risk register which detailed the main risks and issues it might face, along with appropriate mitigating

actions. The current risk register (document which lists key risks and denotes a risk rating against each key risk) was requested for this inspection, but not provided. We were unable to assess how this was being used, the relevance of risks identified and how regularly the register was updated.

- In response to our request for the risk register, we were provided with the following:
  - Health and Safety Audit (March 2020);
  - Health and Safety Risk Assessments (February 2020);
  - Portable Appliance Inspection and Test records (2019/20);
  - Fire Risk Assessment (March 2020);
  - Legionella Risk Assessment (March 2020);
  - COVID-19 Risk Assessment (30 April 2020); and
  - COSHH (control of substances hazardous to health) Risk Assessment (2019/20).
- Following the serious incident raised in concerns, no notification has been made to CQC as required by the HSCA regulations and contrary to service policy. We are unable to determine the effectiveness of any investigation of the incident, lessons learnt, training needs identified, changes to practice and mitigation put in place to avoid repetition.
- The service did not provide information that it submitted appropriate levels of data to the Breast and Cosmetic Implant Surgery Registry. This records the details of any individual who has breast implant surgery so they can be traced in the event of a product recall or other safety concern, all providers of breast implant surgery are expected to participate.
- The service did not provide information that it submitted appropriate levels of data to the Private Healthcare Information Network, an independent, government-mandated source of information about private healthcare, working to enable patients to make better informed choices of care provider.
- The service had a business continuity plan to be followed in the event of a severe threat or interruption to the service. The focus of the plan was to cancel all forthcoming activity and communicate as widely as possible with staff and patients until the service could be restored.
- The electricity supply to the theatre was supported by a battery-pack which would provide an hour of electricity in the case of a power failure. This would give the surgical team time to make the patient safe and arrange an emergency transfer should there be an electrical failure or interruption.
- The service was registered with the Medicines & Healthcare products Regulatory Agency (MHRA) Central Alerting System (CAS) so that it received medical-device and medicine alerts that may be relevant to its practice.

Managing information

The service collected data.

- Staff told us they had access to up-to-date and comprehensive information on patients' care and treatment.
- Policies and procedures were stored on electronic systems and in hard copy in the administration team's office. However, not all staff were clear about where to find and how to follow the policies and procedures.
- Patient information and records were stored safety and securely in lockable cabinets, in line with the Data Protection Act 2018.
- Staff told us that there had never been any breach of data security at the service.

Engagement

Leaders and staff actively and openly engaged with patients and staff to manage services.

- The service asked all patients to complete a post-surgery survey. We reviewed 19 surveys provided by the service after inspection.
- These showed all patients would recommend the service (extremely likely), were involved in decisions about care and treatment, a member of staff told them about medication side effects to watch for when at home and were treated with respect and dignity.
- All patients rated the level of trust they felt in the clinical staff as 'very good'.

Inadequate

Surgery

- We were provided with specific feedback forms following breast surgery for 9 patients. These showed all patients were either 'very satisfied' or 'somewhat satisfied' with the outcome.
- The registered manager held regular staff meetings and was available for informal conversations.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure the nominated safeguarding lead has the appropriate training and competence to carry out this role.
- The provider must ensure equipment in the operating theatre is maintained to a suitable standard.
- The provider must ensure training and practice is carried out for the evacuation of patients in an emergency situation.
- The provider must ensure relevant staff have the appropriate skills and knowledge to recognise and apply the appropriate levels of sedation consistent with the service Statement of Purpose.
- The provider must develop and apply a clear, documented process for the monitoring, assessment and management of a patient under sedation.
- The provider must develop and apply a clear, documented process for the recognition, monitoring, assessment, management and escalation of a deteriorating patient.
- The provider must identify and apply exclusion criteria from procedures for patients.
- The provider must ensure patient records are clear, compliant with service policies, legible and comprehensive and contain appropriate patient measurements and metrics.
- The provider must ensure the anaesthetic section of the patient record is fully completed with appropriate information, in a timely manner.
- The provider must ensure a service level agreement and arrangements are in place to obtain blood products in an emergency situation.
- The provider must ensure a licence issued by the Home Office for the possession and management of controlled drugs is held by the service.
- The provider must ensure an Accountable Officer for Controlled Drugs is clearly identified and carries out their responsibilities appropriately.
- The provider must ensure incidents are investigated, learning identified, and changes made in practice when appropriate.
- The provider must ensure the registered manager is able to demonstrate full understanding of their responsibilities in carrying out and managing regulated activities and meeting the standards required by the HSCA regulations.
- The provider must ensure documentation supporting the granting of practising privileges records current and valid medical indemnity insurance, Disclosure and Barring Service (DBS) checks, appraisals and revalidation consistent with service policy.

Action the provider SHOULD take to improve

- The provider should ensure policies and procedures are specific to the provider and do not refer to other organizations.
- The provider should ensure compliance with additional training requirements for nursing staff and operating department practitioners.
- The provider should ensure arrangements are in place for overnight facilities. If a patient is not fit for discharge and needs on-going care and treatment.
- The provider should ensure 'cooling off' periods are compliant with professional standards and service policies.
- The provider should ensure risks to the effective running of the service are identified and managed.

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
	Regulation 7 HSCA (RA) Regulations 2014 Requirements relating to registered managers Surgical services

Regulated activity	Regulation
	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Surgical services

Regulated activity	Regulation
	Regulation 17 HSCA (RA) Regulations 2014 Good governance Surgical services

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must immediately suspend the carrying out of any surgical procedures which require local anaesthetic or sedation on service users at Natural Look Clinic, 104 Thorne Road, Doncaster, South Yorkshire, DN2 5BJ until 16 October 2020.