

Aesthetic Beauty Centre

Quality Report

2 Ashmore Terrace Sunderland SR27DE Tel: 0191 567 2900 Website: www.aestheticbeautycentre.co.uk

Date of inspection visit: 26 July 2020 Date of publication: 12/10/2020

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

Ratings

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

Overall summary

Aesthetic Beauty Centre (Sunderland) is operated by Aesthetic Beauty Centre LLP. The service is registered to provide a range of surgical and cosmetic procedures under local anaesthetic to fee paying patients over 18 years old.

The service is situated in a large terraced house which has been converted into a clinic, that is wheelchair accessible to ground floor level (but without ramps) and is located conveniently for access to local public transport networks, and there is public parking nearby.

There is a downstairs reception, waiting room, and a consulting room and unisex toilet. There are stairs and an electronic stair lift, to a half landing with a unisex toilet and storage. There is a further staircase and electronic stair lift to the first-floor consulting rooms and an office

space. There are further staircases but no stair lifts to the second floor where there is a treatment room and pre-treatment room, together with a room used by staff for administrative purposes.

We inspected this service using our responsive inspection methodology following information we received from the provider that they had carried on provision of their service in breach of conditions in place until 4 April 2020 and when dormant in June 2020. We carried out a short notice announced inspection on 26 July 2020 along with virtual interviews on-line with staff on 27 July 2020.

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

The main service provided by this hospital is Aesthetic Beauty Centre - Newcastle upon Tyne. Where our findings on Aesthetic Beauty Centre – Newcastle upon

Tyne – for example, management arrangements – also apply to other services, we do not repeat the information but cross-refer to the Aesthetic Beauty Centre – Newcastle upon Tyne service level.

Services we rate

We had not previously rated this service which was registered in October 2010. As this was a focussed responsive inspection, we looked at specific areas and did not cover the whole domains on key questions. Therefore, we inspected but did not rate the service.

We found the following issues, where the service provider was not meeting regulations:

- The provider had stopped decontamination of their own surgical instruments but had not been able to provide CQC with a copy of a contract or service level agreement to ensure surgical instruments were decontaminated in line with regulations.
- The provider had procured equipment to transport clinical waste or contaminated instruments within the building. This did not meet regulations and was not suitable for its intended use.
- Previous inspections had identified patient risk assessments were not always completed and updated in line with best practice. We found this had not improved at this inspection.
- Previous inspections had identified operation notes were not recorded on appropriate documentation for their purpose. Because of this they were difficult to find and not easily legible. At this inspection we found current consultation notes given to CQC by the provider for review were not always updated from previous consultations which had taken place up to a year ago and legibility remained very poor.
- There were no environmental risk assessments and no risk assessments carried out for new equipment. There were stairs to two floors with stair lifts to the first floor. The provider had carried out no risk assessments and although CQC staff had raised this at a registration visit and at the previous inspection in February 2020, staff had not recognised this as a risk.
- Previous inspections had identified policies within the service did not reflect the environment or

- accurate processes used within the service. At this inspection we found a new policy and procedure manual had been produced but the old policies remained in place and there were still policies where roles and the environment were not accurately reflected. New patient pathway documentation referred to policies that did not exist or remained unchanged.
- Previous inspections had identified there was no audit of pre-operative risk assessments to ensure these were thorough and complete. At this inspection we found patient preassessment documentation was still not fully completed, signed or dated even though patients were booked for surgery.
- Previous inspections identified the leadership team
 were unable to demonstrate full understanding of
 their responsibilities in carrying out or managing
 regulated activities and meeting the standards
 required by the HSCA regulations. At this inspection
 we found this had not improved. Some
 responsibilities had been delegated to a business
 consultant including the creation of a new policy and
 procedure manual, but the leadership team were still
 unable to demonstrate a full understanding of their
 roles and responsibilities as providers of a healthcare
 service.
- The provision of out of hours care was not robust. At previous inspections we were not assured a patient who required urgent treatment, when the surgeon was operating at other locations would receive care from medical professionals who would have the appropriate skills and competence. Although the provider assured us there was an agreement in place with a local NHS trust, this could not be provided to us.
- There was out of hours cover provided at another facility where procedures were carried out under practising privileges. However, patients did not stay at the facility overnight following procedures.

However:

 The provider had addressed some areas of infection prevention and control. These included replacements of the theatre table and the sink waste in the treatment room.

 At our previous inspection in February 2020 we had found medicines were not stored securely or correctly, but at this inspection we found the provider had taken actions to rectify this.

Following this inspection, we were not assured the provider had taken sufficient action to comply with all of the Health and Social Care Act (HSCA) 2008 Regulations (2014) and there was a significant ongoing risk of harm to

patients undergoing cosmetic surgery procedures at this location. We will add full information about our regulatory response to the concerns we have described to a final version of this report, which we will publish in due course.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Our judgements about each of the main services

Service

Surgery

Rating Summary of each main service

At this inspection we rated the service as **Not rated** overall.

We found the provider had carried out face to face consultations and procedures which were in breach of CQC conditions on the provider.

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

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

The provider had stopped decontamination of their own surgical instruments but had not been able to provide CQC with a copy of a contract or service level agreement to ensure surgical instruments were decontaminated in line with regulations.

Equipment used to transport contaminated instruments did not meet requirements.

Not all patient consultations, in particular first consultations, were recorded.

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

Patient consultation notes were not clearly documented and not always updated from previous consultations.

A new policy and procedure manual had been produced but old policies remained in place and policies did not accurately reflect roles and the environment. New patient pathway documentation referred to policies that did not exist or remained unchanged with incorrect references to the service or unrelated services.

Patient preassessment documentation was not always fully completed, signed or dated even though patients were booked for surgery in the month following the inspection.

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

business consultant, the leadership team were still unable to demonstrate a full understanding of their roles and responsibilities as providers of a healthcare service.

However:

Medicines were stored securely and correctly.

Contents

Summary of this inspection	Page
Background to Aesthetic Beauty Centre	8
Our inspection team	8
Information about Aesthetic Beauty Centre	8
The five questions we ask about services and what we found	10
Detailed findings from this inspection	
Outstanding practice	18
Areas for improvement	18
Action we have told the provider to take	19



Aesthetic Beauty Centre

Services we looked at

Surgery

Background to Aesthetic Beauty Centre

Aesthetic Beauty Centre is operated by Aesthetic Beauty Centre LLP. The service opened in 2010. It is a private independent cosmetic surgery service in Sunderland, Tyne and Wear. The service primarily serves the communities of Tyne and Wear. It also accepts patient self-referrals from outside this area.

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

The service has had a registered manager in post since

Aesthetic Beauty Centre provides the following regulated activities:

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

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

We inspected this location in February 2020 following which CQC took enforcement action. We imposed conditions to prevent the provider from carrying out surgical procedures requiring local anaesthetic until 4 April 2020.

We planned to carry out a full comprehensive inspection in March 2020, prior to the conditions expiring. However, CQC conditions were overtaken due to government restrictions on all independent health providers during the Covid-19 pandemic. The provider assured CQC, in line with government restrictions, they would remain dormant until 01 July 2020. The provider agreed to inform CQC two weeks prior to re-commencing services so this would allow sufficient time for a full comprehensive inspection before the first patients were seen and procedures were booked. We maintained engagement and monitoring activity with the provider and staff provided lists of consultations which showed the service had recommenced prior to 01 July 2020.

We carried out this responsive, focused inspection to ensure improvements to patient care and safety had been made.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, a CQC inspection manager, and two specialist advisors; one of which was a plastic and cosmetic surgeon, the other specialist advisor had

expertise in independent health service theatre management and infection prevention and control. The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection.

Information about Aesthetic Beauty Centre

The service is registered to provide the following regulated activities:

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

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

The provider senior management team comprised a registered manager who was also the lead nurse and a lead doctor. These individuals were also the directors of the service.

There was an administration manager and a secretary, All staff worked across each of the two main locations on alternating days. This meant the staff worked together as a single team at either location for a full day at a time. The lead doctor also had practising privileges at other services in other geographical areas so was not available every working day.

The provider used agency staff to provide nursing and operating department support. However, no additional staff had been used during the inspection period.

Due to CQC conditions and Covid-19 restrictions the provider informed us they would suspend all face to face consultations and procedures in line with the Government recommendations on non-essential travel and social distancing. During this time, we held regular engagement with the provider to monitor their progress against their action plan. The provider informed us they would recommence regulated activity from 01 July 2020.

During the inspection, we visited the treatment room, patient waiting room and main reception. We spoke with three staff including the lead doctor, lead nurse, and a secretary. We also spoke with a business consultant employed by the provider to support governance of the service. We spoke with eight patients who had attended for consultations or procedures between February and July 2020. During our inspection, we reviewed four sets of current 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 was previously inspected in February 2020. We found the service was not meeting all standards of quality and safety it was inspected against.

Activity (January 2020 to July 2020)

- In the reporting period January to July 2020 there were 42 consultations and 10 surgical procedures recorded.
- 100% of all patients were self-funded.

No anaesthetists worked at the service under practising privileges during the inspection period. No agency nurses, health care assistants or operating department practitioners were employed during the inspection period. The accountable officer for controlled drugs (CDs) was the registered manager.

Track record on safety

- No Never events
- No serious incidents had occurred at this location

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Laser protection service
- Laundry
- Maintenance of medical equipment
- Pathology and histology

Other outsourced services

• Decontamination of surgical instruments

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated it as **Not rated.**

Care premises, equipment and facilities were unsafe.

Staff did not have knowledge of appropriate regulations or apply national guidelines to ensure patients were safe at all times. The service did not have the correct equipment, or knowledge of regulations to keep patients safe.

The service did not control infection risk well, although staff kept equipment and the premises visibly clean.

Staff did not always complete and update risk assessments for each patient to remove or minimise risks.

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

However:

Staff stored and managed medicines well.

Are services well-led?

We rated it as **Not rated**.

The leadership team were unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations. Leaders did not run the service well. They did not use reliable information systems including organisational policies and processes for staff to follow.

Not all staff understood the service's vision and values, and how to apply them in their work. Processes were not always focused on the needs of patients receiving care.

Leaders did not operate effective governance processes throughout the service. Staff were not always clear about their roles and accountabilities.

Staff told us they were committed to improving services continually. However, leaders lacked insight and knowledge of regulations to make sufficient improvements.

Leaders and teams did not identify or escalate all relevant risks and issues or identify actions to reduce their impact. There were insufficient plans to cope with unexpected events.

The service did not provide care and treatment based on national guidance and evidence-based practice. Managers did not check to make sure staff followed guidance.

The provider failed to manage the expectations of patients. However, they engaged well with patients and staff felt respected, supported and valued.

Safe

Well-led

Are surgery services safe?

This was a focused inspection and looked at the following areas only:

Cleanliness, infection control and hygiene

The service did not control infection risk well, although staff kept most equipment and the premises visibly clean.

We found that the provider failed to install appropriate ventilation, air exchange and environmental temperature control system in the procedure room. This was not in line with Health Technical Memorandum (HTM) 03-01 and posed an increased infection risk to patients. In addition, this formed part of the evidence in the urgent conditions imposed on the Sunderland location in February 2020.

We found that the provider had failed to ensure the procedure for carrying clinical waste from the procedure room in this location was in line with HSE guidance. This formed part of the evidence in the urgent conditions imposed on the Sunderland location in February 2020. The provider told us during engagement they had been provided appropriate solutions by their clinical waste disposal company. However, during the inspection staff told us they had searched the internet and purchased a box which was not suitable to meet the requirements in the guidance.

The provider failed to provide documented evidence of the service level agreement (SLA) regarding the management of decontamination and sterilisation with a third-party provider. As part of the inspection we requested this. We had been informed during routine engagement and at a previous inspection this was in place. However, the provider had only been able to produce a letter written by the provider and addressed to the third party dated 19 February 2020. During our onsite inspection staff said they were unable to contact the third-party provider because the person was on leave. However, they also told us during interview they had not followed this up and did not have a copy of the SLA.

The policy and procedure manual referenced a decontamination procedure which would take place on site. Staff told us this was a plan for the future to convert rooms to a decontamination suite at the Newcastle location. This did not reflect the current practice; therefore, we could not be assured which decontamination and sterilisation process staff were following.

Staff kept equipment and the premises visibly clean. Staff had developed checklists to ensure items of equipment and clinical areas were cleaned and we found these had been completed.

Environment and equipment

The service did not have the correct equipment and staff did not have knowledge of appropriate regulations or apply national guidelines to ensure patients were safe at all times. The provider did not ensure that the premises and equipment used to deliver care and treatment met service users' needs.

The treatment room was located on the second floor of the premises. There was a staircase with stair lifts to the first floor only and no lift for patients to use. Staff told us they would not be able to provide surgical procedures for patients who could not climb the stairs although there was no written policy regarding this.

The provider did not demonstrate an understanding of the importance of risk assessments for the environment and equipment in relation to stairs at this location. We found the provider had failed to carry out a risk assessment for use of the stair lifts to the first floor and the staircase to the second floor. When questioned, staff told us this had been mentioned during their registration visit when the clinic first opened and at the previous inspection in February 2020. However, they did not identify this as a concern and therefore had not taken any action. We found, there was insufficient planning to mitigate risks to patients and patients could be exposed to the risk of harm.

Assessing and responding to patient risk

Staff did not always complete and update risk assessments for each patient to remove or minimise risks.

During the inspection, we looked at four patient records. We found these records did not contain suitable and sufficient risk assessments to effectively manage patient risk. Two patients had attended for consultations in February and March 2020 and were booked for surgery at a service in Liverpool. Staff provided theatre lists showing patients were booked for surgical procedures in August 2020. However, there was no evidence these risk assessments had been reviewed and updated at each consultation. We spoke with two patients who confirmed they had had further consultations with the doctor meaning that patients records should have been updated. In addition, we could not see evidence of all the consultations in the records we reviewed, or in the lists provided to CQC.

We found that the patient disclaimer had not been signed by the doctor in three of the four patient records we reviewed.

We saw a National Early Warning Score (NEWS) scoring sheet within the patient pathway documentation provided to inspectors but staff policies did not identify how or when staff would act upon patients at risk of deterioration. During interviews, the clinical leads gave differing accounts of how or when they would act should a patient's condition deteriorate. We found there was insufficient planning and understanding of this risk assessment tool to remove or minimise risks to patients should the service resume surgical procedures.

Records

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

Staff told us they did not document or record initial and virtual consultations with patients in line with professional standards. Therefore, there was no evidence of appropriate patient selection, in terms of inclusion or exclusion for the environment.

Prior to this inspection, staff told us they had produced new patient pathway paperwork, and this would be used for all new patients using the service. However, we found old paperwork still in use in three out of four records we

reviewed. These records were for patients who had been booked for surgical procedures in the following month. Writing and diagrams of the procedures to be carried out were not clearly documented, and not always signed and dated by the lead doctor in line with professional standards.

During our inspection staff told us they always gained patient's consent for all procedures carried out. However, we spoke to eight patients and were told by two patients they were unsure if they signed a formal consent form during their consultation. Patients we spoke with could not tell us if they had received a copy of their consent in line with the Royal College of Surgeons Consent: supported decision-making (2016). In addition, we were unable to identify the procedures the patients were agreeing to in three patient records we reviewed. We were also unable to identify a formal consent form within the patient records we reviewed.

Records were filed at the location the patient was last seen at and were easily available to all staff providing care.

Medicines

The service used systems and processes to safely record and store medicines.

At our last inspection we found medicines were not stored correctly or kept in a suitable locked cupboard. At this inspection we found staff had relocated medicines to suitable locked storage.

Are surgery services well-led?

Leadership

The leadership team were unable to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations. Leaders did not run the service well. They did not use reliable information systems including organisational policies and processes for staff to follow.

There was a history of breaches in regulation and patient safety concerns. We inspected this location on 13 February 2020. Following these inspections, CQC issued reports identifying areas where Aesthetic Beauty Centre had failed to comply with HSCA Regulations 12(1), 15(1) and 17(1).

We used our urgent enforcement powers under section 31 and imposed conditions on 14 February 2020 until 04 April 2020. These conditions had expired in April due to the COVID pandemic and the current national guidance. The provider confirmed they would be following this guidance and would not be re-starting services until 01 July 2020.

During the inspection we found that staff carried out a procedure which was in breach of the provider's urgent section 31 conditions on 22 February 2020 where one patient had a mole removal at the Sunderland clinic. CQC had imposed urgent conditions on 14 February 2020 on the Sunderland location which stated:

The Provider must immediately suspend the carrying out of any surgical procedures which require local anaesthetic on service users at the location Aesthetic Beauty Centre, 4 Ashmore Terrace, Sunderland, SR2 7DE, until 04 April 2020.

Excision of a mole is classed as a surgical procedure and would require the patient to have local anaesthetic so the procedure could be undertaken.

Staff failed to notify CQC in a timely manner that they had recommenced regulated activities following Covid-19 restrictions and were no longer a dormant service.

Prior to our inspection of 27 and 28 July 2020 CQC had not inspected the Sunderland location since the urgent conditions were imposed and expired. Therefore, we had been unable to make an up to date judgement on the safety of services since our previous inspection in February 2020 when we had serious patient safety concerns. However, we also found that two patients had undergone procedures in June 2020 which required excision and local anaesthetic whilst the service was dormant and whilst the lead Doctor had conditions on their professional registration.

We found the senior team, including the registered manager continued to be unable to demonstrate full understanding of their responsibilities in carrying out and managing regulated activities and meeting the standards required by the HSCA regulations.

Staff failed to ensure the new policy and procedure manual (PPM) was fit for purpose and was specific and related to the service that was provided at this location.

We found staff had failed to ensure written documentation had improved in the service, despite conditions being imposed on the provider's registration in February 2020. Throughout engagement meetings we had discussed the importance of robust documentation of all patient consultations in line with professional standards.

During the inspection staff continued to ask CQC for advice and stated "if we make that change would that make you happy". This demonstrated limited understanding of their own responsibilities as required by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 or of changing practice to improve safety for patents.

We asked the provider to formally notify CQC of the definitive list of procedures which they planned to undertake at the clinic locations. Staff advised us on 29 June 2020 they would send this in the updated statement of purpose, however when we received the updated documents on 07 July 2020 the information requested was missing. Despite repeated requests this has still not been provided to us.

We found the provider had failed to install appropriate ventilation, air exchange and environmental temperature control system in the procedure room. This formed part of the evidence in the urgent conditions imposed on the Sunderland location in February 2020. We also found staff continued to carry out procedures at the Sunderland location during February 2020 knowing this requirement was not being met.

We found staff had failed to ensure the procedure for carrying clinical waste from the treatment room in the Sunderland clinic was in line with HSE guidance. This was a requirement from the urgent conditions imposed on the Sunderland location in February 2020. Staff told us during engagement they had been provided appropriate solutions by a clinical waste disposal company. However, during the inspection staff told us they had searched the internet and found a box to carry waste or contaminated instruments through the building and down the stairs, which they showed to the inspection team. This box did not meet the requirements.

Staff failed to provide documented evidence of the service level agreement (SLA) regarding the management of decontamination and sterilization of surgical instruments with a third-party provider. We were informed during routine engagement and inspection this was in place. However, we were only provided with a letter from the provider addressed to the third party and dated 19

February 2020. During our onsite inspection staff told us they had been unable to contact the third-party provider because the person was on leave. However, staff also told us during interview they had not followed this up and did not have a copy of SLA.

The policy and procedure manual referenced a decontamination procedure which would take place at the Newcastle clinic location. When questioned about this, staff told us this was a plan for the future to convert rooms to a decontamination suite. This did not reflect the current practice. Therefore, we could not be assured which decontamination and sterilization process staff were following.

This further demonstrated to us that the provider did not understand their roles in meeting the regulations and they did not take action to ensure breaches of regulation were addressed.

Vision and strategy

Not all staff understood the service's vision and values, and how to apply them in their work.

Processes were not always focused on the needs of patients receiving care.

Staff provided updated statements of purpose on 07 July 2020. However, these did not include the procedures which were planned to be undertaken at the Sunderland site. We had made this request a number of times during engagement and inspection interviews. Staff failed to provide these.

Staff told us verbally during engagement and during the inspection they would provide hair transplant and removal of skin "lumps and bumps". They stated the regulations allowed them to continue offering these procedures and they would not require ventilation in the treatment room. This was incorrect and would not meet regulations.

The updated policy and procedure manual (PPM) provided to us stated that the doctor would use the Bupa Schedule to categorise procedures. However, this was not reflected in the interview with the lead doctor. We could not be assured the doctor was following the Schedule to categorise procedures and therefore they would not be following their own policy.

Governance

Leaders did not operate effective governance processes throughout the service. Staff were not always clear about their roles and accountabilities.

Staff had not ensured they had effective systems in place to assess and monitor the quality of care for patients

Staff informed us due to the Covid 19 pandemic they would not be carrying out any activity at either Aesthetic Beauty Centre location. Due to this assertion we informed the provider on 08 June 2020 that we would treat Aesthetic Beauty Centre as a dormant service. We requested staff advise us two weeks prior to recommencing any regulated activity. In response to the dormancy letter staff told us they planned to recommence activity on 01 July 2020.

Staff provided records that showed staff carried out a consultation at Sunderland on 18 June 2020 and a procedure on 23 June 2020 whilst dormant. We spoke with one patient who confirmed they had their procedure on 23 June 2020 and who also needed to return to the clinic before 01 July 2020 for a revision.

Not all pre-assessment documentation was fully completed or legible. We saw four patient records since activity was recommenced on 01 July 2020. We found the pre- assessment documentation was not fully completed in all but one record, and the disclaimer had not been signed or dated by the lead doctor in three out of four records. In addition, staff had told us during engagement meetings that new documentation was ready to be used in patient records. We saw old documentation had been completed for three out of four patients who had recently attended for consultations and had been booked for surgery in the month following the inspection. Only one record was completed on new documentation that the provider told us had been ready to use during engagement meetings. This single record was the only one that had been completed fully.

We found the new policy and procedure manual (PPM) was not fit for purpose or specific to the services provided. Written policies and procedures were brief and contained no references to best practice or national standards. There was no review date for the manual or policies included within it, although staff told us these were planned for annual review. However, there was no documented evidence of such a plan. The review process of the PPM had

limited clinical oversight. In addition, the document was not individualised to the service as we found inappropriate references to a "victim" and "rescuer" in the resuscitation policy.

We found there was confusion as to the role of the PPM between the lead nurse (who was also the registered manager) and the lead doctor. Staff had informed us through engagement the PPM was in place and being used. However, we found not all staff we interviewed were aware of it. In addition, the lead doctor told us the PPM was linked directly to the old versions as background evidence. Also, staff told us the new PPM had not been ratified, therefore, it was not clear which policies staff at the Aesthetic Beauty Centre LLP were working to. We had identified during multiple inspections the previous policies were not appropriate for the services provided.

Key elements such as the safer surgery checklist and national early warning score (NEWS) within the new patient pathway documentation were not underpinned by an associated policy. This meant that there was no understanding of actions expected by staff. Every action such as a checklist or task should be backed up by associated policy which is linked to best practice and national guidance. In relation to the NEWS in the patient record score the provider had identified that a NEWS score of 7 or more would trigger a call for 999. However, there was no evidence of a deteriorating patient policy. This led us to believe staff continued to have limited understanding and learning of the risks within their standalone locations, in particular on the occasions when there would only be two clinical members of staff to manage unexpected patient deterioration despite there being two patients in the previous year that had deteriorated.

Staff failed to ensure there was a documented process for how incidental findings would be reported or communicated. The service undertakes mole removal, however, there was no policy or procedure should histology be returned with a malignancy. During interview the lead doctor described a process, however, agreed it was not documented. They gave several iterations of what would happen and advised they had not had to do this for 6 years. However, immediately following our inspection and before the lead doctor's interview we found histology of a lesion had been undertaken a few weeks earlier.

Managing risks, issues and performance

Leaders and teams did not identify or escalate all relevant risks and issues or identify actions to reduce their impact. There were insufficient plans to cope with unexpected events.

The service did not provide care and treatment based on national guidance and evidence-based practice.

Managers did not check to make sure staff followed guidance.

We found staff failed to ensure all pre-assessment documentation was fully completed and clearly documented.

Staff failed to ensure key elements (safer surgery checklist and NEWS) of the new patient pathway documentation were underpinned by an associated policy. This meant that there was no understanding of the detail expected by staff.

Staff failed to ensure there was a documented process for how incidental findings would be reported or communicated. The service undertook mole removal, however, there was no policy or procedure should histology be returned with a malignancy.

Staff failed to mitigate risks to patients and staff. During our discussions with patients we were told the lead doctor had driven patients to and from a clinic in the North West in their private car for surgical treatment. The risk assessment staff provided stated:

"adequate motor vehicle insurance cover provided i.e. for personal business use".

However, the car insurance certificate staff provided identified they had not adhered to their own risk assessment. The certificate stated:

"Limitations as to use, use for social, domestic and pleasure purposes (including commuting) EXCLUSIONS: Use for business purposes".

There was no evidence that the risk assessment residual rating had been appropriately assessed, as staff had rated the above as low risk, yet staff did not meet the requirements of the assessment. In the event of an accident the doctor's car insurance may have been null and void.

Engagement

The provider failed to manage the expectations of patients. However, they engaged well with patients and staff felt respected, supported and valued.

Staff provided lists of patients to CQC. All had attended for consultations or procedures between January and July 2020. We spoke with two patients who were expecting to have their surgeries in at another location in the North East and two patients who were expecting to have a procedure under general anaesthetic in Newcastle. The provider did not have the facilities at the Newcastle location to undertake a general anaesthetic and the lead doctor did not have practicing privileges at any other services in the North East.

Seven patients we spoke with said they had been surprised they could not have their surgery locally. Two patients said staff had told them this was because there were building works ongoing and a further three patients said they were told there were better facilities at a different location. One patient told us the provider's website showed there were locations in other areas and following their consultation they understood procedures may be carried out elsewhere.

Patients we spoke with said they had completed post-operative questionnaires following their procedures and felt positive about their experiences.

Staff we spoke with said they enjoyed working for the service and felt very much a part of the team.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

The service must record and complete all patient risk assessments and update them in line with best practice.

The service must ensure surgical instruments are decontaminated in line with regulations.

Equipment used to transport contaminated instruments must meet requirements.

The service must ensure all patient consultation notes are updated from previous consultations with clear legibility.

The service must ensure all patient preassessment documentation is always fully completed, signed and dated on every occasion.

The service must ensure policies and procedures accurately reflect current practice, roles and the environment.

The service must ensure all new patient pathway documentation includes relevant and appropriate references to policies and current national regulations, guidance and best practice.

The service must ensure the leadership team are able to demonstrate full understanding of their responsibilities in carrying out or managing regulated activities and meeting the standards required by the HSCA regulations.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment
Treatment of disease, disorder or injury	

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment
Treatment of disease, disorder or injury	

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance
Transport services, triage and medical advice provided remotely	

Regulated activity	Regulation
Surgical procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent