Signature Medical Limited

Signature Clinic - Manchester

Inspection report

93A Manchester Road
Rochdale
OL11 4JG
Tel: 01706452550

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inadequate
Are services caring?	Good
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this service went down. We rated it as inadequate because:

- Staff had a basic understanding of how to protect patients from abuse and the safeguarding lead in the service did not have the required level of safeguarding training for their role. The service did not have sufficiently trained staff to care for patients. The service did not manage safety incidents well and there was limited learning from incidents. The service did not always control infection risk well. Staff did not assess risks to patients or act on them and staff did not keep good care records. They did not manage medicines well.
- Staff did not always have access to good information about patient outcomes. The service did not always follow national guidance to gain patients' consent. They did not always support patients to make decisions about their care.
- The service did not always take account of service users' individual needs, and it was not always easy for people to raise their concerns.
- Managers did not fully monitor the effectiveness of the service or make sure staff were competent. Leaders did not use reliable information systems to run services well. Leaders did not always support staff to develop their skills. Staff had limited understanding of the service's vision and values, or how to apply them in their work. Staff were not always clear about their roles and accountabilities. The service did not always engage well with patients to plan and manage services and there was a lack of focus on quality improvement in the service.

However:

- Staff had training in key skills.
- Staff provided good care, gave patients enough to eat and drink, and gave them pain relief when they needed it. Staff worked together for the benefit of patients. Key services were available 7 days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to service users.
- The service planned care to meet the needs of local people. People could access the service when they needed it and did not have to wait too long for treatment.
- Staff felt supported by their managers. They were focused on the needs of patients receiving care.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inadequate 	

Summary of findings

Contents

Summary of this inspection

Background to Signature Clinic - Manchester

Signature Clinic Manchester is operated by Signature Medical Limited. The service offers a range of cosmetic surgery treatments for adults over 18 years old, on a private fee-paying basis. The main types of procedures offered are blepharoplasty and gynaecomastia. Between July 2022 and June 2023, a total of 1,722 cosmetic surgery procedures had been provided.

The main service provided by this clinic is cosmetic surgery, the provider is registered for the regulated activities Surgery and Treatment of Disease, Disorder, or Injury. At the time of inspection, the service had submitted an application for CQC registration for Diagnostic and Screening procedures, for provision of cosmetic dental services at the same clinic location. The registered manager at the location is also the registered manager for 2 other locations of Signature Medical Limited.

The cosmetic surgery services are provided from the clinic location in Rochdale, which has a reception and waiting room area on the ground floor, with 2 theatres and recovery areas for service users, on the first floor. The premises also has bathroom and toilet facilities, different storage areas and a staff room. The clinical areas are not accessible for disabled people, which is not indicated on the service website.

In January 2023, we received concerns about the service and had requested information and assurances from the registered manager in response. The concerns related to oversight of infection prevention and control systems and practice in the service; sufficient availability and maintenance of equipment within the service; and other concerns about staffing levels and staff competencies. We also received other concerns from service users about poor experience of care and when making contact with the service.

During the inspection we identified immediate patient safety concerns which we raised with service leaders. Following the inspection, we carried out enforcement action and issued the provider with a section 31 Letter of Intent with a requirement for the provider to respond with mitigating actions. In response, the provider voluntarily suspended their clinical service activities at the location for a period of 4 weeks. Signature Medical Limited engaged in a service level agreement with another CQC registered provider for continuing care to patients during this period. The registered manager also submitted an action plan in response to the concerns raised, indicating immediate actions and learning, with timescales for achieving these.

Following the period of voluntary suspension, we reviewed further information received from the provider. Following this review, we served the provider a Warning Notice under Section 29 of the Health and Social Care Act 2008. The warning notice told the provider they were in breach of Regulations 12 Safe Care and Treatment and 17 Good Governance and gave the provider a timescale to make improvements to achieve compliance. The principles we use when rating providers requires CQC to reflect enforcement action in our ratings. The warning notice identified concerns in the safe and well-led domains. This means that the warning notice we served has limited the rating for safe and well-led to inadequate.

How we carried out this inspection

We carried out an inspection of the service on 18 July 2023. Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity.

Summary of this inspection

The inspection was carried out by 2 CQC hospital inspectors, a CQC operations manager, and a specialist advisor. We observed care, spoke with 5 patients and reviewed care records for 20 patients. We spoke with 8 staff of all grades including senior leaders, medical staff, and healthcare assistants.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The provider must ensure that they assess the risks to the health and safety of service users receiving the care or treatment and they do all that is reasonably practicable to mitigate such risks. Regulation 12 (1)(2) (a)(b)
- The provider must ensure that persons providing care or treatment to service users have the qualifications, skills, and experience to do so safely and that relevant staff complete an appropriate level of life support skills training. Regulation 12 (1)(2)(a)(b)(c)
- The provider must ensure that premises used by the service provider are safe to use for their intended purpose and are used in a safe way. Regulation 12 (1)(2)(a)(b)(d)
- The provider must ensure the proper and safe management of medicines 12 (1)(2)(a) (b)(h)
- The provider must ensure that there is a designated level 3 safeguarding lead with the appropriate level of completed safeguarding training available in the service. Regulation 13 (1) (a)
- The provider must review and improve complaints procedures to ensure there are effective and accessible systems for identifying, receiving, recording, handling, and responding to complaints by service users. Regulation 16(1) (2)
- The provider must review and implement effective systems and processes for assessing monitoring and improving the quality and safety of the services provided. Regulation 17 (1)(2)(a)(b)
- The provider must ensure staff maintain securely an accurate, complete and contemporaneous record in respect of each service user, including a record of the care and treatment provided to the service user. Regulation 17 (1)(2)(a)(b)(c)
- The provider must ensure sufficient numbers of suitably qualified, competent, skilled, and experienced persons are deployed in the service and that they receive appropriate support, training, professional development, supervision and training as necessary to enable them to carry out the duties they are employed to perform and be enabled where appropriate to obtain further qualifications appropriate to the work they perform. Regulation 18(1)(2) (a)(b)

Action the service SHOULD take to improve:

- The service should ensure that equipment is suitably labelled to indicate when last cleaned, and cubicle curtains are dated.
- The service should ensure that external clinical waste bins are kept locked.
- The service should ensure staff and patients have access to call bells in patient areas, in case of emergency.
- The service should ensure that MRSA swabs are completed for all patients having cosmetic surgery procedures under general anaesthetic.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inadequate	Inadequate	Good	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inadequate	Good	Requires Improvement	Inadequate	Inadequate

Inadequate

Surgery

Safe	Inadequate
Effective	Inadequate
Caring	Good
Responsive	Requires Improvement
Well-led	Inadequate

Is the service safe?

Inadequate

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

Mandatory training

The service provided mandatory training. However, this did not include key skills which would be required for medical staff to have completed.

Staff received and completed mandatory training in an eLearning programme. Core mandatory training subjects included basic life support, safeguarding – adults and children, manual handling, infection control, health and safety, food safety, Data Protection Act, COSHH, Equality and Diversity, Fire Training, Sharps Awareness, Risk assessment Awareness, DSE, COVID-19, Social Distancing, Hand Hygiene, Safeguarding - Child, Complaint Handling, Conflict Management, Deprivation of Liberty Safeguarding, Anaphylaxis, Sepsis, Medical Gases. Subject areas aligned to the Skills for Health core skills training framework UK. At the time of inspection, staff were compliant with the required training in the mandatory subjects identified.

However, the mandatory training was not fully comprehensive and did not meet the needs of patients and medical staff.

Medical staff received mandatory training eLearning. Medical staff had completed basic life support skills training and only one of the four consultant surgeons working under practising privileges had currently completed any immediate life support skills (ILS) or advanced life support skills (ALS) training, however this consultant was only available 3 - 4 days a month in the service. Since May 2023, the service had started carrying out procedures under general anaesthetic, and surgeons would not have had the level of life support training needed for monitoring vital signs and recognising and responding to a deteriorating patient should this occur.

Clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities, autism, and dementia.

Managers monitored mandatory training and alerted staff when they needed to update their training.

Inadequate

Surgery

Safeguarding

Not all staff had completed the required level of training on how to recognise and report abuse. Staff understood how to protect patients from abuse.

The registered manager was the designated safeguarding lead for the service. However, their latest training for safeguarding level 3 was in February 2020 and they had not completed any update training since this time. This did not meet the recommended requirements for being the designated safeguarding lead for the service, which recommends refresher training every 3 years. Following the inspection, the service confirmed the clinic manager had in addition subsequently completed safeguarding level 3 update training. The provider had also identified three safeguarding leads, including at the other CQC registered locations.

Medical staff received training specific for their role on how to recognise and report abuse. Consultants working in the service under practising privileges arrangements had completed Safeguarding level 2 children and adults training in an eLearning programme.

Support staff received training specific for their role on how to recognise and report abuse. Healthcare assistants employed in the service had completed safeguarding level 2 children and adults training in an eLearning programme.

Staff had awareness of how to identify adults and children at risk of, or suffering, significant harm. The service had a safeguarding policy and flowchart for actions to follow in case staff had concerns. Staff would raise these to the registered manager, or in the registered manager's absence, to the clinic manager. There had been no safeguarding incidents or concerns reported in the service over the last 12 months.

Staff were aware of contact numbers for the local authority if they needed to make a safeguarding referral and who to inform if they had concerns.

The service did not treat children under 18 years old. The service did not actively ask patients to confirm their identity and age when booking and attending appointments, however there were no reported concerns about people accessing the service who may be under 18 years of age.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. The service used systems to identify and prevent surgical site infections. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept most equipment and the premises visibly clean.

We saw in clinical areas that cubicle curtains did not have dates on to monitor their use. Bedside tables in clinical areas were not appropriate for the management of infection control and prevention, otherwise, areas appeared visibly clean and had suitable furnishings which were clean and well-maintained.

Staff used records to identify how well the service prevented infections. However, we noted on our inspection that the service did not always routinely complete swabs for Methicillin Resistant Staphylococcus Aureus (MRSA) for patients having local anaesthetic procedures.

Staff followed infection control principles including the use of personal protective equipment (PPE).

Staff cleaned equipment after patient contact, although labels were not used to indicate when equipment had been last cleaned. The service had access to autoclave equipment onsite for decontamination of surgical instruments used in local anaesthetic procedures. However, this was not in accordance with service guidance in (HTM 01-01) for the Decontamination of surgical instruments. The provider had a service level agreement with a local independent hospital for decontamination of surgical equipment used in general anaesthetic procedures.

Staff worked effectively to prevent surgical site infections. We observed staff following Aseptic Non-Touch Technique (ANTT) when carrying out surgical procedures under local anaesthetic. The service reviewed patients for any possible occurrences of surgical site infections and doctors provided antibiotics where patients presented with signs of infection.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. Staff did not ensure they managed clinical waste well or store substances in line with Health and Safety Executive guidance for Control of Substances Hazardous to Health.

There was no emergency call bell in the recovery area and staff could not summon assistance in case of a patient emergency in this area. Service users also did not have access to call bells following their procedures. Staff told us they would remain with patients for observation in the immediate post treatment phase, although we could not confirm this from patient records we reviewed. Following the inspection, the provider confirmed that emergency call bells were now in place.

The design of the environment did not follow national guidance for procedures carried out under general anaesthetic. The premises had 2 theatres available, neither of which had an air filtration system in place. Since May 2023, the provider had carried out 15 procedures under general anaesthetic in this environment, which potentially exposed patients to an increased risk of infection. There was no lift access to the first floor where the theatres were located, and the provider did not have an evacuation or escalation protocol for emergency response if patients required transfer whilst under general anaesthetic.

There were systems for carrying out daily safety checks of specialist equipment. However, we saw during inspection that these appeared to be completed in a routine manner and were not always accurate. One example we saw was for the items checked as complete on the checklist for the resuscitation trolley. We saw when we checked during inspection that these did not correlate with the location of items stocked in the trolley. Some medicines were also missing from the emergency resuscitation trolley, although checks had indicated these were present.

The provider did not submit any evidence of staff training for specific use of any equipment. However, staff had completed sharps training.

During inspection we were told of 2 patient safety incidents in which patients had been injured by cautery burns from diathermy equipment whilst they were under anaesthetic. One diathermy machine had been removed from service following this incident, however, 3 remained in service, continuing to be used. There was no standard operating procedure for use of this equipment and the service had not reviewed their systems and processes, including appropriate practice following these patient incidents. We received further information following inspection which indicated a third patient had sustained injury from a cautery burn from diathermy equipment whilst they were under anaesthetic.

In the theatre recovery area, we observed 2 trolleys, one was visibly rusty, the second had surgical drapes placed over. However, when these were removed, the trolley had sticky surgical tape marks in partly adhered to the trolley, indicating it was not clean.

Inadequate

Surgery

We observed 2 clinical waste bins outside the premises, one of which had a faulty lock and was not secure, which we raised during the inspection. We saw from April 2023 an incident report of clinical waste bins not being collected, with actions noting that the waste management service had been unable to collect the clinical waste at the time.

During the inspection we saw the Control of Substances Hazardous to Health (COSHH) cupboard remained open with the keys in the lock and were potentially accessible to members of the public. This was not in line with Health and Safety Executive guidance for Control of Substances Hazardous to Health. The service provided details of completed risk assessment records for COSHH items. However, aside from a number of generic safety information bulletins about different products, there were only 4 specific risk assessments included in these documents. All were past their review dates and were related to another location of Signature Medical Limited.

The service provided details of completed environmental risk assessments, including some of the following: use of the autoclave; body fluid spillage; latex gloves; and disposal of clinical waste.

Where we checked this, we saw that equipment which required calibration and other maintenance had been checked and was in date.

The service had a reception area suitable to meet the needs of patients' families.

Assessing and responding to patient risk

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

Staff did not routinely use a nationally recognised tool to identify deteriorating patients and did not always escalate them appropriately. We were informed the service had only just in the last 2 weeks introduced National Early Warning Scores (NEWS 2) for monitoring patients during and following procedures. We saw during inspection that NEWS2 was being used and the available records we reviewed confirmed this. However, NEWS 2 had only recently been implemented in the 2 weeks prior to inspection and there were limited records available to monitor this overall compliance. Healthcare assistants would observe patients following their procedure, and using their judgement raise any concerns to the surgeon where necessary. Staff had not completed specific training in assessing and responding to risk. The service did not have a management of the deteriorating patient policy or standardised process for staff to follow in case of any concerns regarding their patients. The provider advised that in the absence of a formal working policy, they had a statement of working practice that was in place. This indicated that where there was any patient deterioration which required transfer to an NHS hospital, this would be arranged for by the surgeon. We did see this in one patient record however, where care was arranged through individual contact for a patient who needed urgent transfer to NHS services, following their poor recovery post operatively.

The service did not follow a standardised process for staff to complete risk assessments for each patient on their admission. They did not use a recognised tool, or review this regularly, including after any incident. Specific patient risks were not always considered, including the possibility of patients who may be pregnant when undergoing general anaesthetic.

Consultants we spoke with during the inspection told us how they would assess and respond to any psychological needs' patients may have in relation to their surgery, and how this was an important part of their assessment. However, records we reviewed did not always support or indicate this aspect had been clearly discussed with patients or documented. Consultants did not provide examples of how they had signposted or referred patients to other services for psychological support, where any concerns had been identified or this may have been needed.

Inadequate

Surgery

The service had safety notices displaying the World Health Organisation's (WHO) 5 steps to safer surgery. We observed surgical procedures during the inspection and saw these were not always completed fully or in a timely way. The service did not have any Local Safety Standards for Invasive Procedures (LocSSIPs) for staff to complete when carrying out surgical procedures.

Staff recorded risks of venous thromboembolism only for patients having general anaesthetic procedures. Otherwise, the service did not have any other patient specific risk assessment protocols. However, the service had a reference document titled 'patient selection criteria for general anaesthesia.' This was a large document detailing 61 different criteria, including clinical and non-clinical situations, with actions to follow in considering if a patient was suitable for surgery. It was not clear how staff followed this document and in records we reviewed there was no reference to this having been considered. We saw no evidence of completed risk assessments based on the patient selection criteria document. We saw that for patients who had undergone procedures under general anaesthetic, some patients appeared to have more complex comorbidities. In addition, records for these patients did not specifically reference the patient selection criteria document.

We observed during inspection that patients did not have ID bands on in theatre to indicate whether they had any allergies or relevant risks. Following the inspection, the provider informed us that as the service only treats one patient at a time the use of wrist bands had not been put into practice. Allergies are checked for at consult and in the World Health Organisation's safer surgery checklist. Where patients had treatment under General Anaesthetic, an ID wrist band and red allergies wrist band was used by the service. However, we were unable to confirm this from records we reviewed and our observations during inspection.

Following their procedures patients would be given an email address and telephone number to make contact with the aftercare team if needed. This included a daytime number and out of hours number. The after-care service was based at the administrative and call centre in Glasgow, available as a 24-hour service and run on a rota system. A registered nurse was available according to their shift pattern in the aftercare service. We were informed that if the aftercare team get a call about any concerns, they will immediately contact the surgeon.

Following inspection, the service provided details of their Local Anaesthetic Infiltration Policy for procedures where liposuction is performed under tumescent local anaesthesia, which appeared as a guidance document rather than a standardised policy. The service clarified following the inspection, that Royal College of Anaesthetist (RCAn) guidelines on identification and treatment of local anaesthetic toxicity were displayed in the service although we did not observe this. Also, we were informed that surgeons received a copy of this document which was available at all times in theatre and that the service stocked intralipid in the resuscitation trolleys. However, the provider did not have a specific standard operating procedure to manage the additional risks presented by this procedure. Also, the guidance did not indicate whether staff would have been available or had any appropriate training to monitor the patient for signs and symptoms of toxicity arising from such procedures.

There was no standardised procedure for staff to share key information to keep patients safe when handing over their care to others. Where needed, staff passed on verbal information to colleagues in shift handovers.

Staffing

The service did not have enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers did not review and adjust staffing levels and skill mix. The service gave agency staff an induction.

Inadequate

Surgery

The service did not have enough nursing and support staff with the right qualifications, skills, training, and experience to keep patients safe. Healthcare assistants who were employed in the service were overseas nationals and originally qualified as nurses in their home countries. However, none of these staff had any equivalent UK qualifications and none were registered with the UK Nursing and Midwifery Council (NMC). We saw that job titles varied between staff who were employed for the same role, and that they undertook different and wide-ranging tasks within the scope of these roles. Some of this included acting in a clinical capacity, such as administering medication and recovering patients post operatively, and acting as surgical assistants. Staff had not completed any specific training for these activities and were not qualified to undertake them. The service did not employ any Surgical First Assistants (SFAs), or Operating Department Practitioners. Following the inspection, the provider took immediate action to ensure that staff with the appropriate qualifications were being deployed in the service.

The registered manager informed us that Registered Nurses working as agency staff had been employed to support the general anaesthetic procedures that had been carried out in the service since May 2023. In addition, the service had engaged with a recently retired NHS anaesthetist for the carrying out the general anaesthetic procedures. Following the inspection, we saw HR records which confirmed this.

We also saw in records there had been a consultant surgeon involved in these procedures who was not included as one of the 4 consultant surgeons employed. The registered manager told us they had previously been working in the service but had now left the organisation. The service had suspended the general anaesthetic procedures at the time of inspection, this was following several patient safety incidents that had occurred. There were no immediate plans for reinstating the general anaesthetic procedures at this time.

Managers did not calculate or actively review the number of healthcare assistants needed for each shift, but staff were allocated work on a baseline matrix of staffing, comprising a surgeon, a scrub nurse, 2 circulators and 1 support staff as the standard requirements for surgery. The provider did not follow national guidance for staffing levels and as an employer had opted out of the European Working Time Directive (EWTD). Healthcare assistant staff we spoke with during inspection told us they were frequently required to work in other Signature Medical clinic locations in England, and we heard they also often worked long hours in the service. Data received from the provider following the inspection indicated that between January and June 2023, for 8 healthcare assistant staff the highest in average weekly working hours was 53 hours. Between January and June 2023, for 8 healthcare assistant staff there were 39 occasions where staff worked above 60 hours per week. We saw that one individual member of healthcare assistant staff had worked 103.25 hours in one week in January 2023. We had concerns about the impact of long working hours on staff, and the consequences of this on their ability to provide safe care and treatment for service users.

The service was in the process of recruiting additional healthcare assistants at the time of inspection. This was to allow staff to work two shifts and to reduce the total hours worked overall by staff.

The service had a clinic manager in post as part of their staffing. The clinic manager was mostly desk based in their role but worked flexibly to support clinical areas when this was needed.

The service had low turnover and sickness rates.

Managers limited their use of agency staff and made sure all agency staff had an induction and understood the service.

Medical staffing

The service had enough medical staff to provide care and treatment.

Inadequate

Surgery

The service had enough medical staff. Four cosmetic surgeons were available working under practising privileges in the service. Services were provided flexibly in response to demand and consultant availability. Three of the 4 cosmetic surgeons worked exclusively for Signature Medical Limited, with one consultant having regular NHS practice commitments in addition, outside of the service.

The service had low vacancy, turnover and sickness rates for medical staff.

Service leaders confirmed there would always be a consultant available on call during evenings and weekends. Staff clarified that patients would be directed to contact the after-care service phone line in the first instance, for any post-operative concerns they may have. Service leaders informed us that patients had access to nursing and medical advice through this system and staff would redirect any contacts received to the local surgeon where needed.

Records

Staff kept records of patients' care and treatment. Records were not always clear or up-to-date. Records were stored securely and available to all staff providing care.

Staff used a combination of paper records and electronic systems to record patients care and treatment, and all staff could access them easily. However, records we reviewed were not always clear, comprehensive, or up to date. Some records we reviewed, including medical notes and notes of patients' surgery, were completed to a poor standard.

We reviewed 20 patient records of different types during the inspection. Of these, none included a record of a patient care plan. Pain assessment and management was inconsistently noted in different records. In 2 records the World Health Organisation (WHO) surgical safety check list was not completed. Of the 15 patient records of general anaesthetic procedures, we saw that in 5 cases there were no surgeon written records of surgery completed in the notes. In one record there was only one entry included in the notes: this was documented by the recovery nurse and stated that patient had a delirious episode after waking up. In 3 patient records there was minimal information recorded in the notes overall.

None of the records included any discharge communications to the patient's GP. Staff informed us that patients may have refused consent for their GP to be contacted, however this was not documented in any of the patient records we reviewed, or actions indicated should there be any untoward findings following procedures at the service. Following the inspection, the registered manager informed us the service has a Discharge summary that is handed to the patient on discharge, with advice to hand this to their GP if they had no objections to this.

Records were stored securely. The service had an electronic record system for some records, as well as paper records for some of the care documents completed by healthcare assistants.

Medicines

The service did not follow systems and processes to safely prescribe, administer, record and store medicines.

Staff did not follow systems and processes to prescribe and administer medicines safely.

Staff did not complete medicines records accurately or keep them up-to-date.

Staff did not store and manage medicines and prescribing documents safely. Throughout inspection we saw the medicines cabinet remained open with the keys in the lock. The medicines cabinet was in an unlocked clinical room on the first floor, which was fully accessible from the ground floor.

Inadequate

Surgery

The service had been carrying out procedures under general anaesthetic from May 2023. The service did not have a secure medicines cabinet for storage of Controlled Drugs (CDs), or a Controlled Drugs register for the recording and administration of CDs when needed. The service did not have a Home Office licence which would be required for the management of controlled drugs. The service did not have a Home Office licence for the management of Controlled Drugs but had applied for this prior to inspection. The service had implemented a temporary system in which the anaesthetist would hold the CDs required for patient administration during general anaesthetic lists. However, the CD medicines used during the course of any GA lists would otherwise still need to be securely stored on the clinic premises.

We saw that in one record antibiotics had been administered however there was no related record of these having been prescribed or dispensed. We heard and saw that doctors would prescribe paracetamol for pain relief following local anaesthetic procedures; however, this would be administered by staff in theatre or recovery areas who were not qualified or competent to carry this out.

We saw from patient records that healthcare assistant staff administered paracetamol for patients requiring pain relief. However, these staff were not trained or appropriately qualified to be able to do this.

Incidents

The service did not manage patient safety incidents well. Staff did not recognise and report incidents and near misses. Managers did not comprehensively investigate incidents or share lessons learned with the whole team and the wider service.

Staff had a basic understanding of incidents which they described mostly in context of patient accidents or falls. They had a limited awareness of the types of incidents which could occur in the service and there was a lack of focus on incidents, sharing learning and promoting safety widely across the service. The provider had an incident reporting policy and process; however, this was not actively used in day-to-day practice. Staff did not always raise concerns and report incidents and near misses in line with the providers policy.

We saw that staff did not always report serious incidents clearly and in line with service policy. During the inspection we were told of 2 incidents where patients had sustained harm during their treatment. The provider had not shared details of these in a Statutory Notification to CQC. In our review of patient records, we saw details of a third patient who had sustained a similar injury which again had not been shared in a Statutory Notification or recorded as an incident. Another patient had needed to be transferred to an NHS hospital following their surgery; this was also not recognised or recorded as an incident.

The service had a duty of candour policy and staff understood the principles of being open and transparent, and giving patients and families a full explanation if and when things went wrong. Staff did not give any examples of when they had applied duty of candour processes.

Staff we spoke with said they did not receive feedback from investigation of incidents, but they would raise them to the clinic manager or registered manager when these occurred.

Staff met to discuss general feedback from managers and look at improvements to patient care.

Managers had a process for investigating incidents. At the time of inspection, a total of 4 incidents had been documented over a 12-month period, including the 2 incidents of patient harm. Service leaders planned to complete a serious incident investigation and root cause analysis for these incidents.

Inadequate

Surgery

Is the service effective?

Inadequate

Our rating of effective went down. We rated it as inadequate.

Evidence-based care and treatment

The service provided care and treatment which was not always based on national guidance and evidence-based practice.

The service had a range of policies related to different clinical and non-clinical activities. The policies we reviewed had been compiled by the registered manager and included key service areas, such as health and safety, safeguarding and recruitment. However, we saw that policies did not always reference best practice and national guidance. The service did not demonstrate in its policies how it ensured that cosmetic surgery was managed in accordance with professional and expert guidance for example as published by the Royal College of Surgeons.

From our observations and review of notes during inspection we saw there was limited evidence of how staff followed service policies. We could not determine from notes how people's physical, mental health and social needs were holistically assessed, and how their care, treatment and support was delivered in line with legislation and evidence-based practice to achieve effective outcomes.

Consultants working in the service informed us they would ensure that cosmetic pre-operative assessment included appropriate and relevant psychiatric history and discussion with people about body image before surgery is carried out. They described how any risks relating to body dysmorphia would be identified from this and the assessment documentation indicated this as a question. We did not see any examples of where consultants had noted psychological concerns which meant patients did not proceed to surgery. During our interview with service leaders, they informed us from the psychological point of view that patients were thoroughly assessed by different doctors to gauge their expectations. Leaders described how all this was taken into consideration, with mental health a high concern, and the service having a strong duty of care. Leaders informed us that 47% of patients do not proceed to treatment, after consultation.

At handover meetings, staff routinely referred to the psychological and emotional needs of patients.

Nutrition and hydration

Staff gave patients enough food and drink to meet their needs.

Staff made sure patients had enough to eat and drink.

Staff did not always fully and accurately complete patients' fluid charts where needed.

Pain relief

Staff assessed but did not always monitor patients regularly to see if they were in pain. They gave pain relief in a timely way.

Staff assessed patients' pain using their judgement and gave pain relief in line with individual needs.

Patients received pain relief soon after requesting it.

However, we saw from our review of patient records that some patients had experienced their pain was not well managed during procedures. They needed to continue to ask for additional pain relief during their procedure.

Doctors prescribed pain relief however this was administered by healthcare assistant staff who were not trained or competent to do this. Staff recorded administration of pain relief accurately.

Patient outcomes

Staff did not always monitor the effectiveness of care and treatment. They did not use the findings to make improvements and achieve good outcomes for patients.

The service did not participate in any relevant national clinical audits. The registered manager informed us they were aware of the Royal College of Surgeons' recommendations, also the Competition and Marketing Authority's future requirement, for Patient Reported Outcome Measures (PROMS) or 'QPROMS' data collection to be collected. This was anticipated to be introduced from July 2024.

Currently, the service's audit schedule included resuscitation trolley audits; medication expiry date audits; infection control audits; and fire safety audits. Results of these audits were included in a monthly quality audit.

The service provided details of their quality assurance programme which indicated results of the routine daily and weekly checklists that had been completed, and general areas of service activity. Included as part of these were results of daily cleaning logs, equipment servicing checklists; staff survey; adverse events management; policy and procedures review; and risk register.

However, the quality assurance programme did not include any direct detail of clinical outcomes for patients, or reference any key areas related to the service, such as how the service ensured that cosmetic surgery was managed in accordance with professional and expert guidance, for example as published by the Royal College of Surgeons. There was no specific reference to clinical professional standards relevant to the specialism, or auditing against these to determine the clinical quality and effectiveness in the service.

Managers reviewed the audit results for the general activities which had been completed, but these audits were not clinically comprehensive and did not have any direct relationship on improving patients' outcomes. The service's clinical audit policy stated that 'doctors and nurses may choose to carry out clinical audits. This will be discussed with the medical director in the first instance to clarify the scope of audit, data to be used, methodology and end objectives. Time frames will be then defined prior to audit commencing.' The service did not provide any examples of such audits and managers could not demonstrate how they used information from audits to improve patient care and treatment outcomes.

Competent staff

The service did not always make sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Inadequate

Surgery

Staff were experienced, but did not all have the required qualifications, skills, and knowledge to meet the needs of patients. At the time of inspection, none of the consultants in the service participated in the Royal College of Surgeons' Cosmetic Surgery certification scheme. Although this was not mandatory for consultants practising in independent health, the scheme would support the service in demonstrating how it was meeting the RCS's Professional Standards for Cosmetic Surgery2016.

Healthcare assistants worked unsupervised in areas of practice which they were not qualified or trained for.

Managers gave all new staff an induction before they started work, however, we were not assured that there were effective systems in place to ensure that staff were competent for the roles Included as subjects in staff induction, dependent on staff roles, were basic reception skills; clinic manager skills; registered manager skills; circulating practitioner/ support staff skills; scrub practitioner skills. The skills were recorded in a checklist, which supervising managers recorded when complete. We saw the clinic manager had signed off staff as competent when skills had been completed for clinical skills such as scrub practitioner and circulating practitioner. However, these were not formal competencies and staff had not completed accredited training in these areas of clinical practice.

The service provided details of staff appraisals which had been completed. We saw that healthcare assistant staff had met with the clinic manager and received regular monthly supervision.

Although managers met regularly with healthcare assistants, they did not always support staff to develop through yearly, constructive appraisals of their work. Healthcare assistant staff who had been recruited from overseas were not always being actively supported to progress their overseas nursing qualifications to achieve registration with the UK Nursing and Midwifery Council.

Staff had the opportunity to discuss training needs with their line manager but were not always supported to develop their skills and knowledge. We saw from staff appraisals that where staff had identified any training needs, managers had not always provided them the time and opportunity to develop their skills and knowledge. One such example was where a staff member had indicated they wanted to have full training as a scrub practitioner, however actions to support this were not identified.

Consultants working under practising privileges completed their annual appraisals with the General Medical Council (GMC) Responsible Officer, although record of this currently having been completed was not provided for one of the consultants. Another of the consultants whose main work was external to the service completed their annual appraisal in the NHS. The service held these records as their assurance of medical practitioners' competence to practice. Otherwise, there was limited evidence of how managers supported medical staff to develop through regular, constructive clinical supervision of their work.

Managers made sure staff attended team meetings or had access to full notes when they could not attend.

Multidisciplinary working

Doctors and nurses worked together as a team to benefit patients. They supported each other to provide care.

Staff worked with each other as a team to provide care for patients. Staff understood their role and responsibilities within the team setting. Staff described how there were limited circumstances which required working across health care disciplines and with other agencies. We did see however how doctors had engaged with NHS services to provide urgent care for a patient when this had been required.

Inadequate

Surgery

Seven-day services

Key services were available 7 days a week to support timely patient care.

Consultants worked flexibly in the service on different days in response to patient demand. This could include service activity at weekends.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not always support patients to make informed decisions about their care and treatment. They did not always follow national guidance to gain patients' consent.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

However, we saw that staff did not always gain consent from patients for their care and treatment in line with legislation and guidance. During inspection we noted that patients' consent was documented on the day of the procedure only and there was no record of any prior consent seen in the notes.

Staff did not always make sure patients consented to treatment based on all the information available. Following the inspection, we received concerns about how the service gained consent from patients on the day of the procedure which did not reflect the service's consent policy. At inspection, from records we reviewed, the service did not demonstrate how it ensured their consent policy was followed. The provider informed us processes were in place to ensure service users had a 14-day cooling off period to make a final decision about their care and treatment. However, patients we spoke with were not always clear about this and our review of records did not provide evidence of this process in practice.

However, where patients had undergone general anaesthetic procedures, we did see consent processes were appropriately followed and recorded and staff clearly recorded consent in the patients' records.

Staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards.

Is the service caring?

Good

Our rating of caring stayed the same. We rated it as good.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Where we were able to observe this during inspection, we saw that healthcare assistants were discreet and responsive when caring for patients. They took time to interact with patients and those close to them in a respectful and considerate way.

Patients we spoke with said staff treated them well and with kindness.

Staff followed policy to keep patient care and treatment confidential.

Inadequate

Surgery

Staff understood and respected the individual needs of each patient. The service provided examples of caring responses, including how staff ensured patients were comfortable in the clinic. Patients said how they felt very relaxed and at ease with the team, including for example how they could choose what music they wanted to listen to during their procedures.

Emotional support

Staff provided emotional support service users to minimise their distress and understood patients' personal needs.

Staff described how they gave patients and those close to them help, emotional support and advice when they needed it.

Staff described how they would support patients who became distressed in an open environment. We saw how staff understood the sensitive contexts of the care they were providing for patients, and they helped them maintain their privacy and dignity. We saw examples of how staff were able to support patients if they were anxious about their treatment and care.

Staff understood the emotional and social impact that a person's care, treatment, or condition had on their wellbeing.

Understanding and involvement of patients and those close to them

Staff supported service users to understand their condition but did not always support them to make decisions about their care and treatment.

Staff made sure patients and those close to them understood their care and treatment.

Staff talked with service users in a way they could understand.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. Patients were directed to complete a patient satisfaction survey following their surgery and results were positive.

Staff did not always support service users to make informed decisions about their care.

Patients gave positive feedback about the service.

Is the service responsive?

Requires Improvement

Our rating of responsive went down. We rated it as requires improvement.

Service delivery to meet the needs of local people

The service planned and provided care to meet the needs of local people seeking cosmetic surgery treatments.

Managers planned and organised cosmetic surgery services to provide for the needs and choices of fee-paying service users.

Service users had a choice of appointment and treatment times to suit their preferences.

Inadequate

Surgery

Meeting people's individual needs

The service took account of patients' individual needs and preferences although premises were not fully accessible.

Staff completed training in equality and diversity and were aware of the different individual needs which service users may have.

There was disabled access to enter the clinic from outside, and the reception area was fully accessible. The clinical treatment areas were on the first floor however were not accessible to wheelchair users or those with more limited mobility.

Staff in the service informed us they could access support for interpreting and translation if this were needed. We did not hear of any examples of where staff had needed to use this service.

The service did not have any information leaflets available in languages spoken by the service users in the local and wider community, however teams were able to produce these if required.

Access and flow

People could access the service when they needed it and received care promptly.

The service was available 5 days a week, between 8 am and 10 pm. Services were provided flexibly across each day, in response to demand and availability of consultants. We heard that this was equivalent to approximately 25 days a month on average. The service's aftercare team was available via the main administrative and call centre, this was routinely between 8am to 11pm every day, with on call arrangements outside of these hours.

Waiting times were short or negligible, depending on the treatment procedures being requested.

Learning from complaints and concerns

It was not always easy for people to give feedback and raise concerns about care received. The service had a process to investigate concerns and complaints.

Service users knew how to complain or raise concerns. Those we spoke with during the inspection said they were aware they could raise any issues with the service and that information was available on the clinic's website for this.

We did not see any information about how to raise a concern either displayed in patient areas or on the company website. Following the inspection, the registered manager informed us that the service makes contact with every patient by phone the next working day and where concerns are raised, a complaints form would be emailed to them.

Service leaders told us they aimed to resolve any issues that were raised at an early stage and that there was a low level of complaints received. Managers shared any feedback from complaints with staff.

The service had a policy on complaints and managers investigated complaints, with 5 documented complaints recorded at the time of inspection. We reviewed these and observed the service's letter responses to complaints appeared dismissive of the concerns and seemed abrupt in tone. The service appeared to primarily consider any complaints raised as being made in context of service users seeking financial recompense. We saw wording in the service's response

appearing to support this, including such as "risk of pain is present in the surgical consent form you have signed. In light of the above we will not be offering you any sort of refund. If you are dissatisfied with this response, please feel free to seek legal advice on your alternative options." The style of the complaints responses we reviewed appeared defensive, with language and wording poorly constructed. There was limited evidence of learning from complaints.

Both prior to and following the inspection we heard from other service users who had experienced a poor response in seeking follow up to their concerns, and who also felt inhibited from raising any further complaint due to a strongly worded response received from the provider.

The service did not signpost service users to other routes for resolution of their complaint and was not a member of the Independent Services Complaint Advisory Services (ISCAS), or the Independent Doctors Federation (IDF) with regards to complaints management.

Is the service 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 manage the priorities and issues the service faced. They were visible and approachable in the service for staff. They did not always support staff to develop their skills and take on more senior roles.

There was a registered manager and a clinic manager locally in the service. The registered manager was a former GP and was the medical director and company director of Signature Medical Limited. The company's senior leadership structure also included a chief executive and a chief medical officer based in the services administrative and call centre headquarters in Glasgow. Together with the registered manager, the senior leadership team had oversight across all the different service locations in day-to-day practice. During inspection we spoke with the chief executive and chief medical officer who told us they spent on average 2 weeks in every month at the Manchester clinic. The senior leadership teams' visits also included to service locations and clinics in Scotland and Wales, which were under regulation by the equivalent regulatory bodies in those countries. The service also had an operations manager who was being supported into this role, having previously been the company's human resources manager.

Although there was a leadership structure, we saw that leaders did not have a clear focus on good safety practice in the service. They did not ensure that employees who are involved in the performance of invasive procedures were given adequate time and support to be educated and updated in good safety practice, to train together as teams and to understand the human factors that underpin the delivery of safer patient care.

The registered manager described how they were available at the location on a regular basis. However, they were also the registered manager and had oversight of the 2 other registered locations in England, as well as having frequent visits to the service's administrative and call centre headquarters, in Glasgow. We heard that the registered manager had the lead responsibility across a range of different operational activities, including being the lead for safeguarding, the incident investigator, as well as being a director of Signature Medical Limited. The registered manager described how they had been training up the clinic manager to become the CQC registered manager, and how they had a similar plan for

upskilling staff into this role at the Birmingham and London clinic locations. However, we had concerns about the registered manager's capacity to fulfil such a wide range of day-to-day responsibilities in practice. Although the registered manager was visible for staff whenever they were at the location, we observed there was a lack of shared leadership and delegated responsibility in the service overall.

Leaders did not ensure that processes were clearly in place which all staff followed when carrying out cosmetic surgery procedures. The clinic manager appeared to have responsibility for decisions about any escalation and in order to respond to concerns, issues, and requests from healthcare assistants as well as consultants employed in the service.

Vision and Strategy

The service had a vision for what it wanted to achieve but did not have a strategy to turn this into action. Staff were not aware of the services vision and leaders did not implement actions or monitor progress to implement a strategy.

The service provided details of their vision and strategy document which included details of the company's values. These were expressed as

● Great Results that are life changing – All treatments we offer have the potential to give life changing results. Treatments are offered by qualified registered Surgeons with significant experience in the treatments.

● Friendly Positive Experience - Right from the time of making an enquiry, to visiting the clinic and aftercare - we provide a friendly, warm experience.

● Minimally Intrusive – We focus on procedures that are carried out under local anaesthesia and patients are only in clinic for as long as required clinically.

Whilst service leaders had identified a clear vision for the service, staff we spoke with had limited knowledge of the company's values. The values did not specifically reference service quality and sustainability as key priorities.

The service's strategy document was generalised and did not articulate how leaders prioritised safety as central to the cosmetic surgery services provided. The provider did not have a clear clinical strategy to support delivery of the service's vision.

Culture

Staff told us they felt supported. They were focused on the needs of patients receiving care. The service did not provide opportunities for career development. The service did not always have an open culture where service users and staff could raise concerns without fear.

Staff we spoke with during the inspection said they felt supported by managers. Managers described the culture as being strong. We heard the culture was centred around the clinic manager, who had a key role in leading staff in their day-to-day service activities. We observed that the clinic manager held a wide responsibility for operational activities and that in practice, healthcare assistants routinely directed their queries, requests, or concerns to the clinic manager rather than other clinical or managerial staff, should this be needed.

We saw that healthcare assistants appeared to be focused on the needs of patients when providing care.

However, there was limited opportunity for career development. We did not see how the staff who were aiming to progress to registration with the UK Nursing and Midwifery Council were being actively supported to achieve this.

Consultants were positive about their experience of working in the service and said they felt they had opportunity to raise any issues or concerns to senior leaders, and that these would be responded to.

Although we mostly heard positive comments from staff we spoke with, the culture in the service did not always appear to be open. In particular, we had some concerns from our review of complaints responses that staff in the service did not always acknowledge the issues being raised, and tended to dismiss patients when they were seeking clarification or advice if they were worried.

Governance

Leaders had a governance process in the service although there was lack of clarity in these arrangements. Staff at all levels were not always clear about their roles and accountabilities. Staff did not always have regular opportunities to meet, discuss and learn from the performance of the service.

The service provided details of their clinical governance framework and terms of reference, which had been introduced in April 2023. This stated clinical governance meetings would be held monthly, chaired by the medical director, and attended by the chief executive and operations director, with attendance by others with prior approval from the chair. Meeting minutes over the past 3 months indicated there was a standing agenda with items reviewed including the number and types of procedures completed in service activity; a review of incidents and a review of complaints.

One of the consultants advised that there were regular clinical governance meetings held every 3 to 4 weeks and that the surgeons and co-founders attend these. This consultant informed us they had been responsible for the quality assurance processes for a time and had produced a report on these to this meeting. We were also informed by the registered manager that the operations manager had responsibility for clinical governance, which the operations manager confirmed in addition. The registered manager had previously been the human resources manager and was in the process of being supported into the role of operations director.

There were unclear, and ineffective systems and processes in place for assessing, monitoring, and improving the quality and safety of the services provided. Communications between different parts of the service and individual responsibilities at senior levels were not always clear; there was a lack of formal recording in meeting minutes, with an apparent reliance on the registered manager's knowledge of the service in day-to-day practice. The governance framework was newly implemented and not yet embedded in the service and there was a lack of whole service development in building robust systems for oversight and governance in the service.

The chief medical officer informed us they met in weekly calls with the consultants working in the service under practising privileges. This was primarily a call to manage planning for clinical procedures and beyond discussion of scheduling details was not a meeting which was formally recorded in meeting minutes. The registered manager informed us they held meetings for the Medical Advisory Committee (MAC) to oversee employment of consultants working under practising privileges. We saw from our review of meeting minutes the service did not have a robust process for the oversight and management of practising privileges. The MAC minutes did not demonstrate the full oversight of clinical risk assessment and decision making.

The service did not provide details of full team meetings and we heard from staff that these were not currently being held.

Inadequate

Surgery

Management of risk, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not always identify or escalate relevant risks and issues or identify actions to reduce their impact.

The service documented key risks in a risk register document. At the time of inspection, the identified risks included "No ventilation in theatres for GA; Risk of smoke inhalation with electrocautery; Medical Gas training for staff; and Burns from electrocautery unit (in GA patients)." However, actions identified to mitigate any risks were not always comprehensive and assurance systems were weak. The service had introduced general anaesthetic procedures in the knowledge that there were significant risks of carrying these out in the environment. The service had not identified risks relating to NHS guidance in Health Building Note (HBN) 10-02- day surgery facilities.

The risk register also did not include any of the key risks we had identified during inspection, with regards to medicines management, staff qualification, training and competency, infection prevention and control, and oversight of service performance.

Performance issues were not always escalated appropriately through clear structures and processes were not in place to ensure these were regularly reviewed and improved.

Information Management

The service collected data and patient information relevant to the service. Staff could find the service information they needed, to understand performance. The information systems were integrated and secure.

The service used electronic computer systems for storing and transferring information about service users. We saw these were password protected. Staff had access to service documents through computer terminals.

Engagement

Leaders and staff responsively engaged with patients and staff. However, they did not proactively engage with people who use services to help shape services.

The service engaged with staff in email communications and social media platforms. There was some level of staff engagement so that their views were reflected in the planning and delivery of services. The majority of engagement with service users was in response to website enquiries and other contacts through the service's social media platforms.

The service did not actively engage otherwise with people who use services, community groups of others interested in being involved in decision-making to shape services and culture.

Learning and continuous improvement

There was a lack of understanding of quality improvement methods and limited skills to use these, although staff were generally committed to improving services.

Leaders did not use any standardised improvement methods in the service and there was a lack of focus on quality improvement and innovation.

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
Treatment of disease, disorder or injury Surgical procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing The provider did not ensure there were sufficient numbers of suitably qualified, competent, skilled, and experienced persons deployed in the service and that they received appropriate support, training, professional development, supervision and training as necessary to enable them to carry out the duties they are employed to perform. They did not support staff where appropriate to obtain further qualifications appropriate to the work they perform

Regulated activity	Regulation
Treatment of disease, disorder or injury Surgical procedures	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints The provider did not have effective and accessible systems for identifying, receiving, recording, handling, and responding to complaints by service users.

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
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider did not have systems and processes in place to manage the safe use of the clinical environment and equipment. The provider did not have did not have systems and processes in place for the proper and safe management of medicines. The provider did not use risk assessments to identify, manage and mitigate the risks to the health and safety and welfare of people using the service. The provider did not ensure that persons providing care or treatment to service users had the qualifications, competence skills and experience to do so safely.

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider failed to ensure there were effective systems for good governance in the service and did not have processes to ensure that any risks to the health, safety and welfare of people who use the service were identified, assessed or mitigated. The provider had unclear, and ineffective systems and processes in place for assessing monitoring and improving the quality and safety of the services provided.