

The Hair Loss Clinic (NW) Limited

Leenside Surgical

Inspection report

367 Derby Road
Nottingham
NG7 2EB
Tel: 07791039239
www.ukhairtransplantclinics.co.uk

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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

We have not previously inspected this location. We rated it as inadequate because:

- The service did not control infection risk well. There were gaps in monitoring and assurance of safety standards, practices, and the environment. The service was not compliant with multiple national standards.
- Staff training was inconsistent, and records did not provide assurance of good standards.
- Staff lacked oversight of key clinical safety measures and processes, including for emergency medical equipment and health and safety equipment.
- There was limited monitoring of the effectiveness of care and the service did not have a patient outcome audit programme.
- Leaders did not operate the service with reliable information systems that provided assurance of quality, safety, and performance. Outsourcing of some key processes and policies to another organisation had resulted in risks to patients and staff that the provider had not identified.
- Staff did not understand all their roles and accountabilities and had not identified or acted on clear, demonstrable risks. The provider had no oversight of these gaps.
- The provider did not effectively manage policies and procedures, some of which were significantly overdue for review or undated.

However:

- Staff had training in safeguarding and understood how to protect patients from abuse.
- The service had enough staff to care for patients. Staff assessed clinical risks to patients, acted on them, and kept good care records.
- Staff provided good standards of surgical care and managed pain well.
- Staff worked well together for the benefit of patients, supported them to make decisions about their care, and had access to good clinical information.
- The service planned care to meet the individual needs of people.
- Staff worked within high standards of medical ethics. They felt respected, supported and valued and were focused on the needs of patients.
- Staff treated patients with compassion and kindness and helped them understand treatment options.

As we found the provider breached the regulations, we took action to ensure they improve. Following our inspection, we have served 2 Warning Notices under Section 29 of the Health and Social Care Act 2008. We notified the provider that they failed to comply with The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014; the provider failed to comply with Regulation 12 (1)(2)(a)(b)(d)(e)(f)(g)(h)(i), Safe care and treatment, and Regulation 17(1)(2)(a)(b), Good governance. The provider is required to achieve compliance with the relevant requirement within the timescale set in the Warning Notices.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inadequate 	We rated this service as inadequate. Please see the main summary.

Summary of findings

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Summary of this inspection

Background to Leenside Surgical

Leenside Surgical is operated by The Hair Loss Clinic (NW) Limited. The service provides private hair transplant surgery for aesthetic, non-medical purposes to self-paying adult patients. Staff deliver follicular unit transplantation (FUT) and follicular unit extraction (FUE), which relate to specific types of hair transplantation.

The service is provided from rented space in a clinic that is owned, operated, and maintained by another CQC-registered provider. The service employs or contracts its own staff and is responsible for patient care and outcomes but uses equipment, medicines, and medical consumables provided by the building operator. While the building operator does not form part of our judgement, the areas of responsibility of staff working for or providing care under the registration of The Hair Loss Clinic (NW) Limited are included.

The provider did not deliver any care under its CQC registration between December 2022 and June 2023. Between July and December 2023, the service provided treatment to an average of 2 patients per week. Data and evidence in our report relate to this 6-month period.

The service registered with CQC in March 2018 to provide the following regulated activities:

- Surgical procedures

We have not previously inspected the service.

After our inspection the provider told us they had submitted an application to deregister this location.

How we carried out this inspection

We carried out an unannounced inspection of the service on 15 December 2023 using our comprehensive methodology. During our inspection we spoke with staff and patients, observed care and treatment, reviewed patient records, and assessed local facilities and safety procedures. After our inspection we spoke with the registered manager and chief executive officer, and asked the provider to submit a range of evidence.

The inspection team consisted of a lead CQC inspector, a specialist advisor, and off-site support from an operations manager.

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 service **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:

Summary of this inspection

- The service must ensure staff are aware of the emergency equipment, including medicines, on site and understand their location and use. Regulation 12(1)(2)(d)(e)(i).
- The service must ensure medicines management processes provide assurance of safety and follow good practice. Regulation 12(2)(f)(g).
- The service must ensure patients are protected from the risks of surgical site infections, such as those caused by poor adherence to infection prevention and control policies. Regulation 12(1)(2)(a)(b)(h)(i).
- The service must ensure surgical instruments are handled in accordance with manufacturer guidance and that staff maintain the sterile field when preparing for surgery. Regulation 15(1)(d)(f)(2).
- The service must ensure patients are protected from the risks of poor cleanliness and contamination through effective management and assurance of the clinical space. Regulation 15(1)(a)(e).
- The service must ensure compliance with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 in relation to sharps management. Regulation 15(1)(d).
- The service must ensure compliance with the Control of Substances Hazardous to Health (COSHH) Regulations. Regulation 15(1)(d).
- The service must ensure assurance of good standards of fire safety. Regulation 15(1)(d).
- The service must ensure the complaints policy and procedure is readily available for patients. Regulation 16(2).
- The service must ensure effective governance processes are implemented so as to provide oversight of all the above 'must' requirements. Regulation 17(1)(2)(a)(b).
- The service must ensure processes are implemented that provide staff with assurance of effective cleaning of clinical areas and equipment before delivering care. Regulation 17(1)(2)(a)(b).
- The service must ensure governance systems support the safe and well led delivery of care, including monitoring of standards that are the primary responsibility of other organisations under service level agreements. Regulation 17(1)(2)(a)(b).
- The service must ensure staff follow infection prevention and control policies and procedures through consistent assurance processes. Regulation 17(1)(2)(a)(b).
- The service must establish and maintain oversight of staff training so that it has assurance of competence. Regulation 17(1)(2)(a)(b).
- The service must ensure staff training reflects the needs of patients and treatment offered. Regulation 18(2)(a)(b).
- The service must ensure staff are competent for their roles and have access to up-to-date policies and standard operating procedures. Regulation 18(1)(2)(a).

Action the service **SHOULD** take to improve:

- The service should ensure staff follow consistent standards of practice in the use of personal protective equipment. Regulation 12.
- The service should ensure there are systems and processes in place that monitor and evidence patient outcomes. Regulation 17.
- The service should ensure risk mitigation is in place to address areas of non-compliance with clinical environment standards, including the Department of Health and Social Care Health Building Note 00/10. Regulation 17.
- The service should ensure staff have a consistent, good standard of induction that includes local procedures. Regulation 18.

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

Surgery

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

Is the service safe?

Inadequate 

We have not previously inspected safe. We rated it as inadequate.

Mandatory training

The service provided mandatory training in key skills to all staff although completion was inconsistent.

Staff received mandatory training although there were significant gaps in the provider's documentation and tracking of completion. The provider maintained 2 tracking documents, 1 of which showed all staff had up to date training in 9 core modules including infection control, safeguarding, equality and diversity, and privacy and dignity. However, a second training tracker included contradictory or irrelevant information. For example, staff completed infection prevention and control (IPC) training, but the tracker showed no staff had completed hand hygiene training.

The tracker listed 'foot care' as a required module despite the service not providing any type of care involving feet. After our inspection, the provider told us IPC training included hand hygiene and they did not know why foot care appeared on the training requirements. During our inspection, information the provider supplied indicated they did not track training compliance as proportion or percentage, which reflected gaps in oversight. However, after our inspection, the provider sent us information that evidenced 100% compliance with training standards.

All staff worked on zero-hour contracts and completed online training. The registered manager said they were responsible for ensuring everyone remained up to date although there was no structured format for this to take place.

Safeguarding

Staff understood how to protect patients from abuse. They had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. All staff completed training in safeguarding adults level 3 and in safeguarding children to a minimum of level 1. While the clinic did not treat patients under the age of 18, staff completed training in safeguarding children and young people. This was good practice as children could be present in the clinic when accompanying a patient.

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The provider maintained an up-to-date safeguarding policy with contact details for the local authority safeguarding team. Staff had good knowledge of how to raise a safeguarding concern, including in an urgent or crisis situation.

Cleanliness, infection control and hygiene

The service did not control infection risk well. Systems to identify and prevent surgical site infections were inconsistent and there were gaps in effective control measures. Staff kept equipment and the premises visibly clean but had limited assurance of effectiveness.

Clinical and waiting areas were visibly clean although some furnishings were unsuitable and there were gaps in maintenance. For example, surgical theatres were equipped with domestic hot air hand dryers instead of paper towels. This was not compliant with the Department of Health and Social Care (DHSC) Health Building Note (HBN) 00/09 in relation to infection control in the built environment. This was because the hand dryers risked contamination of surgical sites by circulating dust around the theatre. During our inspection, we spoke with staff about this who said paper towels were available but kept in cupboards and were not accessible hands-free during treatment. This reflected a gap in understanding and risk management between the building operator and the provider.

After our inspection the provider told us they instructed staff to use paper towels instead of the hand dryers.

Expected standards of cleanliness were directed by the provider's policy and the service level agreement (SLA) with the building operator. This reflected the sporadic use of the clinic and the nature of using rented space.

The provider reported no surgical site infections (SSIs) in the previous 6 months. However, gaps in governance around IPC meant it was unclear if SSIs would be reported by the provider or by the building operator. After our inspection the provider told us frequent post-operative contact with patients would identify any concerns.

Most staff followed infection control principles including the use of personal protective equipment (PPE). During our inspection, staff used gloves and aprons appropriately. However, the team did not consistently follow good practice in the use of surgical face masks. During our inspection, some staff wore face masks continuously, moving them under their nose or chin when leaving clinical areas. This was poor practice and reduced the effectiveness of the masks. After our inspection the provider told us staff were reminded of the correct use of face masks in line with good practice.

The provider's IPC policy did not reflect local practices in the clinic. For example, staff cleaned clinical spaces after each patient and at the end of each list and recorded photographic evidence of this as part of the assurance process. However, the policy instructed staff to clean areas, such as cupboard doors and light fittings, which was not routine practice. In addition, 2 technicians we spoke with were unaware of the cleaning checklist the provider expected them to use at the end of each shift.

On the day of our inspection all but 1 member of staff were unfamiliar with the location of biohazard spill kits, including for blood and vomit spills. The use and location of these kits were included in the provider's IPC policy, but most staff could not locate them or explain the procedure for their use. After our inspection the provider re-inducted staff and included the location and use of spill kits. They also provided their own spill kits, which reduced the risk of poor management from the building operator.

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During our inspection, there were unmitigated risks to patient and staff safety resulting from poor IPC standards. For example, the expiry dates on wall-mounted antibacterial hand gel dispensers had passed over 12 months ago, indicating the gel may no longer be useful. After our inspection, the provider told us the building operator filled up the bottles from a larger container, which was in date. However, there was no documented evidence the provider was aware of this or that staff had noticed and checked expiry dates before using the products.

During our inspection, we saw it was usual practice for staff to keep theatre doors open during procedures. This meant ventilation systems designed to prevent infection would not work effectively and increased the risk of contamination of surgical sites.

Staff cleaned clinical surfaces with antibacterial wipes between patients and at the end of each shift. They photographed each area and uploaded digital images to the provider's secure records portal for the senior team to monitor standards. However, there was no labelling system to give staff assurance equipment had been cleaned and sanitised before the service began. The provider delivered care from the premises sporadically and did not know how the clinical spaces were used between these dates. While they had an SLA with the building operator to maintain cleanliness ready for surgery dates, there was no documented assurance or checks, other than an assumption of good practice and a visual check. During our inspection, the radiator grill in the main surgical room was coated in a layer of dust. Despite staff telling us they checked cleanliness and were happy with the standard, none of the team had noticed this, which presented a risk of contamination of surgical sites.

After our inspection the provider improved cleaning processes to provide assurance of consistent standards, including the introduction of pre-treatment checklists.

Cleaning records were disjointed and there was no local assurance of consistent standards of practice. A maintenance record stated a requirement for the completion of a daily cleaning checklist supplemented by cleaning after each clinical procedure. However, this record had not been completed in the previous 4 days and staff said they did not know who was responsible for it.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment needed maintenance in some areas. Staff managed clinical waste well but were exposed to risk caused by poor practices of the building operator.

Most of the environment followed national guidance. However, there were gaps in compliance. For example, sinks in surgical rooms had water overflows, which was not in line with DHSC HBN 00/10 in relation to the design of healthcare facilities. Overflows present a risk of bacterial growth, such as Legionella, and design guidance recommends they are not present in surgical suites.

Most areas of the clinic were in a good state of repair. However, some floors and skirting were damaged and had gaps in the wooden joints. This presented a risk of bacteria growth because it meant the floors could not be adequately cleaned. This meant the service was not fully compliant with the DHSC HBN 00/10 in relation to the design of healthcare facilities.

This provider was not responsible for the maintenance or design of the building. However, there were no risk assessments or other mitigating processes in place to protect staff and patients from the risks. Staff on duty had not noticed any of the damaged areas and after our inspection the provider told us they were unaware of the issues.

Staff disposed of clinical waste safely and in line with the DHSC Health Technical Memorandum (HTM) 07/01 in relation to the safe disposal of healthcare waste. They used appropriate streaming and colour-coded bags. However, on the day of

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our inspection there was evidence of hazardous waste disposed of in a domestic waste bin in the car park. This presented a risk to the public and we escalated concerns urgently to the local authority environmental health department. Staff told us they did not use the bin and the hazardous waste belonged to the building operator. This system meant staff and visitors were at risk from poor practices by the building operator, of which the provider had no oversight.

The service was not compliant with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 or the DHSC HTM 07/10 because not all sharps bins had labels completed with a signature and date. After our inspection the provider added this issue to the pre-surgical checklist to provide assurance of consistent practice.

The service was not compliant with the Control of Substances Hazardous to Health (COSHH) Regulations. Chemicals were stored in an unlocked cupboard with no restricted access and no hazard or product information notices. This presented a risk of unauthorised access by people who could be harmed.

Staff carried out surgery with single-use, disposable instruments. This was good practice because it reduced the risk of cross-contamination. However, staff did not manage these in line with best practice guidance. During our inspection, we observed it was common practice for staff to unwrap sealed items ahead of a procedure and lay them out in the surgical room with the door open. This presented a risk of contamination by dust and bacteria. After our inspection the provider told us this was not standard operating practice and said they would remind staff of the correct process. The provider amended the pre-surgery checklist to require staff to sign to confirm single-use instruments had been opened only once treatment commenced.

While staff told us they were happy with the clinical environment, cleanliness, and equipment during our inspection, the provider's most recent technician survey indicated staff had a range of experiences in the clinic, including a need for more consistent standards of cleanliness and availability of equipment.

There were significant gaps in fire safety that presented a risk to anyone in the building. The most recent fire risk assessment took place in August 2022 and was carried out by a specialist contractor. It found there was no responsible or appointed competent person in undertaking preventative and protective measures, no fire doors, and no safe means of evacuation for people with mobility disabilities. The provider did not have a fire warden, did not carry out fire drills, and staff had limited knowledge of equipment. The provider told us this was the landlord's responsibility, although this individual was not usually present when regulated activities took place. After our inspection, the registered manager and lead technician completed fire warden training.

Fire exits were clearly marked but the location and availability of fire extinguishers did not meet national standards. There was no signage in place to indicate the location of fire extinguishers, some of which were stored in an unmarked utility area and others behind a door to the staff changing room. Fire extinguisher safety posters displayed above them did not accurately represent the types of extinguishers in place, which meant users may not understand the risks of using the incorrect type of extinguisher. This reflected poor fire safety practice. We spoke with staff about this who said they did not know where fire extinguishers were located and that this was the responsibility of the building owner. Staff did not have awareness of their own safety or that of patients and colleagues. After our inspection the provider sent us evidence of improved practice, including more accountability for local procedures that were previously the responsibility of the building operator.

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The last documented fire alarm check took place in November 2020, over 3 years prior to our inspection. There were no fire extinguishers in the waiting room or adjacent areas, and access to the rear fire exit was partially blocked by floor to ceiling blinds. After our inspection the provider sent us a log that indicated monthly fire alarm tests had been carried out during the previous 12 months. This log also indicated monthly evacuation training had been carried out although it was unclear who this involved or how it was assessed.

Biohazard spill kits, including for the safe removal of blood and other bodily fluids, had expired over 5 years previously. While these products were the ultimate responsibility of the building operator, they were made available for use by clinic staff without an assurance process that they were in date and ready for use.

It was not evident in the clinic which organisation was providing care or operating the building. Sign-in logs were placed on the reception desk but none of the staff on duty during the inspection had signed in. A log was dedicated to providing assurance to staff, patients, or visitors, that everyone knew about the risk of COVID-19 infection. However, staff were unaware of the log or who needed to sign it. Leaflets regarding surgeon accreditation by the American Board of Hair Restoration Surgery were in the waiting area and consultation rooms but it was unclear if these applied to this provider or to the building operator. After our inspection the provider told us they provided each patient with details of their surgeon's credentials in advance of treatment.

The building underwent an annual Legionella check and risk assessment, which were in date.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient but systems to keep people safe were poor.

Staff used a nationally recognised tool to identify deteriorating patients and escalate them appropriately. This system was integrated in the electronic patient records system and provided staff with a single tool for all clinical observations.

Staff completed risk assessments for each patient on arrival and reviewed this during procedures. Surgical teams used a version of the World Health Organisation surgical safety checklist modified for cosmetic hair transplants. During our inspection staff completed checklists thoroughly and made sure patients were fit for surgery by checking baseline measures such as blood pressure. Surgeons reviewed each patient's consultation notes and medical history prior to the start of treatment. Where they found risks or a need for further investigation, they met with patients ahead of surgery to plan treatment safely.

Staff took account of patient's psychosocial needs at the consultation stage. This was a process to reduce the risk of providing inappropriate treatment to patients who presented with potential barriers to treatment. For example, staff found men under the age of 25 often rushed into a decision about treatment without considering the recovery process and potential risks. They also recognised repeated attempts to secure surgery, and decisions made in very short periods of time, as potential risks that required more in-depth discussions. This approach worked well in practice. For example, a surgeon had recently declined to proceed with treatment when the patient had stated their treatment goal was to "look perfect".

Systems and practices for managing clinical emergencies were inadequate. An emergency equipment box was located near the treatment rooms. However, the contents were poorly maintained and would present a significant risk to patients in the event of a medical emergency. For example, the emergency box contained ampules of adrenaline, a medicine used to treat anaphylaxis. However, there was no equipment in the box to administer the medicine, such as syringes. The

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surgeon told us the emergency box contained an EpiPen, which was not the case. These issues combined presented a risk to patient safety because staff response to anaphylaxis would be delayed due to a lack of equipment and inaccurate knowledge of stock. In addition, a battery-powered laryngoscope had expired in January 2020 and the contents label of the emergency equipment box did not match the contents.

The emergency box included an automatic external defibrillator that was ready for use but instructed the user to call 911 instead of 999. In addition, single-use emergency items, such as airway masks and tubes had all expired between 3 and 5 years previously. The first aid box had expired 2 years previously and the sodium chloride used to irrigate eyes in the emergency eye wash kit had expired 2 years previously. This reflected the lack of safe working processes and policies and no accountability from staff working in the clinic or managers responsible for them. After our inspection the provider told us the surgeon would use saline to address an eye emergency as this was always available during treatment.

After our inspection the provider changed practice and provided their own emergency bag, which included in-date equipment and was intended to improve accountability and safety.

The provider had processes in place to maintain safety when patients requested a different treatment on the day of surgery than had been agreed at the consultation. This was a surgeon-led process and they worked with the patient and surgical team to make sure treatment was safe, appropriate, and within the consent process.

Surgeons required a normal blood pressure before surgery could begin. The service established each patient's baseline blood pressure at the consultation stage. If the patient's blood pressure was elevated just prior to surgery, the surgeon waited for this to lower before proceeding. If this did not happen in a reasonable period of time, they sent the patient home with a blood pressure monitoring device for 2 days to establish if their baseline had changed. This was good practice and reflected the contradiction between good risk assessment processes in relation to treatment and poor processes in the clinical environment.

Staffing

The service had enough staff with the right qualifications, skills, and experience to provide the right care and treatment. However, there was limited assurance the induction process was effective.

The service had enough staff to keep patients safe. As this clinic was used only on demand, it did not have a substantive staff team. Instead, the provider arranged a surgeon and technicians in advance when patients requested treatment. A team of 1 surgeon working under practising privilege arrangements and 12 technicians working under zero-hour contracts provided care and treatment.

The provider carried out appropriate pre-employment checks with each member of staff before they could start work. This included a Disclosure and Barring Service check and the receipt of professional references. The process met the provider's obligations under national legislation.

Managers made sure all staff had an induction and understood the service before they provided care. This included a provider-level induction followed by a clinic induction to familiarise staff with local procedures. While this reflected good practice, there was limited assurance the induction process was effective. During our inspection, some technicians were unfamiliar with the environment. They could not locate critically important equipment, such as biohazard spill kits or fire extinguishers, and knew little about local procedures. None of the staff on duty could name who led their induction. After our inspection the provider told us the building operator carried out the orientation and site induction. While this was useful based on ownership and governance arrangements, the provider had no assurance of the quality or usefulness of such processes.

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Technicians worked for up to 3 organisations in this clinic; this provider, the building operator, and for a surgeon who delivered care to their own patients under a separate registration. When providing care to patients being treated by this provider, staff were accountable to the registered manager and the provider's policies.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive, and all staff could access them easily. The provider used an electronic records system that enabled staff to record and access consultation, treatment, and postoperative information remotely. Staff recorded information about their discussions with patients such as their intended goals and any worries.

An on-call surgeon was always available for urgent out of hours patient queries. They had access to care and treatment information remotely using the electronic system.

Records were stored securely with digital encryption, restricted access, and back-up systems to protect against IT failures.

The registered manager carried out a continuous auditing programme of patient documentation and reviewed this after each procedure. Audits from the previous 6 months demonstrated consistently good practice, with 100% of records including completed consultation notes, surgical scripts, and discharge letters.

Medicines

Systems and processes to prescribe, administer, record, and store medicines did not provide assurance of safe practice.

Staff followed systems and processes to prescribe and administer medicines safely. They completed medicines records accurately and kept them up to date. The building operator supplied medicines in advance of planned procedures by leaving them out in treatment areas for staff to access. The surgeon ordered medicine in advance of treatment after reviewing the patient's treatment plan. Medicines were limited to local analgesia (pain relief) and antibiotics for use postoperatively.

Surgeons documented the batch numbers and expiry dates of medicines in patient records, which was good practice.

Staff did not have access to medicine storage. The SLA between the provider and the building operator meant it was the responsibility of the supplier to maintain appropriate standards, such as safe temperature ranges. While this system was intended to make sure staff had assurance of good medicine management practices, the environment was not well managed. For example, during our inspection, a box of painkillers and antibiotics had been left on the table of an unlocked consultation room with the door open. In the technician's room, an ampule of adrenaline and ampules of anaesthetic were discarded on a counter surface. This presented a risk of unsafe access.

During our inspection, staff did not have easy access to stock, such as in the event of a spillage. The surgeon on duty during our inspection told us they would call the building operator if they needed more stock. However, the operator was a practising surgeon at another facility and there was no agreement in place for expected response times. After our inspection the provider told us extra medicine was always prepared in advance and available to staff. We were unable to establish why the provider and staff on site had a different understanding of the system.

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The provider introduced an emergency grab bag after our inspection, which contained emergency medicine and a contents list and auditing checklist. This meant there was new assurance of a structured, appropriate range of equipment.

The provider had an agreement with a third-party pharmacist who sent prescriptions to patients if they were issued postoperatively by a surgeon. This enabled patients with extended recovery times to access medicines without delay.

Incidents

The service had no track record of acting on incidents although staff said they knew how to report them.

Staff said they knew what incidents to report and would contact the registered manager to do so. None of the staff on duty during our inspection had reported an incident or could describe learning as a result of an incident elsewhere.

The provider had an incident reporting policy and the registered manager maintained oversight of staff concerns and near misses. However, there were no reported incidents at this location and there was no assurance the provider applied learning from incidents elsewhere. After our inspection the provider told us about incidents at their Manchester clinic and said learning was identified across their locations. However, staff said they did not know about any incidents when we spoke with them during the inspection.

The provider had stopped in-person meetings for staff and instead communicated using e-mail and digital apps. There was no evidence the provider made sure staff were up to date with incident investigations or national safety alerts. After our inspection the provider told us such information was monitored by the senior team and disseminated to staff on a “need to know” basis

Is the service effective?

Inadequate 

We have not previously inspected effective. We rated it as inadequate.

Evidence-based care and treatment

The service provided care and treatment based on published guidance. However, the provider had limited assurance of evidence-based practice.

Staff followed guidance from The National Institute for Health and Care Excellence and the International Society of Hair Restoration Surgery to deliver care and treatment. We saw this in practice during our inspection. However, the provider did not have a system for auditing or quality assurance that demonstrated consistent standards of practice. After our inspection the provider told us they had implemented a quality and monitoring audit process that assessed the effectiveness of each stage of the treatment cycle.

Policies and standard operating procedures (SOPs) were of inconsistent quality and did not have standard quality tracking features, such as version control or accountable, named authors. For example, the privacy and decency policy dated from 2018 and a review was 3 years overdue. Staff on duty during our inspection, could not articulate how they accessed policies or SOPs other than by asking for them from the registered manager. This meant patients did not have assurance care was provided by staff who had appropriate access to essential information. After our inspection the provider implemented a digital tracking system that would enable the registered manager to identify when policies needed review.

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The chief executive officer was a senior hair loss advisor and provided oversight of standards of care and practice according to governance records and team meetings. We could not establish how this maintained or improved adherence to best practice and patient outcomes. After our inspection the provider sent us details of improvements made as a result of governance reviews. This included a change in advice to patients about shaving their head in advance of treatment, which was found to irritate the skin.

The provider encouraged surgeons to attend conferences and monitor international research in the field. Where new treatment techniques or emerging care options were introduced elsewhere, staff built an evidence base to establish if it would benefit patients.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain and gave pain relief in a timely way.

Staff assessed patients' pain using a recognised tool and gave pain relief in line with individual needs and best practice. Surgeons used local anaesthetic during procedures and checked with patients regularly to address any discomfort. During our inspection, staff were skilled at empowering patients to speak up about discomfort and pain and tailored their response accordingly. For example, the surgeon suspected a patient was trying to cover their discomfort for fear of being embarrassed. They spent time reassuring the patient and let them know it was okay to admit to discomfort, which could easily be addressed.

Staff asked each patient to assess their level of pain at the end of each procedure using a scale from 1 (no pain) to 10 (a high level of pain). The provider audited the results to ensure staff were effectively managing anaesthesia. In the previous 6 months, patients reported an average pain score of 3.5, reflecting a range from 1 to 5.

Patient outcomes

There was no formal system to monitor patient outcomes.

The service did not participate in clinical audits to benchmark clinical outcomes. While the provider had a clinical audit cycle based on a quality improvement and benchmarking model, there was no data or outcomes to support its use or demonstrate the effectiveness of care. However, patient-reported satisfaction was high and demonstrated the majority of patients achieved their goals.

Staff provided patients with a series of checks and reviews during the treatment process to check progress and support good outcomes. This included 3 pre-surgical calls at different stages before treatment followed by post-operative checks at 2 weeks, 4 weeks, 3 months, and 6 months after the procedure.

Competent staff

The service did not make sure staff were competent for their roles.

Staff had the right clinical skills and knowledge to meet the needs of patients. All staff underwent clinical supervision at least every 6 months and participated in peer review exercises. While staff demonstrated acceptable clinical skills, there was a lack of competence in other areas. For example, technicians did not have an understanding of areas of responsibility and accountability and had poor knowledge of local procedures and important safety information.

The senior team communicated with staff using digital chat services and e-mail, which they said replaced formal meetings some time ago. Staff said they felt communication with managers was good although could not recall any recent updates about policies, practice, training, or learning. However, there was limited evidence staff had a good

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understanding of working practices in this specific clinic. For example, when we asked a technician about the location and availability of biohazard spill kits they said, “I don’t know, I don’t usually work here.” Another technician took us to the storage location but did not recognise the spill kits. This equipment was essential for clinical procedures that typically produce a lot of blood and the lack of team knowledge reflected gaps in competence.

The surgeon decided at the start of each list whether to hold a briefing or huddle with the team. This was a vague and informal system that meant the provider did not have assurance of a structured, planned surgical process. After our inspection, the provider told us they were happy with the briefing process and said if staff were not present for it a colleague would update them on arrival.

The provider facilitated a culture that valued and promoted peer review between technicians and surgeons. This was a strategy designed to improve professional development and competency by providing staff with support to critically assess each other’s work. The senior team used the findings from these exercises to plan shifts based on skill mix. This ensured patients were seen by the most appropriate staff. While this reflected good practice, staff did not undergo a formal annual appraisal process.

Technicians were trained as surgical assistants and carried out pre-operative safety checks, such as blood pressure to ensure the surgeon was safe to proceed. They were also trained to extract and transplant hair follicles while surgeons monitored competencies.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients’ consent.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. This followed a two-stage process in which staff obtained consent during the initial consultation and then again before carrying out surgery.

All treatment was elective, and staff agreed to treatment only when patients were aware of the potential risks and benefits and could consent without support.

Records audits demonstrated staff consistently sought and documented patient consent at key stages of care, including the consultation and pre-surgical stages. In the previous 6 months, 100% of patient records included evidence of consent.

Staff provided patients with enough time to consider and understand consent prior to surgery. During our inspection staff took the time to explain the consent form and encouraged patients to ask questions before providing a digital signature.

The provider required each patient to have a 2-week cooling off period from the point of consultation to surgery. This was in line with national good practice and reduced the risk of patients rushing into decisions without properly considering their options. Where a patient changed the treatment date and the cooling off period extended beyond 2 weeks, the provider required a new consultation assessment and consent process.

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Is the service caring?

Good 

We have not previously inspected caring. We rated it as good.

Compassionate care

Staff treated patients with compassion and kindness, and took account of their individual needs. There were gaps in how patient privacy and confidentiality were managed.

Staff 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. During our inspection, staff adapted their care and communication approach to the needs of patients. For example, 1 patient was confident in their treatment and needed no reassurance whereas another was anxious and sought compassion. Staff were caring and empathetic and built a good rapport with patients.

Patients said staff treated them well and with kindness. The service used a feedback survey to ask patients how happy they were with the surgeon and how they would 'rate' technicians. In the previous 6 months, all patients rated staff as 'very good', the maximum score.

Patients spent considerable time in the clinic, often several hours, and staff attitude and approach reflected this. They made people feel at home and relaxed. On days the provider delivered care they had use of the whole clinic, providing patients with space.

There were gaps in how patient privacy and confidentiality were managed. For example, staff carried out treatment with the doors to surgical rooms open. While the low number of patients present and the provider's exclusive use of the clinic meant the risk of a confidentiality breach was low, practice still needed improvement. After our inspection, the provider told us it was policy to keep theatre doors closed during treatment.

Emotional support

Staff provided emotional support to patients to minimise anxiety.

Staff gave patients emotional support and advice when they needed it. They recognised the decision to undergo hair transplant surgery was personal and emotive and supported patients to understand the potential benefits and risks. For example, staff had built an understanding of the typical reasons people in different age groups sought cosmetic surgery and they knew how to realistically explain the likelihood of success.

Staff provided patients with time and space to calm their anxiety and answer questions to address any worries. During our inspection, a patient with a high level of anxiety arrived for their first treatment. Staff provided reassurance and used different techniques to help the patient relax.

Understanding and involvement of patients and those close to them

Staff supported patients to understand and make decisions about their care and treatment.

Staff made sure patients understood their care and treatment. They discussed options at the first consultation appointment and followed this up with additional sessions if the patient had questions or concerns. On the day of treatment, the surgeon met the patient, discussed the clinical plan, and offered them time to ask questions.

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Staff supported patients to make informed decisions about their care by explaining non-surgical alternatives to treatment. Where patient expectations were unrealistic, staff worked with them to find other options.

Patients gave consistently good feedback about the service. Staff asked each patient to complete a feedback survey after their first follow-up appointment. In the previous 6 months patients reported 100% satisfaction. In the same period 100% of patients said they were happy with how staff responded to their needs and with the clarity of discharge instructions.

During our inspection, the surgeon maintained communication with patients throughout treatment. They explained what they were doing and why and what would happen next. The team provided a detailed overview of the planned treatment before it started.

Is the service responsive?

Requires Improvement 

We have not previously inspected responsive. We rated it as requires improvement.

Service delivery to meet the needs of people

The service planned and provided care in a way that met the needs of people.

Managers planned and organised services so they met demand. The provider's main service was based in Manchester and the Nottingham clinic operated on demand as a satellite service. Staff arranged clinical lists on request from patients.

The service reminded patients about treatment times in advance to minimise the risk of missed appointments.

The service had an end-to-end care pathway that ensured each patient had a single point of contact at each stage of treatment. The office manager spoke with each patient at the end of the recovery process to ensure they had everything they needed.

The service declined to treat around 15% of patients who booked a consultation. The senior team had a treatment process clearly guided by medical ethics and where a patient would not see the results they hoped for, staff signposted them elsewhere.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences.

The service required patients to have the capacity to understand their planned treatment and to provide consent. Where staff found a patient could not fully understand their treatment options, they declined treatment and provided advice on alternatives. Staff required a letter of approval from an appropriate health professional to provide treatment to patients with certain diagnosed mental health conditions. This protected patients from the risk of inappropriate treatment.

Staff arranged interpreters in advance and planned this from the consultation stage.

Each patient had access to post-operative clinical support if they had questions or needed to report unexpected side effects. An on-call surgeon was available out of hours and the service provided contact details to patients after their procedure.

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Access and flow

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

The service did not have a waiting list and staff coordinated clinical care based on each patient's preferences and the need for a 2-week cooling off period between consultation and surgery.

Patients had access to an on-call telephone service for clinical advice and guidance after treatment. A duty surgeon was available 24/7 for this service.

In the previous 12 months, 6 planned treatments were cancelled. The provider tracked the reasons for cancellations, all of which had been agreed with the patient for reasons such as cost and a change of personal priorities.

Learning from complaints and concerns

It was not clear how people could raise concerns about care received. However, a policy was in place to treat concerns and complaints seriously and investigate them.

A complaints and feedback poster was on display in the clinic but this referred to the building operator and not this provider. The provider's website did not include a complaints policy or guidance on how patients could make a complaint. Contact details for the Cosmetic Redress Scheme (CRS), an intermediary for the resolution of complaints, were on display in the waiting area but had expired several years previously.

After our inspection the provider added information how to make a complaint to their website. They also sent each patient the complaints policy as part of their treatment information.

Staff were unfamiliar with the complaints policy and said they would direct any concerns to the registered manager. After our inspection the provider told us this was the expected process to follow, and staff did not have access to a formal policy.

The provider had a complaints policy that included formal procedures and guidance for staff on handling and resolving minor concerns raised during treatment. We were unable to establish why local staff were unfamiliar with this, but it was available on request from the senior team. The policy included up to date contact details for the CRS, which formed the final stage of the policy in the event the provider could not resolve the complaint.

The provider reported no formal complaints for this location in the previous 6 months.

Is the service well-led?

Inadequate 

We have not previously inspected well-led. We rated it as inadequate.

Leadership

Leaders could not evidence they had the skills and abilities to run the service. They did not understand and manage the priorities and issues the service faced.

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The clinic manager and registered manager were based substantively in the provider's main clinic in Manchester and visited the Nottingham service on an as-needed basis. Along with a senior hair loss advisor and operations manager, this team formed the managerial operations team.

The operating surgeon led shifts, including technicians, when clinical care was underway and acted as liaison between patients and the provider.

Technicians on shift during our inspection were not able to articulate areas of responsibility and accountability in the clinic. They understood how to contact the registered manager but said they did not know who was responsible for local safety, leadership, or governance, and could not remember critical safety information from their induction.

The wide range of issues and areas of non-compliance in the service indicated a lack of consistent and skilled leadership presence and oversight.

Vision and Strategy

The service had a tenuous vision for what it wanted to achieve. Staff had limited understanding of vision and strategy and there was a clear divide between staff and leadership about this.

The provider's vision and strategy were based on an overarching objective of delivering an "excellent patient experience." Underpinned by a range of patient-centred measurable standards, the vision and strategy incorporated aims to secure the services of the "best" employees in high standards of practice with patients appropriately assessed to undergo treatment. After our inspection the provider redeveloped the vision and strategy, set out how goals would be achieved, and worked with staff to make sure they understood it.

The senior team described the vision as "1 service, 1 vision" and said this helped staff to deliver consistent care across the provider's network of clinics. While staff we met during our inspection demonstrably cared about the standard of service they provided to patients, there was limited buy-in or understanding from temporary staff about organisational values.

Culture

Staff felt respected, supported, and valued. However, there was not a coherent or identifiable culture that focused on patient safety and accountability.

The provider had a whistleblowing policy that included staff who worked on a temporary or on-demand basis. The policy was based on national guidance and legislation and meant staff could raise concerns anonymously and be assured the senior leadership team would investigate.

Staff spoke positively about the provider, working culture, and relationships with senior staff. Technicians told us they liked the zero-hour contract system and the flexibility this provided. However, working arrangements and structures had not resulted in good standards of responsibility and accountability. We raised numerous concerns with staff during our inspection in areas that directly affected their safety. In all cases staff blamed other people for not managing the environment properly. The team had poor levels of awareness and a general attitude of no responsibility for local risks. For example, we asked a technician about their induction after they were unable to locate a fire extinguisher or biohazard spill kit. They said, "I can't remember it [the induction]. And I hardly ever work here, others will know where the equipment is kept."

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The provider asked staff about working culture in an annual survey. The survey required surgeons to comment on the standard of work of technicians, and vice versa. In the most recent survey, surgeons rated 3 technicians as poor at working as a team and 1 technician as poor at maintaining theatre protocol and cleanliness. The survey did not include details of how the provider used the information to make improvements.

The provider worked from an ethical obligation that surgery should be the last option for patients. Surgeons directed patients elsewhere to try non-invasive options where this was a more appropriate initial course of action.

Governance

Leaders did not operate effective governance processes.

The senior team used 2 parallel governance processes in the operation of the service. The first was the provider's own governance structure that included policies, staffing, and standard operating procedures (SOPs) across the clinic network. The second was a governance arrangement with the building operator and included the management and maintenance of the clinic.

The governance arrangement with the building operator did not provide staff and the senior team with assurance of safe standards of maintenance and resource management. For example, the agreement relied largely on assumptions that the building operator maintained the premises, facilities, and equipment in line with expected standards. Staff and the senior team did not routinely check these areas, which meant they operated with increased risk of infection or incident. The senior team was not often present in this clinic and the governance arrangements meant there was no system in place to identify the areas in need of urgent improvement.

After our inspection the provider temporarily stopped delivering care from the clinic to review local standards of practice. This was a voluntary arrangement based on our findings and the provider reopened the service with the expectation that the registered manager would be present whenever clinical practice took place, as part of a more effective governance system. The new system removed the reliance on the building operator to uphold standards.

The provider did not use an effective version control or tracking system for policies and SOPs. For example, most policies were either undated or had no planned review dates. This meant the provider did not have assurance of good governance because the policies and SOPs that underpinned care were poorly controlled and may not reflect the most up to date guidance.

The chief executive officer, registered manager, office manager, 3 surgeons, and a technician formed the clinical governance committee. This was representative of staff roles across the organisation and meant the committee overall should have had good oversight of risks and operational challenges. However, the system had not translated to effective governance for this location. As there was a lack of quality monitoring of local standards, the provider did not have assurance governance was effective. For example, a fire risk assessment in August 2022 found a number of areas of high risk that required the building operator to take immediate preventative action. The risk assessment criticised the lack of a health and safety policy and clarity over areas of responsibility. The provider used this risk assessment as their own but without knowledge of action in the areas for improvement. Another risk assessment from the building operator criticised the lack of a competent trained person for Legionella risk management. This had potential to impact the provider's staff and patients but there was no mitigation in place.

The operations team met monthly. Meeting minutes demonstrated a consistent focus on patient satisfaction and feedback and advanced planning to ensure staffing levels met demand. The operations team reviewed incidents and complaints during the meetings and used the time to review changes to guidance or policy.

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Management of risk, issues and performance

There were limited systems to manage performance effectively. The leadership team had inconsistent awareness of risks and issues.

The provider maintained a risk register to document, track, and mitigate risks in the clinic. At the time of our inspection there were 8 active risks including health and safety, staff competency, and staffing levels. The registered manager was responsible for the risks included on the risk register and reviewed this regularly. While this reflected good practice, the risk register did not include significant risks we identified during our inspection. This meant the system was not effective at managing risks.

The provider used a staff survey as a quality assurance tool. The survey asked technicians, who formed the largest staff group, to provide feedback on their experiences of working in the clinic. As staff teams changed frequently, the provider designed the survey to provide an oversight of the consistency of standards. Results from the most recent survey were mixed. For example, technicians rated the organisation, communication, and management skills of the surgeon between 'poor', 'satisfactory', and 'very good'. There were no comments from technicians who considered standards less than very good to document their feedback. In another measure, the survey asked technicians about the surgeon's ability to effectively interpret patient pain during treatment. In this clinic, 13% of technicians rated surgeons as 'highly ineffective' and 75% rated them as 'highly effective'. Such a broad range of results may represent areas for improvement but have minimal efficacy without qualitative information to provide context and detail.

The provider tracked the hair extractions per graft report, including the percentage of hair grafts by each technician and the planned number of grafts compared with the actual figure. Most results were similar to the planned number of grafts, which reflected effective consultations and planning.

While the provider had an SLA with the building operator to provide and manage safety equipment, the service did not carry out its own monitoring or routine checks. After our inspection we discussed our concerns about expired emergency equipment, including for resuscitation, and biohazard spill containment, with the senior team. They contacted the building operator for a response and found the operator had a very limited understanding of acceptable standards of practice. For example, they believed ampules of adrenaline without the means to administer this was sufficient. The provider changed procedures to shift accountability in house and introduced new monitoring systems.

Information Management

Information systems were integrated and secure. Information management was poor.

The provider stored patient data using a secure digital system. Staff had remote access using electronic tablets and information was encrypted and protected by the provider's cybersecurity system. A remote server ensured all data were backed up. In the event of a systems failure on the day of treatment, staff used paper records to avoid delaying treatment, and then scanned these into the secure system.

Information management systems for the use of CCTV in clinical areas were inadequate and was not compliant with the Data Protection Act. For example, the service had not completed a privacy impact assessment and the certificate of membership with the Information Commissioner's Office (ICO) in the waiting room belonged to the building operator. Staff did not know if CCTV was in use or if their activities were being recorded. However, signage was in place to advise patients about the use of CCTV.

All staff had completed General Data Protection Regulation (GDPR) training.

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The provider had an information sharing protocol to support staff in making decisions about data management, security, and confidentiality. The protocol was undated, had no version control information, and did not reference published guidance or legislation. This meant the provider did not have assurance staff made information decisions in line with good practice.

Engagement

Leaders and staff actively and openly engaged with patients. There were gaps in effective communication between the senior team and staff delivering care.

Staff routinely engaged with patients after treatment and there was evidence all patients completed this process. Feedback indicated patients were consistently happy with this process and found the provider easy to reach by e-mail or phone.

Staff working in the clinic had poor understanding of assurance processes of safety and governance. For example, we raised concerns about expired equipment and resources and a member of the team said, “That’s the [building operator’s] responsibility, we don’t have our own assurance.”

After our inspection, we discussed concerns with the provider. We found some areas in which staff were working outside of policy and training. For example, the provider told us it was not usual practice for staff to open single-use surgical instruments before a procedure or to carry out procedures with surgery doors open. In addition, the senior team told us they expected staff to sign in using the logbook daily and did not know why this practice had stopped. The provider sent us assurances of changed monitoring procedures although could not explain how the existing system had not identified our wide range of concerns.

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
Surgical procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment The service did not ensure surgical instruments were handled in accordance with manufacturer guidance and staff did not consistently maintain the sterile field when preparing for surgery. The service did not ensure patients were protected from the risks of poor cleanliness and contamination through effective management and assurance of the clinical space. The service did not ensure compliance with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013 in relation to sharps management. The service did not ensure compliance with the Control of Substances Hazardous to Health (COSHH) Regulations. The service did not have assurance of good standards of fire safety.
Regulated activity	Regulation
Surgical procedures	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints The service did not readily provide information on how to make a complaint or how patients could access the complaints policy.
Regulated activity	Regulation
Surgical procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing

This section is primarily information for the provider

Requirement notices

The service did not ensure staff training reflected the needs of patients.

The service did not ensure staff were competent for their roles and had access to up-to-date policies and standard operating procedures.

The service did not ensure staff had a consistent, good standard of induction that included local procedures.

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	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service did not ensure processes were implemented that provided staff with assurance of effective cleaning of clinical areas and equipment before delivering care. The service did not ensure governance systems supported the safe and well led delivery of care, including monitoring of standards that were the primary responsibility of other organisations under service level agreements. The service did not ensure staff followed infection prevention and control policies and procedures through consistent assurance processes. The service did not have established oversight of staff training as assurance of competence. The service did not ensure there were systems and processes in place that monitored and evidenced patient outcomes. The service did not ensure risk mitigation was in place to address areas of non-compliance with clinical environment standards, including the Department of Health and Social Care Health Building Note 00/10.

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service did not ensure staff were aware of the emergency equipment, including medicines, on site and understood their location and use.

This section is primarily information for the provider

Enforcement actions

The service did not ensure medicines management processes provided assurance of safety and followed good practice.

The service did not ensure patients were protected from the risks of surgical site infections, such as those caused by poor adherence to infection prevention and control policies.

The service did not ensure staff followed consistent standards of practice in the use of personal protective equipment.