Harley Street Healthcare Ltd

Harley Street Healthcare - 96 Harley Street

Inspection report

96 Harley Street
London
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Date of inspection visit: 14 & 15 September 2021
Date of publication: 21/12/2021

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 responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

Harley Street Healthcare Limited is operated by Harley Street Healthcare Limited. The service was registered by CQC on 26 March 2021. The service providers dermatology treatment and day case surgical hair transplant procedures to private patients over the age of 18. There are two methods of hair transplantation: follicular unity transplant (FUE) and follicular unit extraction (FUE). The service provided only FUE. This was provided at Gray's Inn Road, London. The service also treated dermatology conditions such as, mole removal, cyst removals and dermatological investigations. This was provided at 96 Harley Street, London. All procedures were undertaken using local anaesthesia.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 14 and 15 September 2021. As part of the inspection, we visited 96 Harley Street, London and Gray's Inn Road, London.

During the inspection we visited reception areas, waiting areas, treatment rooms, consultation rooms and a decontamination room. We spoke with three senior staff members, including the registered manager, two surgeons, a receptionist and two practice managers. We did not speak with any patients at the time of inspection due to low patient activity.

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.

The key questions we asked during this inspection were, was it safe, effective, responsive and well-led. **As a result of this inspection, we served a notice under Section 31 of the Health and Social Care Act 2008 to suspend the registration of the service provider for an initial period of four weeks in respect of the regulated activities.**

We are placing the service into special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action.

We did this because we believe that a person will or may be exposed to the risk of harm if we did not take this action.

The service is registered to provide the following regulated activities:

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

Information supplied by the service showed that the following activity was completed since registration:

- Hair transplantations: 32 per month
- Mole remove: 20 per month
- Cyst removal: 19 per month

Summary of findings

- Consultations for dermatology: 88 per month

There has been a registered manager in post since the service registered with CQC. The registered manager was also the business owner. The service employed one chief executive officer, one chief operating officer, two practice managers, three dermatologists, three hair transplant surgeons, five hair technicians, one healthcare assistant and three patient co-ordinators.

We have not previously inspected this service.

We rated it as inadequate because:

- Staff did not follow infection control principles including the use of personal protective equipment (PPE).
- The clinic manager, with responsibility for ensuring staff had a valid DBS, was unable to clearly tell us about or show how the service checks to ensure staff have current and valid DBS certificates.
- Risk assessments were not clear or fully completed as part of everyday practice. It was unclear who carried out risk assessments and the purpose of them.
- Consent was not obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016)
- The service was unable to show us how they assessed staff performance and identified their learning needs.
- The provider could not demonstrate to us that photographs of patients were being taken in accordance with General Data Protection Rules (GDPR).
- The policy for monitoring the deteriorating patient was not service specific and did not outline what staff should do when recognising someone was becoming unwell.
- The provider was not using the World Health Organisation (WHO) safer surgery checklist.
- The service could not demonstrate that all staff had completed mandatory training.
- The provider did not show an understanding of how to protect patients from avoidable harm or abuse.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Outpatients	Inadequate	

Summary of findings

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Summary of this inspection

How we carried out this inspection

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The key questions we asked during this inspection were, was it safe, effective, responsive and well-led.

Areas for improvement

Action the service MUST take to improve:

- The provider must take prompt action to address concerns identified during the inspection in relation to safeguarding, incident recording and reporting, and the governance of the service.
- The provider must ensure they have measures for staff to follow for minimising the risk of coronavirus infection between staff, patients and visitors.
- The service must register as a designated body in accordance with The Medical Profession (Responsible Officers) Regulations 2010.
- The provider must ensure they have suitable arrangements for staff to follow, which protect patients from the risk of harm related to the taking of and use of photography.
- The provider must ensure mandatory safety training is completed by all staff, that it is checked and reviewed regularly.
- The provider must ensure that staff understand their responsibilities for safeguarding vulnerable adults and that there are clear processes for the reporting of a potential safeguarding concern.
- The provider must ensure there are clear processes in place for recording, reporting and investigating incidents. Learning from such investigations must be shared with staff.
- The provider must ensure complaints are handled in line with their own policy and demonstrate concerns are taken seriously and are investigated sufficiently. Outcomes of the investigation of complaints must be shared with all staff.
- The provider must ensure there are effective systems in place for managing risk.
- The provider must ensure all staff have a valid DBS.
- The provider must ensure patient consent is obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016)
- The provider must demonstrate a systematic approach to the annual performance review process and regular staff reviews.
- The provider must ensure the policy for monitoring a deteriorating patient is service specific and outlines what staff should do when recognising someone is becoming unwell.
- The provider must ensure they use the World Health Organisation (WHO) safer surgery checklist to minimise the risk of unnecessary surgical harm.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Outpatients	Inadequate	Inadequate	Not inspected	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inadequate	Not inspected	Requires Improvement	Inadequate	Inadequate

Inadequate

Outpatients

Safe	Inadequate
Effective	Inadequate
Responsive	Requires Improvement
Well-led	Inadequate

Are Outpatients safe?

Inadequate

Mandatory training

The service could not demonstrate that all staff had completed mandatory safety training. The training platform used did not cover areas such as information governance training, sepsis management training or management of the deteriorating patient.

All staff members were employed directly by the service and there was an expectation staff would complete mandatory training to enable them to work there. However, the service was unable to demonstrate that all staff were compliant with their training.

The service was unable to demonstrate which training subjects staff were required to complete, for each role. There was no system set up to clearly manage the monitoring of staffs completion of mandatory training.

We were given assurance that the registered manager had undertaken some mandatory training modules and saw certificates to evidence this.

The clinic manager told us they recognised it was a difficult task to ensure clinical staff had completed their mandatory training. However, the clinic manager said there was not much they could do if the staff member repeatedly failed to complete the required training. The clinic manager stated that staff would be able to remain working for the service despite numerous attempts to ensure they completed their mandatory training.

Safeguarding

The provider did not show an understanding of how to protect patients from abuse. The safeguarding policy and procedure did not reflect details specific to the service.

The service had an adult safeguarding policy; the designated safeguarding lead was the clinic manager. The policy in use was not specific to the service. The policy did not detail how staff should raise a safeguarding concern and did not detail who the safeguarding lead was.

The adult safeguarding policy did not detail the contact details for onward referral to external agencies. Post inspection, the provider supplied us with a copy of an emergency contacts list which included details of local safeguarding authorities. The provider told us this was accessible to all staff.

There was confusion amongst the staff we spoke with about how to raise a safeguarding concern. The policy did not make clear what should happen in the first instance a staff member has a safeguarding concern. We spoke with three members of staff who gave us differing opinions on how a safeguarding concern should be raised.

The majority of staff employed by the service declined to speak with inspectors during and post-inspection, therefore we could not test their knowledge of a safeguarding concern.

It was unclear how many staff had completed safeguarding training. The registered manager and clinic manager could not produce a list of staff who had undertaken mandatory safeguarding training. Post inspection, we asked the provider to supply us with copies of completed certificates of safeguarding training for all staff. This was not provided.

Cleanliness, infection control and hygiene

The service did not control infection risk well. Whilst equipment and the premises were visibly clean, there were no control measures in place to minimise the risk of Coronavirus infection.

Staff did not follow infection control principles related to COVID-19, including the use of personal protective equipment (PPE). During our inspection visit, we saw three members of staff not wearing masks and four patients not wearing face coverings. We also saw two patients walk through the clinic without being encouraged to use hand sanitiser. This was evident at both services locations.

Post inspection, the provider told us they were carrying out COVID-19 testing, biweekly, on all staff. The provider sent us evidence of a COVID-19 positive log, which, if completed would include the names of any staff who had tested positive. The log did not contain any names on the day we reviewed it.

Equipment was not labelled to show when it was last cleaned. There was no cleaning schedule in place to show the frequency of cleaning required for equipment within the service. This was not in line with the National Standards of Healthcare Cleanliness 2021.

Cleaning of the environment was outsourced to a 3rd party company. The provider was unable to produce a contract of required standards and how these were checked and monitored.

The infection prevention and control policy was not specific to the service and did not detail information relating to the use of PPE and correct disposal of clinical waste within a hair transplant setting.

The service had completed a hand hygiene audit in August 2021. It showed 100% compliance; however, the clinic manager informed inspectors that the staff recorded over each month's result so there was no history of audits prior to this date. It was not possible therefore to see if there was any times where staff did not meet the required standard or if there were any trends in staff practices.

The premises and equipment used for patient treatment and care appeared visibly clean. There were suitable furnishings which were visibly clean and well-maintained.

Environment and equipment

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

It was unclear if the service had an equipment policy. Not all equipment had evidence it had been recently tested, for example, air conditioning units in each treatment room did not have any sticker on them indicating they had been portable appliance tested (PAT). The provider did not keep a log of equipment checks.

Post inspection, the provider stated there was an equipment log in place at the time of inspection, although this was not evidenced during the inspection despite the inspection team asking for this. The provider subsequently provided a PAT log of all equipment showing when equipment required servicing.

Staff carried out daily safety checks of specialist equipment such as an autoclave machine used for sterilising surgical instruments.

There was no signage in either premises to indicate that medical gases were held on site. The gases were not separate from other storage items. The storage of medical gases (oxygen) did not comply with the Health and Safety Executive HTM02 guidance. Warning notices should be placed near medical gases to prohibit smoking and naked lights within the vicinity of the storage. We saw no evidence of warning notices placed near the oxygen cylinders.

All stock and single-use items were stored in a locked room and regular stock checks were done.

The design and layout of the environment followed national guidance, which made it suitable for the services being provided.

Assessing and responding to patient risk

We found that the policies and procedures to protect deteriorating patients were not service specific and did not support staff in identifying and responding to a deteriorating patient.

The policy for monitoring a deteriorating patient was not service specific and did not outline what staff should do when recognising someone becoming unwell. This posed a risk to patient safety because staff did not have written guidance to support them in recognising or responding to a deteriorating patient to keep them safe during and after a procedure. We did not have sufficient evidence that staff had been trained to recognise a deteriorating patient.

All procedures were carried out under local anaesthesia and dependent on the procedure being carried out, could last from one hour to four hours in duration. During hair transplantation, the patient would have the procedure carried out by a hair transplant surgeon who was supported by a hair transplant technician. These procedures were considered outpatient procedures and once the patient had been observed for at least 30 minutes post procedure, to ensure they felt well and showed no signs of clinical deterioration, were free to leave unaided.

The hair transplant technician would be responsible for ensuring the patient was appropriately monitored during the procedure. For example, the hair transplant technician would be responsible for undertaking clinical observations on the patient during the procedure and ensuring the patient remained in a comfortable position.

The service did not use the National Early Warning Score (NEWS). NEWS is a tool developed by the Royal College of Physicians which improves the detection and response to clinical deterioration in adult patients and is a key element of patient safety and improving patient outcomes. This was not in routine use; we could not be reasonably assured that staff would both recognise and respond as expected in the event of a patient becoming unwell.

We lacked assurance that patient screening pre-operatively was being undertaken and recorded appropriately. We viewed four patient records which had minimal details relating to the patients' medical history.

Inadequate

Outpatients

A review of four patient records showed that clinical observations were recorded only on one occasion during surgery. The registered manager told us that clinical observations should be taken at varying intervals throughout surgery. However, there was no policy of guidance in use which suggested how often clinical observations should be taken. All surgical notes were recorded on an electronic record platform.

There was resuscitation equipment, including oxygen and an Automatic External Defibrillator (AED) at both locations. There was also an anaphylaxis kit in each treatment room, for use in the event of a patient have an allergic reaction.

The provider was not using the World Health Organisation (WHO) safer surgery checklist. The registered manager told us they had not directed the surgeons use the checklist. We asked them if there were any other procedures in place for reducing unnecessary surgical harm and complications. They told us there were no other procedures in place. The WHO safer surgery checklist is recommended for use in reducing errors and adverse events and improving communication between staff members during any surgical procedure.

Post inspection, the provider told us they were using the WHO safer surgery checklist at the time of inspection. They informed us this was contained within cloud-based systems within their IT network. However, we did not see evidence of this during the on-site inspection and the provider did not make the inspection team aware this was the practice being carried out at the time of inspection. The registered manager did not appear to be aware of the cloud-based system when asked about the lack of WHO checklist.

Post operatively, patients had access to a patient co-ordinator who could contact their operating surgeon in the event of any post-surgical complications or advice. This service was available during business hours. Patients were instructed to contact an out-of-hours doctor or A&E outside of these hours if they had any concerns.

Staffing

The provider ensured clinical support staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm. However, the service was not prescribed as designated body and therefore did not employ a responsible officer to evaluate medical professionals fitness to practice.

The service employed all members of staff and did not have any medical staff working on practising privileges arrangements. The service was not registered as a designated body in accordance with The Medical Profession (Responsible Officers) Regulations 2010. The regulation states, any organisation which carries out surgical procedures (including any pre-operative and post-operative care associated with such procedures) undertaken by or under the supervision of a medical practitioner who is employed by, or who contracts with, that organisation must be defined as a designated body.

Some medical staff working at the service had access to a Responsible Officer (RO) as part of their employment in NHS practice. Although these medical staff working at the service were directly employed, this was on a part-time basis and the majority of their employment was in an NHS setting.

However, during inspection we were aware of at least one full time doctor working at the service on a full-time basis with no other employment elsewhere. The registered manager was unable to explain the requirements relating to the evaluation of this staff members fitness to practice or whether this staff member had any prescribed connection to another designated body. As the service was not defined as a designated body, there was no responsible officer appointed. A RO is accountable for the local clinical governance processes focusing on the conduct and performance of doctors.

Inadequate

Outpatients

The service had enough staff to keep patients safe and did not use any bank or agency staff.

All staff received an induction into the service on commencement of employment.

Staff had their training credentials and practice licences checked prior to employment.

However, the service was unable to demonstrate a systematic approach to annual appraisals or staff reviews. We saw some evidence of appraisals for clinical staff; however, these were inconsistent in their format and it was not evident when staff were next due for an appraisal.

Records

Staff kept records of patients' care and treatment. Records were not always clear or detailed. However, they were stored securely and easily available to all staff providing care.

Patient notes were inconsistent in their style and detail. We reviewed four patient records and noted that all of them detailed differing degrees of patient information. Two of the records we reviewed detailed very little notes throughout, including a lack of medical history, allergies and medications the patient currently takes.

Patient notes were held electronically using a 3rd party management record system. The patient record policy did not state how long patient records were held for and who had access to these records outside of the service using them.

Medicines

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

Staff followed systems and processes when safely prescribing, administering, recording and storing medicines.

Staff stored and managed medicines and prescribing documents in line with the provider's policy.

The service did not use any controlled medicines.

If medication was required following hair transplant surgery, the operating doctor signed a prescription on the day of surgery, which was given to the pharmacy dispensing the medication on the day of surgery.

Incidents

The process surrounding incident reporting was not robust, we were not assured staff would be able to recognise and report incidents and near misses.

There was no assurance regarding the reporting of incidents and types of incident that should be reported. The clinic manager were unable to demonstrate how incident reporting worked in the service. There was confusion amongst staff about how incidents were reported. One staff member told us there was an online system which they were unsure how to use and another staff member told us they would report any incident to the clinic manager.

The service informed us there had been no serious incidents or never events.

The service did not monitor incident themes or trends or share learning from incidents with staff.

Inadequate

Outpatients

The incident reporting policy was generic and not specific to the service and did not detail how incidents should be reported.

Post inspection, the provider produced an incident log which contained a list of incidents throughout 2020-2021. We saw incidents had been added to the log but there was little information in the incident description, and it was unclear who had reported the incident and what the concern was. We also saw that no action had been taken to minimise or reduce the reoccurrence of the incident. We also saw incidents had not been fully investigated and there was no learning to reduce a reoccurrence.

Are Outpatients effective?

Inadequate

Evidence-based care and treatment

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

Policies had not been adapted or revised to ensure they fitted the scope of the service. Information contained in several policies showed they were more relevant to a hospital setting.

The service had not instigated a process to evidence and record that staff had read and understood all policies.

We found no evidence that the service used relevant national guidance for cosmetic surgery or hair transplant surgery. The service did not use reference to NICE or Royal College of Surgeons (RCS) guidelines in their policies.

Nutrition and hydration

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

As procedures could last over prolonged periods, patients were given a break during treatment for food and drink.

Pain relief

We did not see evidence that staff had their pain assessed and recorded. We could not be assured patients had access to pain relief in a timely way.

It was not clear from four patient records we reviewed that staff had assessed patients' pain using any recognised tool, such as a numerical rating scale (NRS). (0 being no pain and 10 being extreme pain). We were not assured staff gave pain relief in line with individual needs and best practice.

We reviewed two patient records during inspection which evidenced that staff had recorded the administration of local anaesthetic detailing type, batch number, amount, expiry date and site of administration.

Staff told us that mild pain relief was routinely prescribed for the patients to take home. However, we did not see evidence recorded in individual patient records of this.

Inadequate

Outpatients

We were not reasonably assured from our discussion with the registered manager that the provider, fully understood the requirements of registration to participate and undertake audit practice to monitor and improve patient outcomes. For example, we did not see any evidence of audits related to pain assessment and management practices.

Patient outcomes

The provider did not monitor the effectiveness of care and treatment and audit practice was not fully developed or carried out in practice. The provider did not actively monitor post-surgical infection rates.

We saw evidence the provider held meetings with staff to discuss audits or review performance. However, it was not clear what actions had been taken to improve the service as a result of these meetings.

It was unclear if all patients were followed up post-surgery or at which stage they may have been followed up. From four patient records we reviewed we could see one patient had been contacted by the service in the days following surgery. However, a clear documentation of this conversation was not recorded.

Competent staff

The service did not ensure staff were competent for their roles. Managers could not demonstrate that staff undertook appraisals or that staffs work performance was assessed.

During inspection we asked the registered manager and clinic manager to support us in looking for evidence of staff appraisals or anything similar which took place to ensure staff had learning goals and objectives completed. For non-clinical staff, there was no evidence of this. The registered manager and clinic manager were unable to tell us if staff had been appraised or if there was a similar process in place to capture staffs yearly objectives. There was no evidence non-clinical staff had their work evaluated.

Post inspection, the provider told us they had an appraisal system in place which assessed staff performance annually. Staff whose employment was under one year, did not yet have an appraisal with the service. The provider also supplied one staff member's appraisal dated February 2021, this was not shown during the on-site inspection. This was the only appraisal document submitted to CQC. The provider told us that where additional learning needs were identified, training would be given to staff using an online training system.

We did see one annual appraisal for a hair transplant surgeon which was completed within their NHS organisation. This appraisal highlighted concerns that the surgeon had failed in the past year to meet the objectives set at the previous appraisal. The registered manager was unaware of this until it was pointed out on inspection.

During our inspection, we saw evidence that two members of clinical staff had no in-date information governance training. The clinic manager told us there was no firm plan to have these members of staff trained in the immediate future.

We reviewed five staff records and three of these had Disclosure and Barring Service (DBS) records missing from their file, despite the clinic manager telling us that each personnel file should have a DBS recorded. The clinic manager, with responsibility for ensuring staff had a valid DBS, was unable to clearly articulate or demonstrate how the service checks to ensure staff have current and valid DBS certificates. Post inspection, the provider told us they used an online software system to monitor DBS renewal dates. This was not fully explained nor demonstrated during inspection.

Medical staff working for the service were on the General Medical Council (GMC) register with the necessary qualifications and experience relevant to their role.

We did not see any evidence hair transplant technicians had undergone any formal training. The clinic manager told us that these staff had been through a detailed training programme, although they were unable to provide evidence of this on the day of inspection.

Post inspection the provider demonstrated they followed Cosmetic Practice Standards Authority (CPSA) guidance with regards to hair transplant assistants. Although the CPSA does not make it mandatory for hair transplant assistants to undergo any formal training, the service did provide evidence that a technician received formal training in this field.

The majority of staff, including all hair transplant technicians working at the service, declined to speak with inspectors post-inspection, therefore we could not test the knowledge or understanding of staff within their role.

Multidisciplinary working

All staff worked together as a team to benefit patients. They supported each other to provide good care.

We saw evidence that staff worked well together in the best interest of patients. Two members of staff we spoke with told us that team working was well established within the service and they had no issues working with their colleagues.

Seven-day services

The service was open Monday to Friday at varying times depending on patient activity.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

We were not assured staff supported patients to make informed decisions about their care and treatment.

Consent was not obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016) which states that, consent should be gained by the doctor who will be delivering treatment, 14 days prior to treatment, to ensure the patient has a cooling-off period. Staff we spoke with were unsure how long patients should be given as a cooling off period and the services' consent policy did not specify or make clear the RCS professional standards requirements.

We reviewed four patient records, in two of these it showed that patients did not have a 14-day cooling off period.

In two patient records we reviewed, we could see the patient had signed an electronic consent form prior to surgery and on the day of surgery. The consent form referred to any complications or associated risks of surgery but did not outline what these were. We could not find documentary evidence in these two patient records which outlined that discussions about risks and potential complications had been discussed. This was a risk to patients because we could not be assured that people were being given the necessary information about the risks, complications and any alternatives, which would be expected as part of the informed consent process.

The patient had a face to face initial consultation with the operating surgeon. If the surgeon changed throughout a patient's journey, we saw evidence of the new operating surgeon carrying out their own initial consultation.

Inadequate

Outpatients

Are Outpatients responsive?

Requires Improvement

Service delivery to meet the needs of local people

Service delivery to meet the needs of people. The service planned and provided care in a way that met the needs of local people and the communities served.

Facilities and premises were appropriate for the services being delivered.

Managers ensured that patients who did not attend appointments were contacted.

Patients were provided with post-discharge care information, which included clinic contact details for post-operative advice and specific instructions about hair care.

There was no parking available at either location but both locations were easily accessible from public transport.

Meeting people's individual needs

The service did not take into accountant patient's individual needs.

96 Harley Street, London had portable ramps and a lift which wheelchair users could use. However, there was no wheelchair friendly access available at Gray's Inn Road, London. The registered manager told us that if they were contacted by a disabled patient who could not be accommodated for, they had an agreement to sign post them to another service where there was wheelchair access available.

During the inspection the provider told us they could provide a chaperone service if required. However, the clinic manager was unable to tell us if any member of staff had undergone any chaperone training. We did not see any information situated throughout either location, advising patient's that a chaperone service was available.

There was no audit process in place to ensure each patient had received appropriate treatment based on an assessment of their needs and preferences.

During the inspection, we were told there was no written information available in other languages or formats.

During the inspection, we were informed there was a hearing loop available. However, information was not suitably displayed for visually impaired patients.

The clinic provided treatment for male, female and trans-gender patients.

The appointment system appeared easy to use and supported people to access appointments. Patients could arrange an appointment by telephone or make an enquiry using the clinic's website.

Access and flow

People could access the service when they needed it and received the care in a timely way.

Inadequate

Outpatients

Initial face to face consultations were held with patient co-ordinators who took patients through a range of options and a discussion regarding finance and cost. During the initial consultation the patient would be given pre-operative information and their expectations regarding the results of treatment were discussed. If the patient wished to continue from here, the patient co-ordinator booked the patient in with a hair transplant surgeon for a medical consultation.

All procedures were booked in advance. Once the procedure was confirmed with the surgeon, hair transplant technicians were contacted to support the procedure.

There were no waiting times for consultations or procedures.

There were no service level agreements with the NHS if patients became unwell.

Learning from complaints and concerns

The complaints procedure was not displayed or explained to patients as to how they could give feedback and raise concerns about care received.

The service had a complaints policy. However, the policy did not clearly outline the process patient's should follow to raise a complaint. It also did not detail the process staff should follow when dealing with a complaint.

The service did not display information about how to raise a concern in patient areas.

We did not see evidence that managers investigated complaints and identified themes. We asked to see evidence of complaints investigation; however, the registered manager was unable to produce this during the inspection or post inspection.

It was unclear if staff knew how to acknowledge complaints and we did not see evidence that patients received feedback from managers after the investigation into their complaint.

Staff could not give examples of how they used patient feedback to improve daily practice.

The service was not registered with the Independent Sector Complaints Adjudication Service (ISCAS) which provides independent adjudication on complaints for independent healthcare providers registered with them.

Are Outpatients well-led?

Inadequate

Leadership

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

The service was led by the registered manager who was also the CQC nominated individual. The registered manager was responsible for ensuring compliance by the provider with the fundamental standards of care. The registered manager was responsible for recruiting clinical and non-clinical staff.

Inadequate

Outpatients

During the inspection the registered manager did not demonstrate an understanding of the obligations placed on them by their role as registered manager, and, how compliance with the fundamental standards of care helped to ensure maintenance of quality at the location and continuous improvement.

The provider did not show an understanding of how to protect patients from abuse. The safeguarding policy and procedure were generic, with no specific amendments for the service.

Vision and Strategy

The service had a business plan outlining what it wanted to achieve but had no formal strategy to turn it into action.

The service had a business plan which outlined future care objectives and values. However, it was not clear from this plan how these would be achieved. It also did not state the timeframe or deadline for completion.

Staff we spoke with were unsure on the future vision of the service and were unable to tell us what they thought were the key priorities in the vision or how these would be achieved.

Due to the lack of service strategy there was no ability to measure progress.

Culture

Staff we spoke with felt respected, supported and valued. Staff told us they focused on the needs of patients receiving care.

The majority of staff working for the service declined to speak with inspectors during the inspection or thereafter. The staff we did speak with felt there was a culture of teamwork and that every staff member strived hard to achieve excellence in patient care.

We were not assured the culture encouraged openness and honesty in response to incidents. There was a lack of understanding of the importance of recording incidents to learn and prevent recurrence.

Post-inspection, we saw that the provider had set up a staff appraisal process for non-clinical staff members. However, at the time of inspection, this practice was not audited to evidence ongoing professional development.

Governance

Leaders did not operate effective governance processes. However, staff had regular opportunities to meet, discuss and learn from the performance of the service.

There was no evidence of effective structures, processes and systems of accountability to support the delivery of service improvement and to ensure good quality sustainable care and treatment.

There were no governance structures for the service. We were told senior leaders held monthly meetings, but we did not see evidence that these meetings covered governance related items.

We did see evidence that staff of all levels had opportunity to meet, discuss and learn from the performance of the service. However, due to the lack of clear minute taking it was unclear what actions, if any, arose from these meetings.

The doctors who had worked at the service were all registered with the General Medical Council and had indemnity insurance.

Management of risk, issues and performance

It was unclear if any system was used to identify risks and no clear plan to eliminate or reduce them. The recognition and management of risks was not clear or routinely happening in practice.

We saw limited evidence that the service used systems to manage performance effectively. The provider had undertaken a risk assessment of the service; however, this was not detailed and carried out as routine practice. Leaders of the service did not demonstrate they had the knowledge or experience to fully embed systems to manage performance.

The service had a risk management log. This was provided post inspection and detailed several risks the registered manager felt the service faced. However, there were no clear mitigations and it was unclear who took the lead on each risk and what had been done to reduce or eliminate the risk.

Risk assessments were not clear or routinely considered as part of everyday practice. It was unclear who carried out risk assessments and if staff understood the purpose of them.

There was no service level agreement with a provider to give assurance surrounding fire extinguisher checks or a certified inspection of the premises. Post inspection, the provider supplied us with copies of fire risk assessments. These were not presented during the inspection the inspection team requesting them.

Information Management

The information systems were integrated and secure. However, the provider could not demonstrate photographs were being taken in accordance with General Data Protection Regulation GDPR rules.

All initial patient contact was recorded on a secure computerised electronic system. Notes from the day of treatment were also recorded electronically.

Photographs of patients' treatment were taken, with consent, and uploaded to the patient records. However, it was unclear on the storage or deletion of the original photograph. For instance, staff we spoke with were inconsistent in their understanding of how photographs were taken and stored. One member of staff told us that all photographs were taken on business phones issued by the service, whilst another member of staff told us they always used a password protected laptop to take photographs. We were not reasonably assured the service was taking and securely storing photographs in line with General Data Protection Regulation (GDPR) requirements.

Post inspection, the provider informed us that they use a cloud-based patient notes system for taking and storing images of patients. However, we did not see any evidence to support this and the inspection team did not see a demonstration of this system during the on-site inspection.

The service did have a retention of photographs and images policy. However, this was not specific to the service and did not detail how or where images and photographs should be stored.

The service had invested in antivirus and firewall protection software. All computers we saw in use were password protected and locked when not in use.

Inadequate

Outpatients

Engagement

Leaders actively and openly engaged with staff. We did not see evidence of any patient engagement.

During the inspection, we saw evidence that staff had opportunities to meet and discuss the service. However, it was unclear from the minutes of these meetings what the discussions were centred around. We did not see evidence of a clear agenda which staff used to structure their meetings.

There was no evidence of staff involvement in the planning of the service.

We saw there was a website which gave information about the service

Learning, continuous improvement and innovation

There was no evidence of innovation at the service.

During the inspection we saw no evidence of continuous learning, improvement or innovation. The service did not participate in any research projects or recognised accreditation schemes.

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
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance **Areas for improvement** **Action the service MUST take to improve:** • The provider must take prompt action to address concerns identified during the inspection in relation to safeguarding, incident recording and reporting, and the governance of the service. • The provider must ensure they have measures for staff to follow for minimising the risk of coronavirus infection between staff, patients and visitors. • The service must register as a designated body in accordance with The Medical Profession (Responsible Officers) Regulations 2010. • The provider must ensure they have suitable arrangements for staff to follow, which protect patients from the risk of harm related to the taking of and use of photography. • The provider must ensure mandatory safety training is completed by all staff, that it is checked and reviewed regularly. • The provider must ensure that staff understand their responsibilities for safeguarding vulnerable adults and that there are clear processes for the reporting of a potential safeguarding concern. • The provider must ensure there are clear processes in place for recording, reporting and investigating incidents. Learning from such investigations must be shared with staff. • The provider must ensure complaints are handled in line with their own policy and demonstrate concerns are taken seriously and are investigated sufficiently. Outcomes of the investigation of complaints must be shared with all staff. • The provider must ensure there are effective systems in place for managing risk.

This section is primarily information for the provider

Requirement notices

- The provider must ensure all staff have a valid DBS.
- The provider must ensure patient consent is obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016).
- The provider must demonstrate a systematic approach to the annual performance review process and regular staff reviews.
- The provider must ensure the policy for monitoring a deteriorating patient is service specific and outlines what staff should do when recognising someone is becoming unwell.
- The provider must ensure they use the World Health Organisation (WHO) safer surgery checklist to minimise the risk of unnecessary surgical harm.

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
Diagnostic and screening procedures Treatment of disease, disorder or injury Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance **As a result of this inspection, we served a notice under Section 31 of the Health and Social Care Act 2008 to suspend the registration of the service provider for an initial period of four weeks in respect of the regulated activities.**