Pro-Med Surgical Limited

Gro Clinics

Inspection report

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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	Inspected but not rated
Are services safe?	Inspected but not rated
Are services effective?	Inspected but not rated
Are services well-led?	Inspected but not rated

Summary of findings

Overall summary

We did not rate this service following this inspection.

•The service did not always control infection risk well. The service did not have systems to identify and prevent surgical site infections. The service did not use systems and processes to safely prescribe, administer, record and store medicines. The service did not have a clear process for the management of incidents. Staff were not trained in how to recognise and report incidents and near misses.

The service did not make sure staff were competent for their roles. Staff did not always support patients to make informed decisions about their care and treatment. They did not follow national guidance to ensure that patients gave consent in a two-stage process with a cooling off period of at least 14 days between stages.

Leaders did not operate effective governance processes throughout the service. Staff met monthly but they did not always discuss and learn from the performance of the service. Leaders and teams did not always use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to reduce their impact.

However:

The clinical flooring in the treatment room had recently been replaced and the clinic appeared to be clean.

We wrote to the provider under Section 31 of the Health and Social Act 2008 to consider whether to use CQC's regulatory powers to take potential enforcement action. We did this because we had reasonable cause to believe that, unless CQC acted people would be or may have been exposed to the risk of harm. The letter was in relation to the management of medicines, staff training and competence, and systems and processes to assess monito r and improve the quality and safety of the service. The provider responded to the letter and provided detailed information on how they are going to manage the issues detailed in the Section 31 letter of intent. CQC will continue to monitor this.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inspected but not rated	

Summary of findings

Contents

Summary of this inspection

Background to Gro Clinics

Gro Clinics Manchester is operated by Pro-Med Surgical Limited. The service provides hair transplant cosmetic surgery and platelet-rich plasma hair restoration therapy for private fee-paying adults. The service uses the follicular unit excision method of hair transplant cosmetic surgery. In follicular unit excision, individual hair follicles are extracted and then implanted into small incisions in the patient's scalp. The service provides platelet-rich plasma hair restoration therapy as a stand-alone treatment or alongside hair transplant procedures. The therapy involves extracting plasma from the patient's blood and injecting it into the scalp to promote hair growth.

The service employs a small team of staff made up of a clinic manager, a hair transplant technician and a hair growth specialist. The clinic manager has been in post since February 2022. The service has two doctors who attend the service to perform the surgical steps of the hair transplant procedures.

The premises used to deliver the service is a leased office suite within Blackfriars House, Manchester. Gro Clinics is on the third floor of the building which can be accessed by a lift or stairs.

Gro Clinics is registered for two regulated activities; Treatment of disease, disorder or injury and Surgical procedures. At the time of our inspection, the service did not have a registered manager. The clinic manager was in the process of applying to be the registered manager for the service.

Following our last inspection in November 2021, we issued the service with two warning notices under Section 29 of the Health and Social Care Act 2008 because they were failing to comply with the relevant requirements of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. This inspection was carried out to assess compliance with the warning notices.

How we carried out this inspection

We carried out an unannounced inspection on 28 April 2022. This was a focused inspection to follow up on the concerns that we raised in the two warning notices.

During our inspection we interviewed two members of staff who were based at the service.

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 provider must ensure there is a suitably qualified, skilled and competent professional, who will be a qualified nurse or pharmacist, to undertake oversight of medicines management which will include monthly audits for the registered provider.
- The provider must ensure regular audits are in place regarding the management of medication, including ordering, prescribing, supplying, administering and storing of medications, including setting out action taken (or to be taken) as a result of the audits.
- The provider must ensure that all staff are suitably qualified and competent to carry out their roles at Gro Clinics, including those working under practising privileges.
- The provider must ensure that policies, systems and processes are in place to govern the service, and that they are up to date and in line with best practice guidelines. Including but not limited to, policies and systems for the management of medicines, granting of practising privileges and recruitment and ongoing employment checks.
- The provider must ensure that informed patient consent is gained and recorded in a two-stage process with a cooling off period of at least 14 days between stages.
- The provider must have effective governance processes to ensure they are able to assess, monitor and improve the quality and safety of the service
- The provider must always have oversight of risks and challenges which could cause potential harm to people who use the service or disrupt the provision of the service.

Action the service SHOULD take to improve:

- The provider should ensure that staff are trained and understand their responsibilities in relation to incident reporting and duty of candour.
- The provider should ensure processes are in place to monitor compliance with cleaning schedules.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

Inspected but not rated

Surgery

Safe	Inspected but not rated
Effective	Inspected but not rated
Well-led	Inspected but not rated

Are Surgery safe?

Inspected but not rated

Cleanliness, infection control and hygiene

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

At our last inspection, we found that infection prevention and control processes were not effective or in line with best practice guidelines. In addition, cleaning records were not always completed.

During this inspection we found the service had cleaning schedules for the contracted cleaning staff outlining what they were expected to clean. However, there was no record of what had been cleaned and when.

The clinic manager told us of their intention to complete cleaning audits to monitor the effectiveness of cleaning, however there was no audit schedule or template in place and no audits had been completed.

The service stored cleaning products in a locked cupboard. When we asked, staff in the clinic were unable to access this cupboard without contacting the contracted cleaning staff. Not all staff demonstrated that they understood what products should be used for environmental cleaning. We also found products used for cleaning the skin of patients were out of date by more than 12 months.

The service had a colour coding system in place for cleaning and used disposable cloths and mop heads. However, mops and buckets were not always stored in line with best practice guidance. For example, buckets of different colours were stacked inside of each other, brushes of difference colours were stored together, and mops were stored head down touching mops of other colours.

Clinical waste was segregated in the clinic. However, staff were required to walk through a public area of the building to dispose of clinical waste. This had not been identified as a possible infection, prevention and control risk and was not listed on the service risk register.

The service did not have a process in place to record and monitor post-operative infection rates. Although the clinic manager told us that infections would be recorded as incidents, they were unable to tell us infection rates and how this data was used to change or improve practice.

Since our last inspection, the service had removed the benchtop steriliser and had moved to using single use items only.

Surgery

The client health questionnaire that patients were required to complete included questions about past medical history including blood borne viruses.

The service had cleaning schedules for staff outlining what they were expected to clean. We saw that these had been completed.

Clinical and non-clinical areas all appeared clean. The flooring in the clinical room had recently been replaced with impervious flooring to allow easier and more effective cleaning.

All staff had completed infection, prevention and control training.

Medicines

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

At out last inspection we found the service did not use a local policy, systems or processes to manage medicines and could not be sure that staff knew how to store, prescribe, administer, record and dispose of medicines safely.

During this inspection, we found that medication records were not always accurate, up to date or legible. Medication stocks did not always match the balance recorded in the record book. Staff were not following the service's policy for daily stock checks.

Not all medications were stored in appropriate boxes, had clear expiry dates or patient information leaflets present.

The services Medicines Management Policy and Drug Book Protocol contained information relating to legislation which was not relevant in the UK. In addition, the Medicines Management Policy was not dated, and it was not clear when this was last updated.

The Medicines Management Policy did not contain any information about temperature monitoring. Staff were recording the current fridge temperature, but not the minimum or maximum temperature. During our inspection we found the minimum fridge temperature to have been -6.2c and the maximum to have been 18.4c; which is outside of the recommended cold chain temperatures of 2c to 8c. Staff were unable to tell us when the fridge had breached the recommended temperature and if the medicines were still safe and fit for use.

Ambient room temperatures were not recorded in the room where medicines were stored. This room was not temperature controlled. Staff were unable to tell us if these medicines had been stored in accordance with manufacturer recommendations and if they were safe and fit for use.

The staff member who was identified as the service lead for Medicines Management had received no training for the role and did not demonstrate that they understood key medicines management principles.

The service did not complete any audits or monitoring of medicines management. The clinic manager was unable to tell us how they were assured that medicines were ordered, stored, prescribed, dispensed, administered or destroyed safely.

The service's Medical Waste Procedure dated December 2021 stated that '*expired or unwanted medicines should be returned to pharmacy for proper disposal. Tracking and documentation to be completed in DD book*'. No further guidance was available for this process. Staff told us that medicines were destroyed by taking them to the local pharmacy, but no record of this was kept and no contract was in place for this.

Inspected but not rated

Surgery

The service had a policy in place for the monitoring of Central Alerting System (CAS) alerts which was not dated. The clinic manager was monitoring, and actioning CAS alerts and they had a record of what action was taken.

The client health questionnaire completed by patients included information about medication history and allergies. On a review of five sets of patient records, we found that allergies had been recorded on all five operation records.

Incidents

The service did not have a clear process for the management of incidents. Staff were not trained in how to recognise and report incidents and near misses.

The service had an Incident, Accident and Near Miss Reporting Procedure dated December 2021. The service also had a separate Professional Candour and Client Incident Reporting policy dated December. The Incident, Accident and Near Miss Reporting Procedure did not refer to the Professional Candour and Client Incident Reporting policy so there was a risk that staff would miss important information if both policies were not read by staff.

Not all staff that we spoke with were aware of how incidents were recorded or investigated. In addition, they were unable to tell us about any incidents or any lessons that had been shared within the clinic or from other clinics managed by the provider.

The clinic manager was able to tell us that they would be responsible for investigating incidents, but that there had not been any at the time of our inspection.

Following out inspection, the service shared an incident investigation with us that had been completed shortly after our inspection. However, we found that this investigation was not completed in line with the recommendations of the service Incident, Accident and Near Miss Reporting Procedure. For example, a 'five whys' approach was not used, the investigation report did not identify any actual or possible harm.

Incidents were included on the agenda for the monthly governance meeting. However, no governance meetings had yet taken place.

We reviewed team meeting minutes from March and April 2022 and although incidents was listed as a topic, there was no record of any incidents or learning being discussed.

Are Surgery effective?

Inspected but not rated

Competent staff

The service did not make sure staff were competent for their roles. Managers held meetings with staff to provide support and development.

The service had competency checklists for all staff groups. However, no competency checks had been performed and the clinic manager was unable to tell us how they were assured that staff were delivery a safe service.

Inspected but not rated

Surgery

The service employed a hair restoration technician that appeared to have responsibilities in the clinic outside their scope of knowledge and was using a clinical title though not registered to do so. They were the lead for medicines management and completed all post-operative follow ups independently, but they were unable to demonstrate that they had the skills, knowledge and experience to carry out these roles safely.

We found that professional registrations checks had not been completed since November 2021. Professional registration fees had been due in February 2022, so there was a risk that the fees may not have been paid and the registration could have been cancelled. The clinic manager was unable to tell us how they maintain regular oversight of professional registration checks.

The clinic manager told us they intended to create a training matrix which included all training and employment requirements. However, this was not in place at the time of our inspection and the clinic manager was unable to demonstrate how they had oversight of staff training and competence.

The clinic manager told is that all staff received an annual appraisal which was carried out virtually with the leadership team in Australia. The clinic manager told us that they were able to have oversight of these appraisals and input information if they felt it was necessary.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff did not always support patients to make informed decisions about their care and treatment. They did not follow national guidance to ensure that patients gave consent in a two-stage process with a cooling off period of at least 14 days between stages.

The service had a consent policy which was not dated. This policy outlined the requirement for consent to be obtained 'early in the hair transplant journey'. However, the policy did not provide timeframes for when consent should be obtained and by who. This policy did contain information about the Mental Capacity Act (2005) and guidance for staff to follow if they were concerned about a patient's capacity to make decisions.

The service had a separate Cooling Off Period Policy which was not dated, but this did not make any reference to obtaining consent.

During our inspection, we reviewed five patient records and did not see any evidence that patients were provided with information about the procedure to enable them to make informed decisions. Consent was obtained on the day of surgery for all five patients. When we discussed this with the clinic manager following our inspection, they informed us that information is provided to the patients and initial consent is gained by a hair transplant specialist during a consultation at least two weeks before surgery. This not in line with The Royal College of Surgeons Professional Standards for Cosmetic Surgery which states that the Doctor carrying out the intervention is responsible ensuring that there is a shared understanding of expectations and limitations and to seek consent. The professional standards state that this responsibility must not be delegated.

Following our inspection, we were provided with an information sheet that is sent to prospective service users, however, there was no consent process included in this.

Some staff had completed training in the Mental Capacity Act, Deprivation of Liberty Safeguards (DoLS) and Consent. However, it was not clear if all staff had completed this training or if it was required as the service Training and Development Policy did not include information about what training staff were required to complete.

Inspected but not rated

Surgery

Are Surgery well-led?

Inspected but not rated

Governance

Leaders did not operate effective governance processes throughout the service. Staff met monthly but they did not always discuss and learn from the performance of the service.

The clinic manager told us that over 60 policies had been created since the last inspection, however, they did not have oversight of which staff had read and understood these policies. The clinic manager stated that most policies were created by the management team in Australia, and that they did not have the required access to review and update policies, including dates.

We found that there were often multiple policies for the same topic. Staff told us that the system used to access policies was often difficult to navigate because there were so many policies.

The service's Incident, Accident and Near Miss Reporting Procedure dated December 2021 did not make any reference to Duty of Candour requirements. However, the service did have a separate Professional Candour and Client Incident Reporting policy dated December 2021. It was not clear why two policies were required and there was a risk that staff would not miss important information if both policies were not read.

The service had a Medical Waste Procedure dated December 2021. Although this provided some guidance for staff about the disposal of clinical waste, it did not outline where clinical waste should be stored in the clinic, and how often staff were expected to empty clinical waste bins.

The clinic manager told us that the service no longer had an overarching Infection, Prevention and Control Policy and that they had been broken down into separate policies. The service had a Needle Stick Prevention Policy dated December 2021. The process in this policy for staff to follow if they received a sharps injury was not in line with best practice national guidelines. The service had a Single Use Instrument Policy. However, the policy was not dated, and it was not clear when it was due for review.

The service had two policies for the management of medication. One named 'Medication Management' which was not dated, and one named 'Drug Book Protocol' dated December 2021. The service also had a Gro Clinics document labelled 'Prescribing Medications- National Institute for Health and Care Excellence (NICE) which was not dated. There was a risk that staff could miss important information if they were not aware that there were three policies. In addition, two of the policies referenced Australian legislation rather than UK legislation and none of the policies contained guidance for staff about ordering medicines.

The service had a policy for recruitment and selection dated December 2021, however it did not include all requirements of Schedule 3 of the Health and Social Care Act 2008. In addition, the service did not have a policy which outlined how often Disclosure and Barring Service (DBS) checks or professional registration checks would be performed. One member of staff had not received a DBS check since March 2018 and the clinic manager was unable to tell us when this would be repeated. Professional registration checks performed by the clinic manager were out of date and did not provide assurance that staff held the required professional registrations for their role.

The service did not have a policy in place outlining the process for granting of practicing privileges.

Inspected but not rated

Surgery

The service had implemented a 'Regulation fulfilment tracker' which, following our last inspection, they told us that they were using this to monitor their compliance with the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. However, this document had not been updated for one month and contained information which was not relevant.

The clinic manager told us that he planned to have monthly governance meetings with the Chief Executive Officer (CEO) of the provider. These meetings had not yet taken place; however, the clinic manager had created an agenda of topics they planned to discuss.

The clinic manager was unable to demonstrate how they monitored the quality and safety of the service being delivered. They were able to tell us about their intention to carry out audits and measuring outcomes, but no audit schedule was in place and no audit activity had been completed.

We reviewed minutes of team meetings which took place in March and April 2022. The minutes of the meetings were very limited, which meant that it would be very difficult for staff who were not present at the meeting to know what they had missed.

Management of risk, issues and performance

Leaders and teams did not always use systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to reduce their impact. They had plans to cope with unexpected events.

The service had a risk register in place. Risks were graded in terms of impact and probability and mitigations were recorded. However, the risk register was not dated so it was not clear when these risks were added or when they were due to be reviewed. In addition, not all known risks were included. For example, the clinic manager told us that safety catches had recently been fitted to the windows due to the risk of people accidentally or intentionally falling from them. However, this was not listed as a risk on the risk register. Clinical waste management was also not listed as a risk.

The clinic manager had subscribed to receive patient safety alerts from the Central Alerting System (CAS). The manager had a record of all alerts and if any action had been taken. The service had a policy in place outlining this process, however it was not dated so it was not clear when this was created or due for review. In addition, there was no process in place for monitoring of alerts in the absence of the clinic manager.

The service had a Business Continuity Plan in place which was not dated. The Business Continuity Plan covered potential events which could impact the service and responsibilities for staff.

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 Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider did not have effective governance processes to assess, monitor and improve the quality and safety of the service The provider did not always have oversight of risks and challenges which could cause potential harm to people who use the service or disrupt the provision of the service.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 11 HSCA (RA) Regulations 2014 Need for consent The provider did not ensure that informed patient consent was gained and recorded in a two stage process with a cooling off period of at least 14 days between stages.

Regulated activity	Regulation
Treatment of disease, disorder or injury Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider did not ensure that medicines were ordered, prescribed, supplied, administered and stored safely and in accordance with best practice guidelines. The provider did not ensure that all staff werre suitably qualified and competent to carry out their roles at Gro Clinics, including those working under practising privileges.

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider did not ensure that policies, systems and processes were in place to govern the service, and that they were up to date and in line with best practice guidelines.