

The D'Souza Clinic

Quality Report

55 Harley Street
London
W1G 8QR
Tel: 020 7770 6538
Website: www.thedsouzaclinic.co.uk

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

Ratings

Overall rating for this location		Not sufficient evidence to rate	
Are services safe?	Good		
Are services effective?	Good		
Are services caring?	Not sufficient evidence to rate		
Are services responsive?	Good		
Are services well-led?	Not sufficient evidence to rate		

Summary of findings

Letter from the Chief Inspector of Hospitals

The D'Souza Clinic is operated by CMDSouza LTD. The service provides independent surgical treatment for hair restoration called Follicular Unit Extraction (FUE) and Follicular Unit Transplant (FUT), using local anaesthetic.

The service has no inpatient beds. Facilities include one clinical room with an operating chair and microscopes.

We inspected the service using appropriate key lines of enquiry from our framework for cosmetic surgery.

We inspected this service using our comprehensive inspection methodology. We carried out a short-announced inspection on 30 April 2019 and 1 May 2019.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

Services we rate

We have not rated this service before. We rated safe, effective and responsive good and did not rate caring and well-led. We did not rate this service overall because there was insufficient evidence to support our rating as there had only been three cases of regulated activity undertaken between the clinic opening and our inspection.

We found following areas of good practice;

- Staff understood how to protect patients from abuse.
- The service controlled infection risk well. Staff kept themselves, equipment and the premises clean.
- The service had enough medical staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- Staff gave patients enough food and drink during their visit to meet their needs and improve their health.
- Staff of different kinds worked together as a team to benefit patients.
- Staff we spoke with told us how they would care for a patient in a respectful and kind manner.
- The provider involved patients in decisions about their care and treatment.
- The service took account of patients' individual needs.
- The provider treated concerns and complaints seriously, investigated them and learned lessons from the results.
- The service had plans in place to engage with patients and staff and collaborated with partner organisations effectively.

However, we also found the following issues that the service provider needs to improve:

- The provider did not consistently make sure that staff completed mandatory training in key skills.
- The provider had not carried out any risk assessment to ensure that resuscitation bag location was easily accessible in an emergency for staff based on the fourth floor. The evidence was provided to us post inspection.
- At the time of the inspection, the provider had not carried out a control of substances hazardous to health (COSHH) risk assessment. The evidence was provided to us post inspection.

Summary of findings

- The hair technicians were not aware of the location of the resuscitation grab bag and how to use the telephone panic system in case of an emergency,
- There was no documented flow chart for the deteriorating patient.
- Although the surgeon asked for consent to contact the patients GP at the initial consultation and did so where appropriate, this was not documented clearly within patient notes.
- We found that there was no pharmaceutical waste bin within the building.
- The provider had limited understanding of systems that were in place for receiving, disseminating and acting on patient safety alerts from the Medicines and Healthcare Regulatory Agency (MHRA). The evidence was provided to us post inspection.
- At the time of the inspection, the hair technicians (HTs) we spoke with, were not aware of any formal incident reporting system.
- We found Disclosure and Barring Service (DBS) certificates held within staff files were not in line with the provider's policy.
- The provider did not keep any documented evidence of staff induction.
- We found that because the consent forms were completed and signed electronically, patients were not offered a copy of the consent form. There was no option on the form to indicate if a copy had been offered to the patient.
- Consent for the use and retention of medical photographs was not documented on the three consent forms we viewed.
- Policies and procedures were not yet shared with the hair technicians as only four technicians had been to the clinic on three occasions for three cases that had taken place.
- We found that the risk register contained only health and safety risks, not clinical risks.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with one requirement notice that affected the D'Souza Clinic. Details are at the end of the report.

Professor Edward Baker

Chief Inspector of Hospitals

Overall summary

Summary of findings

Our judgements about each of the main services

Service

Surgery

Rating

Summary of each main service

Not sufficient evidence to rate



Hair transplant surgery was the main activity of the hospital.

We have not rated this service before. We rated safe, effective and responsive as good and did not rate caring and well-led. We did not rate this service overall because there was insufficient evidence to support our overall rating as there had only been three cases of regulated activity undertaken between the clinic opening and our inspection.

Summary of findings

Contents

Summary of this inspection

	Page
Background to The D'Souza Clinic	7
Our inspection team	7
Information about The D'Souza Clinic	7
The five questions we ask about services and what we found	9

Detailed findings from this inspection

Overview of ratings	13
Outstanding practice	25
Areas for improvement	25
Action we have told the provider to take	26

Location name here

Services we looked at

Surgery

Summary of this inspection

Background to The D'Souza Clinic

The D'Souza Clinic is operated by CMDSouza LTD. The service opened at its current location in December 2018. It is a private clinic in London. The D'Souza Clinic provides consultations, examinations, and day case hair transplant surgery.

Mr Christopher D'Souza is the CQC registered manager, the nominated individual and the medical director of the service and responsible for running the service on a day-to-day basis. Mr. D' Souza is the sole provider of the service with experience in hair transplant surgery and is registered with the General Medical Council.

The business has been in operation since January 2018. The premises were moved in December 2018 to 55 Harley street, within a large shared building. There is a shared reception area where patients are met and taken through to the clinic room. There are accessible facilities for any patient with mobility issues. For example, there are ramps

and level floor surfaces. The provider does not have overall responsibility for maintaining the building but obtains assurances of maintenance and upkeep from the premises provider.

The provider did not employ any permanent staff. The hair technicians were hired on an ad hoc basis to support the surgeon for procedures as required. A virtual personal assistant (PA) service was used via an external company for managing new/follow-up appointments, organising and booking procedures.

The clinic is open Monday to Friday from 9am to 5pm and appointment times were generally held between 10am to 4pm. Patients are seen by appointment only. Patients who had a surgery had access to the surgeon via a dedicated number which they were given following an operation.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, one other CQC inspector, and a specialist advisor. The inspection team was overseen by Terri Salt, interim Head of Hospital Inspection.

Information about The D'Souza Clinic

The clinic has one consultation or treatment room and is registered to provide the following regulated activity:

- Surgical services.

During the inspection, we visited the clinic. We spoke with two hair technicians who had worked at the clinic on ad hoc basis and one administrator via telephone. We were unable to observe any procedures as none were planned during the inspection. We spoke with one patient who attended for an initial consultation. We also spoke with the premises' clinic manager. During our inspection, we reviewed three sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC.

Activity (December 2018 – April 2019)

- There were three day-case episodes of care recorded and eight outpatient consultation appointments at the D'Souza Clinic. All of these were self-referrals and privately funded.
- There were no overnight beds.

The clinic was run by one surgeon who was the registered manager. The provider did not employ any permanent staff. The hair technicians were hired on an ad hoc basis

Summary of this inspection

to support the surgeon for procedures as required. A virtual personal assistant (PA) service was used via an external company for managing new, follow-up appointments, organising and booking procedures.

There were no controlled drugs used at the clinic, hence there was no accountable officer for controlled drugs (CDs).

Track record on safety

- No never events
- No clinical incidents.
- No serious injuries
- No reported incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

- No reported incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)
- No reported incidences of hospital acquired Clostridium difficile (C.diff)
- No reported incidences of hospital acquired E-Coli
- There were no current complaints.

Services provided at the clinic under service level agreement:

- Cleaning service
- Clinical and or non-clinical waste removal
- Interpreting services
- Grounds maintenance
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We have not rated this service before. We rated safe as good because:

Good



We found the following areas of good practice:

- Staff understood how to protect patients from abuse.
- The service controlled infection risk well.
- The service had suitable premises and equipment and looked after them well.
- Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.
- The provider hired enough support staff to provide the right care and treatment.
- The service had enough medical staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The provider kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.

However, we also found the following issues that the service provider needs to improve:

- The provider did not consistently make sure that staff completed mandatory training in key skills.
- The provider had not carried out any risk assessment to ensure that resuscitation bag location was easily accessible in an emergency for staff based on the fourth floor. The evidence was provided to us post inspection.
- At the time of the inspection, the provider had not carried out a control of substances hazardous to health (COSHH) risk assessment. The evidence was provided to us post inspection.
- The hair technicians were not aware of the location of the resuscitation grab bag and how to use the telephone panic system in case of an emergency.
- There was no documented flow chart for the deteriorating patient.
- Although the provider asked for consent to contact patients GP at the initial consultation and did so where appropriate, this was not documented clearly within patient notes.

Summary of this inspection

- We found that there was no pharmaceutical waste bin within the building.
- The provider had limited understanding of systems that were in place for receiving, disseminating and acting on patient safety alerts from the Medicines and Healthcare Regulatory Agency (MHRA). The evidence was provided to us post inspection.
- At the time of the inspection, the hair technicians (HTs) we spoke with, were not aware of any formal incident reporting system.

Are services effective?

We have not rated this service before. We rated effective as good because:

We found the following areas of good practice:

- The service provided care and treatment based on national guidance and evidence of its effectiveness.
- All surgical treatments followed a 'cooling-off' period from the initial consultation enabling the patient to return at a later date for the treatment once they had made an informed decision. This was in line with best practice.
- Staff gave patients enough food and drink during their appointment to meet their needs and improve their health. The service made adjustments for patients' religious, cultural and other preferences.
- Staff assessed and monitored patients regularly to see if they were in pain.
- Staff of different kinds worked together as a team to benefit patients.
- The provider understood his roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005.

However, we also found the following issues that the service provider needs to improve:

- Though the service made sure staff were competent for their roles. We found Disclosure and Barring Service (DBS) certificates held within staff files were not in line with the provider's policy.
- Although new staff received induction and there was an induction programme in place. The provider did not keep any documented evidence of staff induction.

Good



Summary of this inspection

- Policies and procedures were not yet shared with the hair technicians as only four technicians had been to the clinic on three occasions for three cases that had taken place.

Are services caring?

Are services caring?

We did not rate caring because, there was insufficient evidence to support our rating as there had only been three cases of regulated activity undertaken between the clinic opening and our inspection.

We found the following areas of positive practice:

- The clinic had plans to monitor patient satisfaction by implementing a feedback survey.
- Patients could be referred to a psychiatrist based in same premises, if required.
- Staff we spoke with told us how they would care for a patient in a respectful and kind manner.

Not sufficient evidence to rate



Are services responsive?

We have not rated this service before. We rated responsive as good because:

We found the following areas of positive practice:

- The provider planned and provided services in a way that met the general needs of the patient group.
- The service took account of patients' individual needs. We saw detailed pre and post-operative information leaflets available and provided to patients.
- People could access the service when they needed it. There were no delays or cancellation.
- The provider treated concerns and complaints seriously, investigated them and learned lessons from the results. The clinic was a member of the Cosmetic Redress Scheme (CRS), which is a government authorised redress scheme to assist dispute resolution.

However, we also found the following issues that the service provider needs to improve:

- We found that as the consent forms were completed and signed electronically, patients were not offered a copy of the

Good



Summary of this inspection

consent form. There was no option on the form to indicate if a copy had been offered to the patient. The provider informed us that this would be rectified, and a section within the consent form for this would be included.

- We found that consent for the use and retention of medical photographs was not documented on the three consent forms we viewed.

Are services well-led?

We did not rate well-led because, there was insufficient evidence to support our rating as there had only been three cases of regulated activity undertaken between the clinic opening and our inspection.

- The surgeon had the right skills and abilities to run a service providing high-quality sustainable care. The service was led by the registered manager, who was also the CQC responsible individual. He was responsible for all of the organisation's governance and was the nominated safeguarding lead.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action.
- The provider promoted a positive culture that supported and valued staff.
- The service had plans in place to engage with patients and staff and collaborated with partner organisations effectively.
- The provider was committed to improving services.

However, we also found the following issues that the service provider needs to improve:

- We found that the risk register contained only health and safety risks, not clinical risks.

Not sufficient evidence to rate



Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Good	Good	Not rated	Good	Not rated	Not rated
Overall	Good	Good	Not rated	Good	Not rated	Not rated

Surgery

Safe	Good 
Effective	Good 
Caring	Not sufficient evidence to rate 
Responsive	Good 
Well-led	Not sufficient evidence to rate 

Are surgery services safe?

Good 

The main service provided by this clinic was hair transplant surgery.

We have not rated this service before. We rated safe as **good**.

Mandatory training

The service did not consistently make sure that staff completed mandatory training in key skills.

- The surgeon had completed training modules for fire safety, infection prevention and control, General (GDPR), Control of Substances Hazardous to Health (COSHH), handling patients, 2013 (RIDDOR), handling violence, dealing with complaints and lone working. All training records were in date.
- There was a staffing policy, which identified mandatory training requirements for staff and included: fire safety awareness, health and safety, adult and child safeguarding, mental capacity, manual handling, resuscitation and infection control.
- The clinic kept training record of all hair technicians (HTs) that they planned to hire on an ad hoc basis. The provider used a colour coding system to ensure that only those staff that have all relevant training were hired to support a procedure. We reviewed five out of 10 files of staff that could be hired; all staff had completed training in infection control, safeguarding adult level two, safeguarding children level one and basic life support. We found, inconsistency in other training records. For example; three out of five staff had up to

date General GDPR training, two staff had manual handling training and only one staff had recorded fire safety training record in their file. This was not in line with the provider's policy.

Safeguarding

Staff understood how to protect patients from abuse.

Staff had training on how to recognise and report abuse and they knew how to apply it.

- An up-to-date safeguarding vulnerable adult policy, with flow charts for the escalation of concerns was available. The policy referenced relevant national guidance and included relevant contact numbers. Though the clinic did not see any children, a child safeguarding policy was also available for staff, in case there were any concerns about a child who may attend with a patient. However, this policy had not been shared with staff at the time of inspection. The surgeon informed us that he planned to share all relevant policies with the staff in the next few weeks.
- The surgeon was the safeguarding lead for the service and completed safeguarding vulnerable adult level three training and safeguarding children level two training.
- The surgeon informed us that safeguarding was part of the clinic's mandatory requirement for hiring a hair technician. We reviewed files of five hair technicians who had been approved to work at the clinic and all had undertaken safeguarding vulnerable adult level two training.
- Between December 2018 and April 2019, the clinic did not report any safeguarding concerns to the local

Surgery

authority and no notifications were recorded by the CQC. However, the surgeon was clear on how they would do this and who else to inform if any concerns were raised by other staff.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.

- All areas that we inspected were visibly clean and dust-free, including equipment. There was an infection prevention and control policy, which referenced to current legislation and relevant guidelines.
- The surgeon told us that all portable equipment was cleaned after every use. The electric couch was clean and fully compliant with health building notice (HBN00-09), as it was found to be wipe-able and had roller towel to cover between patients. There were pedal bins available in the clinic to minimise infection risk by not touching the bins.
- All surgical instruments used during a procedure were single-use. The surgeon was aware of measures to take to limit the spread of infection. For example, disposable clipper heads were used for hair clipper.
- Unlike many forms of surgery, hair transplant surgery (HTS) is not performed under sterile conditions but instead is. The surgeon told us that only one case was operated in a day. The hair technicians would clean down the couch, microscopes and all portable equipment in the morning and prepare the room, as well as cleaning at the end of the day after the procedure. In addition, every morning, the cleaners from the external cleaning company cleaned the room, using a checklist. We saw two months records of daily cleaning by cleaners and there were no gaps or omissions.
- Adequate supplies of personal protective equipment (PPE) including gloves and aprons, were available. The surgeon informed that all staff would change into blue scrubs style uniform and adhered to 'bare below elbows' (BBE) dress code. We were unable to observe whether doctor and clinical staff adhered to this as there were no patients or procedures that took place during the inspection.

- The clinic did not screen patients routinely for MRSA or other multiple drug resistant organisms as they had no inpatients and was not necessary for the setting and types of procedures undertaken.
- A dispenser with hand sanitising gel situated in appropriate place within the clinic. Guidance for effective hand washing was displayed by hand washbasins. Hand washbasins were equipped with soap and disposable towels. We were unable to observe hand washing in practice as there were no staff and patients or procedures that took place during the inspection.
- A six-monthly infection control audit was carried out by an external company as part of a service level agreement (SLA) of hiring the premises. The D'Souza clinic's first audit was due in May 2019, so no results were yet available.
- Clinical waste disposal was provided through a service level agreement (SLA) with an external provider.
- Sharps containers within the clinic were dated and signed when assembled, not overfilled and temporarily closed when not in use.

Environment and equipment

The service had suitable premises and equipment and looked after them well.

- The reception and waiting area were located on the ground floor of 55 Harley street. The clinic was on the fourth floor. There was step-free access to the clinic via a lift. The building had a manager and reception staff at the front door, who welcomed and directed all patients, as well as providing assistance to any people with mobility issues who required wheelchair access via portable ramps.
- The clinic was used for both consultations and as a treatment room. The two areas within the room were well defined and separated into sections. There was a desk and chairs in the consultation section of the room. The treatment area was equipped with six microscopes and an electronic patient couch. The treatment areas also had easily accessible disposable equipment which was in date and stored appropriately.
- There was a fully equipped adult resuscitation grab bag. This included medications for anaphylaxis, an automated external defibrillator (AED), equipment to maintain airways and oxygen. The resuscitation bag was provided and managed via a service level agreement by the company who owned the premises. We saw

Surgery

evidence that the resuscitation bag had been checked every other week and was last checked on 17 April 2019. Emergency drugs were available and within the use by date. However, we found a dextrose gel expired in March 2019. We brought this to the attention of the premises' clinic manager, who assured us that this would be replaced immediately.

- The resuscitation bag was located in a cupboard in level -1, close to the lift and stairs. The service had not carried out any risk assessment to ensure that resuscitation bag was easily accessible in an emergency for staff based on the fourth floor. Following inspection, a risk assessment was submitted, which provided assurance that the location of the bag was adequate for the clinic needs.
- The health and safety of the building was managed by the premises' clinical manager, who undertook monthly checks. The provider gained assurance that these were undertaken. Portable appliance testing (PAT) for electrical equipment and fittings had been undertaken in March 2019. All portable equipment we checked had been tested and labelled to indicate the next review date.
- There was a safety and suitability of premises and equipment policy available. The clinic had an up-to-date fire risk assessment and a fire evacuation plan. A legionella risk assessment had been carried out (legionella is a term for a particular bacterium which can contaminate water systems in buildings) and there were no actions to follow up.
- At the time of the inspection, the provider had not carried out a control of substances hazardous to health (COSHH) risk assessment. This was provided to us post inspection. We were assured that flammable substances within the clinic were kept locked and stored safely.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.

- There was a 'admission acceptance policy'. The surgeon informed us that for hair transplant surgery, the majority of the patients were fit and well with no past medical history, no drug history and no history of adverse reactions. All procedures were low risk and performed under local anaesthetic. As such, there was no specific list of exclusion criteria.

- Before providing treatment, the surgeon ensured he had adequate knowledge of the patient's health, any relevant test results and their medicines history. A thorough medical history was taken for all patients, to identify any patients who may be at higher risk due to other medical conditions. The surgeon would refer patients to relevant specialties, for example; cardiologist, dermatologist, to ensure patients were fit for surgery.
- Consultations for procedures were face to face, with the surgeon assessing and examining the patient and explaining their treatment options, any risks and the expected outcome. Patients were seen by appointment only.
- Patients who had undergone surgery had access to the surgeon via a dedicated number which they were given following an operation. Patients were also provided a dedicated number to the surgeon's personal assistant for any non-clinical issues.
- The surgeon understood his responsibilities to manage emergencies and to recognise those in need of urgent medical attention. The surgeon had undertaken basic life support (BLS) training. In the event of any emergency, 999 would be called. However, there was no documented flow chart for the deteriorating patient.
- A telephone panic system was in place in the clinic. There were instructions posted on the wall about how to use the panic system in case of an emergency. The surgeon was aware of how to use the system.
- All hair technicians (HTs) had completed BLS, and this was one of their conditions of employment. The two HTs we spoke with were clear of their responsibilities in the event of an emergency. However, neither HT was aware of the telephone panic system or how to use it, or the location of the resuscitation grab bag. Following inspection, the surgeon confirmed that all HTs had now been informed about the telephone panic system and the location of the resuscitation bag.
- The surgeon told us that he would assess and discuss every patients psychiatric and emotional health to determine if patients had body image issues. This was done in line with professional guidance. If there were any concerns, patients were asked to complete a detailed body image questionnaire. We saw the template for this. There was a psychiatrist within the same building if patients needed to be referred on for further support with any issues.

Surgery

- The surgeon used the World Health Organisation (WHO) safety checklist for patients having a hair transplant surgery, including marking of the area, to prevent or avoid serious patient harm. This was in line with national recommendations (NPSA Patient Safety Alert: WHO Surgical Safety Checklist). There were plans to audit WHO checklist on an annual basis as part of the premises provider's audit programme, once the surgeon had a sufficient number of patient records. However, the proposed audit would focus on only the documentation of the 'sign in' and 'sign out' parts of the process.
- There were appropriate building indemnity arrangements in place to cover all potential liabilities.
- The surgeon also had current medical indemnity cover.

Support staffing

The surgeon was the only permanent staff member. No other permanent staff were employed. The provider hired enough support staff to provide the right care and treatment.

- Hair technicians were independently contracted from a pool of about 20, although the surgeon said that he regularly used four hair technicians from this pool. This was not unusual, as technicians are usually self-employed, hired as required for the majority of hair transplant services.
- Currently, there is no formal training or recognised qualification for hair technicians. All training was given on the job. The surgeon showed us records of hair technicians that he hired and who had worked under his supervision in the past.
- The surgeon told us that depending on the number of grafts required, he would have three to four technicians for a procedure, to ensure there were enough support staff.
- An external company provided personal assistance and administration support for managing appointments and booking patients.

Medical staffing

The service had enough medical staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.

- The surgeon had the skills, knowledge and experience to carry out his role.

- The surgeon was registered with the General Medical Council (GMC) and was up to date with revalidation.
- The surgeon was a diplomat of the American Board of Hair Restoration surgery, vice president of the British Association of Hair Restoration Surgery and a member of the Royal College of Surgeons. He was also an associate of the International Society of Hair Restoration Surgery.

Records

The service kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.

- Patient records were stored electronically. The clinic used an online clinical management system to store patient records and information. Any handwritten records, such as operative notes, were scanned and uploaded to the system. The system was password protected. In the event of a power failure, the surgeon informed us that notes would be written by hand and stored in cabinets, until they could be entered onto the system. All pre and post-operative pictures of the patient were linked and stored electronically.
- We saw a comprehensive pre-assessment medical questionnaire, that the surgeon planned to use from May 2019 for all patients having surgery at the clinic. This included questions about any recent surgery, medications, any treatment for any medical conditions, allergies, and if female patient could be pregnant or breast-feeding.
- We looked at three patient records who had a procedure at the clinic. We found all records contained a medical history, description of the problem, an assessment of the patient and post procedure advice, information given to the patient, such as graft care, hair care and hair styling.
- The surgeon informed us that majority of the patients would not want their GP to be informed about their treatment. Although the surgeon asked for consent to contact the patients GP at the initial consultation and did so where appropriate, this was not documented clearly within patient notes. The surgeon informed us that he would action this and include this within the pre-assessment questionnaire.
- There was a medicine optimisation and management policy. The clinic held limited stocks of medicines relevant to the service they offered.

Surgery

- Medicines were stored in a secure locked cupboard within the clinic. The clinic had climate control system and all medications were stored within the manufacturers recommended range. All stock medicines which we inspected were in date.
- Stock medicines were only given as first dose to the patient at the clinic, then take-home medication was prescribed by the surgeon for the patient to collect at their choice of pharmacy. The clinic used electronic prescriptions and gave printed copies to patients.
- No controlled drugs were in use or stored at the clinic.
- There was an antibiotic policy which referenced to relevant national guidance.
- There were no medicines that required to be stored in a fridge. However, the clinic's medicine management policy did not reflect the clinic's working practice as it referred to managing and storing medicines in a fridge.
- We found that there was no pharmaceutical waste bin within the building. Following inspection, the provider informed us that this would be rectified within the next six months. Meanwhile any expired medicines would be disposed of in the sharp bins within the clinic, clearly labelled 'pharmaceutical waste to be incinerated'.
- The surgeon had limited understanding of systems that were in place for receiving, disseminating and acting on patient safety alerts from the Medicines and Healthcare Regulatory Agency (MHRA). After the inspection, the provider confirmed that as part of the SLA, the premises' clinical manager received all MHRA alerts and distributed these to relevant clinicians if applicable. There had been no alerts relevant for the clinic.
- There was a 'significant events, adverse events and near misses policy' dated December 2018. We reviewed the policy, which was in line with current national guidance and included a protocol and incident form for reporting, reviewing and investigating any serious incident. The surgeon told us that he planned to discuss what reporting system was used by the premises provider and introduce a similar system to share with the visiting staff.
- The hair technicians (HTs) we spoke with, knew that the surgeon was working on developing a policy. However, at the time of inspection they had not seen the policy and were not aware of any formal reporting system, as they have supported only few procedures at the clinic. HTs said that they would inform the surgeon if there were any concerns.
- The nature of service provided at the clinical did not require mortality and morbidity reviews.
- The Duty of Candour (DoC) is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. This means providers must be open and honest with service users and other 'relevant persons' (people acting lawfully on behalf of service users) when things go wrong with care and treatment, giving them reasonable support, truthful information and a written apology. There were no incidents which met this threshold. The surgeon demonstrated a culture of openness and honesty.

Incidents

The service managed patient safety incidents well.

When things went wrong, staff understood their responsibility to apologise and gave patients honest information and suitable support.

- The service did not report any never events between December 2018 and April 2019. Never events are serious incidents that are entirely preventable as guidance or safety recommendations providing strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- No serious incidents (SIs) or clinical incidents were reported between December 2018 and April 2019.

Safety Thermometer (or equivalent)

The clinic did not use any clinical quality dashboards to monitor safety due to the nature and size of the service.

- The clinic, unlike NHS trusts, was not required to use the national safety thermometer to monitor areas such as venous thromboembolism (VTE). The clinic did not use any other clinical quality dashboards to monitor safety due to the nature and size of the service.

Surgery

Are surgery services effective?

Good

We have not rated this service before. We rated effective as **good**.

Evidence based care and treatment

The service provided care and treatment based on national guidance and evidence of its effectiveness.

- Clinical policies and procedures we reviewed were all in date and referenced relevant National Institute of health and Care Excellence (NICE) and Royal College guidelines. The clinic also used guidance from the International Society of Hair Restoration Surgery. This organisation promotes best practice for this type of surgery.
- Policies and procedures were available in a folder at the clinic. The policies folder had a list for staff to sign once they had read the policies. This was not yet completed by any hair technicians as only four technicians had been to the clinic on three occasions for three cases that had taken place. The surgeon informed us that he would ensure that policies were signed by relevant staff at their next visit.
- All surgical treatments followed a 'cooling-off' period from the initial consultation enabling the patient to return at a later date for the treatment once they had made an informed decision. This was in line with best practice.

Nutrition and hydration

- Staff gave patients enough food and drink during their appointments to meet their needs and improve their health. The service made dietary adjustments for patients' religious, cultural and other preferences.
- As procedures lasted a long time, patients needed to have a drink and something to eat during treatment. On arrival at the clinic, patients were asked what they would like for lunch and a member of staff would organise this.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain.

- There was a pain management policy. Pain was measured by verbal report of the patient, on a scale between zero and 10. The surgeon told us that he would assess pain throughout the procedure, but more specifically three hours into the procedure, as by that time the local anaesthetic would start to wear off and this would need to be re-administered. All procedures were carried out under local anaesthetic. Due to the nature of the procedures, no formal pain assessment tools were used.
- All patients were prescribed paracetamol or co-dydramol for pain control following a procedure.
- A post-operative information leaflet, given to each patient, included guidance on pain relief that should be taken once at home.

Patient outcomes

Managers monitored the effectiveness of care and treatment and used the findings to improve them.

- Patients had an initial consultation with the surgeon, who would assess their suitability for treatment and advise how many hair follicles they would need transplanted to achieve the expected results following surgery. Photographs were taken at the time the patient was accepted for treatment.
- Patients had a follow review every six, 12 and 18 months to review hair growth progress against expected results. Photographs were taken at each stage. The 18-month measure was the level of patient satisfaction with the treatment. No data was yet available.
- During December 2018 to April 2019, the provider reported no surgical site infection.
- The provider told us that 'patients sometimes had unrealistic expectations of what the surgery could offer and that these needed to be managed and some patients would require further consultations'. The provider said that 'he would not perform a procedure where there were unrealistic expectations.'

Competent staff

Though the service made sure staff were competent for their roles. We found Disclosure and Barring Service (DBS) certificates held within staff files were not in line with the provider's policy.

- The registered manager was the only full-time surgeon employed by the service with experience in hair transplant surgery. The surgeon had valid General

Surgery

Medical Council (GMC) registration, a valid fitness to practice certificate and up-to-date criminal record checks. The surgeon was a diplomat of the American Board of Hair Restoration surgery, vice president of the British Association of Hair Restoration Surgery, and a member of the Royal College of Surgeons. He was also an associate of the International Society of Hair Restoration Surgery. We saw evidence that he had attended regional and international conferences and meetings.

- The surgeon had his appraisals and revalidation undertaken by an independent body as he did not work at an NHS trust. We saw evidence of these.
- The provider did not employ any permanent staff. A virtual personal assistant (PA) service was used, provided by an external company. This managed new/follow-up appointment, as well as organising and booking procedures. Hair technicians were booked to support the provider for procedures as required.
- We were provided with evidence to show that the clinic held staff records for those working freelance at the clinic. These staff files included relevant documents such as: immunisation records, references, training records, CVs, and copies of identification.
- The surgeon told us that there was an induction programme, all staff when they first visit the clinic were given an induction. Both hair technicians we spoke with confirmed this. we found however, no formal checklist or record was kept of this induction. Following inspection, evidence of staff induction checklist was submitted. The surgeon informed us that this practice had been introduced.
- The provider carried out staff checks at the time of recruitment or hiring a technician. Disclosure and Barring Service (DBS) checks were undertaken on all staff members. DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable. The clinic's 'staff recruitment policy' stated that 'the clinic may accept an existing DBS check provided by a new member of staff provided that the DBS check is not more than 3 months old, and it is considered suitable for the position applied'. We reviewed five staff records, and all staff had Disclosure and Barring Service (DBS) certificates held within their files, but all these were issued for a different provider and were more than two years old. This was not in line with the provider's policy.

Multidisciplinary working

Staff of different kinds worked together as a team to benefit patients.

- The surgeon showed a willingness to work with patients' GPs. However, the surgeon would only share information regarding a procedure with patients consent.
- The surgeon gave examples of working with other services. For example, the liaising with patients GPs, dermatologists and other healthcare providers as required.
- Staff we spoke with all understood their own personal responsibility regarding patient care and told us that the overall responsibility belonged with the surgeon.

Seven-day services

- The clinic was open Monday to Friday from 9am to 5pm, with surgery generally scheduled on Tuesday and Wednesday.
- Patients were seen by appointment only. Patients who had undergone surgery had access to the surgeon via a dedicated number which they were given following an operation. Patients were also provided a dedicated number to the surgeon's personal assistant for any non-clinical issues.
- The surgeon also offered consultation clinics on alternate Saturdays.

Health promotion

- The surgeon informed us that where patients' needs could not be met by the service, he directed them to the appropriate service for their need. For example, to dermatologist for any scalp and skin care conditions.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The surgeon understood his roles and responsibilities under the Mental Health Act 1983 and the Mental Capacity Act 2005.

- We found that the surgeon sought patients' consent to care and treatment in line with legislation and guidance.
- There was a 'consent to care and treatment policy'. The provider had developed protocols and procedures to

Surgery

ensure that consent for procedures and treatment was obtained and documented. Consent forms contained benefits and risks associated with the hair transplant procedure.

- After the initial consultation, a minimum of two week 'cooling-off' period (time given to the patient to consider whether they wanted to proceed with the surgery) was applied, after which the patient would complete a consent form along with the medical questionnaire.
- We looked at three sets of patient records and found clear documentation of consent, including signed electronic consent forms, in all. All records that we reviewed had a clear gap of two weeks from final consultation to the surgical procedure.
- The surgeon understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Capacity Act 2005. There was a mental capacity policy, which made reference to carrying out mental capacity assessments where necessary and included a mental capacity assessment form and best interest form. The clinic only accepted low risk, medically fit patients for surgical procedures so patients lacking capacity were not treated at the clinic. The surgeon informed us patients were self-referred and he would not take on any patients for procedures who lacked capacity.
- We found that as the consent forms were completed and signed electronically, patients were not offered a copy of the consent form. There was no option on the form to indicate if a copy had been offered to the patient. The surgeon informed us that this would be rectified, and a section within the consent form for this would be included.
- Although the surgeon told us consent was obtained for the use and retention of medical photographs, this section was not completed by the patients in the three consent forms we viewed.

Are surgery services caring?

Not sufficient evidence to rate

We have not rated this service before. We did not rate caring because, there was insufficient evidence to support our rating.

Compassionate care

We could not verify if staff cared for patients with compassion, because no surgery patients attended during our inspection.

- During our inspection we were unable to observe any clinical patient interactions as the clinic did not have any patients having a surgery.
- The clinic environment ensured privacy as only one patient was booked for a procedure for each day. Staff we spoke with confidently told us how they would ensure privacy and dignity of all patients.
- Staff we spoke with demonstrated a good understanding of providing compassionate care to patients. They told us of examples where they would reassure nervous patients and allow for extra time during their appointments.
- We were not able to speak with any patients who had a procedure at the clinic. We spoke with one patient who attended for consultation and was happy with his experience.
- Patient testimonials on the clinic's website were all very positive about the service provided. The clinic did not carry out any formal patient feedback surveys, as there had been very few patients. The provider showed us the patient feedback policy and the feedback form that he planned to use from next month.
- There was a chaperone policy. There was a sign displayed within the clinic to inform patient if they needed a chaperon. The provider told us that the nature of procedures would not generally require a chaperon but there was provision for this if requested by patients.

Emotional support

We could not verify if staff provided emotional support to patients to minimise their distress, because no patients attended during our inspection.

- The provider told us that a patient's mental and emotional health was assessed during their initial consultation with the lead clinician. Patients that were deemed to have mental or emotional health issues such as body dysmorphia, that may influence their treatment decision were refused treatment.
- The provider could refer patients to a psychiatrist based in same premises, if required.

Understanding and involvement of patients and those close to them.

Surgery

The service involved patients in decisions about their care and treatment.

- Patients were advised of the cost and expectations of their treatment at the initial consultation appointment. Patients were given a 'cooling-off' period after the initial consultation, in line with best practice guidelines. All patients were required to sign an agreement stating terms and condition before the procedure.
- The surgeon was able to tell us about the importance of managing patient expectations prior to surgery. This ensured patients were realistic about the final outcomes of surgery. The patient we spoke with told us that the surgeon had discussed the surgery outcome and they had realistic expectations.
- The surgeon informed us that partner and relatives were involved if patients requested it.

Are surgery services responsive?

Good



We have not rated this service before. We rated responsive as **good**.

Service planning and delivery to meet the needs of local people

The provider planned and provided services in a way that met the general needs of the patient group.

- The clinic was open five days a week and provided consultations and elective hair transplant surgery by appointment only, at a time to meet the needs of the patient group. The clinic generally operated on a Tuesday or Wednesday. Appointments were generally arranged on the phone.
- The clinic provided elective cosmetic procedures to patients aged over 18 years. No procedures conducted involved an overnight stay at the clinic.
- The communal building waiting area had access to water, coffee and tea making facilities, newspapers, television and magazines.

Meeting people's individual needs

The service took account of patients' individual needs.

- The hair transplant procedure could last over seven hours. The surgeon informed us that during the procedure, patients were given light lunch and that all dietary requirements could be catered for.
- The provider offered clinics on alternate Saturdays for patients who could not attend during the week due to other commitments.
- At the time of inspection, the surgeon was not clear of the provision of interpreter services. Following inspection, we were informed that there was a system in place for Arabic interpreters through the service level agreement (SLA) with the premises provider. The surgeon informed us that once the clinic had fully established, he would review the provision of the interpreter service to include further languages depending on the demand.
- The clinic produced a detailed pre and post procedure information leaflet on Follicular Unit Extraction (FUE) and Follicular Unit Transplant (FUT). All information was available in English only. The surgeon informed us that there hadn't been any requests to translate any information, but if required to do so, he would use a widely available internet translation tool. The website also provided clear information about the procedures.

Access and flow

People could access the service when they needed it.

- The service provided elective and pre-planned hair transplant procedures to self-referring patients. Patients could phone and book an appointment for a date and time that suited them. The surgeon told us that there was no waiting period for appointments. Patients would only have to wait if the surgeon was away on leave.
- Administrative staff and hair technicians we spoke with told us that as the service was new, there were no delays or cancellations.
- The clinic was using an external provider which centralised all patient contacts, queries appointments, with an electronic record system.

Learning from complaints and concerns

The provider treated concerns and complaints seriously, investigated them and learned lessons from the results.

- The clinic had a formalised process of handling complaints which was outlined in a written policy. The

Surgery

policy stated that all complainants would receive a written acknowledgement within two working days of the complaint and a full written response within 20 working days, or otherwise agreed timeframe.

- The service received no complaints in the period of December 2018 to April 2019.
- The surgeon told us that he always tried to handle a complaint informally, with the patient referred to the complaints procedure if required. If no resolution could be reached, the clinic would refer the complaint for independent mediation. The clinic was a member of the Cosmetic Redress Scheme (CRS), which is a government authorised redress scheme to assist dispute resolution.

Are surgery services well-led?

Not sufficient evidence to rate

We have not rated this service before. We did not rate well-led because, there was insufficient evidence to support our rating.

Leadership

The surgeon had the right skills and abilities to run a service providing high-quality sustainable care.

- The service was led by the surgeon who was the medical director of the company, the registered manager and the CQC nominated individual. He was responsible for all of the organisation's governance and was the nominated safeguarding lead.
- All external staff we spoke with, said that the surgeon was approachable, and they enjoyed working at the clinic

Vision and strategy

The service had a vision for what it wanted to achieve and workable plans to turn it into action.

- The service had a clear vision to provide the very best level of care and treatment in the field of hair restoration.
- There was a clear business plan and strategies to deliver this vision.

Culture

The provider promoted a positive culture that supported and valued staff.

- The provider had purposefully developed a service with a focus on patient experience, personal, one-to-one service, and contact with the doctor throughout the patient journey. The provider had created a culture and environment to attract highly skilled, happy, motivated staff, who would share his passion and enthusiasm. The surgeon told us that he aimed to 'hire permanent hair technicians as the clinic and service grew'.
- We saw that patients completed a contract which clearly stated what course of treatment they had chosen and the cost. We saw that terms and conditions were clearly recorded and the person receiving the treatment was required to sign this contract prior to surgery. We asked one patient who confirmed that total cost and what was included in the cost was clearly explained to him at the initial consultation.
- There was a duty of candour (DoC) policy. The surgeon had relevant training and was aware of the requirements of the duty of candour.
- Though there was limited online patients' feedback, all feedback demonstrated the surgeon ensured a culture that was caring and supportive.
- The hair technician we spoke with told us that they enjoyed working at the clinic and that the surgeon and other hair technicians were "just like my friends".
- There was a whistle blowing policy. However, this had not been shared with the hair technicians at the time of inspection.

Governance and Managing risks

We were unable to verify the effectiveness of the governance and risk management system as it was recently established.

- The service had established a governance framework and produced records to demonstrate that processes were completed. For example, we saw WHO surgical checklists, cleaning schedules and surgery procedures. Relevant governance policies and clinical guidelines were available. However, these policies were newly developed and required time to be embedded.
- The service kept a risk register. The risk register recorded the location of risks, a brief analysis, a description, the severity and likelihood rating, any mitigation measures, a responsible person and a target date to review. The risk register contained only health and safety risks, not clinical risks. Whilst on inspection, some risks (such as location of resuscitation bag and control of substances

Surgery

hazardous to health (COSHH)) were identified by us, but no risk assessment had been completed for these.

Comprehensive risk assessments for these were submitted following the inspection.

- At the time of inspection, the provider had not carried out any clinical audit and there was no patient outcome data as there had been limited activity at the service.
- The surgeon informed us that he liaised with the premises' clinic manager at each visit to the clinic. Once he had a more established patient activity, there were plans to set up formal, minuted meetings to discuss complaints, incidents and governance related issues.

Managing information

The service managed and used information well to support all its activities, using secure electronic systems with security safeguards

- The clinic used an electronic patient record management system, which centralised all patient data in one place.
- The clinic was registered with the Information Commissioner's Office as a data protection officer under the Data Protection Act 1998.
- The external company used by the provider for managing and booking appointments was compliant with General Data protection Regulations (GDPR).

Engagement

The service had plans in place to engage with patients and staff and collaborated with partner organisations effectively.

- The clinic did not carry out any staff surveys as there was no established team yet and there were no permanent staff. From speaking with hair technicians (HTs), we found that they were able to provide direct feedback and input into the running of the service, if they felt anything could be improved. The HTs told us that they felt valued and liked their views were listened to. One hair technician told us that she had been involved in the setting up of the clinic and felt that her views were taken on board and she and other HTs were invited to the clinic before it was officially opened.
- Patient feedback was received via the clinic website and a review site. The clinic did not carry out any formal patient feedback surveys, as there had been very few patients. The surgeon showed us the patient feedback policy and the feedback form that he planned to use from next month.

Learning, continuous improvement and innovation

The provider was committed to improving services

- The clinic was relatively new, with a limited number of consultation and procedures so far.
- The surgeon offered a free-of-charge first consultation for referred patients, and recently changed the policy to offer free initial consultations to all new patients, to increase patient flow.
- The surgeon told us that he was always striving to improve and focused on reflective practice.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that all relevant staff have completed mandatory training as per policy.
- The provider must ensure that there is a formal induction process for all new staff.
- The provider must ensure that staff are aware of how to report an incident.
- The provider must ensure that all relevant staff are aware of the clinic policies.
- The provider must ensure that correct Disclosure and Barring Service (DBS) checks are in place for hair technicians, as per their policy.

Action the provider **SHOULD** take to improve

- The provider should have a system in place to monitor that staff completes mandatory training in key skills as per the provider's policy.
- The provider should review the disposal processes for medicines and have a pharmaceutical waste bin within the building.

- The provider should make all staff aware of how to escalate and respond in an emergency, in particular: the location of the resuscitation grab bag (which was located opposite to the theatre in basement) and location of panic button.
- The provider should review the risk register to reflect clinical risks.
- The provider should have a flow chart for the deteriorating patient.
- The provider should have a system in place to document patient's consent to contact their GP.
- The provider should have a system in place to document if a copy of consent form had been offered to the patient.
- The provider should have a system to document consent for the use and retention of medical photographs.

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	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>1.Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.</p> <p>2.Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—</p> <p>b. assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;</p> <p>f. evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).</p> <p>Regulation 17 (1)(2)(b)(f)</p>