Baruch hair Transplant Centre Limited

Quality Report

First Floor
ABS House
Viaduct Street
Stanningley
LS28 6AU
Tel:01132567594
Website: www.baruchhairtransplantcentre.com

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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

Are services safe?	
Are services effective?	
Are services caring?	
Are services responsive?	
Are services well-led?	

Overall summary

Baruch Hair Transplant Centre Limited is operated by Baruch Hair Transplant Centre Limited (BHTC). Facilities include a hair transplant treatment room, a recovery area and a consultation room. The service has no overnight beds. The service provides surgical hair transplant procedures only. There are two methods of hair transplantation: follicular unit transplant and follicular unit extraction. The service only provided follicular unit extraction. In follicular unit extraction individual follicles are extracted and then implanted into small excisions in the patient's scalp.

We found several areas of concern during our last inspection on the 27 June 2019; however, the immediate risk to patients was low due to the number of procedures undertaken by the service. Immediately following the

Summary of findings

inspection, we requested evidence from the provider under section 64 and section 65 of the Care Standards Act for further assurance of the safety of patients using the service.

We inspected this service using our focused inspection methodology. We carried out the announced part of the inspection on 4 December 2019. We focused on specific parts of the service which were identified as inadequate since our last inspection. The key questions we asked during this inspection were, was it safe, effective, responsive and well-led. Due to the inspection being focussed we did not rate this inspection.

Following this inspection, we carried out enforcement action and served a notice under Section 31 of the Health and Social Care Act 2008 to suspend the registration of the service provider in respect of the regulated activities: surgical procedures.

We also served a warning notice under section 29 of the Health & Social Care Act 2008. This warning notice was given because we believe that a person will or may be exposed to the risk of harm if we did not take this action.

Services we rate

Due to the inspection being focussed we did not rate the service.

We found the following issues needed further improvement:

- Invasive procedures, such as hair transplants, require clinical ventilation to reduce the risk of surgical site infection. However, we inspected the treatment room during the inspection on 4 December 2019 and saw that there was no specialist ventilation provision. This was not in line with the department of health HTM guidance 03-01. This posed a risk of surgical site infection as hair transplants are invasive procedures involving multiple surgical incisions over several hours.
- Consent was not obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016) which states that, consent should be gained by the doctor who will be delivering treatment, 14 days prior to treatment, to ensure the patient has a cooling-off period.
- The policy and process for monitoring a deteriorating patient was not robust or embedded into practice.
- Although the registered manager had plans to improve governance structures to monitor and improve the quality and safety of the services they provided; these had not been implemented following the last inspection in June 2019.
- The action plan submitted by the provider following the last inspection in June 2019 had not been fully completed by the provider, actions remained incomplete.
- We saw limited evidence that management used systems to manage performance effectively. Audit practice was not robust or embedded into practice.
- The provider had improved governance processes surrounding hand hygiene and the recording of fridge temperatures;
- The provider had instigated a process to monitor patient feedback; however, audit of this feedback had not yet commenced.
- Whilst risks and issues were identified and escalated, there was limited evidence to show actions to reassess and reduce their impact.
- The safeguarding policy had not been revised following the last inspection in June 2019. The policy in use was generic with no amendments for safe systems and processes surrounding recognising vulnerable adults at risk and onwards referral to external agencies.
- There was not an effective incident reporting and management process in place.
- There was no evidence the service used any national guidance for cosmetic surgery.
- The service held no staff meetings or evidence of staff involvement in running the service.
- There were limited systems to improve service quality and safeguard high standards of care.
- Although the service had a vision for what it wanted to achieve, the strategy to turn it into action was not yet in place despite this being identified as a concern at our previous inspection.

However;

- We were assured that there was a process in place to ensure that all staff had undertaken mandatory and safeguarding adults training. Prior to a clinical procedure being undertaken staff training was checked to ensure compliance.

Summary of findings

- The provider had improved training requirements to ensure staff had the relevant qualifications, competence, skills and experience to care for patients safely.
- The provider had instigated the World Health Organisation (WHO) safety check list process into practice.
- Clinical waste streams were managed appropriately in line with guidance.

Following review of the provider action plan, which had been drafted and completed by the provider following the last inspection, we suspended this inspection, because we were not assured that the provider had made substantive changes to practice following the last inspection.

We served an urgent notice of suspension to the provider in January 2020 following review of data requests submitted post inspection.

Following this inspection, we told the provider that regulations had been breached and the service needed to improve. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery		Surgery was the only activity of the service. We carried out the announced part of the inspection on 4 December 2019. We focused on specific parts of the service which were identified at our last inspection in June 2019. The key questions we asked during this inspection were, was it safe, effective, responsive and well-led. Due to the inspection being focussed we did not rate this inspection.

Summary of findings

Contents

Baruch Hair Transplant Centre Limited

Services we looked at: Surgery

Summary of this inspection

Background to Baruch hair Transplant Centre Limited

The service is a private clinic providing hair transplants and hair solutions to the public situated in Leeds. Although it serves the population of Leeds, patients travel from across the country for treatment.

The service is registered to provide the following regulated activities:

- Surgical procedures

There has been a registered manager in place since the clinic opened in 2016.

We last inspected this service in June 2019 and found overall that the service was inadequate. We rated the service as inadequate for safe, effective and well-led, responsive as requires improvement and good for caring.

Our inspection team

The team included a Care Quality Commission (CQC) lead inspector with one supporting CQC inspector. The inspection was managed by Nicola Kemp inspection manager and overseen by Sarah Dronsfield, Head of Hospital Inspection.

Information about Baruch hair Transplant Centre Limited

The service provides surgical hair transplants. From June 2019 to November 2019, the clinic treated two patients.

During the inspection, we visited the clinic and spoke with the registered manager. Staff were not employed permanently by the service but were called upon as required when there was patient treatment including one doctor and two hair technicians. There was no regulated activity at the time of this inspection. We reviewed one patient record at the time of this inspection.

All procedures were undertaken using local anaesthesia.

Track record on safety:

- The service had not reported any never events.
- The service had not reported any clinical incidents.
- The service had not reported any serious injuries.
- The service had not reported any complaints.

Infection control.

- Zero reported incidences of Hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- Zero reported incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- Zero reported incidences of hospital acquired Clostridium difficile (c.diff). There were no reported incidences of hospital acquired Escherichia coli (E-Coli).

Services provided under service level agreement:

- Clinical and or non-clinical waste removal.
- Maintenance of electrical equipment.
- Building maintenance.

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?

At this inspection, due to the inspection being focused we did not rate the service.

We found the following issues needed further improvement:

- Although some improvements had occurred following the last inspection in June 2019, the provider needed to ensure continued management oversight and that these were sustained.
- The provider did not monitor or record room temperatures in the treatment room. The treatment room did not have adequate ventilation in line with Health Technical Memorandum 03-01(HTM) guidance.
- The policy and process for managing the deteriorating patient was not robust or embedded.
- The provider's safeguarding policy had not been revised following the last inspection. The policy in use was generic with no amendments for safe systems and processes surrounding onwards referral to external agencies.
- The provider's safeguarding policy stated that staff should be familiar with the local adult safeguarding and maintain an up to date resource centre containing all current contact information and templates on the computer software system accessible to all members of staff via a desktop icon. The provider was unable to locate the safeguarding policy during this inspection and did not suggest that the service had access to an external safeguarding agency contact or resource.
- There were no processes to show learning from incidents.
- The service-controlled infection risk. Hand hygiene audits were in use; however, there was no evidence to support shared learning outcomes with staff.
- The provider had improved governance processes surrounding the recording of fridge temperatures; however, there was no evidence to support shared learning outcomes with staff through audit practice.

We found the following areas of good practice:

- We were assured that all staff had undertaken mandatory training and there was a process to review training undertaken. The service had improved record keeping in relation to mandatory training undertaken for all staff members.

Summary of this inspection

- The provider had improved training requirements to ensure staff had the relevant qualifications, competence, skills and experience to care for patients safely.
- The provider had improved record keeping in relation to staff safeguarding training. Although, due to the lack of regulated activity we were unable to speak to staff during this inspection to gain assurance on their understanding of safeguarding and how the service would report, act on or monitor any safeguarding issues.
- The provider had instigated the World Health Organisation (WHO) check list process into practice following the last inspection.
- The provider had improved the storage of clinical waste which was managed according to Health Technical Memorandum 03-01(HTM) guidance for the safe management of healthcare waste.

Are services effective?

At this inspection, due to the inspection being focused we did not rate the service.

We found the following issues needed further improvement:

- The provider was not following national guidance for patient consent. There had been no action taken to improve the consent policy and process surrounding two stage consent since the last inspection in June 2019.
- The provider action plan, created after the previous inspection in June 2019, stated that the action to update policies and distribute to staff for use in practice, was signed off by the provider as completed on 1 December 2019. However, we found all policies were still generic with no amendments for BHTC and so they had not been revised since the last inspection in June 2019.
- People's care and treatment did not reflect current evidence-based guidance, standards or practice.
- There were limited audits in place to ensure the provider was assured that policies and procedures were being followed and were effective.
- There was no audit process to evidence patient outcomes of care and treatment. There had been no action taken to instigate audit practice since the last inspection in June 2019.

We found the following areas of good practice:

Summary of this inspection

- The provider had improved governance processes surrounding hand hygiene and the audit of practice to prevent and protect people from a healthcare-associated infection. However, there was no evidence available to support the sharing and feedback of this practice with staff.

Are services caring?

At this inspection, due to the inspection being focused we did not rate the service.

We did not rate caring at this inspection

Are services responsive?

At this inspection, due to the inspection being focused we did not rate the service.

We found the following areas of good practice:

- Surgery was booked to meet the needs of the patient.
- There were no complaints made regarding this location.
- Following the last inspection in June 2019, the provider had instigated a pre-operative assessment form to ensure treatment was appropriate for each individual patient.
- Following the last inspection in June 2019, the provider had introduced a translation device into practice to support individuals who did not speak English as a first language.
- The provider action plan, created after the previous inspection in June 2019, stated that the action to evidence learning or action taken following patient feedback, was signed off by the provider as completed on 1 December 2019. However, whilst we found the provider had introduced a patient feedback form, (which patients could use alongside providing feedback on the provider website), no audit process was in place, to capture learning or action taken.

We found the following issues needed further improvement:

- The service did not provide additional support for individuals with physical or mental disabilities.

Are services well-led?

At this inspection, due to the inspection being focused we did not rate the service.

We found the following issues needed further improvement:

- Although management understood the priorities and issues the service faced there had been limited improvements made since our last inspection in June 2019.

Summary of this inspection

- The provider action plan, created after the previous inspection in June 2019, stated that the action to update policies and distribute to staff for use in practice, was signed off by the provider as completed on 1 December 2019. However, we found all policies were still generic with no amendments for BHTC and so they had not been revised since the last inspection in June 2019.
- The service held no formal meetings for staff.
- There were no documented processes to review key items such as strategy, values, risk, objectives, plans or governance framework.
- There was a lack of systematic performance management of individual staff and no formal engagement.
- Although the service had a vision for what it wanted to achieve, the strategy to turn it into action was not yet in place despite this being identified as a concern at our previous inspection in June 2019.

Surgery

Safe	
Effective	
Caring	
Responsive	
Well-led	

Are surgery services safe?

At this inspection, due to the inspection being focused we did not rate the service.

Due to the lack of regulated activity we were unable to speak to staff during this inspection to gain assurance on their understanding of mandatory training, safeguarding and how BHTC would report, act on or monitor any safeguarding issues.

Mandatory training

The service provided mandatory training to staff; however, the training platform was not robust in key aspects such as information governance training, sepsis management training or management of the deteriorating patient.

- The doctors and hair technicians were not employed by the clinic but were expected to complete mandatory training to enable them to work there. We were told mandatory training included basic life support training and other modules surrounding infection control and health and safety.
- At the last inspection in June 2019, we could not see evidence the service ensured staff had the right qualifications, skills or training to keep patients safe. Following the last inspection, the service had introduced an electronic on-line training platform. During this inspection we saw the on-line training modules. The provider gave assurance that individual staff training compliance was checked prior to staff allocation of shifts.
- We were given assurance that the registered manager had undertaken some mandatory training modules and saw certificates to evidence this.
- Following review of the action plan provided following the last inspection in June 2019, the provider had stated that sepsis training would be instigated into practice. However, the provider had not introduced sepsis training to date.
- During the inspection, we were informed the service did not provide or ensure staff had undertaken information governance training.

Safeguarding

The provider did not show an understanding of how to protect patients from abuse. The safeguarding policy and procedure were generic, with no amendments for BHTC and had not been revised since the last inspection.

- The service had a safeguarding policy; the designated safeguarding lead was the registered manager. The policy in use was not specific to the service.
- The safeguarding policy had not been revised following the last inspection in June 2019. Although the provider had drafted an action plan following this inspection stating that the policy had been revised to meet the needs of the service, we saw evidence to show this had not been completed.
- The policy in use was generic with no amendments for safe systems and processes surrounding onwards referral to external agencies.
- An example of the generic nature of the policy is as follows. The safeguarding policy (GCR05) stated that staff should be familiar with local adult safeguarding procedures and maintain an up to date resource centre containing all current contact information and templates on the computer software system accessible to all members of staff via a desktop icon. However, the provider was unable to show us how staff had access to external safeguarding agency contact information or resources, as described in the policy. Further, the s

- The safeguarding policy was not being followed.
- For instance, the safeguarding lead, identified as the registered manager, had not undertaken adult safeguarding training level two in line with the policy.
- Evidence provided following inspection showed that a number of staff had up to date training for safeguarding level one and two for adults. Three staff members had undertaken level three safeguarding adults. All staff were transient, and the provider told us that the service had up to 73 staff available to schedule for surgical procedures.

Cleanliness, infection control and hygiene

The registered manager did not have safe systems in place to show how they met the requirements of the Health and Social Care Act 2008; code of practice on the prevention and control of infections to ensure that patients were protected from the risk of infection.

- The service did not use a systematic approach to identify and prevent surgical site infections.
- For example, invasive procedures, such as hair transplants, required clinical ventilation to reduce the risk of surgical site infection. During inspection we noted that, in the treatment room, there was no specialist ventilation provision and room temperatures were not monitored or recorded at this location.
- During the inspection we asked for evidence that infection prevention and control (IPC) audits, such as hand hygiene audits, had been undertaken. We saw evidence of hand hygiene audits undertaken in August 2019 demonstrating 100% compliance. However, there was no evidence to support the sharing and feedback of this practice with staff.
- The service did not have a formal mechanism in place to share information or learning with staff.
- Within the clinic treatment area, we found equipment was visibly clean and sharps disposal bins were stored correctly and labelled.
- The clinical room was locked with a digital lock.
- Equipment was stored within the treatment room in lockable cupboards. The registered manager had a process in place for the management of stock control.

Environment and equipment

The registered manager did not ensure there was suitable equipment available for the delivery of the service. Emergency fire equipment was not available at the entrance to the building which was the main access and exit point.

- During inspection we noted that the provider did not monitor or record treatment room temperatures. The treatment room did not have adequate ventilation in line with the department of health HTM guidance 03-01. The guidance states that day case theatres should be achieving 15 air changes per hour through the provision of specialist ventilation.
- Waste was separated and disposed of. There was a service level agreement in place with a provider to collect clinical waste. The clinical waste was disposed of in suitable bins which were stored outside the property. The locked bins were stored in a gated compound; however, this was not locked at the time of the inspection. The storage compound was an emergency exit for the building.
- At the last inspection staff told us that the extendable light arm in the treatment room was not in use as it did not work. Following the last inspection, the provider had removed this device from the treatment room. As an alternative the team had access to two standalone lights for treatment use which were an adequate light source.
- Following the last inspection, the provider had ensured electric wires running under the treatment couch were covered with rubber/non-slip matting.
- Following the last inspection, the provider had provided a clock which was on display in the treatment room in line with the department of health building note recommendations.
- Following the last inspection, the provider had instigated a local process and statement of process (SOP) surrounding the daily recording of refrigerator temperature readings. We saw evidence of the daily check taking place and recorded to evidence that the refrigerator was within a safe temperature range.
- There was instruction for staff to take if the refrigerator was outside of safe temperature range and who to escalate this to.

- The main stairwell which was the only exit in and out of the building did not have a fire extinguisher. We observed a space on the wall where the previous bracket had been hung; however, the fire extinguisher and bracket had been removed.
- There was no service level agreement with a provider to give assurance surrounding fire extinguisher checks or a certified inspection of the premises. Post inspection, the provider was requested to provide assurance that the location had a service level agreement with an external provider. This was not provided at the time of writing this report.

Assessing and responding to patient risk

We found that the policies and procedures to protect the deteriorating patient were that of an acute NHS hospital trust and did not support staff in identifying and responding to a deteriorating patient in this organisation. Although the provider had drafted an action plan following this inspection stating that the policy had been revised to meet the needs of the service, we saw evidence to show this had not been completed.

- The action plan that the provider told us was in use after the previous inspection on 27 June 2019 showed that the action to update the deteriorating patient policy and distribute to staff for use in practice was signed off by the provider as completed on 1 December 2019.
- However, the policy for monitoring a deteriorating patient that we saw on inspection on the 4 December 2019 was that of an acute NHS hospital trust. It did not include specific information for this service. For instance, it did not address the type of procedure or the escalation processes for this location and what staff should do if a patient deteriorated.
- Further, post-inspection, we requested a copy of this policy; however, the policy that was provided was not the same policy that was reviewed and discussed on the day of inspection in December 2019. The policy provided was not specific to the service either and had other shortcomings. For example, there was no detail surrounding the management of the National Early Warning Score (NEWS).
- The NEWS template was displayed in the treatment room following the last inspection in June 2019. However, this template was not used for individual patients during treatment.
- The issues identified with the policy posed a risk to patient safety because staff did not have written guidance to support them in recognising or responding to a deteriorating patient to keep them safe during and after a procedure.
- At this inspection the registered manger had introduced a twenty-one-step guide to surgery document; which listed the stages of hair transplant surgery offered at BHTC.
- Pre-operative assessment was performed by the registered manager, we were informed all patients were offered an appointment prior to surgery with a doctor. During inspection the registered manager told us that the majority of patients preferred not to see a doctor face to face for consultation. Patients travelled from across the country and from abroad for surgery and preferred the option of a teleconference call which was offered by the provider.
- The registered manager undertaking the pre-operative assessment process was not clinically trained to identify issues such as contraindications in patient's medication.
- The registered manager told us that four out of the last six patients had refused an initial face to face consultation with a doctor. We requested evidence of this; however, this was not provided at the time of writing this report.
- We lacked assurance that patient screening pre-operatively was being undertaken by the doctor undertaking the procedure. The process surrounding patient assessment was not robust. Patients who declined the skype consultation missed out a vital step of the pre-operative assessment process.
- Pre-operative assessments took place at least two weeks prior to the planned date of surgery. Following the last inspection in June 2019, the provider had drafted a process in order to assess patient's preferences and needs including emotional and social. However, we did not see a process for auditing in place.

- Patient observations were recorded on a perioperative medicine's administration record. We received and reviewed evidence of this following inspection.
- We reviewed records for four procedures undertaken from January 2019 to December 2019. Three out of four procedures showed that observations were only taken at the start time of the procedure. One patient record evidenced that observations had been recorded four times over a four-hour period. Procedures could last several hours.
- Following the last inspection, the provider had installed a pulse oximeter in the treatment room.
- Following review of the action plan provided following the last inspection in June 2019, the provider had stated that sepsis training would be instigated into practice. However, the provider had not introduced sepsis training to date.
- The provider had instigated the WHO safety check list process into practice following the last inspection. However, the provider had not commenced audit of this process at the time of inspection.

Nursing and support staffing

The provider ensured medical and clinical support staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

- The service had one permanent member of staff which was the registered manager. Clinical hair transplant assistants and doctors were contracted according to when patients were scheduled surgery. During the past year, the service had contracts with two doctors and seven hair technicians.
- Following the last inspection, the service had distributed job descriptions to all staff to ensure they were fully aware of their roles and accountabilities whilst working for BHTC.
- The doctors who worked for the service were registered with the General Medical Council.
- There was a minimum of one doctor and two hair technicians for every treatment in accordance with best practice as recommended by the Cosmetic Practice Standards Authority for hair transplant standards.

Records

Staff kept records of patients care and treatment. Records were clear and stored securely.

- During inspection we checked one patient record which was clear, legible, up-to-date, stored securely and easily available to all staff providing care.
- During the inspection, we were informed the service did not provide or ensure staff had undertaken information governance training.

Medicines

The service used systems and processes to prescribe, administer, record and store medicines; however, the process surrounding remote prescribing of medication was not in line with good practice guidance.

- Medicines were stored securely, and access was restricted to authorised staff. The treatment room had a lockable refrigerator for medicines storage.
- The service did not use any controlled medicines.
- The registered manager (non-clinician) consulted service users at the location pre-operatively. Patients were asked to complete a pre-consultation questionnaire which covered current medications, known allergies and past medical history.
- Not all service users were then consulted by a doctor face to face. Some, but not all service users received a telephone skype call from the doctor to discuss past medical history, allergies and current medication.
- If the service user was deemed suitable for hair transplant surgery, then the doctor would email a prescription template to the registered manger. This prescription was then taken to the local pharmacy who prepared the medication pre-procedure.
- The operating doctor then signed the prescription on the day of surgery which was given to the pharmacy dispensing the medication on the day of surgery.
- We lacked assurance that the process surrounding remote prescribing was robust. The provider did not ensure that all patients scheduled for surgery were screened face to face or remotely by the operating doctor pre-operatively.

- The registered manager undertaking the pre-operative assessment process was not clinically trained to identify issues such as contraindications in patient's medication.

Incidents

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

- There was no assurance regarding the reporting of incidents and types of incident that should be reported.
- The duty of candour 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.
- The service informed us there had been no serious incidents or never events.
- The service did not monitor incident themes or trends or share learning fromincidents with staff.

Are surgery services effective?

At this inspection, due to the inspection being focused we did not rate the service.

Evidence-based care and treatment

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

- The provider had signed as completed on the provider action plan submitted post inspection in June 2019, that all policies had been revised to fit the scope of the business.
- However, we saw policies that had not been adapted or revised to ensure they fitted the scope of the business.
- The service had not instigated a process to evidence and record that staff had read and understood all policies.
- We found no evidence that the service used relevant national guidance for cosmetic surgery or hair transplant surgery. For example, the service had not done a gap analysis on where its policies and procedures departed from national guidance.
- The service monitored patient's outcomes postoperatively over a period of six to twelve months. Patients received a low-level laser treatment over this time frame which was monitored and recorded on the provider's electronic software system.

Nutrition and hydration

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

- As procedures could last over prolonged periods, patients were given a break during treatment for food and drink.
- There was a kitchen on the same floor as the treatment area where staff could make hot and cold drinks for patients.

Pain relief

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

- Due to scheduled activity on the day of inspection we did not observe patient procedures.
- We reviewed one patient record during inspection which evidenced that staff had recorded the administration of local anaesthetic detailing type, batch number, amount, expiry date and site of administration.
- Mild analgesia was routinely prescribed for the patients to take home and was recorded in individual patient records.
- Instruction advice was discussed pre and post operatively about what to do if discomfort became significant. We saw evidence of the provider's post-operative care advice leaflet which was given to all patients post treatment. This included a section on pain relief advice.

Patient outcomes

The provider monitored the effectiveness of care and treatment; however, audit practice was not robust or embedded.

Surgery

- We were informed the provider did not hold meetings with staff to discuss audits or review performance. This demonstrated a lack of understanding or insight into the importance and value of monitoring and improving the service, as required by regulations.
- Patients had an initial consultation with the registered manager who would assess their suitability for treatment. This included determining how many hair follicles were required to get the results they would expect to achieve following surgery. The registered manager was not clinically trained; however, he did have experience in hair transplant surgery.
- Following surgery all patients were contacted by the registered manager the morning after surgery to discuss after care and offer advice if required.
- Patients were reviewed following surgery for a period of six to twelve months. The provider told us that the progression of the transplant was reviewed by appointments with the registered manager during this period.
- Patients received a low-level laser treatment over this time frame which was monitored and recorded.
- Following review of the action plan provided since the last inspection in June 2019, the provider had not instigated a robust audit programme to demonstrate patient outcomes, hand hygiene, consent process or infection rates.
- The provider had a consultation and treatment or care pathway policy and procedure (GCP01). This policy clearly suggested that staff should use clinical audit to identify and share best practice to drive up the quality of patient care through good communication, integrated working and lessons learned within a cycle of improvement.
- We were not assured that the provider, fully understood the requirements of registration to participate and undertake audit practice to monitor and improve patient outcomes.

Competent staff

The provider had made improvements since the last inspection in June 2019 to ensure staff were competent for their roles.

- The registered manager was the only permanent employee at Baruch Hair Transplant Limited. The service used clinicians to perform procedures as required under practicing privileges.
- We were informed patients could contact the registered manager for aftercare advice out of hours, however the registered manager was not a qualified healthcare professional. There was no clinical staff on call to provide advice.
- The registered manager informed us the provider required all staff to have a Hepatitis B immunisation certificate, to be trained in basic life support and to have a current disclosure and barring service (DBS) check. We did not ask to see evidence of staff files at this inspection.
- Following the last inspection in June 2019, we saw that the provider had instigated a staff appraisal process for hair transplant assistants. However, this practice was not audited to evidence ongoing professional development.

Multidisciplinary working

The healthcare professionals providing regulated activities worked together as a team to benefit patients.

- However, we were informed the service did not consistently liaise with patient's GPs.

Seven-day services

The service was open Tuesday to Friday, 9am to 7pm and Saturday, 9am to 4pm.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

- Consent was not obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016) which states that, consent should be gained by the doctor who will be delivering treatment, 14 days prior to treatment, to ensure the patient has a cooling-off period.

Surgery

- We reviewed the consent process and first stage consent was taken by the registered manager who was not a healthcare professional.
- We reviewed the registered manager's training certificates and found that there was no evidence that the registered manager had received training in the Mental Capacity Act (2005) to be able to assess patients' mental capacity to consent to cosmetic surgical procedures.
- The provider offered a video-conference or face-to-face appointment with the doctor prior to the procedure, however this was dependent on the patient taking up this offer. The provider did not insist that patients were screened by the operating doctor pre-operatively.
- We reviewed the records for the one patient who had undergone surgery since the previous inspection (December 2019). Records showed that first-stage consent was taken and signed by the registered manager on the day of surgery, as well as second-stage consent by the doctor who was carrying out the procedure the same day.
- There was no evidence of a cooling-off period being routinely given prior to a patient consenting to a cosmetic surgical procedure.
- Concerns around the consent process not meeting national guidance was highlighted in the previous inspection carried out on 27 June 2019.
- The need for obtaining consent in line with national guidance was signed off by the provider as completed on 2 August 2019. However, we found that this had not been done. This included reviewing the consent policy and process to fit the scope of Baruch Hair Transplant Limited and distributing to staff for use in practice.
- This was a risk to patients because we could not be assured that people were being given the necessary information about the risks, complications and any alternatives.
- We also could not be assured that a person with the necessary knowledge and understanding of the care and treatment was providing this information and was able to answer any questions about it to help the person give informed consent to a surgical procedure.

Are surgery services caring?

We did not rate caring at this inspection due to scheduled activity at the time of the inspection.

Are surgery services responsive?

At this inspection, due to the inspection being focused we did not rate the service.

Service delivery to meet the needs of people

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

- There was one clinical treatment room, a patient changing area, patient toilets, a consultation area and a waiting area. This was sufficient as only one procedure was conducted at a time.
- Patients travelled from across the country or from abroad for surgery and, if the patient lived more than an hour away from the clinic, they were advised to stay in a nearby hotel the night prior to surgery.
- Patients were provided with post-discharge care information, which included clinic contact details for post-operative advice and specific instructions about hair care.
- We saw there was adequate car parking for staff and patients.

Meeting people's individual needs

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

- During the inspection the provider told us they could provide a chaperone service if required.
- The clinic did not have wheelchair access due to its layout, the service was able to offer alternative solutions for treatment with other providers to patients if required.
- Following the previous inspection, the provider had instigated level two and three safeguarding training for

clinical staff to identify and support individuals with physical or mental disabilities. However, the registered manager who was the clinic's safeguarding lead had only undertaken safeguard training to level one.

- Following the last inspection in June 2019, the provider had instigated a pre-operative assessment form to ensure treatment was appropriate for each individual patient. The pre-operative form evidenced preferences and needs (including emotional and social). However, there was no audit process in place to ensure each patient had received appropriate treatment based on an assessment of their needs and preferences.
- At this the inspection, the provider told us they had a portable electronic translation device. We saw this device in the clinic and the provider was able to explain the process surrounding its use.
- The clinic provided treatment for male, female and trans-gender patients.
- The appointment system appeared easy to use and supported people to access appointments. Patients could arrange an appointment by telephone or make an enquiry using the clinic's website.
- Patients were given a choice of meals, which took into account their individual and cultural preferences.
- During the inspection, we were told there was no written information available in other languages or formats.
- During the inspection, we were informed there was no hearing loop available and information was not suitably displayed for visually impaired patients.

Access and flow

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

- Initial face to face consultations were held with the registered manager. During the initial consultation the patient would be given pre-operative information and their expectations regarding the results of treatment were discussed.
- Patients could arrange an appointment by telephone or on the website which appeared easy to use.
- The service had completed two procedures from June 2019 to December 2019.
- All procedures were booked in advance. Once the procedure was confirmed with the doctor, hair transplant assistants were contacted to support the procedure.
- After the procedure was completed the patient would rest in the recovery room prior to discharge. We were told there was an open-door policy for patients to contact the clinic when needed. We were informed all patients received a follow-up telephone call after their procedure which was instigated by the registered manager. This information was recorded on the clinic's electronic platform.
- There were no waiting times for consultations or procedures.
- There were no service level agreements with the NHS if patients became unwell.

Learning from complaints and concerns

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

- The service had a complaints, suggestions and compliments policy in place.
- The service had reported no complaints since opening in 2016, therefore we saw no evidence of learning or discussion following complaints.
- Staff showed us the patient complaint information leaflet, but said the leaflet was not offered routinely to patients or displayed for patients to see.
- Following the last inspection, the registered manager had introduced a patient feedback form which patients could use alongside providing feedback on the provider website. This form was given to all patients following surgery. We were not assured that the provider had a robust and embedded process and policy in place surrounding patient feedback. The provider told us that the service had not undertaken audit to evidence learning or action taken following patient feedback despite this being signed off on the provider action plan following the last inspection in June 2019.

Surgery

Are surgery services well-led?

At this inspection, due to the inspection being focused we did not rate the service.

Leadership

Although the provider understood the priorities and issues the service faced there had been limited improvements made since our last inspection in June 2019.

- The service was led by the registered manager who was also the CQC nominated individual. The registered manager was responsible for ensuring compliance by the provider with the fundamental standards of care and provided care pre and post operatively. The registered manager was responsible for recruiting doctors and hair transplant assistants.
- During the inspection the registered manager did not appear to demonstrate an understanding of the obligations placed on them by their role as registered manager, and in particular, how compliance with the fundamental standards of care helped to ensure maintenance of quality at the location and continuous improvement.
- At our last inspection in June 2019 we said the service must ensure staff comply with mandatory training requirements. At this inspection we found mandatory training compliance targets had improved and were monitored monthly to ensure compliance.
- Following review of the action plan provided following the last inspection in June 2019, the provider had stated that sepsis and information governance training would be instigated into practice. However, the provider had not introduced this training to date.
- The provider did not show an understanding of how to protect patients from abuse. The safeguarding policy and procedure were generic, with no amendments for BHTC and had not been revised since the last inspection.
- During inspection we reviewed the provider action plan submitted following inspection in June 2019. The provider had signed this action plan off stating that operational policies and procedures had been updated to fit the scope of the business and ensure that staff had signed to say they had reviewed them. There was no evidence to support this.

Vision and strategy

Leaders and staff did not understand the services vision and there was no strategy.

- We were told the service had a vision to expand; we were informed this was not in writing and was not created in collaboration with staff or people who used services.
- Due to the lack of service strategy there was no ability to measure progress.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

- The registered manager stated if there were concerns regarding staff behaviour or performance, the staff member would not be requested to work for the service again.
- The service had an open culture where patients, their families and staff could raise concerns without fear.
- During the inspection, we were not assured the culture encouraged openness and honesty in response to incidents. There was a lack of understanding of the importance of recording incidents to learn and prevent recurrence.
- Following the last inspection in June 2019, we saw that the provider had instigated a staff appraisal process for hair transplant assistants. However, this practice was not audited to evidence ongoing professional development.

Governance

The service worked to improve service quality and safeguarded standards of care; however, concerns remained in several areas regarding oversight of issues and the pace of improvement actions.

- During the inspection we asked for evidence of effective structures, processes and systems of accountability to

support the delivery of the strategy and good quality, sustainable services. We were not assured that the service was moving at pace to improve actions highlighted at the last inspection.

- There was no governance structure for the service: we were informed the service did not hold governance meetings, formal or otherwise.
- We were not assured that staff had regular opportunities to meet, discuss and learn from the performance of the service. As staff were transient to the service there was no scope or process in place for staff meetings.
- Given the changing make-up of the clinical team and the fact that staff were rostered to work when needed, the provider had not developed a well-led way to engage with staff, such as by using e-bulletins, email, or a communication book.
- During the inspection, we were informed the service did not hold operational meetings, formal or otherwise.
- The doctors who had worked at the service over the past year were all registered with the General Medical Council and had indemnity insurance.

Managing risks, issues and performance

There was a system to identify risk with plans to eliminate and reduce risk; however, this was not robust or embedded into practice

- We saw limited evidence that the service used systems to manage performance effectively. At our last inspection we said the provider must assess, monitor and improve the quality and safety of the services provided. The provider had undertaken a risk assessment of the service; however, this was not robust or embedded into practice. We were not assured the service were moving at pace to improve this.
- The clinical area was on the top floor of the building with a single stair case. Post inspection, the provider was to provide a fire safety certificate for the building. This was not provided at the time of writing this report.
- We received evidence of a fire risk assessment which had been undertaken by the registered manager on the 22 December 2019. The risk assessment stated that all fire extinguishers in place were labelled correctly.
- There was no service level agreement with a provider to give assurance surrounding fire extinguisher checks or a certified inspection of the premises. Post inspection, the provider was to provide assurance that the location had a service level agreement with an external provider. This was not provided at the time of writing this report.
- The main stairwell which was the only exit in and out of the building did not have a fire extinguisher. We observed a space on the wall where the previous bracket had been hung; however, the fire extinguisher and bracket had been removed.
- During inspection we observed an electrical convector heater attached to the wall in the main entrance stairwell with a broken bracket.

Managing information

The information systems were integrated and secure.

- All initial patient contact was recorded on a computerised electronic system. Notes from the day of treatment were recorded on paper. Photographs of patients' treatment areas were taken, with consent, and uploaded to the patient records.
- Computers were password protected and locked when not in use.
- The service had invested in antivirus and firewall software.

Engagement

Given the changing make-up of the clinical team and the fact that staff were rostered to work when needed, the provider had not developed a well-led way to engage with staff, such as by using e-bulletins, email, or a communications book.

- During the inspection we were informed the service held no meetings with staff to engage with them or share lessons learned. We saw no evidence of formal staff engagement.
- There was no evidence of staff involvement in the planning of the service.
- There was no formal mechanism for staff feedback and there was no staff survey.
- We saw there was a website which gave information about the service.

Surgery

Learning, continuous improvement and innovation

There was no evidence of innovation at the service.

- Although the registered manager had plans to improve governance structures to monitor and improve the quality and safety of the services they provided; these had not been implemented at pace following the last inspection in June 2019.
- The action plan submitted by the provider following the last inspection in June 2019 had not been fully completed by the provider, actions remained incomplete.
- During the inspection we saw no evidence of continuous learning, improvement or innovation. The service did not participate in any research projects or recognised accreditation schemes.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must make sure that they have, and implement, robust safeguarding procedures and processes that make sure people are protected. Safeguarding must have the right level of scrutiny and oversight, with overall responsibility held at managerial level – Regulation 13 (1) (2)
- The provider must ensure the consent process is robust and in line with national guidance. The provider must ensure staff follow the correct consent procedure - Regulation 11 (1).
- The provider must ensure that safe care & treatment is provided in a safe way for service users at risk of deteriorating by assessing the risks to the health & safety of service users receiving care & treatment. Regulation 12 (1) (2) (a) (b)
- The provider must ensure adequate ventilation is available within the clinical treatment room in line with guidance and daily treatment room temperatures should be recorded and staff made aware of how to escalate if temperatures are not within range. Regulation 12 (1) (2) (a) (b)
- The provider must ensure that operational policies and procedures are updated to fit the scope of the business and ensure that staff have signed to say they have reviewed them. (Regulation 17 (1)(2)
- The provider must assess, monitor and improve the quality and safety of the services provided and mitigate any risks relating to health, safety and welfare of patients. The risk assessment register must be reviewed, updated and reassessed to ensure patient safety. Regulation 17 (1)(2)
- The provider must assess, monitor and improve quality and safety of the services provided in the carrying on of the regulated activity by undertaking regular audit. Regulation 17 (1) (2) (a)
- The provider must ensure that the service has a service level agreement with a provider to give assurance surrounding fire extinguisher checks and a certified inspection of the premises. Regulation 12 (1) (2) (a) (b) (e)

Action the provider SHOULD take to improve

- The provider should ensure processes are in place to ensure learning from incidents.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The provider must make sure that they have, and implement, robust safeguarding procedures and processes that make sure people are protected. Safeguarding must have the right level of scrutiny and oversight, with overall responsibility held at managerial level.

Regulated activity	Regulation
Surgical procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent The provider must ensure the consent process is robust and in line with national guidance. The provider must ensure staff follow the correct consent procedure.

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must ensure that safe care & treatment is provided in a safe way for service users at risk of deteriorating by assessing the risks to the health & safety of service users receiving care & treatment.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must ensure adequate ventilation is available within the clinical treatment room in line with guidance and daily room temperatures should be recorded and staff made aware of how to escalate if temperatures are not within range.

Regulated activity	Regulation
Surgical procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider must ensure that operational policies and procedures are updated to fit the scope of the business and ensure that staff have signed to say they have reviewed them. The provider must assess, monitor and improve the quality and safety of the services provided and mitigate any risks relating to health, safety and welfare of patients. The risk assessment register must be reviewed, updated and reassessed to ensure patient safety. The provider must assess, monitor and improve quality and safety of the services provided in the carrying on of the regulated activity by undertaking regular audit.

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	Regulation 11 HSCA (RA) Regulations 2014 Need for consent Consent was not obtained in line with the Royal College of Surgeons (RCS) Professional Standards for Cosmetic Surgery (April 2016) which states that, consent should be gained by the doctor who will be delivering treatment, 14 days prior to treatment, to ensure the patient has a cooling off period.

Regulated activity	Regulation
Surgical procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The process for monitoring a deteriorating patient policy was not robust or embedded into practice. The treatment room did not have ventilation in line with the department of health HTM guidance 03-01.

Regulated activity	Regulation
Surgical procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment Safeguarding procedures were not in line with the intercollegiate document Adult Safeguarding: Roles and Competencies for Healthcare Staff published August 2018.