

Surgen Ltd

Skin and Follicle

Quality Report

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This report describes our judgement of the quality of care at this hospital. It is based on a combination of what we found when we inspected, information from our 'Intelligent Monitoring' system, and information given to us from patients, the public and other organisations.

Ratings

Overall rating for this hospital	Inadequate	
Surgery	Inadequate	

Summary of findings

Letter from the Chief Inspector of Hospitals

Skin and Follicle Birmingham is operated by Surgen Ltd.

The service provides cosmetic surgery for adults over 18 years either as on a day case basis. The service has no overnight beds.

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 11 September 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.

The main service provided by this service was cosmetic surgery.

Services we rate

This was the first inspection of the service. We rated it as **Inadequate**

We found areas of practice that were inadequate:

- Leaders did not have the necessary capacity or capability to lead effectively.
- The service did not operate effective governance processes. Roles and accountability were unclear. There were limited opportunities for staff to meet, discuss and learn from the performance of the service.
- There was no established effective incident reporting system to demonstrate how incidents were reported, investigated and when appropriate learnt from.
- A lack of incident reporting and incomplete complaint records did not give full assurance of an open culture. Staff did not recognise concerns, incidents or near misses.
- There was a lack of systems and processes to ensure the safe management and storage of medicines and consumables.
- The monitoring of the effectiveness of care and treatment was not effective to demonstrate improvements and identify good outcomes for patients.

We found areas of practice that require improvement:

- Assurance was not available to confirm staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- There was a lack of systems to assess and respond to potential patient risks or abuse. Systems to identify and record surgical site infections were not in place
- The service did not always provide care and treatment based on national guidance and evidence-based practice.
- The service was not inclusive and did not take account of patients' individual needs and preferences. Reasonable adjustments were not in place to help patients access services.

Summary of findings

- · Arrangements for the management of complaints and concerns was inconsistent and did not give assurance they were treated seriously. There was insufficient information available to provide assurance all complaints were investigated, and shared lessons learned shared with all staff.
- The service had a vision for what it wanted to achieve although there was no strategy to turn it into action.

We found areas that were good:

- Staff treated patients with compassion and kindness and respected their privacy and dignity.
- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- Patient records were stored securely.
- Staff gave patients practical support and advice about contacting other agencies to support them to lead healthier
- People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment were in line with national standards.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.
- Medical staff encouraged innovation and participation in research and service improvement.

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 five requirement and one warning notice, the details are at the end of the report.

We are placing the service into special measures. Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Bernadette Hanney

Head of Hospitals

Summary of findings

Our judgements about each of the main services

Why have we given this rating? **Service** Rating

Surgery Inadequate



This is a single speciality service providing cosmetic surgery and hair transplants. We rated this service as inadequate. We rated safe and well led as inadequate, effective and responsive requires improvement and caring good.



Skin and Follicle

Detailed findings

Services we looked at

Surgery

Detailed findings

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Background to Skin and Follicle

Skin and Follicle Birmingham is operated by Surgen Ltd. The service was registered in December 2016. It is a private cosmetic surgery and hair transplant centre in Birmingham in the West Midlands. The centre primarily serves the communities of the West Midlands. It also accepts patient referrals from outside this area.

The service is registered to provide the following regulated activities:

- Treatment for disease, disorder or injury
- Surgical procedures

The service provides consultation, examination and treatments in cosmetic and aesthetic medicine, hair transplantation and treatment of skin diseases and

disorders. Hair transplantation is undertaken both by robotic and manual follicular unit extraction (FUE) under local anaesthetic. Minor surgery such as mole removal, cyst removal, pinnaplasty and upper eyelid blepharoplasty are undertaken under local anaesthetic.

The service also provides injectable treatments, laser treatments and other beauty treatments, which were not inspected as they fall outside the regulations.

The service has had a registered manager in post since December 2016.

This is the first inspection of this service. We carried out an unannounced inspection on 11 September 2019.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and two specialist advisors, a consultant dermatologist and a cosmetic surgery manager. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection.

Our ratings for this hospital

Our ratings for this hospital are:

Detailed findings



Notes Are services safe?

We rated it as **Inadequate** because:

- There was insufficient evidence to provide assurance staff had received mandatory training. Systems were not in place for managers to monitor staff compliance with mandatory training.
- Staff did not know how to protect patients from abuse. There was no assurance staff had received training on how to recognise and report abuse.
- There was a lack of systems to assess and respond to potential patient risks. Systems to identify and record surgical site infections were not in place
- There was a lack of systems and processes to ensure the safe management and storage of medicines.
- The service did not have effective checks of equipment in place.
- Assurance was not available to confirm staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.
- Patient records were not complete.
- There was no established effective incident reporting system to demonstrate how incidents were reported, investigated and when appropriate learnt from.

However:

- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- Patient records were stored securely.

Are services effective?

We rated it as **Requires improvement** because:

- The service did not always provide care and treatment based on national guidance and evidence-based practice.
- The monitoring of the effectiveness of care and treatment was not effective to demonstrate improvements and identify good outcomes for patients.
- The service did not make sure all staff were competent for their roles. There was no evidence managers appraised staff's work performance or held supervision meetings with them to provide support and development.
- There were limited opportunities for multidisciplinary working.

However:

- Staff gave patients practical support and advice about contacting other agencies to support them to lead healthier lives.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Are services caring?

We rated it as **Good** because:

- Staff treated patients with compassion and kindness and respected their privacy and dignity.
- Staff provided emotional support to patients, families and carers to minimise their distress.
- Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

Are services responsive?

We rated it as **Requires improvement** because:

Detailed findings

- The service was not inclusive and did not take account of patients' individual needs and preferences. Reasonable adjustments were not in place to help patients access services.
- Arrangements for the management of complaints and concerns was haphazard and did not give assurance they were treated seriously. There was insufficient information available to provide assurance all complaints were investigated, and lessons learned shared with staff.

However:

- People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment were in line with national standards.
- The service planned and provided care in a way that met the needs of local people and the communities served.

Are services well-led?

We rated it as **Inadequate** because:

- The service had a vision for what it wanted to achieve although there was no strategy to turn it into action.
- Leaders did not have the necessary capacity or capability to lead effectively.
- The service did not collect data to improve the service. There were no assurance appropriate notifications were submitted to external organisations when required.
- The service did not operate effective governance processes. Roles and accountability were unclear. There were limited opportunities for staff to meet, discuss and learn from the performance of the service.
- A lack of incident reporting and incomplete complaint records did not give full assurance of an open culture.
- Systems to identify and manage risk and performance were not effective.
- Leaders and staff did not actively engage with patients or staff to plan and manage services.

However:

 Medical staff encouraged innovation and participation in research and service improvement.

Safe	Inadequate	
Effective	Requires improvement	
Caring	Good	
Responsive	Requires improvement	
Well-led	Inadequate	
Overall	Inadequate	

Information about the service

Skin and Follicle is the only location for the provider Surgen Ltd. The service provides minor cosmetic surgery and hair transplants under local anaesthetic.

The service has four consulting rooms/ treatment rooms and a treatment room where minor surgery is undertaken and one laser room. It is registered to provide the following regulated activities:

- Surgical procedures
- Treatment for disease, disorder or injury.

There are three surgeons who operate under practising privileges and two permanent clinic staff. Other staff work on a sessional basis such as an operating department practitioner (ODP), nurse and hair technicians.

During the inspection, we visited the four consulting rooms, treatment room and clean and dirty utility rooms. We spoke with five staff including two consultants, two clinic staff and a sessional operating department practitioner. We spoke with one patient during the inspected and received comment cards back from four patients following the inspection. During our inspection, we reviewed seven 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 services first inspection since registration with CQC, which found that the service was not meeting all standards of quality and safety it was inspected against.

Activity (March 2018 to February 2019)

In the reporting period March 2018 to February 2019.

- There were 56 day case episodes of care recorded at the service. All were non-NHS funded.
- There were 251 outpatient attendances in the reporting period all were non-NHS funded.

Track record on safety

- No never events
- No clinical incidents: zero no harm, zero low harm, zero moderate harm, zero severe harm, zero death
- No serious injuries

No incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA),

No incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA)

No incidences of hospital acquired Clostridium difficile (c.diff)

No incidences of hospital acquired E-Coli

One complaint

Services accredited by a national body:

None identified by the provider

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal
- Cleaning

- Maintenance of medical equipment
- Histology

Summary of findings



Mandatory training

There was insufficient evidence to provide assurance staff had received mandatory training. Systems were not in place for managers to monitor staff compliance with mandatory training.

- Information we received before the inspection identified all medical staff had completed all required mandatory.
 However, during the inspection, we found there was no information available which evidenced medical staff had received mandatory training.
- Information we received before our inspection identified non-medical staff had not undertaken mandatory training. Information we looked at during the inspection showed one of the two permanent non-medical staff had received a mandatory training day which included health and safety, information governance, fire safety, infection prevention and control, food hygiene, basic life support moving and handling, safeguarding adults and children levels 1 and 2, complaints and conflict management and lone working. We were told the other members of non-medical clinic staff had also attended this training, although evidence of this was not available.
- The service used sessional staff when required which included an operating department practitioner, a theatre nurse and four hair technicians. We observed one hair technician had a record of mandatory training. However, there was no evidence the other staff had received or were up to date with mandatory training.
- We asked the clinic manager for a record of staff mandatory training programme and how frequently it should be updated. We were told there was no overall record of mandatory training record or any information to identify the frequency staff were required to undertake mandatory training.
- We found there was no system in place for managers to monitor mandatory training or alert staff when they needed to update their training.

 There was no evidence available to confirm staff had received training in sepsis. The two consultants present during the inspection told us they had received sepsis training as part of their life support training.

Safeguarding

- Staff did not know how to protect patients from abuse. There was no assurance staff had received training on how to recognise and report abuse.
- There was insufficient evidence to demonstrate staff had received safeguarding training. We saw one staff file of the two permanent clinic staff which identified the member of staff had received adults and children safeguarding level 1 and 2. The registered manager after the inspection sent us evidence of safeguarding training for the three surgeons. No information about the other six sessional staff the service has employed has been sent to us.
- We asked a member of staff what actions they would undertake if they had safeguarding concerns. They were unsure who or what organisations they should contact and were unclear about actions they should take.
- The service did have a safeguarding lead, Information
 we received before the inspection identified the
 safeguarding lead had received level 3 adults and
 children's safeguarding. Following our inspection
 information to confirm the safeguarding lead had level 3
 safeguarding training was sent to us.
- Non-medical staff were not aware who the safeguarding lead for the service was and then said they thought it was the registered manager. This may mean there could be a delay seeking advice or actions to keep vulnerable adults or children safe.
- The service had a safeguarding policy dated 24
 September 2018. The policy identified types of abuse including modern slavery and female genital mutilation, the safeguarding lead and their responsibilities, actions required by staff if abuse or potential abuse was identified and staff training requirements. However, there was no contact details of the local safeguarding team, with this information left blank in the policy. The policy also identified the safeguarding lead should ensure all staff were familiar with the policy and this had also not been undertaken.

- Evidence staff had up to date Disclosure and Barring Service (DBS) checks was not available. The DBS enables organisations in the public, private and voluntary sectors to make safer recruitment decisions by identifying candidates who may be unsuitable for certain work, especially that involving children or vulnerable adults. The registered manager confirmed they would ensure all staff working in the clinic had a DBS check and without evidence of this they could not work in the clinic.
- · Cleanliness, infection control and hygiene
- The service controlled infection risk well although systems to identify and record surgical site infections and staff hepatitis B status were not in place. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- All areas were visibly clean and had suitable furnishings which were clean and well-maintained.
- The service had a contract with an external cleaning company who came in to clean the premises one day a week for four hours. The clinic manager told us they were looking for another company which was able to provide more hours.
- We saw the cleaning company completed cleaning records which confirmed which areas had been cleaned and when. We observed this log was mainly complete although there were some omissions.
- We saw the service had a table- top autoclave in the clean utility area. The registered manager confirmed this was not used. The registered manager told us the service used only disposable sterile single use instruments and disposable operating gowns. which had been sterilised externally. We saw this during the inspection.
- Information to confirm staff had received infection prevention training was incomplete at the time of our inspection. We saw information which identified one of the two permanent clinic staff had received infection control training, there was no information available for medical staff. The service forwarded information following out inspection which confirmed medical staff had received infection control training.

- Staff told us they used a complications book in which they also recorded any surgical site infections. However, the book was not available at the time of the inspection.
- · Environment and equipment

The service did not have effective checks of equipment in place. However, the design and use of facilities and premises kept people safe.

- The clinic environment was modern, well organised and clutter free.
- Staff carried out safety checks before using specialist equipment.
- Information we looked at for equipment used for hair transplantation showed it had been appropriately maintained and a date for the next service to be undertaken by 17 December 2019.
- When we asked about other checks and annual servicing such as the fire extinguisher and fire system checks the clinic manager was unsure if they were available. The registered manager confirmed they had recently been serviced. We were then provided with the evidence which had been stored electronically. However, during the inspection we found the service did not have a log of when equipment was due/had been serviced and instead relied on the equipment servicing companies to book and arrange servicing of the equipment.
- During the inspection we found some consumables were out of date such as sutures with an expiry date
 April 2018, site marking kits ten boxes expiry March 2017
 and July 2019 four boxes, biohazard bags (for the spillage kit) expired April 2017. This meant we were not assured systems were in place to monitor available consumables. We informed the registered manager who confirmed they would be disposed of. We asked the provider to urgently confirm a check had been undertaken of all consumables after our inspection.
 They confirmed this had been undertaken.
- Clinical waste was stored securely and safely whilst awaiting to be collected. However, there was a note within the dirty utility room reminding staff to include the reference details for the service. The clinical waste bags we saw did not have these labels attached. The service had a contract with an external company for the removal of clinical waste.

- All sharps bins should have the date of opening recorded. During the inspection we saw three of the four sharps bins checked did not have a date of opening recorded. We highlighted this to the registered manager.
- Assessing and responding to patient risk
 There was a lack of systems to assess and respond to potential patient risks.
- We were told the service would only operate on low risk patients and anyone who was a medium/high risk would be seen at another private hospital where the risk could be managed more safely.
- We asked the registered manager about criteria for which patients they would operate on. We were told they would only operate on fit and well patients who were non-smokers or had stopped smoking and were not overweight. However, there was no written policy to confirm this. We highlighted this to the provider and registered manager after our inspection and asked for an urgent response. The registered manager sent us a new appropriate policy in response to our request.
- Patients all received an initial consultation by the consultant during which the treatment they were considering was discussed. However, six of the seven patient records we looked at did not detail that patients had a pre-operative assessment of their health before their surgery. This meant no information was readily at hand should patients become unwell during surgery.
- There was no record of any risk assessment completed in the seven patient records we looked at for example for the risk of venous thromboembolism.
- There was a defibrillator and oxygen available in the event of a patient emergency. However, there was no policy available for staff at the time of the inspection which identified actions to be undertaken should a patient become unwell or deteriorated. We highlighted this to the registered manager and provider and asked for an urgent response. A suitable policy and information were sent to us within the required timescale.
- We asked staff what advice patients were given if they
 were unwell or had any concerns following their surgery.
 We were told patient could ring the clinic between 10am
 and 6pm. Out of hours they could ring and leave a
 message or email the clinic and they would be

- contacted by one of the surgeons. If they had urgent concerns they should go to their local NHS hospital accident and emergency department. There was no record this information had been given to patients in the seven patient records we looked at.
- We saw one World Health Organisation (WHO) Safer Surgery check list in one of the seven patient records we looked at, but it had not been completed. There was no information about the WHO Safer surgery checklist in the other six patients' records we looked at. The registered manager confirmed they had identified a need to complete the checklist and this was being implemented.
- The patient records we looked at did not show patients observations such as pulse and breathing rate, blood pressure or temperature had been recorded, before, during and following their surgery. This meant there was no system in place to alert clinicians to early warning signs of a patient who may be deteriorating. We highlighted this both at the time of the inspection and in a letter sent following the inspection to the registered manager and provider following our inspection and requested an urgent response. An appropriate policy was sent to us within the required timescale which confirmed patient observations would be taken and an early warning scoring system would be used. Details about the early warning scoring system was also included.
- Medicine to address local anaesthetic toxicity and a
 policy identifying actions which should be taken were
 not available at the time of the inspection. We
 highlighted both at the time of the inspection and in a
 letter to the registered manager and provider asking for
 an urgent response. We received assurance within the
 required timescale the medicine had been ordered and
 an appropriate policy was sent to us.
- There were no protocols in place for the transfer of people using services to NHS in the event of complications from surgery. We highlighted this to the registered manager and provider and a policy was sent to us after our inspection.

 Patients had to give consent for the service to contact their GP. We were told the clinic provided letters for patient which provided enough information about the procedure to allow another practitioner elsewhere to manage complications if needed.

Staffing

Assurance was not available to confirm staff had the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

- There were three surgeons who had practising privileges and two permanent members of staff (non-clinical) who were based at the clinic on a fulltime basis.
- The three current surgeons were all directors of the service. There were no records available for the three surgeons at the time of the inspection. There was no evidence the qualifications or experience had been checked as part of their practising privileges including an appropriate appraisal from their main employment. This meant there was no effective system to ensure consultants had appropriate skills or expertise to perform the procedures they undertook at the clinic.
- Other staff were contracted according to when patients were booked in such as an operating department practitioner (ODP), theatre nurse and four hair technicians. There was no record of the (ODP), the nurse or three of the four hair technicians' qualifications or experience had been checked. This meant there was no assurance staff had qualifications or experience required to provide the right care to patients.

Records

Records were not complete but were stored securely.

- The clinic used paper patient records and some electronic images. We found all patient records were stored securely, were password protected and were available to staff when required.
- We found a record of pre-operation assessment was not available in six of the seven records we looked at. There was incomplete information recorded about the

- operation procedure which included checks of patient observations and no WHO Safer surgery checklist had been completed in the seven patient records we looked at.
- A patient records audit had been undertaken in February 2019. The audit identified 85% notes were accurate and complete noting abbreviations were used in 75% of records and 90% of notes identified a clinical diagnosis. Information identified 'to be vigilant about completion of notes and to repeat in 4 months'. We were told no subsequent audit had been undertaken.
- Staff records were not complete and did not include all required information in relation to recruitment and training.

Medicines

There was a lack of systems and processes to ensure the safe management and storage of medicines.

- The service only kept a small number of medicines which were.
- We were told patients received a prescription the week before surgery which they were responsible for getting. Patients had instructions on when they needed to take the medicines.
- All emergency medicines within the emergency bag were out of date (adrenalin1:1000 expired December 2017, glucagon expired February 2019, dextrogel expired October 2018, glyceryl trinitrate (GTN) expired October 2018, salamol expired March 2019, aspirin 300mgs expired 6/19, midazalam 10mgs in 1ml expired January 2018. This meant should there have been a patient emergency drugs would not have been safe to be administered. We asked the provider and registered manager to address this urgently. They confirmed within the required timescale they had disposed of the out of date medicines, reordered the emergency medicines and agreed to post-pone all operations until all required emergency medicines were available.
- Staff recorded the room temperatures where medicines were stored and the medicine fridge temperature on the days the clinic was open. We saw the medicine fridge temperatures recorded in the previous two weeks were outside the safe storage range of between 2 and 8 degrees Celsius. We saw no actions were recorded to

address this. This meant patients may have received unsafe or ineffective medicines. We asked the provider and registered manager to address this urgently. They confirmed they had disposed of the medicines, stored in the medicines fridge, had reordered required medicines and received delivery of a new fridge within the required timescale. Information sent to us by the registered manager also included instructions for staff regarding actions they should take if temperatures were outside safe temperatures.

- We saw there was information in some patient records which identified medicines that had been administered. We asked the registered manager about systems to record medicines administration and check medicines stock. They told us there was a book which recorded medicines received and administered. The clinic manager was unaware of this book. When we were shown the book, we observed the last entry was dated August 2018 and had been completed by the previous clinic manager. This meant we were not assured there was safe stock control of medicines in place. There was no evidence of any medicine audits.
- In the seven patient records we checked, it was not evident if patients were asked about medicines or medicine allergies.
- Information provided before our inspection included an antimicrobial stewardship policy. Antimicrobial stewardship is an initiative to educate and persuade prescribers of antibiotics to follow evidence-based prescribing to stop antibiotic overuse which is leading to antimicrobial resistance. The policy identified protocols for the administration of antibiotics. We asked two surgeons about the policy both were aware of it and were using the protocols identified.
- The service did not use controlled drugs. Controlled drugs arecontrolled Drugs

Incidents

There was no established effective incident reporting system to demonstrate how incidents were reported, investigated and when appropriate learnt from,

• We found there was no established incident reporting system. The registered manager provided information which included a paper-based incident reporting

- system. We saw there was no record of any incidents reported. The provider information requested identified no clinical incidents had been reported in the time frame March 2018 to February 2019.
- We asked a member of permanent staff about incident reporting, but they were unaware of the system or how to report an incident.
- During the reporting period there were no serious incidents or never events reported. A never event is a serious incident that is wholly 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. They have the potential to cause serious patient harm or death.
- We saw clinical governance meeting minutes for February 2019 which identified complications following a surgical procedure which required the patient to have a further procedure, this had not been reported. We were not assured all incidents or near misses had been reported.
- The registered manager and surgeon present during the inspection told us they had a 'complications book which was used to report clinical complications including infections. The book could not be located. We were not provided with assurance there was any other system to monitor complications or other untoward clinical incidents.
- We did not see any information about how incidents had been investigated.
- Staff followed infection control principles including the use of personal protective equipment (PPE). The service had a hand washing policy and an infection control policy. During the inspection we observed staff hand washing. We also observed PPE was available for use.
- A hand washing audit had been undertaken in January 2019. The results of the audit identified all surgeons washed their hands appropriately. However, the audit identified handwashing instructions were not available at every handwashing sink. During the inspection we found this had been addressed.

- There was no evidence available to show non-contracted or sessional staff had their hepatitis B and human immunodeficiency virus (HIV) status checked or evidence that all staff had been immunised appropriately.
- We saw a certificate which confirmed appropriate legionella testing had been undertaken.
- Information provided before the inspection included an infection annual meeting dated June 2018. The meeting confirmed some control measures were in place but did not detail full compliance or an action plan. The meeting identified there would be an annual audit of infection control and prevention, but we were not provided with any further updated information during the inspection.

Are surgery services effective?

Requires improvement



Evidence-based care and treatment

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

- Surgeons at the clinic had been involved with developing best practice guidance for cosmetic surgery. However, we found surgeons were not always following other best practice guidance such as preoperative assessment and use of the WHO Safer Surgery checklist.
- We did not see evidence to confirm the service ensured that cosmetic surgery was managed in accordance with professional and expert guidance for example as published by the Royal College of Surgeons (RCS).
- A patient psychological screening assessment was not routinely undertaken. This was not in line with best practice guidance to highlight patient expectations as well as those who may require psychological support.

Nutrition and hydration

Staff gave patients food and drink to meet their needs.

- The clinic manager told us patients were informed about when to stop eating and drinking when applicable before their surgical procedure.
- Hair transplants were long procedures which lasted all day. Staff said they made sure patients had enough to eat and drink. The service had access to hot and cold drinks and snacks if required.

Pain relief

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

- The service ensured that following surgery people received advice about effective pain relief.
- Surgeons told us they regularly asked patient if they
 were experiencing pain or discomfort or would like a
 break particularly during hair transplantation as this was
 a lengthy procedure. Two patients who had hair
 transplants confirmed staff asked them if they were
 comfortable or required pain relief or a break.
- We did not see any information about the use of a pain assessment tool.

Patient outcomes

The monitoring of the effectiveness of care and treatment was not effective to demonstrate improvements and identify good outcomes for patients.

- We found there was limited monitoring of people's outcomes of care and treatment.
- We spoke with a surgeon present during our inspection and the registered manager. We were told surgeons were auditing their own performance and patient outcomes for example outcomes following hair transplantation.
- Information provided showed one surgeon had audited their patients' outcomes, but this information was not available for the service. We asked the registered manager if the service benchmarked performance of its consultants but were told no. This meant the service had not checked the quality of care provided by its surgeons.

- We asked if the service completed patient outcome measures (PROMs) for blepharoplasty (an operation for correcting defects or deformities of the eyelids), a procedure which its consultants performed. We were told they did not complete this. The failure to complete PROMs meant the service missed an opportunity to monitor patients progress and help to improve the quality of the service provided. We raised this following our inspection and the service put in place the Royal College of Surgeons PROMS questionnaire.
- There were no unplanned transfers of care from March 2018 to February 2019.

Competent staff

The service did not make sure all staff were competent for their roles. There was no evidence managers appraised staff's work performance or held supervision meetings with them to provide support and development.

- We were not assured the service had a robust system in place to ensure competent staff worked within the service.
- <> service used sessional staff for some surgical procedures: an operating department practitioner (ODP) and a nurse. For hair transplantation the service used four hair technicians. There was no record of staff qualifications including competencies. Information about the surgeons' qualifications were displayed on the waiting area. Surgeons worked at the clinic under practising privileges. There should be system to check surgeons' qualifications, experience and ensure their competence to perform procedures and review their main employers' annual appraisal. This meant there was no effective system to ensure consultants expertise and competence was appropriate and was being maintained.
- There was no evidence staff training needs were identified or staff had opportunity to develop their skills and knowledge.
- There was no evidence any staff received a one to one meeting or had an appraisal.

Multidisciplinary working

There were limited opportunities for multidisciplinary working.

- Patients gave consent for their GP to be contacted and unless consent was given no letter was sent to the patients GP.
- The team appeared to work well together, with care and treatment delivered to patients in a co-ordinated way.
 However, clinic staff were not aware of all required policies and procedures to ensure patients received timely and appropriate care.
- The service did not hold any team meetings.

Seven-day services

The service ran Monday to Saturday, out of hours patients had access to a phoneline if they had any concerns.

 Patients were given a phone number to call out of hours or when the clinic was not open that they could access a surgeon for advice if they had any concerns. A message could be left, and a surgeon would return their call the same day.

Health promotion

Staff gave patients practical support and advice about contacting other agencies to support them to lead healthier lives.

- Staff told us they would not operate on people who
 were overweight or were smokers. They said they
 explained this was due to an increased risk of
 complications but would give them advice about other
 agencies to contact for support.
- We saw no evidence psychological wellbeing scores were calculated prior to agreeing to go ahead for surgery. One staff member told us if they had any concerns they would refer the person for counselling.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. This was assessed by the surgeon before consenting any patients for their procedures.

• Staff gained consent from patients for their care and treatment in line with legislation and guidance.

- The consent forms were appropriate and thorough.
 From the documentation it appeared that patients were suitably informed prior to any surgery about the proposed surgery, benefits and risks.
- All patients had the capacity to provide consent for their treatment.
- The service had undertaken an audit to check consent was appropriate recorded in February 2019. The audit identified consent was appropriately recorded in100% of the patient records reviewed.
- All patient records we looked at had the two weeks 'cool
 of time' prior to surgery. This is in accordance with the
 General Medical Councils guidelines which state that
 patients should have a mandatory cooling-off period
 between the initial consultation and committing to the
 procedure.
- Staff clearly recorded consent in the patients' records. In seven out of the seven records we looked at consent had been clearly documented. We saw records to confirm consent had been gained for clinical photographs.
- There was no information to confirm staff had completed training on the Mental Capacity Act or consent training at the time of our inspection.

Are surgery services caring? Good

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

- During the inspection we spoke with one patient and four patients returned feedback cards following our inspection. All patients told us they were treated with kindness and respect and staff introduced themselves.
- All patients said staff made sure their privacy and dignity were maintained.
- Two patients said they were nervous and were put at ease by the surgeon and clinic staff.
 - **Emotional support**

- Staff provided emotional support to patients, families and carers to minimise their distress.
- Staff were available to meet and greet patients on arrival. Patients told us staff introduced themselves and explained their role.
- Patients said staff offered reassurance about procedures and supported them during the treatment.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their condition and make decisions about their care and treatment.

- Staff made sure patients and those close to them understood their care and treatment. Staff told us that they were honest when discussing surgery and did let patients have inappropriate surgery.
- One patient told us the procedure was fully explained to them, along with the cost, potential complications and expected outcomes. They told us they had attended other clinics but felt Skin and Follicle was the only service not to pressure them to decide about the treatment.
- We observed a phone call; a potential patient had rung up to discuss the treatment available and associated costs. They were spoken to with respect and in a professional manner.
- Patients and their families could give feedback on the service and their treatment and staff supported them to do this via a patient feedback website. All ratings were identified as excellent, comments included: "The staff are so lovely, friendly and supportive and provide you with lots of information. I would highly recommend". "I was anxious about my pinnaplasty procedure, I was put at ease and it's a brilliant job. (the surgeon) was genuine, friendly and always remained professional".



Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

- Managers planned and organised services, so they met the needs of the local population. We saw discussion regarding the purchase of new equipment which would provide additional treatment options for patients.
- The service was designed to provide low risk surgery under local anaesthetist only. Patients who required surgery that was outside the scope of what could be offered at this location were given appointments with the surgeon at local private hospitals where there was more support in case of any complications arising.
- There was one clinical treatment room where the minor surgical procedures were untaken and a separate room where hair transplantation was undertaken.
- We saw there was adequate car parking for staff and patients.

Meeting people's individual needs

The service was not inclusive and did not always take account of patients' individual needs and preferences. Reasonable adjustments were not in place to help patients access services.

- There was no screening for individuals with physical or mental disabilities.
- We were told patients with mobility difficulties would be seen in a ground floor treatment room. However, we observed there was a small step to access the front door. Staff told us one toilet was larger and patients who had mobility difficulties could use this. However, we saw there was insufficient space for a wheelchair.
- There was no written information available in other languages or formats.
- The service had no interpreting facilities available. Staff told us they did have patients who attended whose first language was not English. They told us they would ask a family member to attend to translate for them. This is not best practice.
- There was no hearing loop available and information was not suitably displayed for visually impaired patients.

 Patients were provided with information about aftercare and a post-operative appointment. We were told this information included clinic contact details although we saw this was not provided to all patients. Information we received following the inspection identified all patients would be given contact details for the service.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment were in line with national standards.

- We asked staff how long patients had to wait for a first appointment and then if required to treatment. Staff told us most patients waited around two weeks for an initial appointment and around six to eight weeks if they decided to have the surgery. However, this was not monitored.
- For cosmetic surgery there was a mandatory cooling off period of two weeks from appointment for patients to think about their decision to undergo the surgery all the patients records we looked at confirmed this was usual practice.
- Patients we spoke with all told us they did not have to wait long for an appointment and they were given a choice of day and time.
- Appointments could be made easily by either telephoning the service or via the web site. The service took patient self-referrals.
- The service did not monitor the number of patients who did not attend appointments.

Learning from complaints and concerns

Arrangements for the management of complaints and concerns was inconsistent and did not give assurance they were treated seriously. There was insufficient information available to provide assurance all complaints were investigated, and lesson learned were shared with all staff.

 The service clearly displayed information about how to raise a concern in patient areas. Patients we spoke with told us they would contact the service should they have any concerns.

- The service had a policy on complaint management which identified all complaints should be acknowledged in two working days (unless a full response could be made within five working days) and a full response would be made within 20 working days. However, we were not assured these arrangements were in place and the requirements of the policy met.
- We saw information about the number of complaints made about the service was inaccurate. Information provided by the service to the Care Quality Commission on 28 March 2019 identified no complaints had been received between March 2018 and February 2019. In another section it was identified one complaint had been received about the service by the Care Quality Commission.
- During the inspection we asked for information about complaints and found a complaint had been made in May 2018 which was within the timeframe we asked for information about. There was no information recorded about the complaint made to the Care Quality Commission such as concerns raised, and actions undertaken, although this had been discussed with the service. We were not assured appropriate actions and when appropriate lessons would be put in place to ensure complaints would be learnt from.

Are surgery services well-led? Inadequate

Leadership

Leaders do not have the necessary capacity or capability to lead effectively.

- The service had been set up with three consultants all of whom were employed elsewhere and included: the registered manager, nominated individual and one other surgeon who was a director of the service.
- The registered manager was employed on a full-time basis by another employer. Staff told us the registered manager was usually at the clinic at least one day a week but could be contacted and a message left to ring the service.
- There was a clinic manager who was available in the clinic on a day to day basis.

- The leadership arrangements did not ensure staff were given adequate time and support to be trained and fully understand good safety practice. For example, actions required to highlight incidents such as a fridge temperature which were outside a safe range, checking consumables and ensuring required staff records were available to ensure the delivery of safe patient care.
- During our inspection, the registered manager acknowledged the shortfalls particularly around record keeping, missing information and a failure to ensure appropriate checks were in place. It was evident the registered manager whilst committed to improving the service may not have enough capacity with current arrangements to ensure this.

Vision and strategy

The service had a vision for what it wanted to achieve although there was no strategy to turn it into action.

- The service had a vision to expand, have additional surgeons and provide high quality patient care and treatment, however, we did not see this in writing.
- There was no strategy for achieving priorities or for delivering good quality, sustainable care.
- Due to the lack of service strategy there was no ability to measure progress.

Culture

Staff felt respected and valued and were focused on the needs of patients receiving appropriate care. A lack of incident reporting and incomplete complaint records did not give full assurance of an open culture.

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- The culture was centred around the needs and experiences of people who used the service. Surgeons told us they gave patients honest information about the treatment and potential benefits or improvements they may experience. One surgeon told us I would rather tell the patient the outcome would not be what they were hoping for than they have unreal expectations.
- Information we saw showed the service only carried out marketing that was honest and responsible and complied with the guidance contained within the Committee on Advertising Practices (CAP).

- People using the service were provided with a statement that included terms and conditions of the services being provided to the person and the amount and method of payment of fees. Prices for different treatments were clearly advertised on the service's website.
- 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.
- We saw no information relating to Duty of Candour. Duty of candour is being open and honest if things go wrong.
- The service did not have processes in place to provide staff with appraisals or development.

Governance

The service did not operate effective governance processes. Roles and accountability were unclear. There were limited opportunities for staff to meet, discuss and learn from the performance of the service.

- During this inspection we found the service did not have robust assurance systems in place. Audit was inconsistent, monitoring systems for medicines and consumables were not routinely undertaken, risks were not identified or monitored, and patient outcomes were not recorded and monitored.
- Lines of accountability were unclear with medical staff appearing to work as individuals and not as a team for the service.
- Clinical governance meetings were held every four months.
- No staff team meetings were held which discussed governance arrangements, risks and risk management and performance of the service.

Managing risks, issues and performance

Systems to identify and manage risk and performance and were not effective.

 We found there was no effective system for identifying, monitoring and managing issues and risks. Minutes of the clinical governance meetings held between February 2018 and June 2019 included no information

- or agenda item in relation to risk or risk management. This meant there was no assurance risks were being assessed, monitored and when possible mitigated against.
- There was no evidence of risk management taking place, although the service did have a risk management policy. We found there was little understanding or management of risk.
- There was no risk register for the service. During
 inspection we identified several risks that had not been
 identified by the service such as lack of incident
 reporting, unsafe storage of medicines, out of date
 consumables and incomplete or unavailable staff
 records. This meant risks were not being identified,
 assessed or mitigated against to ensure patient safety.
- There was no evidence the performance of the service was being monitored such as infection and complication rates or other patient outcomes, patient attendance and financial management.

Managing information

The service did not collect data to improve the service. The information systems were secure. There was no assurance appropriate notifications were submitted to external organisations when required.

- There was inadequate access to and challenge of performance by leaders and staff.
- The service did not collect data in relation to the effectiveness of the service. The service did not conduct audits or measure any patient outcomes at the time of our inspection.
- There were robust arrangements in place to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems, in line with data security standards.
- The service used mainly paper patients records and were kept securely in a locked filing cabinet, the room was also locked when staff were not present. Clinical photographs of patients' treatment areas were taken and stored securely electronically, with the patients consent. Computers were password protected and locked when not in use.
- We did not see evidence that staff had completed information governance training.

 The service did not have any notifiable incidents in the year before our inspection which would require it to report to external organisations. However, staff were not aware of what they would need to report and how they would report them.

Engagement

Leaders and staff did not actively engage with patients or staff to plan and manage services.

- There was no formal mechanism for staff engagement or feedback including staff meetings.
- There was no evidence of staff involvement in the planning of the service. Staff were not aware of key policies such as the safeguarding, risk management and incident reporting.
- Patients were encouraged to provide feedback about the service via an external website. However, the service did not undertake any patient feedback surveys to assess the quality of the service provided.
- We saw there was a website which gave information about the service.

Learning, continuous improvement and innovation Medical staff encouraged innovation and participation in research and service improvement.

- The clinical governance meeting minutes showed agenda items included research and innovation. We saw discussion during these meetings included purchase of the latest equipment for treatments to benefit their patients and their needs and involvement of the service in research with collaboration of a university.
- The surgeons working at the service met up with other
 plastic surgeons to discuss issues in the area and any
 new ways of working. The clinical governance meetings
 identified shared learning from an international training
 day for hair transplants.
- We did not see any arrangements in place for the service to encourage, record or monitor Royal College of Surgeons (RCS) Certification for surgeons who carry out cosmetic surgery. Staff did tell us as specialists in their fields the surgeons spoke at national and sometimes international conferences. However, no evidence of this was provided.

Outstanding practice and areas for improvement

Areas for improvement

Action the hospital MUST take to improve Action the provider MUST take to meet the regulations:

- The provider must ensure all staff complete mandatory training in key skills and evidence of this is available (Regulation 18).
- The provider must ensure staff are up to date with safeguarding training and are aware of the correct safeguarding procedures (Regulation 13).
- The provider must ensure the use of the World Health Organisation Safer Surgery Checklist is established (Regulation 12)
- The provider must ensure all information required by the regulations to ensure fit and proper people work within the service (Regulation19).
- There must be robust systems in place to ensure the safe storage of medicine and this should be monitored (Regulation 12).
- The provider must ensure evidence is available to show staff including non-contracted or sessional staff had their hepatitis B and human immunodeficiency virus (HIV) status checked and all staff have been immunised appropriately (Regulation 12).
- The provider must ensure a pre-operative patient health assessment is undertaken and this is recorded before people have any surgical procedure (Regulation 12).
- The provider must assess, monitor and improve the quality and safety of the services provided (Regulation 17).
- The provider must assess, monitor and mitigate the risks relating to the health, safety and welfare of patients (Regulation 17).
- The provider must ensure checks of equipment are in place and are completed (Regulation 12).

- The provider must ensure an effective incident reporting system is in place and staff understand how to report incidents including near misses (Regulation 12).
- The provider should ensure there appropriate practising privileges arrangements are in place (Regulation 19).
- There must be appropriate arrangements in place to record and respond to complaints about the service (Regulation 16).

Action the hospital SHOULD take to improve

- The provider should ensure there is a system in place to monitor staff compliance with mandatory training.
- The provider should ensure an appropriate system in place to monitor available consumables including use by dates.
- The provider should ensure there is robust system in place to monitor servicing agreements for equipment and other contracts.
- The provider should undertake audits of the use and completion of the World Health Organisation Safer Surgery Checklist.
- The provider should consider using patient psychological screening assessment.
- The provider should ensure the effectiveness of care and treatment is monitored.
- The provider should ensure systems to identify deteriorating patients are assessed and monitored.
- The provider should appraise staff's work performance.
- Reasonable adjustments should be in place to help patients access services.
- Identified strategies to develop the service should be in place to ensure the vision of the service can be met and monitored.
- The provider should ensure leaders have the skills and capacity to run the service.

Outstanding practice and areas for improvement

- The provider should consider collecting data to improve the service.
- The provider should ensure patient and staff feedback mechanisms are strengthened.

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment Care and treatment must be provided in a safe way for service users The registered person had not done all that is reasonably practicable to mitigate risks. Regulation 12(2)(b)
	The registered person had not ensured sufficient medicines were available in case of emergencies and appropriate medical devices to safely meet patients' needs Regulation 12(2)(f)
	The registered person had not ensured the proper and safe management of medicines. Regulation 12(2)(g)

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The provider had not ensured staff were up to date with safeguarding training and were aware of the correct safeguarding procedures. Regulation 13(2)

Regulated activity	Regulation	
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Requirement notices

Surgical procedures

Treatment of disease, disorder or injury

Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints

The registered person had not established or operated a system for identifying, receiving, recording, handling and responding to complaints by service users.

Regulation 16(2).

Regulated activity Regulation Surgical procedures Regulation 18 HSCA (RA) Regulations 2014 Staffing The provider had not ensured staff employed by the service had appropriate support, training, supervision and appraisal as was necessary to enable them to carry out the duties they are employed for. Staff had not completed mandatory training in key skills and evidence of this is available (Regulation 18(2)(a).

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The registered person had not ensured persons employed were of good character and had the qualifications, competence. skills and experience that were necessary for the work they performed. (Regulation 19((1)(a) and (b)

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Regulated activity Surgical procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance Systems and processes were not established or operated effectively to ensure compliance with the requirements in this part Regulation 17(1) The provider had not assessed, monitored and improved the quality and safety of the service provided. Regulation 17(2)(a) The provider had not assessed, monitored and mitigated the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from carrying on the regulated activities. Regulation 17(2)(b) The provider had not maintained an accurate, complete and contemporaneous record in respect of each service user, including the record of the care and treatment provided to the service user and of decisions taken in
	relation to the care and treatment provided. Regulation 17(2)©.