LXIR Medical Ltd

Harley Cosmetic Group

Inspection report

41 Harley Street
London
W1G 8QH
Tel: 02072551668

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inadequate
Are services caring?	Insufficient evidence to rate
Are services responsive to people's needs?	Inadequate
Are services well-led?	Inadequate

Summary of findings

Overall summary

Harley Cosmetic Group is operated by LXIR Medical Ltd. It is a private cosmetic and dental clinic in central London. The cosmetic service is a consultant-led provider of cosmetic services. There is one consultant working for the service. No surgical procedures requiring general anaesthetic are undertaken at the location. Patients requiring general anaesthetic surgery are referred to an independent private clinic in Harley Street, London.

The main service provided by this service is cosmetic procedures and dental services. There was one registered manager for both cosmetic procedures and dental services.

Patients at Harley Cosmetic Group are seen for a full range of dental procedures and pre- and post-operation cosmetic consultations, for example, liposuction, (this is a type of fat-removal procedure). Patients can self-refer or are referred from the Harley Body Clinic referral website. All procedures are performed by the Harley Cosmetic Group.

The cosmetic service operates from Monday to Friday, with occasional Saturday clinics. The dental service operates on Monday and Thursday.

The service primarily serves the communities of the London area. It also accepts patient referrals from outside this area. The provider is registered for the regulated activities: treatment of disease, disorder or injury, surgical procedures and diagnostic and screening procedures.

We carried out an unannounced responsive inspection, in response to concerns received, at the Harley Cosmetic Group on Wednesday 1 December 2021 and Friday 3 December 2021. The provider had not been previously inspected.

We rated Harley Cosmetic Group as inadequate overall because:

- The service did not ensure staff received effective training in safety systems, processes and practices. We requested mandatory training records documentation for all staff. We were not provided with evidence of formal training records and evidence of where the training had taken place.
- Staff told us they had completed basic life support training. We requested these records during the inspection. However, these were not produced.
- We found the policy on the management of deteriorating patients did not identify a clear escalation pathway. We asked for evidence of a service level agreement in the event of a patient needing to be transferred to another facility. However, we were told these were not yet in place.
- The service did not have a documented pathway for patients' journeys through treatment including: assessment, planning, implementation and review. We did not see evidence of pre-surgical risk assessments.
- The service did not ensure medications were safely stored. We saw medicines stored in an unlocked theatre medicines fridge and unlocked consultation room cupboard. There was a risk because the fridge and cupboard could be accessed by unauthorised persons.
- We found loose medicines in the theatre medicines fridge and consultation room cabinet.
- We found out of date medicines in the theatre fridge and consultation room cabinet. There was no system of medicines audit or stock control. This posed a risk that out of date medicines were not being monitored by the service and patients could be given out of date medicines.

Summary of findings

- The service did not adhere to their policies relating to the management of clinical waste. We saw clinical waste in an orange plastic bag on the floor in the sluice room. The sluice room was also used to store clinical dressings. There was a risk of cross-contamination.
- We found an open sharps bin in the theatre containing used syringes and needles. There was a risk of sharps bins being knocked over and potentially causing needle stick injuries.
- We saw an electrical safety testing sticker on the base of the electric treatment table in the theatre which showed it had not been serviced since 2019.
- We asked to see all patient records and were not provided with evidence of full individual patient care records including risk assessments. We were told the service did not have access to the records as they had been sent to be digitised. However, the coordinator produced three pre-procedure assessment records., but these were not full patient records detailing treatment, patient details or clinician providing treatment.
- Patients records were not stored securely. We were told that patient records were being held at a person's house who was not employed by the service. This is a breach of patient confidentiality.
- All policies we reviewed were dated 2019 and had no review dates or version controls.
- The service did not have service level agreement in place for patients that were referred to another provider in the event of an emergency.
- The service did not have a service level agreement in place for patients referred to another independent provider, who provided procedures requiring general anaesthesia on behalf of Harley Cosmetic Group.
- The registered manager was not aware of doctors' practising privileges. Staff told us the consultant had an informal agreement with the dentist, who was the registered manager. However, this agreement was undocumented.
- The registered manager was unable to show us if all staff had had pre-employment checks. We asked for personnel files, but we were told that they did not exist.
- There was no evidence that staff had Disclosure and Barring Service (DBS) checks in place.
- We requested fire risk assessments and Control of Substances Hazardous Health (COSHH) risk assessments and were provided with risk assessments for communal areas of the building only. Staff told us risk assessments for the clinical areas of the service on the fourth floor had not been completed.
- We were not provided with evidence of any systems of audit or risk management systems such as medicines audits, COSHH audits, or a risk register.
- We asked the registered manager for information on how the cosmetic surgery side of the service was managed and run. They told us they were unaware of the details of how the cosmetic service was managed and run.

However:

- We spoke with two patients during our inspection. The patients we spoke with gave positive feedback about the service. They told us staff treated them well and with kindness.

As a result of this inspection, we took urgent action to suspend the registration of the provider for an initial period of eight weeks. We told the provider they must take actions to comply with the regulations and that it should make other improvements. These can be found at the end of the report.

Professor Ted Baker, Chief Inspector of Hospitals said: I am placing the service into special measures. Services placed in special measures will be inspected again within six months. If sufficient improvements have not 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

Summary of findings

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. In addition, we will inspect this service again toward the end of the period of suspension to check if the suspension can be lifted or if it needs to be extended,

Nigel Acheson

Deputy Chief Inspector of Hospitals, on behalf of the Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inadequate 	We rated the service as inadequate because: • The service did not ensure staff received effective training in safety systems, processes and practices. We were not provided with evidence of formal training records and evidence of where the training had taken place, including safeguarding and basic life support (BLS). • We found the policy on the management of deteriorating patients did not identify a clear escalation pathway. • The service did not have a documented pathway for patients' journeys through treatment including assessment, planning, implementation and review. • The service did not ensure medications were in date and stored safely stored. • There was no system of medicines audit or stock control. • The service did not adhere to their policies relating to the management of clinical waste. • We found an open sharps bin in the theatre containing used syringes and needles. • We saw an electrical safety testing sticker on the base of the electronic treatment table in the theatre which showed it had not been serviced since 2019. • We requested to see all patient records and were not provided with evidence of full individual patient care records including risk assessments. • Patients records were not stored securely. We were told that patient records were being held at a person's house who was not employed by the service. • All policies we reviewed were dated 2019 and had no review dates or version controls. • The registered manager was unable to show us if all staff had had pre-employment checks. We asked for personnel files, but we were told that they did not exist. • There was no evidence that staff had Disclosure and Barring Service (DBS) checks in place. • Staff told us risk assessments for the clinical areas of the service had not been completed.

Summary of findings

- We were not provided with evidence of any systems of audit or risk management systems such as medicines audits, COSHH audits, or a risk register.
- The registered manager told us they were unaware of how the cosmetic service was managed and run.

Summary of findings

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Background to Harley Cosmetic Group

Harley Cosmetic Group is located at 41 Harley Street, London W1G 8QH, and is a general dental and medical consultant led provider of cosmetic services. We inspected the service in response to concerns received about the service.

Harley Cosmetic Group is operated by LXIR medical limited. The service opened in 2019. It is a private cosmetic and dental clinic in central London

Harley Cosmetic Group, located at 41 Harley Street, London W1 8QH, was registered with the CQC in August 2019. The service is registered with the Care Quality Commission (CQC) for the regulated activities of treatment of disease disorder or injury, diagnostic and screening procedures and surgical procedures.

The dental lead is the registered manager. The registered manager was registered in August 2019. A registered manager is a person who is registered with the Care Quality Commission (CQC) to manage the service. Like registered providers, they are 'registered persons. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

The service is located within rented premises, on the fourth floor of 41 Harley Street, London W1 8QH. The Harley Cosmetic Group offers both dental and cosmetic services from these premises. The service has access to one consultation room which also serves as an administrative office. There is a dental surgery and a cosmetic theatre on the fourth floor.

All clinics at 41 Harley Street, London, W1 8QH operate as independent businesses, on a sub-let tenancy, with their own opening times and business hours. As part of a tenancy contract, the service has access to a receptionist on the ground floor, a waiting area, toilets and a lift from the ground floor to the fourth floor.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced responsive inspection on 1 and 3 December 2021.

The team that inspected the service comprised of two CQC inspectors and a specialist advisor. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection for London.

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.

We spoke with four members of staff including administrative staff, managers, and a consultant. We also spoke with two patients and reviewed three patient records.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Summary of this inspection

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure there is a programme of mandatory training and all staff are up to date with all modules.
- The service must ensure that all staff have completed basic life support training.
- The service must ensure the policy on the management of deteriorating patients has a clear escalation pathway and that service level agreements, (these are written agreements on service provision), with other providers are in place.
- The service must make sure there is a documented pathway for patients' journeys through treatment including assessment, planning, implementation and review and a full record of the patient's treatment is readily available.
- The service must ensure clinical waste and sharps bins are stored in sealed secure containers in the clinical areas.
- The service must ensure medicines are stored securely in locked cabinets.
- The service must ensure there is a system of stock control and audit for medicines.
- The service must ensure all electrical equipment receives regular safety testing and there is a documented schedule for testing electrical equipment.
- The service must ensure all individual patient care records including risk assessments are always accessible to staff and have a documented named clinician.
- The service must ensure the security of patients' personal information. Records stored off site should have a written agreement on how the records will be transferred and stored, to prevent unauthorised access to patient personal information.
- The service must ensure policies are regularly reviewed and have version controls.
- The service must ensure doctors have documented practising privileges.
- The service must ensure all staff have pre-employment checks including references, photographic ID, interview notes, records of past employment history, and Disclosure and Barring Service (DBS) checks.
- The service must complete fire risk assessments and Control of Substances Hazardous Health (COSHH) risk assessments for tenanted the fourth floor, 41 Harley Street, London, W1 8QH..
- The service must have risk management systems and systems of audit to ensure there is a systematic programme of clinical monitoring.
- The service must ensure the registered manager has knowledge and oversight of the cosmetic service's operational processes.
- The service must ensure there are regular infection prevention and control audits.
- The service must ensure all cleaned equipment has a clear label to show it is clean and ready for use.
- The service must ensure the storage of oxygen cylinders is risk assessed and stored in accordance with Health and Safety Executive (HSE) guidance.

Action the service SHOULD take to improve:

- The service should ensure there is a service level agreement with independent providers of general anaesthetic services.
- The service should ensure there is a system in place to review medicines order forms for mistakes and errors.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Surgery	Inadequate	Inadequate	Insufficient evidence to rate	Inadequate	Inadequate	Inadequate
Overall	Inadequate	Inadequate	Insufficient evidence to rate	Inadequate	Inadequate	Inadequate

Inadequate

Surgery

Safe	Inadequate
Effective	Inadequate
Caring	Insufficient evidence to rate
Responsive	Inadequate
Well-led	Inadequate

Are Surgery safe?

Inadequate

We rated the service as inadequate for safe because.

Mandatory training

Mandatory training records were requested, but not produced. The provider could not be assured all staff received mandatory training in key skills.

At the time of inspection, we asked to see mandatory training records for all staff. We were told these records were not available. We were therefore not assured that staff had up to date training.

We asked staff for the details of the training provider. We were told training was completed by e-learning, but staff could not tell us the name of the training provider. This meant the provider could not be assured mandatory training was comprehensive and met the needs of people using the service and staff. There is a risk that patients will or may be exposed to harm if staff working for the provider have not completed the necessary training, as they may not have the skills to provide safe care for patients.

Due to a lack of training records the we were not assured clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities, autism and dementia. Furthermore, we were not assured that the provider was able to ensure staff were up to date with their mandatory training.

Safeguarding

We requested evidence of staff training in safeguarding, but this was not produced. The provider could not be assured staff had training on how to recognise and report abuse.

We requested staff Disclosure and Barring Service (DBS) checks. We were told these had not been undertaken on all staff. DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable. The consultant told us they had a DBS check and they would forward this to the CQC the following week, this was not received.

Inadequate

Surgery

The service told us they did not use qualified nursing staff.

The service had three health care assistants (HCA) on shift at the time of inspection. Staff told us they received training specific for their role. However, we asked to see copies of staff training records, including safeguarding, and were told this was not available or staff did not know the location of the training records. We were therefore not assured that staff had received training in safeguarding and knew how to recognise and report abuse.

Cleanliness, infection control and hygiene

Although, the service kept equipment and the premises visibly clean. The service did not have adequate control measures to protect patients, themselves and others from infection.

Clinic areas were visibly clean and had furnishings which were visibly clean. However, the service did not audit infection prevention and control. This meant the provider could not monitor infection control risks and take action to prevent the risk of infection.

We saw staff cleaning equipment in the cosmetic surgery theatre after a patient contact. However, the equipment was not labelled to show when it had been cleaned. This meant there was a risk of staff using equipment that had not been cleaned, as there was no labelling of equipment to show when equipment had been cleaned.

Floors were covered with washable floor coverings and were visibly clean. Other clinical area surfaces were visibly clean. However, there was a communal area outside of the cosmetic surgery theatre, which was carpeted and was managed by the landlord of 41 Harley Street, London, W1 8QH. We saw that patients used the area following cosmetic procedures to enter Harley Cosmetic Group's recovery room. According to research, (Damani, 2006), carpet harbours large numbers of microorganisms and therefore, its use in clinical areas should be avoided. The communal area on the fourth floor used by Harley Cosmetic Group to transfer patients between the cosmetic surgery theatre and recovery room had not been risk assessed.

The recovery room had a couch roll inventory. However, we did not see the use of couch rolls in the recovery area.

We saw staff followed infection control principles including the use of personal protective equipment (PPE). We saw staff wearing scrubs, masks and gloves when providing a liposuction procedure for a patient.

Environment and equipment

The service did not risk assess the design, maintenance and use of facilities, premises and equipment to keep people safe. Staff did not manage clinical waste well.

The service consisted of one consulting room, one cosmetic surgery theatre, one dental surgery and one recovery area.

We found the electric treatment table in the cosmetic surgery theatre had a sticker recording the most recent electrical safety test being completed in August 2019. Electrical medical equipment requires regular testing to ensure it is in a safe condition to use, to identify electrical faults and avoid electrical accidents.

We found two oxygen cylinders in the cosmetic theatre. One of the cylinders was not secured and was stored in the corner of the cosmetic surgery theatre, next to a trolley which had electrical equipment, including a visual display unit (VDU). The

cylinders were also stored next to combustible items, which were stored in a corner, next to a cupboard containing medicines. There was a risk the cylinder could fall or be knocked over. The storage of the oxygen cylinders had not been risk assessed. This was not in accordance with guidance from the Health and Safety Executive (HSE) on oxygen use in the workplace.

The service was operating from leased premises. Maintenance and facilities management of communal areas was managed by the landlord. We saw evidence that the fire alarm warning system and firefighting equipment was regularly maintained by an external contractor and there was evidence of lift maintenance and gas safety certificate. The provider showed us the landlord's risk assessments. However, the landlord informed inspectors that tenants were responsible for undertaking environmental risk assessments of their own premises. We asked the provider if they had undertaken environmental risk assessments of their premises. We were informed they had not, as the provider thought they were covered by the landlord's risk assessments. Hence, the provider could not be assured risks resulting from the layout of the premises or risks relating to the use of equipment had been identified and had taken action to mitigate these risks. This meant the provider could not be assured the service had suitable facilities to meet the needs of people using the service.

We saw signage explaining the symbols relating to the control of substances hazardous to health (COSHH) on the wall in the sluice room next to the cosmetic surgery theatre. We asked the provider if they had completed COSHH risk assessments of their premises and were informed they had not, as the provider thought they were covered by the landlord's COSHH risk assessments. For example, we saw two containers of skin disinfectant in the sluice room which were marked as flammable. This was not in accordance with COSHH regulations which require all employers to assess the risks to health arising from hazardous substances created by work activities, and then decide what precautions are needed in order to prevent or adequately control exposure. A COSHH risk assessment identifies substances and activities where there may be exposure to hazardous substances. The aim is to know how workers or people using the service are exposed, what they are exposed to and what are the probability of adverse health effects arising from exposure.

We found an open sharps bin in the theatre containing used syringes and needles. This was a risk because the sharps bin could easily be knocked over and cause needle stick injuries to both patients and staff.

Staff did not manage clinical waste safely. The provider had an allocated area for domestic waste and clinical waste in the basement of 41 Harley Street, London, W1 8QH as part of their tenancy agreement. However, the provider was responsible for the provision of their own waste management and collection. During our inspection, we saw clinical waste in an orange plastic bag on the floor in the sluice room. The sluice room was untidy and used to store clean dressings and boxes. This could expose people using the service to a risk of cross-contamination.

We found a dental whitening machine in the fridge in a small lobby outside the consultation room. The fridge was also being used to store staff food, such as yoghurts.

Assessing and responding to patient risk

We found the process surrounding patient assessment was not robust or adequately documented. The service did not have service level agreements in place regarding the transfer of patients at risk of deterioration.

The service did not have a formal admission policy or eligibility criteria in relation to patients who could or could not be seen by Harley Cosmetic Group.

Inadequate

Surgery

The service did not have a clear, documented procedure for deteriorating patients, including assessment and escalation; or a pathway for managing those patients with severe local anaesthetic toxicity where ventilation may be required. We asked to see patient records, and were shown three pre-procedure documents, but we did not see evidence in the records that the service used a nationally recognised tool, such as National Early Warning Score (NEWS) scoring to identify deteriorating patients or the World Health Organisation (WHO) safety checklist to prevent or avoid serious harm.

Staff told us in the event of a patient deteriorating in the clinic they would provide first aid and call 999. The service did not have a protocol or service level agreement in place with a local NHS provider in the event they needed to transfer a patient to hospital. This was not in accordance with the provider's critical care policy, which mentioned two hospitals for the transfer of patients in the event of patient deterioration. Staff at the service told us they had emailed two NHS hospitals in the previous two weeks regarding a service level agreement. We asked staff to show us these emails at the time of inspection, however these were not provided.

Staff told us they had completed basic life support training. We requested these records during our inspection however these were not produced. We were therefore not assured that staff had the necessary training to care for patients in the event of a patient deterioration.

We requested but did not receive completed pre-surgical risk assessments for each person using the service on admission / arrival, using a recognised tool, and evidence that this was reviewed regularly, and risk assessment outcomes recorded, including after any incident.

The service did not have a documented pathway for patients journeys through treatment that included: assessment, planning, implementation and review. There is a risk that a lack of a documented procedural pathway could expose patients to harm if: assessment; planning; implementation; and review, documents are not fully completed and a full record of the patient's treatment is not readily available, such as people's medical histories and allergies. We were not assured that the provider ensured procedures were suitable for people receiving treatment.

We reviewed printed copies of some of the provider's policies, as well as the provider's policy register. We found the provider's policy register did not include a policy for the management of sepsis, in accordance with NICE NG51 'Sepsis: recognition, diagnosis and early management.'

Staffing

The service had enough staff. However, the provider could not produce evidence of staff qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment.

All staff we spoke with felt the staffing levels were enough to cover the work required. However, when inspectors requested evidence of staff qualifications, skills, training and experience the service were unable to provide this.

The service had one consultant cosmetic surgeon and one dentist, who was also the registered manager. We were told a further consultant cosmetic surgeon had recently joined the service and had provided a "few" sessions at 41 Harley Street, London, W1 8QH. Staff said the new consultant provided Botox, (this is a procedure that relaxes the muscles in the face to smooth out lines and wrinkles), and dermal fillers, (these are substances injected into the face to fill lines and wrinkles, such as lips or cheeks); but, was hoping to expand their service provision.

Inadequate

Surgery

We spoke with a patient and former patient of Harley Cosmetic Group. The patients told us they were friends and one of them was having a post procedural check on the day of inspection. The patients said they had been given the consultants telephone contact details and could telephone the consultant 24 hours a day. However, staff told us the consultant lived over 90 miles from London. The service did not have a documented policy on how a consultant would be available within a 30-minute timeframe if required to attend a patient following a cosmetic procedure.

The service's coordinator told us staff had completed training as health care assistants (HCA). We requested, but, did not receive evidence of staff HCA training completion.

There was a coordinator/administrator and two health care assistants (HCA) on shift on the 3 December 2021. One HCA was working in the dental clinic and another HCA was working in the cosmetic clinic. Staff told us they were employed on zero hours contracts on a regular basis.

The service coordinator told us all staff had undertaken basic life support (BLS) training. However, when inspectors asked to see records of this. Staff told us they could not locate this. Clinical staff we spoke with knew how to respond to a medical emergency and knew the location of the emergency equipment, which included a defibrillator and medical oxygen.

There were no panic alarms installed in the cosmetic surgery theatre. This meant in the event of an emergency in the cosmetic surgery theatre staff would have to leave the theatre and cross a carpeted landing area to request assistance from staff in the main clinic.

Records

Staff did not keep detailed records of patients' care and treatment. Records were not stored securely and were not easily available to all staff providing care.

During our inspection, we asked to see all patient records and were not provided with evidence of full individual patient care records including risk assessments. We were told the service did not have access to the records as they had been sent to be digitised. Staff told us that patients' records were being held at a person's house who was not employed by the service. Staff said they did not know the person's address, but knew where they lived, as they dropped records at the person's house to be digitised. However, this did not ensure patients confidentiality and privacy. Furthermore, storage of people's personal information in a person's home for processing was not in accordance with Article 32 (2), of the General Data Protection Regulations (GDPR), which requires "the appropriate level of security account shall be taken in particular of the risks that are presented by processing, in particular from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to personal data transmitted, stored or otherwise processed".

We asked staff to retrieve the records from the person's home to facilitate inspectors reviewing that there was accurate and procedural recording of patient information. Staff produced a memory stick with information stored on it. The memory stick did not clearly identify and order patient records into files. Staff showed us three pre-procedure assessment records; but these were not full patient records detailing: assessments, treatments, patient details or the name of the clinician providing the treatment. Patients may be exposed to harm if patient records are not fully completed, as there may not be enough information regarding the person using the service in the event of a medical emergency.

Medicines

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

Inadequate

Surgery

Staff did not store and manage all medicines safely. We saw medicines, such as a vial of Hyaline, (this is a freeze-dried powder for solution for injection or infusion), which was nine months out of date stored in an unlocked theatre medicines fridge. This was a risk because patients could be administered out of date medicines. We saw medicines which were loose in the theatre medicines fridge such as a solution for dental injection. This meant staff would not have access to instruction leaflets on the solution. We also saw a box of Xylocaine with adrenaline, (this is used to numb (anaesthetise) part of the body for surgical operations or to provide pain relief), in the theatre medicines fridge which was unsecured. This was a risk because the fridge did not have a lock and the contents of the theatre medicines fridge was not monitored or audited. This meant staff or people using the service could access items in the fridge and staff may not realise they were missing.

We reviewed medicines which were kept in an unlocked cupboard in the consultation room. We did not find any controlled drugs on the premises. However, the medicines cupboard was untidy, with open boxes and loose medicines. For example, we found one loose tablet of dihydrocodeine, (this is an opiate pain killer, used to treat moderate to severe pain, such as after an operation or a serious injury). We also found three loose tablets of paracetamol, loose blister packs of co-codamol and an antibiotic cream which was three months out of date. As well as an amiodarone injection, (this is used to treat and prevent an irregular heartbeat), which had expired in June 2021. At the time of inspection, staff told us Harley Cosmetic Group did not have any stock checks we could view or audits, as the service did not complete them. This was a risk to patients as the out of date medicines were not being monitored by the service and patients could be given out of date medicines. The unlocked cabinet also posed a risk because it could be accessed by unauthorised persons.

We also found three medicines order forms in the unlocked medicines cupboard in the consultation room. We noted a staff member that was not a qualified doctor had referred to themselves as “Dr”. We asked the staff member about their medical qualifications, they said they were not medically qualified. The staff member said they had used the title doctor in error. Under S.49 (1) of the Medical Act 1983 it is an offence for any person to imply they are a practitioner under the provisions of the act. Therefore, the provider should ensure there is a system in place to review order forms for mistakes and errors, to ensure pharmacists receiving orders are not confused about the role of the person sending the order.

Are Surgery effective?

Inadequate

We rated the service as inadequate for effective because:

Evidence based care and treatment

We were not assured care and treatment was based on up to date national guidance and evidence-based practice as there was no regular schedule for policy reviews or version controls in place.

We found the service’s policies were kept in ring binders in a glass cabinet in the consultation room. However, we found the policies were all dated 2019. Staff told us that policies were updated by the registered manager. We did not find evidence that policies had been regularly reviewed or updated and shared with staff. All the policies we reviewed were dated 2019 and did not have review dates or version controls. This was a risk to patients because the policies could contain out of date best practice guidance. The lack of version control meant that staff could not be assured they were looking at the most recent policy. This was a risk because staff could not be assured policies reflected the most recent best practice guidance, and staff may have used out of date guidance.

Inadequate

Surgery

The provider did not have a policy to ensure staff protected the rights of people subject to the Mental Health Act and followed the Code of Practice. We spoke with two post-operative patients at the time of our inspection. They told us the consultant had routinely referred to their psychological and emotional needs. However, the provider's policy register did not have a policy regarding patients with mental health needs. This meant staff may not be aware of how to address the needs of people with mental health issues.

We reviewed the service's policy register. We noted this contained a policy for termination of pregnancy, dated 2019. Staff assured us that the service did not undertake termination of pregnancies at 41 Harley Street, London, W1 8QH.

Pain relief

On the day of inspection, we did not observe patient procedures. We requested but were not shown evidence in patient records that staff recorded the administration of local anaesthetic detailing type, batch number, amount, expiry date and site of administration.

As we could not access full patient records, we were not shown evidence that staff assessed patients' pain using a recognised tool and gave pain relief in line with individual needs and best practice.

Patients were advised to purchase paracetamol over the counter for post procedural pain relief. Two people that had used the service told us pain relief was discussed pre and post operatively with them, and they were told about what to do if discomfort became significant.

Patient outcomes

Staff did not monitor the effectiveness of care and treatment. Hence, staff could not use the findings to make improvements to outcomes for patients.

The registered manager and staff told us the service had not introduced a programme of repeated audits to check improvement over time. The service did not have a formal clinical audit schedule to facilitate monitoring of patient outcomes and experience. We did not see evidence that the service was submitting to Q-PROMS, (Patient Reported Outcome Measures). The data gathered from the use of PROMs can be used in a variety of ways to empower patients, inform decision making and, where relevant, support quality improvement.

Staff and two people that had used the service told us the contact details of the lead cosmetic consultant were given to patients, along with instructions to contact the service at any time should any complications or questions arise. We were not shown evidence that documented follow up calls had been undertaken following procedures.

Two patients that had used the service told us they were seen regularly after their procedure for a follow-up appointment to review the results of their procedure.

Competent staff

We requested but were not shown evidence that staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

Inadequate

Surgery

At the time of inspection, we asked to review personnel files. We were told that staff did not have personnel files. For example, there was no evidence of disclosure and barring service (DBS) checks, references, photographic ID, interview notes, or full records of staff past employment history including any gaps. This meant there was a risk patients will or may be exposed to the risk of harm as the service had not carried out satisfactory pre-employment checks to ensure staff had the necessary qualifications and experience to carry out their role, or were safe to perform the regulated activity.

Staff told us recruitment processes were informal and based on an interview with either the lead cosmetic consultant or the lead dentist. We asked to see evidence that all new staff a full induction tailored to their role before they started work on the day of inspection. This was not received.

We requested during the inspection a contemporaneous record which identified any training needs staff had and gave staff the time and opportunity to develop their skills and knowledge. Staff told us they did have opportunities to complete training. However, during the inspection we requested, but did not receive, a staff training matrix or records of staff training. The provider did not have a policy or governance framework in relation to staff training. The service used tumescent local anaesthesia. We did not see evidence that health care assistants had appropriate training to monitor patients for signs and symptoms of toxicity.

On the day of inspection, we requested but did not receive evidence that staff were appropriately qualified. Clinical staff were registered with their appropriate professional body. For example, General Medical Council (GMC) and General Dental Council (GDC). However, we asked to see the cosmetic consultant's practising privileges, (the granting of practising privileges is a well-established process within independent healthcare whereby a medical practitioner is granted permission to work in an independent hospital or clinic, in independent private practice, or within the provision of community services). We were told these were not available, although the consultant told us he had them and would forward them to the CQC the following week. These were not received. Furthermore, the registered manager told us they did not know what doctors practising privileges were. Staff told us there was an informal agreement between the registered manager and consultant which was undocumented. This was a risk to patients because the service could not ensure they had oversight of the range of procedures that doctors were competent to perform. We were told the cosmetic consultant and dentist worked privately and did not work with or for the NHS.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team.

Staff told us there were positive working relationships between all individuals at the service due to a small team.

The service referred patients to a local independent provider of general anaesthetic services. Staff told us they worked well with staff from the independent provider. However, the service did not have documented procedures for the referral of patients requiring general anaesthesia. There was no documented pathway which outlined the flow of patients from Harley Cosmetic Group to the independent provider.

Two patients we spoke with had received services from the independent provider following referral from Harley Cosmetic Group. The patients told us they were asked whether they consented for their information be shared with their GPs. However,, we did not see recorded evidence of patients having this recorded in their records.

Seven day services

Key services were available up to six days a week to support timely patient care.

Inadequate

Surgery

Patients could book appointments for cosmetic services 9am and 5pm, Monday to Friday. Staff told us cosmetic services offered occasional Saturday clinics and occasional out of hours services up to 10pm, which were provided upon request.

Dental services were provided from 9am and 5pm on Monday and Thursday. We also found a dental clinic was running on Friday 3 December 2021 on the day of our inspection.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make decisions about their care and treatment

We viewed three patient records where staff gained consent from patients for their care and treatment. In the three pre procedure documents we viewed; consent was obtained. However, the documents did not clearly specify the name of the doctor completing the procedures in accordance 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 to consider their decision to go ahead with surgery. However, two patients we spoke with visiting the service on the day of our inspection, confirmed they had been given a 14 day cooling off period prior to their procedure, (the patients were friends, one was having a post procedural check; the other patient said they had previously had procedures with the service).

The provider did not have a documented policy relating to the Mental Capacity Act, 2005 (MCA). We requested but did not receive evidence staff had received specific training regarding the MCA. Staff told us they had not had any incidents of patients lacking the capacity to consent. Staff told us if they thought a patient lacked capacity to consent to procedures, they would not offer the procedure.

Are Surgery caring?

Insufficient evidence to rate

We did not rate caring during this inspection, as there was insufficient evidence to rate.

Compassionate care

We spoke with two patients during our inspection. The patients we spoke with gave positive feedback about the service. They told us staff treated them well and with kindness. The patients said they were attending the clinic so that one patient could have a post-procedural check-up following eye lift surgery. Both patients told us they had received cosmetic surgery at another location and had pre and post procedural checks at Harley Cosmetic Group.

Emotional support

We spoke with two patients during the inspection. They told us staff gave patients and those close to them help and advice when they needed it.

Understanding and involvement of patients and those close to them

Inadequate

Surgery

The service did not collect patient feedback. Therefore, there was insufficient evidence to rate Harley Cosmetic Group for caring.

Are Surgery responsive?

Inadequate

We rated the service as inadequate for responsive because:

Service delivery to meet the needs of local people

We did not see evidence that the service planned services to meet the needs of people requiring additional support.

The day to day running of non-clinical services was provided by the service's coordinator/administrator. The registered manager told us the service was split into cosmetic surgical services and dental services. The cosmetic services were overseen by the cosmetic consultant. The dental service was overseen by the dentist.

The service was located at 41 Harley Street, London, W1 8QH. The address is close to public transport links. The service had one dental treatment room, one cosmetic surgery theatre, one recovery room and one consultation room.

The service did not have systems to help care for patients in need of additional support or specialist intervention due to learning disability or mental health needs.

Staff told us all patients were self-referred or referred from the Harley Body Clinic website. We saw signage in a shared communal area between the second and third floor of 41 Harley Street, London, W1 8QH, which said Harley Body Clinic was located on the fourth floor. The registered manager told us this was a mistake. The registered manager said the service had covered the Harley Body Clinic sign with tape, but this had been removed by unknown persons. We also saw a sign in a cupboard containing equipment in the Harley Cosmetic Group cosmetic theatre, this said Harley Body Clinic. The registered manager told us Harley Body Clinic was a referral website. The registered manager told inspectors that all cosmetic and dental procedures carried out on the fourth floor of 41 Harley Street, London, W1 8QH were carried out by the Harley Cosmetic Group. We were not assured this was clear to patients due to the incorrect signage we found during our inspection.

The service had a display cupboard of silicone implants; these included breasts, testicular and buttock. Staff told us the implants were samples and used during consultations. We saw that the breast implant was clearly marked as a sample.

Meeting people's individual needs

The service did not have accessible information available to patients in other languages or a range of formats.

Staff told us the cosmetic consultant would clarify if people approaching the service had needs including mental health needs, learning disabilities and dementia, at the initial consultation. Staff told us they would not provide treatments to people with these needs without having a documented referral from a hospital consultant. However, we did not see evidence of such assessments in patient records.

The layout of the clinic meant the service could not offer procedures to patients using wheelchairs.

The service did not have any information leaflets available in languages other than English. Information leaflets were from providers of implants. We did not see information available to people in the clinical areas on services provided by Harley Cosmetic Group.

Staff told us the service did not have access to formal translation services. Patients would be asked to book their own translator if a translation service was required. During the inspection, we were told there was no written information available in other languages or formats. This meant patients that did not speak English may not understand the treatment they were being offered, including risks from surgical procedures and the 14-day cooling off period, following their initial consultation.

Access and flow

People could access the service when they needed it and received care and treatment promptly. However, there was no documented patient pathway for the referral of patients to an independent provider of general anaesthetic procedures.

We were told cosmetic surgery services operated from 9am to 5pm Monday to Friday, with occasional Saturday clinics. Staff told us clinics occasionally operated in the evenings. We were told dentistry operated on a Monday and Thursday. However, when we visited on Friday 3 December 2021 dental services were being provided.

Patients could arrange an appointment via a referral website or by telephoning the service. All procedures were booked in advance at a time to suit the patient.

Inspectors asked staff to explain the patient journey through the service. We were told the service did pre-operative assessments in the consultation room at 41 Harley Street, London, W1 8QH. However, the service also occasionally rented consultation rooms at another address in Harley Street, London, which was used as overflow for consultations. Staff told us they would only rent consultation rooms if they did not have capacity in the Harley Cosmetic Group clinic. Staff told us rooms would be rented hourly for consultations with any procedure.

Patients requiring general anaesthesia were referred to another independent provider, due to the surgical theatre on the fourth floor or 41 Harley Street, London, W1 8QH, not being equipped for the administration of general anaesthesia. Staff told us any procedure requiring general anaesthetic would be referred to an independent provider of surgical procedures, where the theatre was equipped for the use of general anaesthetic. Staff told us Harley Cosmetic Group paid the independent provider to do procedures requiring general anaesthesia on behalf of Harley Cosmetic Group.

Although, staff told us they supported patients when they were referred or transferred between services. There was no documented patient pathway for the referral of patients to the independent provider of general anaesthetic procedures. The provider told us any patients receiving surgical procedures which required a general anaesthetic received an initial consultation at Harley Cosmetic Group. If the patient required a procedure requiring a general anaesthetic, they would be referred to another local independent provider, with facilities for the administration of general anaesthesia. However, the provider told us service level agreements were not in place with the provider of general anaesthetic services. There was also no documented patient pathway for referral of a patient to a provider for general anaesthesia.

We requested information on patients' records. However, at the time of inspection we did not see any documented evidence that managers and staff worked to make sure they started discharge planning and planning for post procedure

after care as early as possible. However, we spoke with a patient, who was accompanied by a friend. (The friend told us they were a previous patient at the service). The patient told us they were attending their post procedural check, which was arranged by Harley Cosmetic Group at an independent clinic in Harley Street, London. The patients told us they had both used services provided by Harley Cosmetic Group and both said their post procedure check-up appointments and after care had been discussed at their initial consultation and following their procedure. Both told us they had been asked at their initial consultation about their mental health and both said they had provided the cosmetic consultant with the details of their GP.

Learning from complaints and concerns

The service did not have signage on their premises informing patients of their complaints procedure.

We were not assured that patients would know how to complain or raise concerns, as the service did not have information clearly displayed for people using the clinic on the fourth floor, regarding raising complaints. The provider had a policy for complaints management on their policy register. However, the provider's policies had not been reviewed since 2019.

Staff told us Harley Cosmetic Group did not gather patient feedback. This meant the service did not improve daily practice based on patient experiences of the service.

Are Surgery well-led?

Inadequate

We rated well-led as inadequate because:

Leadership

Leaders did not understand the priorities and issues the service faced. The registered manager worked part-time and was not visible in the service for patients and staff.

The registered manager was also the CQC nominated individual and lead dentist at Harley Cosmetic Group. At the time of our inspection, we found they delegated many tasks to the coordinator/administrator. The registered manager did not demonstrate an understanding of the obligations placed on them by their role as registered manager or the fundamental standards of care.

We asked the registered manager for information on how the cosmetic surgery side of the service was managed and run. The registered manager said he had limited knowledge of the cosmetic side of the service, as this was overseen by the cosmetic consultant. The registered manager told us they were unaware of the details of how the cosmetic service was managed and run.

The registered manager and cosmetic consultant told us there was an informal agreement regarding the management of the service. The registered manager, as dentist, was responsible for the dental side of the service and the cosmetic consultant was responsible for the cosmetic side of the service. None of the leaders or staff at the service were clear about the remit of their roles and the scope of their responsibilities, as this was not documented.

Inadequate

Surgery

Vision and Strategy

The service did not have a documented vision, set of values, or strategy, developed with all relevant stakeholders.

Arrangements with partners and third-party providers were not governed and managed effectively using service level agreements. For example, the service did not have service level agreements with NHS organisations for patients at risk of deterioration. The service also did not have service level agreements which clearly documented referral pathways and the provision of surgical procedures and general anaesthetic services by an independent provider in Harley Street, London. This meant the service was not clearly aligned to local services and did not have a clearly documented sustainable strategy to direct service provision.

Culture

Staff felt respected, supported and valued.

Staff we spoke with said they felt valued and cared for. Staff told us there was a positive culture amongst staff and managers that promoted cooperative relationships.

Governance, management of risk, issues and performance

Leaders did not operate effective governance processes, throughout the service and with partner organisations. Staff at all levels were not clear about their roles and accountabilities. Leaders did not identify and escalate relevant risks and identify actions to reduce their impact.

The service relied on informal sharing of information. The service did not have a programme of regular minuted governance meetings or a clinical governance group responsible for reviewing surgical procedures.

The service did not have a systematic programme of clinical and internal auditing to monitor quality and operational processes. Staff told us the service did not undertake routine clinical and governance audits, which would allow the service to benchmark against other similar providers, and to identify changes that would improve the service based on information.

The service did not have a risk register that was regularly reviewed, which identified risks and action the service had taken to mitigate identified risks.

It was unclear who the governance and risk lead were for cosmetic services. The registered manager told us the cosmetic consultant was responsible for the cosmetic clinic. The registered manager told us they had very little knowledge of the cosmetic service's governance and risk management processes.

The service did not have a documented business continuity plan in place for major incidents such as power failure or building damage, or in the event of the consultant or dentist being off through long-term sickness.

Information Management

Inadequate

Surgery

The service did not collect reliable data and analyse it. Staff could not find the data they needed, in easily accessible formats, to understand performance, and make decisions and improvements. The information systems were not integrated and secure.

The service did not have arrangements to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems in accordance with data security standards. For example, we were told patient records were being stored at a person's home. The person was not an employee of Harley Cosmetic Group. Staff told us they did not have access to patients records at the time of inspection as the records were at a person's home, as they were being digitised. This meant the service did not ensure patient confidentiality and confidential data was protected in accordance with the General Data Protection Regulations (GDPR).

The service did not collect data via audit. This meant the service could not use audit information to determine if the clinics care and treatment functions were working as intended; or to measure the quality of treatment outcomes and ensure that services were safe.

Engagement

Leaders and staff did not actively and openly engage with patients, staff, equality groups, the public and local organisations to plan and manage services.

We saw three pre-consultation records which recorded patients signed consent. he patient consent records did not record whether people considering or deciding to undergo cosmetic surgery were provided with the right information and considerations to help them make the best decision about their choice of procedure and associated risks.

Staff told us people's views and experiences of their care and treatment were not regularly gathered and acted on to shape and improve the service and culture of Harley Cosmetic Group.

We did not see evidence that staff were committed to continually learning and improving the service. Managers and staff had limited understanding of quality improvement methods. Leaders did not encourage innovation or participation in research.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures	Regulation 12 CQC (Registration) Regulations 2009 Statement of purpose Requirement Notice **Regulation 12** (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way • The service did not ensure the storage of oxygen cylinders was risk assessed and stored in accordance with Health and Safety Executive (HSE) guidance. **Regulation 12** (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: (h) assessing the risk of, and preventing, detecting and controlling the spread of, infections, including those that are health care associated; • The service did not ensure all cleaned equipment had a clear label to show it was clean and ready for use

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	S31 Urgent suspension of a regulated activity **Regulation 17.**—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to: (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity; • The service did not ensure the security of patients' personal information. Records stored off site did not have a written agreement on how the records would be transferred and stored, to prevent unauthorised access to patient personal information • The service did not have risk management systems and systems of audit to ensure there was a systematic programme of clinical monitoring • The registered manager did not have knowledge and oversight of the cosmetic service's operational processes • The service did not ensure policies were regularly reviewed, with version controls. To ensure staff were using the most recent version of a policy • The service did not ensure doctors had documented practising privileges; to ensure the service had oversight of the range of procedures doctors were competent to perform **Regulation 17.**—(1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to: (c) maintain securely an accurate, complete and contemporaneous record in

This section is primarily information for the provider

Enforcement actions

respect of each service user, including a record of the care and treatment provided to the service user and of decisions taken in relation to the care and treatment provided;

- There service did not have a documented pathway for patients' journeys through treatment including assessment, planning, implementation and review; or that a full record of the patient's treatment was readily available, to ensure patients were suitable for procedures and were receiving the correct treatment

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	S31 Urgent suspension of a regulated activity **Regulation 12** (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: (c) ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely; • The service did not ensure that all staff had completed basic life support training • The service did not ensure there was a programme of mandatory training and all staff were up to date with it • The service did not ensure the policy on the management of deteriorating patients had a clear escalation pathway; or service level agreements in place to ensure staff would know what to do if a patient deteriorated and how and where to transfer the patient **Regulation 12** (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: (e) ensuring that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way; • The service did not ensure clinical waste and sharps bins were stored appropriately, including sealed secure containers in the clinical area

This section is primarily information for the provider

Enforcement actions

- The service did not ensure electrical equipment received regular safety testing and there was a documented schedule for testing electrical equipment
- The service did not ensure the storage of oxygen cylinders was risk assessed and stored in accordance with Health and Safety Executive (HSE) guidance

Regulation 12 (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph (1), the things which a registered person must do to comply with that paragraph include: (g) the proper and safe management of medicines

- The service did not ensure medicines were stored securely in locked cabinets
- The service did not ensure there was a system of stock control and audit for medicines to ensure out of date medicines were not given to patients
- The service did not ensure all cleaned equipment was clearly labelled to show it was clean and ready for use

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	S31 Urgent suspension of a regulated activity **Regulation 19** (2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in: (a) paragraph (1) • The service did not ensure all staff had pre-employment checks including: references, photographic ID, interview notes, records of past employment history, and Disclosure and Barring Service (DBS) checks to ensure staff had the necessary qualifications and experience to carry out their role, or were safe to perform the regulated activity