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.

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. However, at the time of this inspection the service was suspended following CQC's inspection on 1-3 December 2021.

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.

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.

This was a follow up inspection to investigate whether concerns from our previous inspection on 1 and 3 December 2021 had been resolved.

We rated Harley Cosmetic Group as inadequate overall because:

- During a previous inspection we found the service did not have a clear escalation pathway for deteriorating patients. During this inspection the service still did not have a clear escalation pathway for a deteriorating patient which was tailored to the service.
- The service did not have eligibility criteria which defined if patients were suitable for cosmetic surgery.
- Clinical staff did not have up to date training in basic life support (BLS).
- Equipment was not serviced in accordance with servicing schedules and manufacturers' instructions. We saw a range of equipment which was out of date, including resuscitation equipment, for example, a defibrillator which had not been serviced since 2019.
- The service did not have a tailored, documented pathway for patients' journeys through treatment including assessment, planning, implementation and review.
- At our previous inspection, we found the service did not ensure medicines were safely stored. During this inspection we found the service still did not ensure medicines were stored safely.
- At our previous inspection we found there was no system of medicines audit or stock control. During this inspection we found there was still no system of medicines audit or stock control.
- The service did not have clear procedures relating to the management of clinical waste including medicines.
- We found a sharps bin in the consultation room which was not signed and dated.
- The registered manager's level 3 safeguarding training was completed in 2018 and had not been updated in accordance with intercollegiate guidance which states level 3 refresher training should be updated every three years.

Summary of findings

- During our previous inspection we requested to see all patient records and were not provided with evidence of full individual patient care records including risk assessments. During our previous inspection 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. During this inspection we were told patients records were still being stored at a person's house who was not employed by the service.
- The service did not have a system in place to review medicines order forms and copies of patient prescriptions.
- Policies were not tailored to the service being provided. The service did not have an infection prevention and control lead, in accordance with the service's policy.
- The service did not have any cleaning schedules or records of cleaning, including theatre deep cleans.
- The service could not produce, when requested, a waste disposal contract which included arrangements for the disposal of medicines.
- Staff did not have full pre-employment checks. Staff did not have references or photographic proof of identify or eligibility to work in the UK.
- There was no evidence, when requested, that one member of staff had applied for a Disclosure and Barring Service (DBS) check.
- The service was unable to produce evidence of a staff training schedules, including frequency of training updates. The service was unable to produce evidence of staff having completed training in Sepsis awareness when requested.
- The service did not audit the use of the World Health Organization (WHO) 'Steps to Safer Surgery' checklist.
- Risk assessments for the clinical areas of the service were not robust and training relating to the risk assessments had not been completed by any staff.
- The service did not have any systems of clinical audit. Risk management systems were not robust.
- 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.

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

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 have a clear escalation pathway for deteriorating patients. • The service did not have eligibility criteria which defined if patients were suitable for treatment. • Clinical staff did not have up to date training in basic life support (BLS). • Equipment was not serviced in accordance with servicing schedules and manufacturers' instructions. • The service did not have a tailored documented pathway for patients' journeys through treatment including assessment, planning, implementation and review. • The service did not ensure medicines were safely stored. • There was no system of medicines audit or stock control. • The service did not have clear policies relating to the management of clinical waste including medicines. • The registered manager's level 3 safeguarding training was not updated in accordance with intercollegiate guidance. • Patient 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. • Policies were not tailored to the service being provided. • The service did not have any cleaning schedules or records of cleaning, including theatre deep cleans. • All staff did not have full pre-employment checks including Disclosure and Barring Service (DBS) checks. • The service was unable to produce evidence of a staff training schedules, including frequency of training updates. • The service did not audit the use of the world health organization (WHO) 'Steps to Safer Surgery' checklist.

Summary of findings

- Risk assessments for the clinical areas of the service were not robust and training relating to the risk assessments had not been completed by any staff.
- The service did not have any systems of clinical audit. Risk management systems were not robust.

Summary of findings

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Summary of this inspection

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 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 a short notice announced follow up inspection to investigate whether concerns from our previous inspection on 3 December 2021 had been resolved. The team that inspected the service comprised of a CQC inspector, an assistant CQC inspector 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 two members of staff including administrative staff and a manager. We spoke with a consultant by telephone.

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 clear escalation pathway for a deteriorating patient which is tailored to the service.
- The service must have clear eligibility criteria which defines if patients are suitable for cosmetic surgery.
- All clinical staff must have up to date training in basic life support (BLS).
- All equipment must be serviced in accordance with servicing schedules and manufacturers' instructions, including resuscitation equipment.
- The service must have a tailored, documented pathway for patients' journeys through treatment including assessment, planning, implementation and review.
- The service must ensure medicines are stored safely.
- The service must ensure there is a system of medicines audit and stock control.
- The service must have clear policies relating to the management of clinical waste including medicines.
- The service must ensure sharps bins are signed and dated.
- The service must ensure safeguarding training is updated in accordance with intercollegiate guidance.
- The service must ensure all patients have full individual care records including risk assessments.
- The service must ensure patients records are always stored securely and accessible in the clinic.
- The service must ensure policies and procedures are tailored to the service being provided.
- The service must ensure cleaning schedules are in place and records of cleaning, including theatre deep cleans are kept.
- The service must ensure there is a waste disposal contract which includes arrangements for the disposal of medicines.
- The service must ensure copies of medicines order forms and patient prescriptions are kept.
- Staff must have full pre-employment checks, including references, photographic proof of identify and eligibility to work in the UK.
- The service must ensure all staff have a Disclosure and Barring Service (DBS) check.
- The service must ensure mandatory training schedules are in place, including frequency of training updates.
- The service must audit the use of the World Health Organization (WHO) 'Steps to Safer Surgery' checklist.
- The service must ensure risk assessments for the clinical areas of the service are robust and training relating to risk assessments are completed by staff.
- The service must ensure there are robust systems of clinical audit and risk management systems.

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 demonstrated a limited amount of training had been completed. We were not assured all staff received mandatory training in key skills.

At our last inspection on 3 December 2021 we asked to see mandatory training records for all staff. We were told these records were not available. During this inspection on 24 January 2022 we found the registered manager had completed the following training modules: anaphylaxis, 18 December 2021 valid for 12 months; health and safety, 18 and 19 December 2021, valid for 12 months, fire safety, 12 December 2021, COSHH, completed 19 December 2021. The registered manager had also completed safeguarding level 2 on the 18 and 19 December 2021.

We saw records that the coordinator had completed the following training modules: basic life support (BLS), completed on 21 January 2022; safeguarding level 2, completed on 21 January 2022; and infection prevention and control (IPC), completed on 22 January 2022. This training was either completed on or post-dated the day of the CQC informing the provider they would be re-inspecting the service on 21 January 2022.

We saw records the cosmetic surgeon had completed the following training modules: fire safety, valid to March 2022. However, other training modules records we saw for the cosmetic surgeon were not in date: moving and handling, valid until April 2020; IPC, valid to December 2021; resuscitation, level 1, BLS, valid to 1 April 2021, – safeguarding including children level 2, valid until April 2020; information governance, valid to March 2021. Hence, we were not assured that staff had up to date training in key skills. 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.

All staff had completed their online mandatory training modules with different online training providers. We requested records of health care assistant (HCA) training. Staff told us prior to the CQC suspending the service in December 2021 they had not provided any training for HCA staff as these staff were employed on zero hours contracts.

Staff showed us a list of proposed training. However, the service did not have a clearly documented plan of mandatory training modules staff should complete, which clearly defined the frequency of training refresher modules or updates. Furthermore, staff were unable to explain and did not have a written plan of how compliance with mandatory training would be monitored. We were therefore not assured that staff had up to date training in key skills.

During our previous inspection 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. During this inspection we found staff had completed some training as detailed above. However, this training had been completed with a variety of training providers. The service did not have a plan in place to ensure consistency of approach from one training provider for all staff regarding mandatory training.

Safeguarding

We were not assured staff had up to date training on how to recognise and report abuse.

During our previous inspection on 3 December 2021, we asked the service for evidence staff had completed safeguarding training. This was not provided to us. During our inspection on the 24 January 2022 we were shown a certificate confirming that the registered manager had completed level 3 safeguarding training in January 2018. However, this was not in accordance with the intercollegiate document 2019, 'Adult Safeguarding Roles and Competencies', which states safeguarding training should be updated every three years. There is a risk that patients will or may be exposed to harm if staff do not have up to date safeguarding training, as they may not have the most up to date knowledge to keep people safe.

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.

During our previous inspection on 3 December 2021 we found there was no procedure to label equipment to show when it had been cleaned. During our inspection on 24 January 2022, we found there was still no system to label clean equipment. 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. There was no plan in place to replace the carpeted areas with washable floor covering. 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 service had sourced an infection control policy, this was part of one policy document, which contained policies the service had sourced from another provider. Staff told us the policies were still being implemented and the intention was to upload the policy into an online drive. However, staff could not show us work which had been undertaken on the

online drive when this was requested. The infection prevention and control (IPC) policy stated the service should have an IPC lead. The IPC lead in the service was not identified in the policy document. Service users will or may be exposed to the risk of harm if there is not an identified IPC lead, as there may be no-one who has oversight over checks and audits to ensure that any risks identified are mitigated.

The service had a staff COVID-19 risk assessment as part of the new policy document but could not provide copies of completed risk assessments for staff when requested.

Staff showed us a copy of a COVID-19 screening form for patients. However, staff were unable to provide copies of any completed screening forms when requested.

We asked staff about the cleaning of equipment that was not single use. We were told there was an external contract for the cleaning of any reusable items, but this was a rare occurrence and only for liposuction probes. However, staff did not provide a copy of the contract or records of cleaning by the contractor, when this was requested.

Staff showed us a contract for a cleaning company and said this was going to be implemented when the service was operational again. Staff said the cleaning company had not previously provided cleaning services. Staff told us previously there had not been a formal cleaning contract in place. However, when we viewed the cleaning contract, we saw that it did not include a schedule of what cleaning tasks would be undertaken or frequency of cleaning tasks. This meant there were no agreed standards or expectations regarding cleanliness.

We asked staff how frequently a deep clean of theatres was completed. Staff told us theatre deep cleans took place every three months. We asked staff to describe what the deep clean covered, staff were unable to describe this. We asked to see records of theatre deep cleans and were told by staff the service did not keep records of theatre deep cleaning.

Environment and equipment

The service had completed a risk assessment of the facilities, premises and equipment. However, this was not robust, and staff had not completed the training associated with the risk assessment.

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

During our previous inspection 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. During this inspection we found some electrical equipment, including the electric treatment table, had now been electrical safety tested on 24 December 2021 and was next due for safety testing on 24 December 2022. However, during this inspection we further identified equipment that did not have up to date electrical safety testing or any planned maintenance including resuscitation equipment. For example, the testing of the defibrillator was out of date from 2019; there were out of date electrodes; and we saw emergency equipment that was not sealed in tamper proof containers. There was no documented record of regular checks on emergency equipment. We identified out of date cannulas, masks, sutures and giving sets, (these are single use devices for the infusion of intravenous (IV) medicines or blood products), in a trolley in the theatre. The wheelchair in the cosmetic surgery theatre did not have a visible service date. This was a risk to patients because if equipment is not serviced and regularly checked, it may not function effectively and safely when required.

The service was operating from leased premises. Maintenance and facilities management of communal areas was managed by the landlord. During our inspection on 3 December 2021 we found the provider had not completed risk assessments of the Harley Cosmetic Group clinical areas, in accordance with their tenancy agreement.

Inadequate

Surgery

During our inspection on 3 December 2021, we requested risk assessments for the clinical areas of the clinic and were told these did not exist. During our inspection on 24 January 2022, although a risk assessment had been completed, staff told us the training required to accompany the risk assessment had not been completed by any member of the staff group, even though we saw this was recorded on the risk assessment as having been completed.

During our previous inspection we saw an oxygen cylinder in the cosmetic theatre which was not secured. During this inspection the oxygen cylinders had been removed from the clinic. Staff told us these had been returned to the provider of the oxygen. Staff told us they would order new oxygen cylinders as required.

During our previous inspection on 3 December 2021 we asked the provider if they had completed control of substances hazardous to health (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. During our inspection on 24 January 2022 we saw COSHH risk assessments had been completed on 21 January 2022 for the use of Butane gas, oxygen, bleach, antibacterial hand gel, and dental tray adhesive. However, the risk assessments were not robust and did not identify that oxygen cylinders, both empty and full, should be secured with an insulated chain or non-conductive belt to protect cylinders from falling or becoming damaged, in accordance with guidance from the Health and Safety Executive.

During our inspection on 3 December 2021 we saw poor clinical waste management practices. During our inspection on 24 January 2022, although some issues with the management of clinical waste had been addressed, we saw further concerns, including a sharps bin which had not been signed. We asked staff if the service could show us a waste disposal contract which included arrangements for the disposal of medicines. The service told us there was a contract in place, but they could not locate it. We were shown a letter dated 17 January 2022 which indicated that the service had contacted the provider of waste disposal services. However, the letter did not provide information about what the waste disposal contract covered.

During the previous inspection on 3 December 2021 we saw there were no panic alarms installed in the cosmetic surgery theatre. During the inspection on 24 January 2022 we saw there were still no panic alarms installed in the 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.

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.

During our previous inspection on 3 December 2021 we found 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. 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. During the inspection on the 24 January 2022, we requested and were told there was no documented policy in place for a patient that deteriorated in the clinic. This meant staff would not know what process to follow in the event of a patient deteriorating in the clinic

During our previous inspection on 3 December 2021 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 (NEWS2) scoring to identify deteriorating patients or the World Health Organisation (WHO) safety checklist to prevent or avoid serious harm. During our inspection on 24 January 2022 staff told us the WHO

Inadequate

Surgery

'Steps to Safer Surgery' checklist was not being applied completely. When asked about a WHO checklist audit, staff told us the service did not complete WHO checklist audits and needed to "make improvements". If information from WHO checklist audits is not collated, this may impact on the delivery of safe care and treatment, as information from the audits cannot be used to improve the safety of procedures for patients.

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. Staff at the service told us they had emailed two NHS hospitals regarding a service level agreement. We asked staff to show us the emails on both the 3 December 2021 and the 24 January 2022, however these were not provided.

During our previous inspection on 3 December 2021, staff told us they had completed basic life support training. We requested these records during this inspection; however, these were not produced. During our inspection on 24 January 2022 we requested evidence of all staff having up to date basic life support (BLS) training. We found the cosmetic surgeon's BLS training had an expiry date of 1 April 2021 and was therefore out of date Service users may or will be at risk of harm if staff do not have up to date skills in providing basic life support to a deteriorating patient.

During our inspections on both the 3 December 2021 and 24 January 2022 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.

During our inspection on the 3 December 2021 we did not see a documented pathway for patients' journey through treatment including assessment, planning, implementation and review. During the inspection on 24 January 2022 we viewed a patient pathway document which had the name of a doctor that did not work for the service on the document. This meant the policy was not tailored to the service. We were not assured that the provider ensured procedures were tailored to the service and suitable for people receiving treatment.

During our inspection on 24 January 2022 we found there was a module on the service's mandatory training list referring to Sepsis awareness, (this is a life-threatening medical emergency, whereby an infection you already have triggers a chain reaction throughout your body) However, the service was unable to produce evidence of staff having completed this when training records were requested. In view of the type of regulated activity the service delivers, it is important for staff to be aware of Sepsis and how to identify the signs. Service users will or may be exposed to the risk of harm if staff do not recognize key signs of sepsis promptly.

Staffing

The service did not have procedures in place around managing, recording and monitoring the use of temporary staff to ensure all staff had the right skills, training and experience to keep patients safe from avoidable harm.

During an inspection on 3 December 2021 we were told 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. We also saw two health care assistants (HCA) working at the clinic. However, during the inspection on 24 January 2022 we were told the only people working for the service were the registered manager, co-ordinator and cosmetic surgeon, as all other staff had left the service.

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 coordinator told us they had recently been employed by the clinic, prior to this they told us they had been employed on a zero hours contract on a regular basis.

Staff told us the service intended to use agency staff going forwards. However, the service did not have procedures in place that would give assurance around managing, recording and monitoring the use of temporary staff. The service had not completed an assessment of the needs of the service regarding staffing skill mix for cosmetic procedures.

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.

The service failed to keep individual care records to keep patients safe. During our inspection on 3 December 2021, 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. During an inspection on 24 January 2022 we requested patient records and were not provided with evidence of full individual patient care records including risk assessments. We were told on both occasions that patient records were being held at a person's house who was not employed by the service and whose address the service did not have.

During the previous inspection we viewed a memory stick containing patient records, which we saw and viewed three partial patient records. However, during an inspection on 24 January 2022 staff told us the memory stick, was held at the coordinator's home. We were told the coordinators home was a two hour round trip from the clinic. Service users may be at risk of harm if a full patient record is not available in the clinic for staff to refer to in the event of a patient deteriorating or experiencing symptoms post-procedure. Staff told us they had contacted a storage facility with a view to storing records. 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".

Medicines

The service did not use systems and processes to safely administer, record and store medicines. We saw medicines which were not to be administered intravenously (IV) stored and mixed with other IV medicines in the same box

Staff did not store and manage all medicines safely. During our previous inspection on 3 December 2021 we saw medicines which were out of date stored in an unlocked theatre medicines fridge and unlocked medicines cupboards. We also saw medicines which were loose in the theatre medicines fridge and unlocked medicines cupboards, which did not have instructions on their use stored with the medicines. Although most of these issues had been addressed. During our inspection on 24 January 2022, we found further medicines issues. The service had allocated one cupboard which was

locked as a medicines' cupboard. However, we saw medicines, which were not to be administered intravenously (IV), stored and mixed with other IV medicines in the same box. This carried the risk that someone may use the incorrect medicine in error. For example, we saw an open box containing two ampules of intravenous antibiotics however the box also contained an ampule of an inhibitor and an ampule of a local anaesthetic. The local anaesthetic should not be given intravenously, whereas the other medicines in the box could be given in this way. There was a risk that staff may take the incorrect medicine in error and attempt to administer the non-IV medicines intravenously. Furthermore, there was only one set of literature for one of the medicines in the storage box, the intravenous antibiotic. This meant staff did not have access to information for the other two medicines stored in the box. Literature should always be kept with medicines in the box they are supplied in to ensure staff have instructions on how the medicine should be stored and administered. Failure to ensure may mean care and treatment is not delivered in a safe way.

During the inspection on 24 January 2022 we requested evidence of theatre records including medicines given during surgery. Staff told us these did not exist. The failure to keep a full record of medicines administered during procedures may prevent the delivery of safe care and treatment, in the event a patient has an adverse reaction or in the event of a patient requiring further medicines to avoid the risk of overdose.

During the inspection on 3 December 2021 we found errors in medicines order forms and order forms not stored securely. During our inspection on 24 January 2022 we asked if we could review copies of medicines order forms and were told by staff these were not available. We also requested copies of prescriptions issued by Harley Cosmetic Group. We were told these were not held by Harley Cosmetic Group and were kept in the cosmetic surgeon's briefcase. We were therefore not assured that the service had an effective system of oversight or governance systems regarding the ordering and prescribing of medicines.

During inspections on 24 January 2022 we asked to see records of medicines fridge temperature recording and were told by staff the service did not record fridge temperatures. This meant the service could not be assured that fridge temperatures were not fluctuating, and medicines were not being exposed to spoilage due to being stored at incorrect temperatures. This was a risk as medicines stored at the wrong temperature can degrade and be less effective if administered to patients.

Incidents

The service did not manage patient safety incidents well. Staff were not trained to recognise incidents and near misses. Staff had no knowledge or understanding of duty of candour.

During the inspection on the 24 January 2022 we identified a medicine for an injection stored in a cupboard in the theatre with other medicines. The patient's name on the label was a staff member. Staff told us this was an error by the pharmacy. However, staff could not produce evidence of having contacted the pharmacy regarding the error, or having recorded this as an incident, when requested. This did not ensure the service had effective oversight of medicines incidents.

Staff were not provided with training on duty of candour or the actions to take if an incident or near miss occurred. (This is a professional duty with the aim of ensuring that those providing care are open and transparent with the people using their services, whether something has gone wrong). Therefore, we could not be assured all incidents were reported and investigated in accordance with the duty of candour.

Inadequate

Surgery

During the inspection on the 24 January 2022, staff told us the service had not had any incidents in the previous 12 months. Staff showed us a new incident logbook and said this had been purchased since the previous inspection, on 3 December 2021. This meant staff did not have oversight over incidents and could not be assured incidents were monitored and themes identified to improve services.

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 record of policies being based on best practice.

During an inspection on 3 December 2021 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 and were not up to date. During an inspection on 24 January 2022, we saw the service had acquired a new set of policies. However, these were held in one policy document on a laptop, and there was no coherent filing or policy management system in place. We viewed the policies and found they were not tailored to the needs of the service. The policies did not refer to clinical best practice such as NICE or Royal College guidance. The provider did not have effective systems in place to maintain oversight of policies to ensure they reflected current best practice guidance, meaning staff may not have access to the most up to date guidance.

Pain relief

On the 24 January 2022 there were no procedures being performed due to CQC having suspended the provider's registration following an inspection on 3 December 2021. Hence, we could not observe patient procedures at this inspection. We requested but were not shown evidence of previous patient records prior to the suspension, where staff recorded the administration of local anaesthetic; detailing type, batch number, amount, expiry date and site of administration.

As staff told us full patient records were not available at the time of inspection, 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.

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.

During our inspections on 3 December 2021 and 24 January 2022 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 (Q-PROMS are 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.

Inadequate

Surgery

During our inspections on 3 December 2021 and 24 January 2022 staff 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.

Competent staff

The provider did not have effective systems in place to ensure all staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

During our previous inspection on 3 December 2021 we were told that staff did not have personnel files. During our previous inspection, we requested evidence of 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. At the time of this inspection the consultant told us they had a DBS check and they would forward this to the CQC the following week, however this was not received. During an inspection on 24 January 2022 staff showed us a DBS check had been undertaken for the consultant on 19 December 2021, this post-dated our inspection on 3 December 2021. We requested but were not provided with any previous DBS checks.

During an inspection on 24 January 2022 we asked to see a specific staff member's DBS check. The staff member told us they had applied for a DBS on 24 January 2022. We asked to see evidence of the DBS application however, staff could not provide evidence of the application having been submitted to the DBS when this was requested.

During an inspection on 24 January 2022 the service had introduced personnel files for the three members of staff working at the service. However, these did not include photographic ID evidence of right to work in the UK, interview notes, or 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 employment checks to ensure staff had the necessary qualifications and experience to carry out their role, or were safe to perform the regulated activity. Of the three staff working at the clinic, only the consultant's personnel file had a reference, this was dated 1 January 2022 and post-dated the previous inspection which took place on 3 December 2021.

During an inspection on 3 December 2021 staff told us recruitment processes were informal and based on an interview with either the lead cosmetic consultant or the lead dentist. During an inspection on 24 January 2022 staff told us the service's plan was to use agency staff going forward and they would rely on the agency to do pre-employment checks. Staff provided a copy of an agreement with an agency which had been signed on 3 December 2021. However, we asked staff to specify the skills that a nurse would require to work in the service and staff were unclear about the skills a nurse would require, such as a scrub nurse.

Evidence was not provided that would give assurance around managing, recording and monitoring temporary staff. The provider told us that the service did not keep any records that would allow identification of staff that had been involved in an individual patient care and treatment episode or records of who had worked on a day.

When asked how the provider accessed scrub nurses or operating department practitioners the provider told us they "were people they knew". There were no formal processes or records of temporary staff used of this type. There were no assurances around DBS, competency and mandatory training checks for these staff.

Inadequate

Surgery

During our previous inspection on 3 December 2021 we requested a contemporaneous record which identified any training needs staff had and gave staff the time and opportunity to develop their skills and knowledge, such as a staff training matrix. Staff told us this did not exist. During our inspection on 24 January 2022 we were shown a list of 16 training courses. Staff told us this was the intended list of courses staff would complete. However, none of the staff or registered manager had completed all the required training on the list. The registered manager had completed five of the 16 courses on the list between 12 December and 19 December 2021. The coordinator had completed three courses on the list between 21 January and 22 January 2022. The consultant had provided the service with evidence of six training courses, five of these were past their expiry date. The five out of date courses were dated between April 2020 and March 2021.

The consultant surgeon and the dentist were registered with their appropriate professional body. For example, General Medical Council (GMC) and General Dental Council (GDC). During our inspection on 24 January 2022 we asked staff for the details of the anaesthetist's registration. Staff told us they had this however, this was not provided for inspectors.

During our previous inspection 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. During this inspection we were shown practising privileges for the consultant, dated 9 December 2021, this post-dated the previous inspection on 3 December 2021. During our inspection on 24 January 2022, we asked to see practising privileges for the anaesthetist that provided services at the clinic. We were told the anaesthetist did not have practising privileges. This was a risk to patients because the service could not ensure they had oversight of the range of procedures the anaesthetist was competent to perform.

Multidisciplinary working

Staff worked together as a team.

Staff told us there were positive working relationships between staff at the service due to a small team of three, a coordinator, dentist and cosmetic surgeon.

During our previous inspection on 3 December 2021 staff told us 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 or a service level agreement for the referral of patients requiring general anaesthesia. During our inspection on the 24 January 2022 staff told us Harley Cosmetic Group did not have an agreement or relationship with the independent provider of general anaesthetic services. We were told the relationship for provision of general anaesthesia was between the cosmetic surgeon and the independent provider.

Seven-day services

At the time of inspection, no services were being provided at the clinic as a result of the services CQC registration being suspended following a previous inspection on 3 December 2021. 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.

Inadequate

Surgery

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

During our previous inspection on 3 December 2021 we viewed three patient records where staff gained consent from patients for their care and treatment. In the three pre procedure documents we viewed we saw 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. During our inspection on 24 January 2022, staff told us there were no patient consent forms on-site, when these were requested. Staff told us that patients had an initial online consultation, and if the patient wanted to proceed, they would have a face to face appointment with 14 days to decide/confirm if they wished to proceed. When asked if this was audited to ensure compliance, we were told this was not audited and no records of consent, initial assessment, planning, treatment and review were available to review on the day of inspection. Consent for surgical procedures is an essential part of the patient's pathway. The service could not be assured that the audit cycle ensured monitoring, assessment and improvements in clinical practice to ensure the delivery of safe care and treatment.

During our inspection on 24 January 2022 staff showed us a copy of a policy relating to the Mental Capacity Act, 2005 (MCA). The policy was out of date in 2021. 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 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. During our previous inspection on 3 December 2021 the registered manager told us the service was split into cosmetic surgery services and dental services and the cosmetic surgery services were overseen by the cosmetic consultant. The dental service was overseen by the dentist. However, during this inspection we were informed that the same cosmetic consultant we interviewed at our last inspection was an independent practitioner and was not involved in the management of the service. Staff told us all patients were self-referred via a referral website. There was 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. Staff 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.

Meeting people's individual needs

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

Inadequate

Surgery

During our previous inspection on 3 December 2021 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. During our inspection on 24 January 2022 staff told us the clinic would not provide treatments to people with mental health needs, learning disabilities or dementia. However, there was no formal procedure in place.

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

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.

Access and flow

People could access the service when they needed it and received care and treatment promptly. However, there was no record of how many patients were seen annually.

At the time of our inspection on 24 January 2022 the service was not providing services. This was as a result of CQC suspending the service following and inspection on 3 January 2021. 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.

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.

We asked staff how many patients were seen annually for cosmetic services at the clinic. Staff initially told us they saw between 60 and 70 patients a year. However, in a later interview during the inspection staff told us they had seen approximately 40 people in the previous 12 months. The service told us they did not collate information on numbers of patients seen annually. This meant the service could not plan services based upon the numbers of patients, to ensure there were enough staff and equipment to ensure the delivery of responsive care for patients.

During our inspection on 3 December 2021 staff told us 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. Staff told us Harley Cosmetic Group paid the independent provider to do procedures requiring general anaesthesia on behalf of Harley Cosmetic Group. However, during our inspection on 24 January 2022 staff told us Harley Cosmetic Group did not have a relationship with the independent provider of surgical procedures. Staff told us the consultant was an independent doctor and they had a relationship with the independent provider. The consultant would arrange for patients requiring general anaesthesia to have procedures with another provider where the consultant had practising privileges.

During inspections on 3 December 2021 and 24 January 2022 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.

Learning from complaints and concerns

Inadequate

Surgery

There was no evidence the service treated concerns and complaints seriously. It had limited knowledge of how to investigate them.

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. Staff told us they had not had any complaints in the 12 months prior to inspection.

Staff told us Harley Cosmetic Group did not gather patient feedback. This meant the service could 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 was also the CQC nominated individual and lead dentist at Harley Cosmetic Group. During a previous inspection on 3 December 2021, 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.

During our previous inspection on 3 December 2021 the registered manager said he had limited knowledge of the cosmetic side of the service, as this was overseen by the cosmetic consultant. During our follow up inspection on 24 January 2022 the registered manager told us the cosmetic consultant did not manage the cosmetic service and provided procedures on an as required basis at the clinic. However, the registered manager was still not able to demonstrate knowledge regarding the management and oversight of the cosmetic service.

During our previous inspection on 3 December 2021 the registered manager and cosmetic consultant had 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. However, during our inspection on 24 January 2022 the registered manager told us the cosmetic surgeon worked on an ad hoc basis as an independent doctor and was not involved in the management of the service.

Vision and Strategy

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

Inadequate

Surgery

During our previous inspection on 3 December 2021 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. Staff also told us during this inspection they did not have service level agreements for the provision of surgical procedures and general anaesthetic services by an independent provider in Harley Street, London. During our inspection on 24 January 2022 staff confirmed Harley Cosmetic Group did not have any relationship with the independent provider of general anaesthetic services. We were told the cosmetic surgeon had practising privileges with the independent provider and the relationship was between the independent provider and the cosmetic surgeon, not Harley Cosmetic Group. 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 in the clinic 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.

During inspections on both the 3 December 2021 and 24 January 2022 we found 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.

During our previous inspection on 3 December 2021 staff told us 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. During our inspection on 24 January 2022 we requested copies of a risk register and medical advisory committee (MAC) meeting minutes. The registered manager forwarded us copies of a risk register and MAC meeting agendas, without minutes. These documents were not robust in identifying risks to patients, for example, the risk register did not identify issues regarding medicines management, WHO checklist, and risk from out of date equipment servicing.

During our previous inspection on 3 December 2021 it was unclear who the governance and risk lead were for cosmetic services. The registered manager told us the cosmetic consultant was responsible for oversight of the cosmetic clinic's governance and risk management processes. However, during our follow up inspection on 24 January 2022 the registered manager told us the cosmetic surgeon was not involved in the management of the service and worked as an independent doctor. Therefore, we were not assured that the provider had robust governance processes with full oversight of risks, issues and performance regarding the provision of cosmetic surgery.

During our previous inspection on 3 December 2021 we found 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. During our inspection on 24 January 2022 we requested at the time of inspection evidence of a business continuity plan, but this was not provided.

Inadequate

Surgery

Information Management

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, during inspections on 3 December 2021 and 24 January 2022 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 these inspection as the records were at a person's home, as they were being digitised. Staff also told us a USB stick containing patient information was being held at the coordinators home, which staff said was a two hour round trip from the clinic. This meant the service did not ensure patient confidentiality and confidential data was protected in accordance with the General Data Protection Regulations (GDPR).

During our inspection on 3 December 2021 and follow up inspection on 24 January 2022 staff told us the service did not collect data via audit. This meant the service could not use audit information to determine if the clinic's 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.

During our inspection on 3 December 2021 and follow up inspection on 24 January 2022 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.

During our follow up inspection on 24 January 2022 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

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Surgical procedures Treatment of disease, disorder or injury Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance S31 Urgent Suspension S17 (1) c Cancel Registration 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, including robust audits and assessment of risk. • 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. • The service did not ensure policies were tailored to the needs of the service

Regulated activity	Regulation
Treatment of disease, disorder or injury Surgical procedures Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

This section is primarily information for the provider

Enforcement actions

S31 Urgent Suspension

S17 (1) c Cancel Registration

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: (a)assessing the risks to the health and safety of service users of receiving the care or treatment;

- The service did not ensure there was a clear policy on the management of deteriorating patients and 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
- The service did not have eligibility criteria which defined if patients were suitable for treatment.
- The service did not have a tailored documented pathway for patients' journeys through treatment including assessment, planning, implementation and review.

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 up to date basic life support training
- The service did not ensure there was a programme of mandatory training, including frequency and refresher training, and all staff were up to date with it.
- The service did not ensure all staff had up to date safeguarding training in accordance with intercollegiate guidance.
- The service did not ensure anaesthetists had documented practising privileges; to ensure the service had oversight of the range of procedures the anaesthetist was competent to perform
- The service did not ensure all staff had full pre-employment checks, including Disclosure and Barring Service (DBS) checks.

Regulation 12 (1) Care and treatment must be provided in a safe way for service users (2) Without limiting paragraph

This section is primarily information for the provider

Enforcement actions

(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 resuscitation equipment received regular safety testing and there was a documented schedule for testing resuscitation equipment
- The service did not have a documented schedule of equipment cleaning in place.
- The service did not ensure all cleaned equipment was clearly labelled to show it was clean and ready for use.
- The service did not ensure sharps bins were signed and dated.

Regulation 12 HSCA (RA) 2014 Proper and safe management of medicines. 12 (2) (g) the proper and safe management of medicines;

- The service did not ensure med**ic**ines were stored safely in their own boxes and with instruction on their use.
- The service did not ensure there was an effective system of stock control and audit for medicines.
- The service did not ensure there were clear procedures relating to the management of clinical waste including medicines.
- The service did not ensure there were systems in place to review medicines order forms and copies of patient prescriptions.