Regency International Clinic Ltd

Regency Clinic - City of London

Inspection report

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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?	Requires Improvement
Are services caring?	Insufficient evidence to rate
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this location went down. We rated it as inadequate because:

- The service could not provide evidence to show that weekly checks were completed for the resuscitation equipment and the automated external defibrillator and there was no checklist of what should be checked.
- The suitcase containing resuscitation equipment was not fit for purpose as the foam padding and fabric had perished which produced a fine dust that contaminated the equipment.
- The deteriorating patient policy did not have clear guidance of what staff should do in the absence of a healthcare professional and there was no service level agreement with the nearby NHS hospital should a patient need to be transferred.
- The service did not have a clinician with advanced life support (ALS) training at the time of the inspection.
- The service did not have a backup generator in event of the loss of power to both lighting and equipment used during procedures.
- The service had excessive storage located between theatres and the recovery area which had evidence of dust collecting in some areas and presented a potential fire hazard and healthy and safety risk.
- The service did not securely store oxygen cylinders both in the recovery room and theatre.
- The service did not have a process to identify medicines that could be affected by safety alerts.
- The service did not complete prescription audits to ascertain if they were completed in full and appropriately.
- Although the service had updated policies to ensure they were in date, we found there were no clinical guidelines based on national guidance and evidence-based practice for the procedures provided.
- The service failed to show evidence on how it monitored performance using appropriate data in order to make improvements for service users.
- Although staff told us they assessed patients' pain levels, we did not see any evidence of pain assessments using recognised pain tools in patient records and the clinic did not have a pain management policy in place.
- Although the service had an audit schedule, it had not been fully embedded at the time of the inspection. Some audits were not comprehensive as they did not include the expected criteria which meant the service did not monitor the effectiveness of care and treatment appropriately to make improvements and ensure good outcomes for patients.
- The service offered limited adjustments which took into account of patients' individual needs and preferences.
- Although leaders were visible and approachable in the service for patients and staff, they did not understand and manage the priorities and issues the service faced.
- The service did not have a documented vision, set of values, or strategy, developed with all relevant stakeholders.
- Although the service has made some improvements in their governance processes since the last inspection, further improvement was still required to ensure there was effective oversight and assurance for these processes.
- The service did not have an adequate process to identify risks and issues or identify actions to reduce their impact. This included plans to cope with unexpected events.
- The service did not have a fully completed risk register and gaps identified included risk owner, date of review and expected date of completion. None of the risks identified during the inspection were listed on the risk register.
- The clinic's website and patient information leaflets had not been updated to reflect the services provided.

However:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse.

Summary of findings

- Staff kept detailed records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.
- Staff knew what incidents to report and how to report them. Most staff had knowledge or understanding of duty of candour.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance to provide support and development.
- Although we were not able to speak with any patients, patient feedback showed that staff treated patients with compassion and kindness.
- Staff felt respected, supported and valued.
- Leaders and staff engaged with patients and staff.

Although the service had made improvements to address the Warning Notice for Regulation 17 and the Requirement Notices for Regulations 12 and 13 from the previous inspection, we still found several areas of concerns within Regulation 12 and 17.

Following this inspection in February 2022, the provider was rated inadequate and the concerns identified resulted in urgent suspension of all regulated activities imposed for a period of eight weeks through a Section 31 Notice of Decision. Details are at the end of the report.

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

Victoria Vallance

Director of Secondary and Specialist Healthcare

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Inadequate 	Surgery was the main activity at this service. Our rating of this location went down. We rated it as inadequate. See the overall summary for details.

Summary of findings

Contents

Summary of this inspection

Background to Regency Clinic - City of London

Regency Clinic – City of London is operated by Regency International Clinic Ltd. The service opened in September 2013, having previously offered services under a different owner and in a different location. It is a private clinic in London. The clinic offers services on self-referral or referral from other private clinics.

The clinic has a registered manager in post. A registered manager is a person who has registered with the CQC to manage the service. 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 main service provided is surgery. All surgical procedures are carried out on a day case basis. The clinic has an operating theatre that is also used for diagnostic imaging and a recovery area with two beds for day case patients.

The service offers gynaecology services and day case operations such as female genital surgery, Trans-cervical Fallopian Tube Unblocking , colposcopy, hysteroscopy and diagnostic ultrasound. As of October 2021, the service no longer provides Hymenoplasty surgery.

Between February 2021 and January 2022, the breakdown of clinic activity was:

- Hysterosalpingography (HSG) – 30
- selective salpingography and tubal catheterisation (SSTC) – 26
- Vaginal wall surgery – 30
- Labioplasty – 1
- Consultations – 77
- Diagnostic ultrasound – 21

Track record on safety for the last 12 months:

- No never events
- No clinical incidents
- No serious injuries
- No incidences of clinic acquired Meticillin-resistant Staphylococcus aureus (MRSA),
- No incidences of clinic acquired Meticillin-sensitive staphylococcus aureus (MSSA),
- No incidences of clinic acquired Clostridium difficile (c. diff)
- No incidences of clinic acquired E-Coli.
- No complaints.

The service was inspected in August 2021 to follow up on a requirement notice issued in the February 2018 inspection. Following the inspection in August 2021, the provider was rated inadequate and other concerns identified resulted in urgent suspension of all regulated activities imposed through a Section 31 Notice of Decision.

We inspected the service in October 2021 to follow up on the concerns from the previous inspection and with an initial review of the evidence supplied, the decision was made to remove the urgent suspension of all regulated activities on 15 October 2021. However, some concerns remained with the governance of the service resulting in a Warning Notice for Regulation 17 and Requirement Notices for Regulations 12 and 13. As the service was unable to demonstrate the embedment of elements of the action plan while the service had been suspended, it was agreed to seek continued assurance through enhanced engagement with weekly submissions of the following:

Summary of this inspection

- Evidence of completed World Health Organisation checklists for all surgery procedures and evidence this is being audited.
- Evidence of completed audits including but not limited to the Infection Prevention and Control audit.
- Evidence of regular staff meetings with clinical staff.
- Evidence of regular meetings with the services Radiation Protection Adviser.
- Evidence of two stage consent being obtained with a 14-day cooling off period for all service users undergoing cosmetic surgery.

This inspection was a comprehensive inspection of the service which included a follow up on the warning notice and requirement notices issued in the October 2021 inspection.

How we carried out this inspection

We reviewed documents that related to the running of the service including policies, equipment checks, meeting minutes, eight patient records, staff training records, results of surveys, audits and patient feedback.

We interviewed all staff members including management team, administrative staff and the regular bank nurse and locum radiographer. We visited all clinical areas of the service.

We carried out the short notice announced inspection on 23 February 2022. We were not able to speak with patients as there were no appointments/day cases scheduled for that day, but we were able to review patient feedback information.

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.

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 that the resuscitation equipment including the suitcase in which it is stored, is fit for purpose and that none of the equipment is contaminated.
- The service must ensure that the resuscitation equipment and the automated external defibrillator is checked weekly against a checklist with evidence to confirm this has been completed and by whom.
- The service must have clear guidance stated in the deteriorating patient policy on the escalation pathway in absence of a healthcare professional.
- The service must ensure they have the necessary service level agreements with the nearby NHS hospital to transfer a deteriorating patient without delay.
- The service must have a clinician who has completed advanced life support (ALS) training.
- The service must have a backup generator in event of the loss of power to both lighting and equipment used during procedures.
- The service must address the excessive storage area located between theatres and the recovery area.

Summary of this inspection

- The service must securely store oxygen cylinders in line with national guidance and this should be detailed in the medicines policy.
- The service must have clinical guidelines or standard operating procedures based on national guidance and evidence-based practice for the procedures provided.
- The service must monitor performance using appropriate data in order to make improvements for service users.
- The service must assess pain using recognised pain tools and ensure this is documented in a pain management policy and in patient records.
- The service must be able to demonstrate due diligence in antimicrobial stewardship.
- The service must have information on the patient eligibility criteria detailed in a policy.
- The service must ensure that the criteria for the audits completed are appropriate and comprehensive in order to obtain useful patient outcome data to make improvements.
- The service must ensure the website and clinic leaflets are updated to ensure information, such as services provided, is up to date.
- The service must continue to embed and strengthen governance processes in order to have better oversight and assurance of the service.
- The service must ensure the risk register is completed fully and that there is an adequate process in place to identify risks and issues including any unexpected events.

Action the service SHOULD take to improve:

- The service should continue to ensure that infection control checklists and WHO checklists are completed in full.
- The service should record patient's medications clearly in records to allow an audit trail.
- The service should have a process to identify medicines that could be affected by safety alerts.
- The service should have mechanisms to ensure appropriate management of medicines.
- The service should consider how it offers more adjustments to consider patients' individual needs and preferences.
- The service should amend the complaints policy and patient information leaflet to ensure that the CQC's remit is not misrepresented.
- The service should ensure cleaning logs are displayed in the correct areas and that they are completed consistently.
- The service should identify clean equipment using dated 'I am clean labels' so that it is clear when equipment was last cleaned.
- The service should have a documented vision, set of values, or strategy, developed with all relevant stakeholders.

Our findings

Overview of ratings

Our ratings for this location are:

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

Inadequate

Surgery

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

Are Surgery safe?

Inadequate

Our rating of safe went down. We rated it as inadequate.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. The training was delivered via an e-learning platform and some modules were face to face. The service had three permanent non-clinical staff members (business manager and two marketing administrators) and one permanent clinical staff (lead consultant). One of the administrators was on long term sick leave. The service used a regular bank nurse and locum radiographer. Staff told us they had protected time to complete their training.

Following our last inspection in October 2021, the service had introduced systems to monitor mandatory training accurately and alert staff when they needed to update their training. We reviewed the training matrix that identified what training staff had to complete and how often this needed to be completed. Managers told us they monitored mandatory training and alerted staff when they needed to update their training.

We reviewed the mandatory training records for all permanent staff and for the regular bank nurse and locum radiographer and found that all staff had up-to-date training.

Safeguarding

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff knew how to identify adults and children at risk of, or suffering, significant harm. Staff had completed training on Female genital mutilation (FGM) as stated in the clinical staff governance meeting minutes for November 2021 and demonstrated awareness. The lead consultant had undertaken an accredited course in difficult conversations to facilitate sensitive discussions around abuse with service users when required.

Staff had access to the service's safeguarding policy as a hard copy in the policy folder or online on the service's computer system. On our last inspection, we found that the policy contained links to national guidance in the safeguarding policy that no longer existed despite the policy being updated in August 2021. On this inspection, we found the service had addressed this and the links had been updated. Although the policy did not list the contact details for the local authorities, the staff induction documentation listed the names and contact details of who to call.

The lead consultant was the safeguarding lead for the service. We reviewed the safeguarding training for the lead consultant and bank radiographer and found this was in date. The lead consultant had completed Level 3 for both Safeguarding Adults and Safeguarding Children's whilst the bank radiographer had completed Safeguarding Adults Level 2. We reviewed the safeguarding training for the bank nurse and found they had completed Safeguarding Adults Level 2 and Safeguarding Adults Level 3.

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.

The clinic had an infection prevention and control (IPC) policy and Covid19 standard operating procedure which was in date. As part of Covid19 measures, we saw the main desk had perspex screens, stickers on the floor to indicate social distancing and posters asking patients to wear masks. There were no treatments taking place during our inspection which meant we were unable to observe or assess staff infection control and hand hygiene practice.

Hand gel was available in reception and in each clinical area. There were signs at the entrance to encourage patients and visitors to use the hand gel. The service had personal protective equipment (PPE), including aprons and gloves available and these were seen in the clinic and theatre areas.

Although antibacterial soap was available at all nine sinks, we found seven sinks had no handwashing guidelines displayed. We saw that the disabled toilet displayed handwashing guidance and the sink in theatres displayed the surgical scrub technique guidance. We raised this with the registered manager who addressed this immediately and we saw evidence of handwashing guidance at all the sinks before leaving the site.

Although the service was visibly clean, we found the cleaning logs displayed were not for the correct area. For example, the recovery area displayed the cleaning log for the medical director's room (clinic room) with dates from 2020 and behind this paper, there was a cleaning log for the toilet dated 2019. We raised this with the lead consultant who was not able to show us any evidence that a cleaning log had been completed for the recovery area. Staff told us they had an external domestic cleaning company who came weekly and if there had been a procedure on Saturday, they would also come on Monday.

The clinic did not identify clean equipment using dated 'I am clean labels' which meant it wasn't clear when equipment was last cleaned. For example, we did not see 'I am clean labels' on equipment in theatre including the trolleys used to hold equipment and on the weighing scales in the recovery room. The cleaning log only included the date of cleaning and a tick box which meant it was not clear what had been cleaned.

The recovery room had leather chairs and leather foot stools with visible seams which may be hard to clean. This was not compliant with the Department of Health (DH) Health Building Notes (HBN) 00-09 which states "Soft furnishings (for example, seating) used within all patient areas should be chosen for ease of cleaning and compatibility with detergents and disinfectants. They should be covered in a material that is impermeable, preferably seam-free or heat-sealed."

The pre-assessment and recovery room had disposable curtains, and all except one were dated 12 February 2022. There was one curtain in recovery which did not have a date on. Staff told us that all disposal curtains were changed every six months and showed us records for this.

The linen room was well stocked with individually wrapped scrubs. The staff changing room had a small shower, toilets and staff lockers. The tile grouting around the shower and toilet was not clean and we could not see the cleaning log for the staff changing room. The staff changing room was small which meant it would not be able to socially distance in this room and there was no signage indicating how many people could be in the room at a time.

The clinic had three toilets on site of which one was a disabled toilet. All the toilets were generally clean and had an emergency pull cord available.

The service submitted completed infection prevention and control (IPC) checklists as part of enhanced monitoring with CQC. We reviewed checklists submitted between 18 October 2021 and 18 February 2022 and found they had been completed fully. The checklist included 20 check points for infection control and health and safety. Infection control checks covered cleanliness of all areas, availability of hand soaps, hand gels and hand drying equipment, bed curtains, medical equipment, PPE stock, emergency equipment and medicines and water supply. Where issues were identified, staff took the appropriate action to ensure it was resolved. For example, the checklist for 20 October 2021 indicated that the light in middle toilet was not working and the staff member escalated this to the business manager. This issue was resolved on 29 October 2021, and we saw this was noted in the documentation. However, it wasn't clear what was included in the emergency equipment/medicines check as we were told this was done by the lead consultant who was the only permanent clinical staff. Most of the IPC checklists were completed by non-clinical administration staff. The clinic's audit schedule showed that the annual IPC audit was due later in the year in November 2022.

There had been no surgical site infections reported in the last 12 months.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe.

The clinic had partitioned an area for storage which was located between the theatre and the recovery area. The area had a disposable curtain to obscure it from view when going past the corridor however this was an IPC risk as patients would need to travel from the theatre past this area in order to get to the recovery room. Items stored in this area included unused equipment (hysteroscopy set, scanner), a medical bed, electrical equipment and cables, paperwork and boxes. Items were piled up high and all over the floor with visible dust on a lot of the equipment. The piles of boxes posed a fire risk and a health and safety risk if the boxes fell on staff members who were going in the area. A delivery arrived during the inspection which was then put into this storage area by the business manager and administration staff. This meant that there was a mixture of things that were being used and items that were not being used stored in the same area.

We raised this with the lead consultant who initially told us that equipment had been decommissioned and that this area would be reviewed as part of the reconfiguration of the service. However, there was no evidence to show that any of the extra equipment had been decommissioned which meant the space was not being used effectively and there was a risk that equipment that was supposed to be decommissioned could be mistakenly used.

There was a maintenance schedule for the Xray machine which had been completed on 28 July 2021 by an external contractor where all 42 criteria checks had been passed. Staff told us that the ultrasound machine had also been checked and the next review was due on May 2022. An external company had completed portable appliance testing (PAT) on August 2021 and we saw evidence of this on equipment such as the weighing scales.

However, we did not see evidence of the weekly checks on the resuscitation equipment and the automated external defibrillator. The lead consultant told us both checks were done weekly but there was no evidence to confirm this. Both equipment items did not have an inventory log, nor a weekly checklist which meant it would not be possible to determine if anything was missing. We found the suitcase containing resuscitation equipment including emergency drugs (adrenaline) was not fit for purpose.

The foam padding and fabric had perished which produced a fine dust that covered the equipment. We found not all the equipment had been packaged which meant dust could be seen within the tubing of the resus bag. We also found an intersurgical guedal airway tube where the packaging had been broken. There were various tubes which were unwrapped and covered in the dust from the fabric. This meant the equipment was not clean, had been contaminated and posed a risk to patients if they were used. There was no paediatric mask available which we raised with the lead consultant. We were told the adult pocket mask could be inverted for use on infants. Although this was mentioned in the Resuscitation policy, the guidance was not clear as the policy also mentioned having clear face masks (in sizes 0,1,2,3,4). The policy also mentioned intravenous fluids but there were no visible fluid bags present.

The resus suitcase was opened by a key which was attached to the handle. This meant that it was easy for the suitcase to be taken and tampered with. The resus suitcase was kept in the medical director's room by the door which was quite a distance from theatre. The lead consultant told us they would move the equipment closer to the theatres when procedures were booked.

The clinic had safe arrangements for the handling, storage and disposal of clinical waste, including sharps bins in accordance with HTM 07/01 The Safe Management of Healthcare Waste 2013. Staff disposed of clinical waste safely and we found the clinical waste bin was not overfilled and labelled clearly. The clinic had contracted an external company for waste management. Staff managed sharps in line with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. This included the storage, labelling and disposal of sharps. We saw sharps bins were securely kept and not full.

The clinic used single use instruments and staff told us that labels for single use instruments such as catheters were kept for patient records. We were told that the clinic outsourced sterilisation for non-disposable instruments.

The service was compliant with the Control of Substances Hazardous to Health Regulations (COSHH) (2002). This included the safe storage, use and disposal of controlled chemicals. The clinic had three fire extinguishers all of which were in date with their service checks.

The theatre was also used to conduct diagnostic assessments. This meant that the Xray machine was within the theatre room along with the Xray aprons. This cluttered the theatre area and posed an infection control risk. The lead consultant told us that the Xray aprons were not moved even when procedures were carried out. There was another storage area adjacent to theatre which was organised and had a checklist for the theatre equipment stored there.

There was a radiation warning notice in place outside of the surgical theatre when diagnostic imaging took place and the clinic had recently installed a lock behind the door which was used to prevent entry when in use. The service had suitable equipment to help them to monitor staff radiation exposure. The service contracted an external provider for a dosimetry service. The contractor provided dosimetry badges every six months and provided reports on the dosimeters collected. Managers told us the last report showed the doses were very low. The service had replaced the radiation badges in September 2021.

The clinic had a reception area with four chairs in the waiting area and a small kitchenette for staff to make drinks. There was a big sign about the services offered by the clinic which included private GP services which was no longer offered. This was later removed during the inspection.

Assessing and responding to patient risk

Although staff completed most risk assessments for each patient, staff did not use a nationally recognised tool to identify deteriorating patients. The service did not have service level agreements in place to transfer of patients at risk of deterioration to the nearby NHS hospital.

The lead consultant carried out a pre-assessment for each patient to ensure surgery would be appropriate. The service provided day case operations under local anaesthetic. The lead consultant confirmed that no sedation or general anaesthetic was used. Although staff completed risk assessments such as Venous thromboembolism (VTE), we found there was no sexually transmitted diseases (STD) or chlamydia screen before Selective Salpingography and Tubal Catheterisation (SSTC) procedures. Staff did not use a nationally recognised tool to identify deteriorating patients to escalate them appropriately. However, we saw evidence that sepsis training had been completed for all staff (including permanent and bank/locum) on 20 February 2022.

The lead consultant and locum radiographer had completed training on Resuscitation: Adult Basic Life support including safe use of automated external defibrillator (AEDs). The lead consultant had also completed training on Paediatric basic life support. All of the training reviewed was in date. However, the lead consultant was yet to complete advanced life support (ALS) which was booked for 4 March 2022. Non-clinical staff had completed training for First Aid in the workplace which was in date. Administration staff had completed Resuscitation: Adult Basic Life Support - including safe use of AEDs which was in date.

Although the service had a Deteriorating Service user – Policy and Procedure Version 2.00, there was no clear guidance or instruction for staff to follow especially given there was no service level agreement with the nearby NHS hospital to transfer patients. The consultant told us they would call the on-call gynaecology team but there were no contact details for this team in the policy or details of the agreement with the team. The policy also did not include any guidance on what to do if a clinical professional was not on site.

The service did not have an emergency backup generator in the event of a power cut. The service had an emergency and business continuity plan which was in date. Although the policy acknowledged the impact of a power cut on the service, it did not mention the impact on diagnostic equipment. The policy also stated that if the power failed, all patient activity would be cancelled until the power was restored, except for matters of immediate clinical urgency. However, the policy didn't state what should happen in matters of immediate clinical urgency.

The service was compliant with the 5 steps to safer surgery, World Health Organisation (WHO) surgical checklist. The service had embedded a modified version of the WHO surgical checklist for surgery and radiological interventions. We reviewed completed WHO checklists between October 2021 and February 2022 and found they had been completed appropriately.

Staff assessed risks to patients and had aligned procedures to act on them including consistent use of the 10-day pregnancy rule. The document entitled Rules for image guided procedures used the 10-day pregnancy rule aligned with the procedures for the Xray imaging document which also used the 10-day pregnancy rule; therefore, there was consistency. The preassessment questionnaire included a question on pregnancy status. Patient information leaflets had been updated to highlight the importance of notifying the service if they could be pregnant. From the patient records we reviewed, we found that seven out of eight recorded pregnancy status.

Inadequate

Surgery

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) and the British Association of Day Surgery (BADS) guidelines state that patients should have access to a 24-hour helpline after discharge. Although the lead consultant told us there was a 24 hour telephone number which was manned by the lead consultant and business manager, it was not clear what would happen if the lead consultant was not available.

All staff were trained to act as chaperones and had an up to date disclosure and barring service certificate (DBS) to be able to do so. The service had a system that reviewed DBS checks annually for staff.

The locum radiographer and administrative staff signed and completed the mandatory radiation dose list at the end of the procedure day. Administrative staff had the responsibility to double check this and ensure completion. We saw evidence of the completed logs which were signed and stored in a file in the reception area.

We requested the clinic's audit for the radiation dose list, and this was not provided. We received the radiation doses for procedures between November 2021 and January 2022 with a narrative from the Medical Physics Expert (MPE). The narrative stated that although the machine displayed accumulated doses which can make comparison of patient doses difficult, the screening times for HSG were very short in comparison to national averages indicating evidence of good practice. However, the national average figure was not included in the narrative.

The service completed audits of fallopian tube catheter kits to show evidence of tracing specific disposable items in event of complication. We reviewed the audit results for the period between October 2021 to January 2022 where six fallopian tube catheter kits were used. The results showed that all patients who had undergone Selective Salpingography and Tubal Catheterisation (SSTC) or Transcervical Tubal Catheterisation (TCTC) had catheter kit stickers attached to either the nurse observations forms or the procedure notes in their records. This ensured the service could effectively trace catheter kits in the event of complication. The lead consultant told us the audit would be repeated annually in addition to spot checks taking place quarterly.

Nurse staffing

The service ensured there was enough nursing and support staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm. Managers ensured bank and agency staff completed a full induction.

Permanent staffing included one lead consultant (who was also the registered manager), business manager, two administrators of which one was on long term sick leave. The clinic had used an agency staff member to replace an administration staff member who had recently left. The service had one permanent clinical staff who was the lead consultant.

The service relied on bank and agency nurses to deliver services. Although the service did not have any permanent nursing staff, managers told us they only used one regular bank nurse.

Managers had created an induction checking process for new starters including permanent, bank and agency staff. At the end of the induction, staff would complete a declaration sheet to confirm they had read and were working in line with local guidance and policies. We reviewed the induction paperwork for the regular bank nurse and found it had been completed in full and signed.

We requested the sickness rate for the last six months and received a breakdown by each staff member and not an overall percentage. One staff member had been on long term sick since August 2021. Staff turnover (which included both clinical and not clinical) in the last six months was 25%.

Inadequate

Surgery

The business manager worked part time and supported administration staff on reception and managed annual leave, appraisals for non-clinical staff, mandatory training for non-clinical staff and complaints.

Medical staffing

The service ensured there was enough medical staff with the right qualifications, skills and experience to keep patients safe to provide the right care and treatment on procedure days.

The service had one permanent clinical member of staff, who was the medical director and owner, and was a gynaecologist and lead consultant. The clinical staff who worked at the clinic were the bank nurse and locum radiographer and this was on days of procedures only (Saturdays). However, the lead consultant told us they also worked bank shifts in another service which was not close to Regency Clinic. This meant that there were times when no clinical staff would be on site. Although procedures were booked for Saturdays, it was not clear who would be able to help any patients who might have a complication and arrive on site after a procedure, in the clinician's absence.

Managers could access locums when they needed additional medical staff. Managers had taken steps to make sure locums had a full induction to the service before they started work. A formal induction process for temporary or permanent staff at the service had been created and management had created a declaration sheet signed by staff to assure themselves that staff were working in line with local guidance and policies. The service did not use any locum doctors in the last six months.

The service had an established process for assessing and granting practising privileges for visiting clinicians. The clinical director was responsible for interviewing external clinicians, establishing their accreditation level, checking evidence of practice and competency and check registrations with professional bodies.

Prior to the Covid19 pandemic, the service had planned to recruit two medical staff working under practising privileges. All the checks had been completed but no work was carried out due to the impact of the pandemic. The registered manager told us competencies would be checked again prior to any work being offered. During the time of the inspection, there were no doctors working under practising privileges at the clinic.

Although the clinic did not offer a 24-hour service, out of hours medical advice was provided by the lead consultant by telephone. Prior to discharge a member of the clinical team advised patients of the procedure to follow if they experienced adverse symptoms.

Records

Staff kept detailed records of patients' care and treatment. Although records were clear, up to date, stored securely and easily available to all staff providing care, the records audit showed that the pre-appointment Covid19 questionnaire was not consistently completed.

Staff used paper-based records which were stored securely, and staff could access them easily. We reviewed eight sets of patient notes all of which were day case surgical procedures (five Hysterosalpingogram (HSG) and three Selective Salpingography and Tubal Catheterisation (SSTC)). All the records were in good condition, legible and secure. We found the notes had been completed in a logical and comprehensive way. We saw evidence of completed WHO checklists, Venous thromboembolism (VTE) risk assessments, preoperative self-questionnaires assessments and post-operative observations. We found the last menstrual period (LMP) status was record in 7 out of 8 records. However, we did not see pain scores recorded in the notes.

The service did not consistently record drugs used clearly within patient notes. We raised this with the lead consultant who told us that they didn't use a lot of medicines, mainly painkillers (which could be bought over the counter) and antibiotics. Recording patient medications clearly in records would allow the service to have an audit trail of medicines used.

Xray images were printed and added to patients notes and also stored on the Xray machine's back up. However, we found two records where the Xray pictures were loose in the patients file. This was a risk as loose pictures could potentially be lost or mixed with the wrong patient files.

Although the service did not have any consultants working under practising privileges, the lead consultant told us that medical notes made by them would be integrated into patient's notes stored in the clinic. This meant records were always accessible by the permanent team.

We requested a recent patient records audit. The records audit provided did not include the date of when the audit took place and who completed it. Records between 18 October and January 2022 were audited. Results showed that all 15 records had notes from consultations, completed consent form, operative notes and completed WHO checklists. However, we saw that the Covid19 pre-appointment questionnaire was not completed in 12 out of 15 cases, and there was no further detail of investigation as to why this happened. The audit did not include any specific criteria about the condition of the notes, if appropriate risk assessments such as VTE were completed, if writing was legible with full details of the doctor for each entry and there was no mention of medication including antibiotic prophylaxis. Therefore, the records audit was not as comprehensive and would not allow for effective monitoring of records completion.

Medicines

Although staff stored most medicines safely, this did not include the safe storage of oxygen cylinders. The service did not have a process to identify medicines that could be affected by safety alerts and the service did not have mechanisms to ensure appropriate management of medicines to ensure safe prescribing.

The service was registered to stock and administer Controlled Drugs (CDs) although there were none on site during our inspection. The lead consultant was the named accountable officer.

Prescription forms were stored in a locked cupboard in the consultation room with controlled access. We reviewed a random sample of five prescriptions and found they were not always fully completed. Two prescriptions did not have patient address and patient reference numbers filled in and one prescription had not been dated. We showed the lead consultant examples where the prescription forms had not been completed fully as this could cause patient delays in obtaining their medication. The lead consultant told us that if they had a prescription query, they would check the duplicate copy in the booklet. We requested a recent prescription audit and did not receive this. The lead consultant told us that prescription audits were not completed.

Medicines were locked away in the medicines cabinet in the medical director's office. We reviewed a random sample of medications and found them to be in date. We reviewed the Drugs and Medicines stock rotation checklist for November 2021 and December 2021. The document included details such as expiry date, tamper checks, quantity, location and actions. However, local anaesthetic batch numbers were not recorded in the medicines stock list or within patient notes which meant in the event of any recall of medicines, it would not be possible to deduce which batch of local anaesthetic patients received. We raised this with lead consultant who told us that there wasn't a lot of space in the notes to document this but told us this would be addressed.

Inadequate

Surgery

Oxygen cylinders were not securely stored both in recovery and theatres which was not compliant with Health Technical Memorandum 02-01. This meant the cylinders could be tampered with and patients could be exposed to harm as oxygen is flammable. The lead consultant told us the clinic no longer used nitrous oxide (Entonox).

There was no antibiotic prescribing policy in place. We were told verbally by the lead consultant which antibiotics were used but this did not always match which antibiotics were documented in the patient records we reviewed. We saw discrepancies in two of the eight records we reviewed.

Incidents

Staff knew what incidents to report and how to report them. Most staff had knowledge or understanding of duty of candour.

Staff knew what incidents to report and how to report them. There was an incident reporting system in place that included a structure for investigation, sharing and learning. Staff demonstrated knowledge of the incident reporting process. The service reported zero serious incidents and zero clinical incidents between September 2021 and February 2022.

Most staff understood the duty of candour and demonstrated knowledge of their responsibilities. The duty of candour is guidance for being open and honest with people when things go wrong, such as after an incident or accident. There had been no previous incidents in which this needed to be used but an up to date policy was in place.

Are Surgery effective?

Requires Improvement

Our rating of effective stayed the same. We rated it as requires improvement.

Evidence-based care and treatment

Although the service had updated policies to ensure they were in date, we found there were no clinical guidelines based on national guidance and evidence-based practice for the procedures provided.

During our last inspection in October 2021, 28 out of date policies had been updated and showed review dates with version controls. The service used a colour coded system to highlight which policies were due for renewal which we saw evidence of on this inspection. All the policies were in date with review dates for 2024 and they were available as hard copies in the policy folder and online on the service's computer system. The business manager had the responsibility to ensure policies which needed updating were flagged to the responsible staff. Staff told us they were made aware of new policies either in team meetings or via emails.

During the October 2021 inspection, we found the access links to further guidance within the Safeguarding policy were no longer in use and this had been overlooked during the updating of the policy. During this inspection, we checked the links in the safeguarding policy and found they had been updated. Although the policy did not list the contact numbers for the local authorities, the staff induction documentation listed the names and numbers of who to call.

However, the service did not have any clinical guidelines or standard operating procedures (SOP) based on national guidance for any procedures provided. We found only two policies which referenced national guidance, and these were the resuscitation policy and safeguarding policy. We raised this with the lead consultant who showed us patient information leaflets for Selective Salpingography and Tubal Catheterisation (SSTC) and Hysterosalpingogram (HSG).

We reviewed the patient information leaflets for HSG and SSTC. The leaflets included details on the procedure, how to arrange an appointment, what to expect in the examination, risks and complications, pain, what happens after, side effects and contact details for the clinic. Both leaflets included advice for patients to notify the clinic if they were pregnant or suspected that they were.

We requested evidence of how the audit schedule was followed to monitor performance within the service. We received a narrative detailing the completed audits between October and December 2021 and we have reviewed them for this inspection. These included audits of 15 Cases of HSG and SSTC, Infection Prevention & Control Daily Checker weekly reports, WHO Checklist weekly reports, Drugs & Medicine Checker Audit and Day Case Accessories Stock Rotation Checker Audit.

Nutrition and hydration

Staff gave patients food and drink to meet their needs where needed.

The service provided day case procedures which meant there was limited need for a formal catering provision or nutrition monitoring. However, staff were able to prepare snacks and drinks for patients in the recovery area using the kitchenette facilities.

All surgical procedures were carried out under local anaesthetic and as such there was no requirement for patients to be nil by mouth for long periods. The preassessment questionnaire included a question on special dietary needs.

Pain relief

Although staff told us they assessed patient's pain levels, we did not see evidence of pain management or pain assessments in patient records.

We reviewed eight patient records and found it wasn't clear what pain management took place during the procedures. Staff told us that post procedure, patients were assessed for level of pain and provided with pain medications where needed. However, we did not see any evidence of pain assessments using recognised pain tools in patients records and the clinic did not have a pain management policy in place.

We asked the lead consultant how pain was managed for patients during procedures and we were told they approved patients for treatment carefully. Where patients had history of pain during previous HSG or invasive procedures, patients would be asked to explore other options such as In vitro fertilisation (IVF). The lead consultant told us that where a patient had a low pain threshold, they would not approve the patient for treatment.

Patient outcomes

Although the service had an audit schedule, it had not been fully embedded at the time of the inspection. Some of the audits were not comprehensive as they did not include the expected criteria. This meant the service did not monitor the effectiveness of care and treatment appropriately to make improvements and ensure good outcomes for patients.

Inadequate

Surgery

We reviewed the latest audit schedule which had been provided as a data request in the October 2021 inspection. The annual plan was to perform one audit per quarter and alternate between clinical and non-clinical cases. On this inspection, we were able to review the audits on records, WHO checklists and medications stock list (refer to relevant subheadings).

However, the audits linked to patient outcomes following procedures carried out at the clinic, were not due at the time of the inspection. HSG and SSTC audits were due between May and June 2022 whilst the vaginal wall surgery audit was due between August and October 2022. During the inspection, the lead consultant told us the success rate for SSTC was gauged at the time of procedure only which is likely to be 100%. Hence, this was not an appropriate criterion for measuring the success rate and there was no mention of fertility outcome being monitored. Similarly, for vaginal wall procedures, we were told that although follow ups were offered at six weeks, the do-no-attend rate was 50%. This would impact on data collection and there was no mention on how this would be addressed or considered.

We asked for evidence of patient outcomes data routinely monitored by the service to monitor and manage performance and quality. We received a short narrative indicating the service reviewed complication rates, complaints, doses compared to accepted levels, pregnancy status, return to theatre and audits of patient satisfaction. However, we did not receive any evidence of patient outcome data regarding the success of the procedures provided at the clinic.

In the last 12 months, the service reported there had been no unplanned or emergency patient transfer to other facilities, unplanned readmissions or returns to theatre.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance to provide support and development.

The service introduced a schedule of training for clinical staff in November 2021. The nurse in charge would lead on infection control, the radiographer/ Radiation Protection Supervisor (RPS) would lead on radiation awareness and the lead consultant would lead on safeguarding (including FGM).

Staff were qualified and had the right skills and knowledge to meet the needs of patients. The service had a trained RPS as required under The Ionising Radiations Regulations 2017. The lead consultant (who was the Radiation Protection Supervisor (RPS)) and the locum radiographer provided training for the bank nurse and administration staff on radiation awareness in November 2021.

The manager had taken on the RPS role and we saw evidence that specific training had been completed to carry this out in Septemeber 2021 and that they understood the role. We were told that the locum radiographer had also been booked onto this course. We spoke with the locum radiographer who confirmed online training had commenced and this was being completed alongside their permanent employment.

Managers gave all new staff a full induction before they started work. The service had created an induction checking process for new starters including permanent, bank and agency staff. At the end of the induction, staff would complete a declaration sheet to confirm they had read and were working in line with local guidance and policies.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. The staff appraisal rate was 100%. Although clinical staff who worked either as bank or locum completed their revalidation and appraisals with their permanent employer, providing evidence to the lead consultant; they also had informal discussions about their work with the lead consultant.

Inadequate

Surgery

We reviewed staff files and found appraisals had been completed and included disclosure and barring service certificate (DBS) certificate numbers with dates visible. However, we noticed that for one staff member who previously worked with an agency and had been offered permanent role, a copy of the DBS certificate was in their staff file. We raised this with the business manager as this should have been returned to the the staff member following the recruitment process and they told us this would be addressed.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. The service implemented quarterly governance meetings with clinical staff. We reviewed the meeting minutes for August 2021 and November 2021. Items discussed included CQC inspection findings, mandatory training, DBS checks, appraisal, IPC audit, patients' complaints and incidents. Attendees included bank nurse, locum radiographer and consultant.

The lead consultant showed us evidence of their completed appraisal in February 2022. However, the lead consultant only completed one hysteroscopy in 2021 which would make it difficult to maintain the necessary competencies given the number of procedures carried out was too small.

Multidisciplinary working

Although the service operated independently, where needed, the service shared information appropriately with other agencies involved in the patients ongoing care.

The clinic operated independently and was not part of a specialist care or treatment network. However where appropriate and with patient consent, the service shared relevant information with other agencies such as the patient's General practitioner (GP) to support patients with their ongoing care and treatment.

Seven-day services

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

The service was open Monday to Friday from 10.00 to 18.00 and day case procedures were scheduled on Saturdays as appointment only.

The clinic provided patients with a 24-hour number which was manned by the business manager or lead consultant in the event of any queries.

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

Staff assessed each patient's health when reviewing the preassessment questionnaire which included questions on smoking status and alcohol intake. Clinical staff told us that they discussed healthy lifestyle choices with patients to promote their chance of fertility.

We requested examples of how the service promotes health. We received patient literature which included information on healthy lifestyle choices to promote fertility. This included topic areas such as maintaining a healthy weight, reducing stress, smoking, alcohol intake, caffeine intake, over exercising and preventing sexually transmitted infections.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff followed national guidance to gain patients' consent. Most clinical staff knew how to support patients who lacked capacity to make their own decisions.

Inadequate

Surgery

The service had implemented a new process to gain consent from patients for their care and treatment in line with legislation and guidance. Managers ensured that a cooling off period was applied between a patient requesting and receiving cosmetic treatment. This was in line with the Professional Standards for Cosmetic Surgery issued by the Royal College of Surgeons.

Staff clearly recorded consent in patients' records. We reviewed 8 patient records of which 3 were for SSTC and 5 for HSG. We saw evidence of the cooling off period where appropriate; for example, for all three of unblocking fallopian tube procedures.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff could describe and knew how to access policy and get accurate advice on Mental Capacity Act and Deprivation of Liberty Safeguards.

The lead consultant and locum radiographer had completed training in Consent, Mental Capacity Act (MCA) and Deprivation of Liberty Safeguards (DoLS) which we found to be up to date. We received training records for the bank nurse which showed consent training was completed in October 2019 and MCA and DoLS training in November 2020. It was not clear if recent training for these areas had been completed by the bank nurse with their permanent employer and if evidence had been provided to the lead consultant to demonstrate this.

Are Surgery caring?

Insufficient evidence to rate

Insufficient evidence to rate

We did not rate caring at this inspection as we were not able to speak with patients as there were no appointments/day cases scheduled. However, we were able to review patient feedback information.

Compassionate care

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

The following was representative of feedback from patients and their families and carers: "massive thank you for everything and I appreciate the hard work that the team did for me", "Big thank you for all of your support" and "you made our dream come true".

The service requested patients to complete surveys as they were being discharged. We reviewed a sample of surveys and comments included: "great feedback and support", "very kind and helpful staff and doctor", "amazing customer service", "I liked the visual information" and "very calm atmosphere and staff put me at ease".

The service audited patient surveys annually. We reviewed the patient survey results for attendances between June 2021 and January 2022 where a total of 49 questionnaires were completed. Results showed 100% of patients felt they were informed of any risk and complications and given after care instructions. The percentage of patients who found their appointments with the consultant either very helpful or helpful was 94% and 6% respectively. Although 100% of patients

found the procedure acceptable, 63% of patients said it was better than expected. Feedback for the service provided by administration staff was either excellent (82%), very good (14%) and good (4%). Despite 100% of patients confirming they had signed consent forms, results showed that 90% of patients were given patient information leaflets before the procedures.

Although the survey results were compared to the previous survey results, there was no data for the previous survey included to use as a reference other than a note to say the service had continued to deliver very helpful and professional service to patients. However, without data to support this, it was difficult to ascertain if figures had improved since the last survey.

The service was exploring online surveys so that patients could have more time to consider their response instead of completing the feedback at time of discharge.

Emotional support

Staff provided limited emotional support to patients and their partners.

Staff showed awareness of the emotional impact that a person's care and treatment had on their wellbeing and on those close to them. The service had a dignity and respect policy in place which staff followed to keep patient care and treatment confidential. However, the service did not offer any counselling services or have a separate counselling room. The two beds in the recovery room were close together and separated by a disposable curtain. This meant it would be difficult to have private conversations without being overheard in this area.

We asked for examples of emotional support provided to patients. We were not given specific examples but were provided with a document that included details on a patient-focused fertility charity, the psychological effects of having problems with fertility and recognising that each patient's fertility journey is individual.

Understanding and involvement of patients and those close to them

Staff told us they supported patients and their partners to understand their condition and make decisions about their care and treatment.

Staff made sure patients and those close to them understood their care and treatment. Patients did not stay overnight which meant there were no issues around limited visiting hours.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. The service collected patient feedback after each treatment and used any themes or trends identified to make service improvements.

During the pandemic, the service followed government guidance and allowed partners to accompany patients where possible. Partners could attend if they produced negative lateral flow tests (LFT) due to the nature of procedure. The service implemented a virtual consultation during the pandemic using guidance from NHS England.

Are Surgery responsive?

Requires Improvement

Our rating of responsive went down. We rated it as requires improvement.

Inadequate

Surgery

Service delivery to meet the needs of their patient population

The service planned and provided care in a way that met the needs of their patient population. However, the service did not have a documented patient eligibility criteria.

Although the clinic provided a private service to patients on request, during the inspection, we found the service did not have a patient eligibility criteria. This meant it was unclear how the service assessed a patient's eligibility for the treatments offered and there was a lack of clarity for patients who wished to access the service.

The clinic provided care to patients from the local area as well as further afield. The clinic was based in an area where there was good public transportation links, making it accessible to patients from a wide geographical area. However, there was limited car parking availability near the clinic.

Patients were offered choices of appointment times and with patient consent, information was shared appropriately with the general practitioner (GP) where necessary. The lead consultant told us that follow up clinics were not routinely offered unless requested by the patient as they would have to pay for this.

There was a small waiting area for patients and access to hot and cold drinks.

Meeting people's individual needs

The service offered limited adjustments which considered patients' individual needs and preferences.

The preassessment questionnaire included a question on whether the patient had any hearing difficulties, wore hearing aids or contact lenses. However, staff did not have access to communication aids to help patients become partners in their care and treatment. We did not see provisions in place to support less abled patients including those with sight, sensory, hearing and learning difficulties.

The lead consultant told us that they have not had patients requiring British Sign Language (BSL) and confirmed that the service did not have anything in place to support patients requiring BSL.

The service did not have information leaflets available in any other language other than English. However, the lead consultant told us that the service offered interpreter services for patients whose first language was not English.

We asked the lead consultant how patients living with mental health problems and autism were supported. The lead consultant told us that they would risk assess patients on a case by case basis and ensure they came with an advocate or carer.

The service had a disabled toilet and was wheelchair accessible. Patients were provided with the 24-hour telephone number on discharge should they have any queries. Although the clinic had an up to date chaperone policy in place, we did not see posters informing patients that they can request a chaperone.

The recovery area had a cabinet of lockers for patients to store their belongings, but they were not within the bed spaces. They were all at one side of the room which could be inconvenient if a patient could not immediately get up from the bed to get their belongings after a procedure.

Access and flow

People could access the service when they needed it and received the right care promptly.

Inadequate

Surgery

The clinic provided a private service on request of the patient. Patients accessed the service by self-referral or on referral from another clinician. There was no waiting list to access services other than the wait for treatment related to the consent and cooling off period and the availability of appropriate specialists. The service completed patient assessments to ascertain where patients needed to be prioritised for treatment.

In the last 12 months, the clinic had two cancellations of which one was due to the patient being booked for the same treatment at a local NHS hospital and the other due to the procedure no longer being offered at the clinic. In both cases, patients received full refunds.

Outpatient appointments were available by appointment only and available as virtual appointments. Although each patient was allocated 30 minutes, staff told us that patients were not limited to 30 minutes and could have longer if needed.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. However, both the policy and patient information leaflet misrepresented the remit of the CQC.

The service received zero complaints (both informal and formal) in the last 12 months. Although the service displayed a patient information leaflet in reception on how to make a complaint, the wording was unclear and misleading as it indicated that the CQC may investigate complaints which is not within the CQC's remit. The CQC had been mentioned under a subheading on how to take complaints further alongside the Parliamentary Health Services Ombudsman. We raised this with the registered manager and clarified the CQC's remit and the clinic's responsibility to manage complaints. We did not see any posters on how to make a complaint.

The registered manager told us complaints were dealt with within 48 hours. Staff understood the policy on complaints and knew how to handle them. We reviewed the complaints policy which was in date and stated the timelines for responses. We saw that a receipt of the complaint should be acknowledged within three working days unless a full reply can be sent in five days. A full response was to be made within 20 working days.

All permanent staff had completed training in complaints handling and conflict resolution. Staff told us that patients raised informal complaints which were not about the service but about parking availability in the area. The policy had a section which included information on further advice and raising concerns with the regulator. However, the policy did not make it clear that the CQC did not investigate complaints on the complainant's behalf.

Are Surgery well-led?

Inadequate

Our rating of well-led stayed the same. We rated it as inadequate.

Leadership

Although leaders were visible and approachable in the service for patients and staff, they did not understand and manage the priorities and issues the service faced.

Inadequate

Surgery

The registered manager was also the CQC nominated individual and the lead consultant (medical director) at the clinic. The lead consultant provided leadership with support from the business manager who worked part-time. However, the lead consultant did not have effective oversight of the service and there would have been times when the service did not have clinical leadership on site.

We spoke with both permanent and non-permanent staff who described the lead consultant as approachable and visible.

Vision and Strategy

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

The service did not have a documented strategy. We requested the vision and strategy for the service, and we received a one page document of bullet points on the vision and values, but the document did not have enough detail. There was no company logo, version control and no indication of a measurable strategy. The narrative as to who had an input into the development was focused on three tiers of governance (clinical, non-clinical and radiation) but there was no mention of patients.

The lead consultant told us the immediate focus was to improve on the CQC rating as it impacted on the clinic's reputation. The long-term goal was to replicate this service in other cities and depending on activity levels, the lead consultant told us they wanted to employ an inhouse practice manager and nurse.

Culture

Staff felt respected, supported and valued.

The service was provided by a small team of four permanent staff and two regular agency and locum staff. We spoke with permanent and bank/locum staff who all felt supported and described the environment as friendly. One individual said they felt they were encouraged to voice ideas for improvement and were given development opportunities in the business area such as social media and marketing.

Staff described the environment as friendly and told us they felt they could raise concerns or make suggestions for the service. Staff told us they enjoyed working at the clinic.

Governance

Although the service has made some improvements in their governance processes since the last inspection, further improvement was still required to ensure there was effective oversight and assurance for these processes.

During the suspension period, the service had updated 28 out of date policies and had implemented a policy tracker to highlight when policies were due for renewal. Managers told us that all staff had access to physical copies of policies and that the service had introduced an annual declaration for both temporary and permanent staff to sign in order to obtain assurance that policies had been read and understood.

However, the service did not have any clinical guidance or standard operating procedures based on national guidance for the treatments provided by the service. We found only two policies which referenced national guidance, and these were the resuscitation policy and safeguarding policy.

The lead consultant was the named Radiation Protection Supervisor (RPS) for the service and was aware of the Radiation Protection Adviser (RPA) and associated roles and responsibilities. The RPA named by the manager was on the RPA 2000 register and was consistently referred to in documents. The lead consultant who was the medical director (and registered manager) was responsible for clinical governance, the RPS (who was the medical director/lead consultant) was responsible for radiation governance and the business manager was responsible for non-clinical governance meeting.

We asked the lead consultant how assurance was obtained regarding the implemented governance processes such as the completion of infection prevention and control (IPC) checklists and WHO checklists. We received an audit on completed IPC checklists between 18 October 2021 and January 2022. Results showed the checklist was completed on each working day and where issues were identified, they were reported and rectified. However, the audit did not review the 20-point checklist criteria to determine if it was still appropriate. For example, the checklist included one check point on emergency equipment including emergency medicines. Although we were told the lead consultant completed the equipment checks (however no evidence was provided for this), the IPC checklists were completed and signed by an administration staff. Therefore, it was not clear what staff checked for this check point.

We received an audit on completed WHO checklists between 18 October 2021 and January 2022 which reviewed 15 completed checklists. Although results showed that most of the checklists had been completed fully, it did not address areas which had been omitted. For example, from the 15 checklists, one checklist did not document if the VTE prophylaxis has been undertaken and another checklist did not document if antibiotic prophylaxis had been given. However, the audit's conclusion stated that all domains had been answered appropriately. Item 7 which was regarding VTE prophylaxis had been documented as 100% which contradicts the results in the table provided. The audit does not include any action points for improving completion where answers had been omitted. Both the IPC and WHO checklist audits do not include details on who completed the audit or a date of when the audit was completed.

The service had arrangements for reviewing staff working under practising privileges. We reviewed the agreement for practising privileges which detailed the appropriate checks carried out such as regulatory requirements, professional requirements, legal requirements and indemnity insurance. The registered manager confirmed that there were no medical staff working under practising privileges at the clinic at present.

Following the October 2021 inspection, the service introduced regular governance meetings. This included regular meetings between the Radiation Protection Advisor (RPA) and Medical Physics Expert (MPE). We reviewed minutes for the Radiation Governance meetings in October 2021 and January 2022 and found that agenda items included CQC inspection findings, RPS duties and responsibilities, audits of doses and action plans for monitoring badges and fluoroscopy procedures. Attendees included MPE, RPA, business manager and medical director (who was also the RPS). Due to the small radiological workload, the service agreed to have radiation governance meetings every six months.

We reviewed the quarterly clinical governance meeting minutes for September 2021 and December 2021. Agenda items included discussion on the cooling off period for 14 days for consent, breakdown of activity, complaints, incidents, RPS role and induction process for staff. Attendees included the medical director, administrator and the MPE.

Management of risk, issues and performance

Leaders did not use systems to manage performance effectively. They did not have an adequate process in place to identify risks and issues or identify actions to reduce their impact. This included plans to cope with unexpected events.

The service had a risk register which was divided into administrative, radiation, medicines and surgical. Although we were told the risk register was reviewed monthly at various governance meetings, we found the risk register was not completed

fully. There were gaps in the register which included details on who was responsible for each risk, date of review and expected date of completion. The risks we identified during the inspection were not listed on the risk register. These included the storage area, no clinical policies based on national guidelines and the lack of service level agreement with a nearby NHS hospital to transfer a deteriorating patient. During our interview with the lead consultant, when asked about the risks to the service, the risks included in the register were not mentioned. This did not give us the assurance that risks were effectively managed.

The service did not have a backup generator which presented a risk in event of a power cut during a procedure. This was not included on the risk register. We raised this with the lead consultant who told us the previous owner's generator was stolen and hadn't been replaced as the service hadn't needed one. However, there was no other system in place should there be a power cut whilst a procedure was ongoing.

The service had an emergency and business continuity plan policy which was in date. However, there were gaps in the policy. For example, although the policy acknowledged the impact of a power cut on the service, it did not include the impact a power cut would have on diagnostic equipment like the Xray or ultrasound. The policy stated that if the power failed, all patient activity should be cancelled until the power was restored, except for matters of immediate clinical urgency. However, the policy did not state what should happen in matters of immediate clinical urgency. Appendix 2 in the policy should list contact numbers for the clinic, staff, suppliers and local authority but it had not been completed.

The policy included details on major incidents such as adverse weather, bomb threats, equipment shortage, staff shortage, natural disasters, loss of power and fire. However, for fires, the policy stated that this would be dealt with in accordance with standard fire orders. It did not mention fire risk assessments for the site which was a concern given the excessive storage on site.

All permanent staff including the locum radiographer had completed fire safety awareness training. Staff told us the clinic had fire training refreshers every month and we saw information displayed on the evacuation procedure.

Information Management

Staff could find the data they needed, in easily accessible formats. However, the clinic's website and information leaflets had not been updated to reflect the changes to the services provided.

Staff had access to all the information they needed as computer stations were available to access the intranet and internet. Staff were aware of how to use and store confidential information. The service used paper-based records and we found paper records were stored securely and staff locked computers preventing unauthorised access. Staff completed modules on Information Governance including Cyber Security as part of their mandatory training. Staff told us that the information technology (IT) system was reliable.

However, the clinic's website listed staff members who no longer worked at the service. We raised this with the registered manager who told us that marketing was outsourced to an external contractor which was an additional expense. The lead consultant told us that these issues had been raised with the marketing team. Administration staff supported the marketing team with the social media aspects. We saw the minutes for the marketing meeting on 10 February 2022 which discussed a new website design, removing services no longer provided including staff and the timelines stated for this to be completed was approximately 3 to 4 weeks. We found the service displayed both the old and new clinic leaflets. The old leaflet included details of private GP services which were no longer offered by the clinic.

Inadequate

Surgery

On this inspection, when we arrived on site, we noticed that the CQC ratings still had not been displayed on the premises despite previous instruction to the registered manager to do so. We raised this with the registered manager who initially told us that the ratings were displayed on the website. We reminded the registered manager that this was a breach of Regulation 20A of the Health and Social Care Act and guidance for this had been provided in previous correspondence. The registered manager addressed this immediately and displayed the CQC ratings which we saw before leaving the site.

Engagement

Leaders and staff engaged with patients and staff.

The service held quarterly staff meetings for non-clinical staff. We reviewed the minutes for October 2021 and January 2022 which was attended by the medical director, business manager and administrators. Agenda items included findings from recent CQC inspection, reminders for completing radiation dose lists, complaints, mandatory training, audit, change in services, sickness/absence/annual leave and handover from the staff member leaving.

Staff surveys included both permanent and non-permanent staff and was completed annually. Although we received staff survey results as part of the data request, there was no date to inform us when the staff survey was completed. The results showed that the percentage of staff that either strongly agreed or agreed that the teams within the organisation worked well together to achieve their objective was 50% respectively for both. Similarly, the percentage of staff who either strongly agreed or agreed that the people they work with were understanding and kind to one another was 50% respectively for both. Although 75% of staff found the work was never emotionally exhausting, 25% selected sometimes for this category. Staff who agreed that their line manager gave them clear feedback on their work was 75% and 100% of the staff expressed that they had never experienced discrimination from managers and patients.

The service requested patients to complete surveys as they were being discharged. We reviewed the patient survey results for attendances between June 2021 and January 2022 and found that patient feedback was positive. Refer to Compassionate Care subheading.

Learning, continuous improvement and innovation

The service did not provide any examples of continuous improvement and innovation.

We requested evidence of examples for continuous improvement and innovation in the service which was not provided. Instead we were provided with a narrative on how the service could create a culture of continuous improvement and innovation.