Regency Clinic - City of London

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Good
Are services safe?	Requires improvement
Are services effective?	Good
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

Overall summary

Regency Clinic – City of London is operated by Regency International Clinic Ltd. Facilities include one operating theatre, a two-bedded recovery ward, X-ray, outpatient and diagnostic facilities.

The service provides gynaecology surgery, outpatient and diagnostic imaging, care and treatment. The service also provides private GP consultations. All procedures that required anaesthesia were carried out using local anaesthetic; the service did not provide general anaesthetic. We inspected surgery and outpatients at this inspection.

In 2017 average monthly activity levels were:

Surgical procedures: three to four

Summary of findings

Diagnostic and screening procedures: four to six

Treatment of disease, disorder or injury: six to eight

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 28 February 2018.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided by this clinic was surgery and outpatients services were also provided.

Services we rate

We rated this service as good overall because:

- The service managed staffing effectively and services always had enough staff with the appropriate skills, experience and training to keep patients safe and to meet their care needs.
- The senior team maintained checks of registration with the General Medical Council and the Nursing and Midwifery Council of professionals who provided services under practising privileges. Radiographers were registered with the Health and Care Professions Council and the senior team monitored this each time a locum radiographer worked in the clinic.
- The service was compliant with the standards set by the British Association of Day Surgery (BADS) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) in relation to medical records, clinical equipment, monitoring patient risk and the provision of a follow-up emergency advice service.
- There had been no instances of unplanned or emergency patient transfers to other facilities or hospitals and no unplanned readmissions or unplanned returns to the operating theatre since the clinic came into operation.
- All permanent staff had undergone an appraisal in the previous 12 months, in line with the provider's policy.
- Clinical staff completed accredited training from nationally recognised bodies.
- All of the patient feedback we received reflected a good standard of kind, compassionate and understanding care. Staff training reflected national standards of care delivery established in National Institute for Health and Care Excellence (NICE) quality statement 15 in relation to dignity and kindness.
- Staff provided clinical services tailored to patient demand, such as a well women clinic.
- There was no waiting list for the service.
- There had been no complaints in the previous four years and staff demonstrated a proactive approach to acting on other feedback.
- The leadership structure and working culture were well established and the senior team valued feedback from staff and patients.

However:

- After the inspection, we reviewed policies which were inconsistent regarding the pregnancy rule which was a concern as the service were performing procedures on women who were trying to get pregnant. The service did not have oversight of these inconsistencies.
- Safety monitoring systems were in place but were not always fully effective as we found emergency equipment that needed to be replaced and expired medicines stored in the clinical room.
- The service did not audit or benchmark patient outcomes against national standards or similar services.

Following this inspection, we issued a requirement notice for the breach of Regulation 12 and told the provider that it should make some improvements to help the service improve. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Interim)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Surgery	Good 	Surgery was the main activity of the hospital. We have reflected on outpatient services in this report although the level of activity was low. Staffing was managed jointly between surgery and outpatients. We rated this service as good overall.

Summary of findings

Contents

Good

Regency Clinic - City of London

Services we looked at

Surgery

Summary of this inspection

Background to Regency Clinic - City of London

Regency Clinic – City of London is operated by Regency International Clinic Ltd. The hospital/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 offered services on self-referral or referral from other private clinics. Patients attended from significant distances for treatment.

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 clinic also offered private GP services. We did not inspect these services.

Our inspection team

The team that inspected the service comprised a CQC lead inspector,a second CQC inspector and a specialist advisor with expertise in gynaecology. The inspection team was overseen by Nicola Wise, Head of Inspection.

Why we carried out this inspection

We inspected this hospital as part of our national programme to inspect and rate all independent healthcare providers.

How we carried out this inspection

We reviewed a wide range of documents and data we requested from the provider. This included policies, minutes of meetings, staff records and results of surveys and audits. We placed comment boxes prior to our inspection which enabled staff and patients to provide us with their views. We reviewed comment cards, which had been completed by patients. We carried out an announced inspection on the 28 February 2018.

We interviewed the management team and spoke with administrative staff. We visited all the clinical areas at the clinic. We would like to thank all staff, patients, carers and other stakeholders for sharing their views and experience of the quality of the care they received at The Regency Clinic London.

Information about Regency Clinic - City of London

The clinic provides surgical and outpatient services; the main service is gynaecology. 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.

During the inspection, we visited all areas of the clinic. We spoke with all permanent staff including the medical

Summary of this inspection

director, business manager and reception staff. We also spoke with a registered nurse who provided on-demand services to the clinic. We received ten 'tell us about your care' comment cards which patients had completed prior to our inspection. During our inspection, we reviewed ten sets of patient records.

There were no special reviews or investigations of the hospital ongoing by the CQC at any time during the 12 months before this inspection. We had not previously inspected the service.

Activity (October 2016 to September 2017)

- In this reporting period there were 283 episodes of care recorded at the clinic. Of these 71% were outpatient attendances and 29% were day case attendances. In all cases patients were privately funded; the clinic did not provide NHS-funded care.
- Of outpatient appointments, 95% were for gynaecology and 5% were for the GP service.
- During this period there were 68 surgical procedures, of which 60% were vaginal wall procedures and 40% was treatment to unblock fallopian tubes.

One gynaecology surgeon (the medical director) worked at the clinic permanently. A consultant obstetrician, a locum radiographer and a radiologist worked at the clinic under practising privileges. One registered nurses, whose substantive post was in an NHS hospital, worked in the clinic when needed. A business manager and two receptionists/administrators formed the non-clinical team. The responsible person for controlled drugs (CDs) was the medical director.

Track record on safety:

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

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement

We rated safe as requires improvement because:

- After the inspection, we reviewed policies which were inconsistent regarding the pregnancy rule. This was a concern as the service were performing procedures on women who were trying to get pregnant. The service carried out a review of policy and procedures as a result and adopted a more consistent approach.
- Safety checks on emergency equipment had not identified that an intubation kit was not sterile and needed replacing.
- A medicines management policy was in place but did not provide continuous assurance of safe stock management.

However:

- Cleanliness and infection control policies and controls were in place, including for the environment.
- The service reported no incidents, never events or surgical infections for the duration of its operation.
- Patient records were completed consistently and to a high standard. Records completed by consultants under practising privileges were fully integrated in the clinic.
- Safeguarding processes and training were in place and staff demonstrated good knowledge of these.
- All staff had up to date mandatory training and the records of those who worked under practising privileges were monitored.
- Systems were in place to monitor risks to patients during surgical procedures.
- The service was compliant with British Association of Day Surgery (BADS) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) standards in relation to equipment, medical records and management of patient risk.

Are services effective?

Good

We rated effective as good because:

- Staff used national standards and guidance for care and treatment as published by recognised organisations including the Royal College of Obstetricians and Gynaecologists (RCOG), the National Institute for Health and Care Excellence (NICE), the British Association of Day Surgery (BADS) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI).

Summary of this inspection

- The medical director monitored the competencies and revalidation of clinicians who worked under practising privileges.
- There had been no instances of unplanned or emergency patient transfers to other facilities or hospitals and no unplanned readmissions or unplanned returns to the operating theatre.
- Staff understood their responsibilities under the Mental Capacity Act (2005) and processes were in place to ensure treatment only took place when a patient was assessed as able to give consent.
- The service had audited key procedures to benchmark patient outcomes against NICE and RCOG standards.

Are services caring?

Good

We rated caring as good because:

- All of the CQC comment cards we received noted positive examples of care.
- All results from the ongoing patient feedback questionnaire indicated staff consistently involved patients in their care and treatment.
- Staff demonstrated empathy and compassion with patients in the context of the sensitive nature of many of the procedures carried out and provided emotional support.
- Policies and training standards were in line with the National Institute for Health and Care Excellence (NICE) quality statement 15 in relation to dignity and kindness.

Are services responsive?

Good

We rated responsive as good because:

- Clinical services were offered in line with patient demand and the clinical team offered less invasive surgical methods and diagnostics than patients typically had access to.
- The clinical team offered a well women clinic that included consultations for a range of specialist conditions.
- There was no waiting list and appointment times were planned in advance to match the availability of specialist staff with patient preferences.
- The service had received no formal complaints in four years and there was a complaints procedure in place and readily accessible by patients.
- All facilities were fully wheelchair accessible and provision was in place for language support.

Summary of this inspection

Are services well-led?

Good

We rated well-led as good because:

- The mission statement, which reflected the service vision and strategy, demonstrated the team's commitment to delivering individualised care.
- The service had a business development plan in place to ensure sustainability and growth.
- There was a clear drive to improve staff knowledge of marketing and to develop the service.
- Leadership structures were embedded and all staff spoke positively of the working culture.

However:

- The service did not have oversight of the inconsistencies regarding the pregnancy rule in two of the policies we reviewed.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Surgery

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

Are surgery services safe?

Requires improvement

We rated safe as **requires improvement.**

Incidents

- Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers. The service reported no never events for the duration of its operation.
- There was an incident reporting system in place that included a structure for investigation, sharing and learning. All staff in the service demonstrated knowledge of the incident reporting process.
- Staff reported no incidents between October 2016 and February 2018.
- The serious incident and reporting policy had been updated in 2017 and was readily available for all staff.
- The medical director led quarterly clinical meetings to discuss patient morbidities and outcomes.
- Staff demonstrated knowledge of their responsibilities under the duty of candour. 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.

Clinical Quality Dashboard or equivalent (how does the service monitor safety and use results)

- The medical director and the business manager monitored safety outcomes. The volume of patients was low and there was not a clinical need for a quality dashboard. There had been no clinical incidents or adverse events in the previous 12 months and no complaints that related to treatment. However the permanent team demonstrated they had the knowledge and capability to address safety issues should they arise.

Cleanliness, infection control and hygiene

- We observed good standards of cleanliness. Each clinical area had a cleaning checklist and we saw the contracted cleaner had documented completion consistently for every day the clinic was open in the previous six months.
- A nominated infection prevention and control lead was in post who was responsible for standards of hygiene and cleanliness. This individual updated the clinic's infection control policies annually and we saw these were up to date.
- The environment met the standards of the Department of Health (DH) Health Building Notes (HBN) 00-09 and 00-10 in relation to infection control practices and building management. The clinical environment was well maintained and there was no damage to flooring or walls that could present a risk of the build-up of bacteria.
- Staff adhered to the standards of the DH Health Technical Memorandum 07-01 in relation to safe standards of waste disposal, including clinical and hazardous waste. For example we saw staff segregated waste in secure, colour-coded bags and maintained a register of the items destroyed.
- There had been no surgical site infections reported between October 2016 and February 2018.

- Antibacterial soap was available in each bathroom and antibacterial hand gel was available at the reception desk and in each clinical area. Signs encouraged patients and visitors to use these regularly.
- Staff training and policies included standards of infection control in line with National Institute of Health and Care Excellence (NICE) clinical guidance 74 in relation to preoperative practice.
- There were no treatments taking place during our inspection and we were unable to observe or assess staff infection control and hand hygiene practice. However, all of the staff we spoke with demonstrated good knowledge of protocols and of the infection control policy. This included the registered nurse who worked in the clinic on demand and who explained how they enforced strict hand hygiene processes during treatment days.
- The team decontaminated reusable medical devices in line with national guidance from the Department of Health. This took place through a contractual agreement and we saw records were up to date without gaps in recording.
- In nine of the 10 comment cards we received, patients commented on the high standards of cleanliness and hygiene they observed during their visits to the clinic.
- The pre-assessment and recovery rooms had fabric curtains in place, which presented an infection control risk. The provider could not confirm how often these had been changed. Staff told us they planned to introduce disposable curtains in the near future. After our inspection the provider submitted evidence the curtains had been dry cleaned every six months and would be replaced with disposable alternatives.

Environment and equipment

- The clinic had resuscitation equipment in place including emergency medicine, oxygen with masks in a range of sizes, an intubation kit and a defibrillator. Some emergency equipment was new and training for all staff had been arranged. Whilst this was completed the previous equipment remained in place. After our inspection the clinical director told us the intubation kit had been decommissioned as the service did not provide procedures under general anaesthetic. However, they had opted to replace this as an additional safety measure.
- The intubation kit was not sterile and the mask and tube needed replacing. We spoke with the medical director about this who said they would replace it. We were not able to establish why regular safety checks carried out by staff had not identified this.
- The environment was compliant with the standards set by the British Association of Day Surgery (BADS) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI), including in the provision of equipment that met national safety standards.
- There was a maintenance schedule for theatre equipment, including equipment used for local anaesthetic that was compliant with Medicines and Healthcare products Regulatory Agency (MHRA) requirements.
- Day case procedures were carried out under local anaesthetic and the clinic was equipped with two recovery trolleys, two beds and three comfortable arm chairs.
- The service was fully compliant with the Control of Substances Hazardous to Health Regulations (COSHH) (2002). This included the safe storage, use and disposal of controlled chemicals. Spill kits included COSHH labels that provided guidance for staff on the management of chemical spills.
- Staff managed sharps in line with the Health and Safety (Sharp Instruments in Healthcare) Regulations 2013. This included in the storage, labelling and disposal of sharps.
- A medical equipment test had been carried out in January 2018 and the provider had taken immediate action to replace two items that failed the safety test.
- The senior team planned to replace reusable surgical equipment with disposables in 2018. Existing sterilisation processes were in place with traceable records for decontamination.
- There was a radiation warning notice in place outside of the surgical theatre where diagnostic imaging took place. However the sign could not be illuminated, which meant it was not possible for people outside of the room to immediately identify if a radiation imaging procedure was underway. We escalated this to the medical director who implemented a new procedure whereby they would move the sign to be displayed on the main theatre entrance door as notification to staff that imaging procedures were underway.
- Radiation shields were available in the theatre although there were no radiation badges in place. Staff did not

have personal radiation badges. Radiation badges are items used to alert staff wearing them if they are beingf exposed to unsafe levels of radiation. Without these in place it is not possible for individuals to monitor their radiation exposure levels.

Medicines

- The service was registered to stock and administer Controlled Drugs (CDs) although there were none on site during our inspection. There was a named CD responsible person in place and the policy relating to the storage, handling, administration and disposal of CDs was up to date and met national standards. As the organisation had fewer than 10 members of staff, it was exempt from the requirement fo a CD accountable officer (AO).
- Prescription forms were stored in a locked cupboard in the consultation room with controlled access. We reviewed a random sample of three prescriptions and found them to be fully completed with patient information, including allergies. In each case the prescribing doctor had legibly printed their name, signed the prescription and included their General Medical Council (GMC) number.
- We carried out a check of medicines stored in the clinical room. Two medicines had expired within the previous three months. We spoke with the medical director about these and they disposed of them. The service had introduced a new template for logging medicines and their expiry dates. We saw this in use however the registered nurse was the lead for this initiative and as they worked on an ad-hoc basis, the system did not achieve continuous safe monitoring. There was also no 'live' document that identified the current stock of medicines on site. This did not meet the requirements of the provider's medicines management policy. This was in date and stated that routine checks of medicines and medicine stock would prevent risks such as expired items.
- Antibiotics were prescribed in line with local antibiotic formularies and the guidance of the NICE quality statement 1 in relation to antibiotic prescribing.

Records

- Staff used a combination of electronic and paper-based records. We looked at the security systems for both and found them to be fit for purpose and used consistently. Electronic records were stored in a password protected system with restricted access. Paper notes were stored in locked, fire-proof cabinets.
- We reviewed ten sets of patient notes, this included nine day case surgical procedures and one outpatient appointment. In each case the clinician had documented relevant risk assessments and a pre-operative assessment. Nurse observation notes were of a high standard and included post-operative vital signs and clear documentation of discharge information given to the patient.
- Patient records were completed and stored in line with AAGBI and BADS standards.
- Staff audited fallopian tube catheter kits; which meant it was possible to trace specific disposable items in the event of a complication.
- Medical notes made by consultants working under practising privileges were integrated into patient's notes stored in the clinic. This meant their records were always accessible by the permanent team.
- The medical director maintained a record of surgical procedures included details of the equipment used and medicines administered. This was stored securely and did not contain patient-identifiable information.

Safeguarding

- Systems, processes and practices were in place to keep people safe and all staff demonstrated understanding of these. This meant people were cared for in an environment and by a staff team equipped to provide additional care, support and referral in the event of a safeguarding incident or concern.
- A safeguarding lead was in post and the service had an up to date safeguarding policy. This was appropriate for the clinical services provided and met national best practice guidance.
- All staff had up to date safeguarding adults and children training to level 2 and this was refreshed annually. Non-clinical staff we spoke with demonstrated a good level of knowledge of the principles of safeguarding, including identifying and responding to different types of abuse.
- There was an up to date safeguarding policy in place that was readily accessible to staff and included guidance to obtain urgent support in circumstances such as suspected female genital mutilation (FGM) or suspected radicalisation.

- We asked each member of staff about their understanding of safeguarding and found an overall good standard of knowledge. This included specialist areas of recognition and action, such as for domestic violence or coercion.

Mandatory training

- All permanent staff were required to complete a mandatory training package that included topics such as safeguarding, infection control and fire safety. At the time of our inspection 100% of the permanent team were up to date with training.
- The business manager maintained a record of the mandatory training completion of professionals who provided services to the clinic but were not permanently employed by them, such as the registered nurse.
- Scheduled quarterly training updates took place for all permanent staff. This was arranged within protected time, which ensured the team remained up to date with required courses.
- Staff spoke positively of training opportunities and said they felt it was updated appropriately and ensured they remained up to date with safe working practices.
- The senior team had minimised the use of online e-learning use for mandatory training as a part of a strategy to ensure staff had the opportunity to develop practical skills.

Assessing and responding to patient risk

- During our quality assurance process, the CQC wrote to the service to request additional information further to the Ionising Radiation Medical Exposure Regulations (IR(ME)R) radiation concerns. The service provided the IR(ME)R 2017 Employers Procedures (known as Schedule 2). Although the service had appointed a Radiation Protection Adviser (RPA) and a Medical Physics Expert (MPE) who had provided the service with draft procedures following a site visit in March 2018, we found there was a discrepancy between two procedures submitted by the service. The document entitled rules for image guided procedures uses the 28 day pregnancy rule and the procedures for x-ray imaging document refers to the 10 day rule. Therefore, there is no consistency which is a concern considering they are performing procedures on women who are trying to get pregnant.
- After our inspection we spoke with the provider about our concerns with safety policies as noted above. The service reviewed and updated the policies with the RPA and adopted a single policy and procedure, to use the 10-day rule for image guided procedures.
- The medical director carried out a pre-assessment for each patient to ensure surgery would be appropriate. This meant patients had assurance their planned treatment was appropriate and, based on their clinical presentation, likely to be safe.
- The service provided day case operations under local anaesthetic that were minimally invasive and considered to be low risk. However the clinical team were equipped to provide care in the event a patient deteriorated and all procedures were carried out with a registered nurse who monitored vital signs.
- 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. There was an up to date chaperone policy in place and clinical staff documented when this had been offered and accepted in patient records.
- The clinic had two single-use biohazard spill kits that could be used to safely contain spillages of blood or other hazardous bodily fluids and waste. One spill kit was designated specifically for urine or vomit spillages. All staff demonstrated knowledge of the location and correct usage of the kits.
- All staff had up to date training in first aid and cardiopulmonary resuscitation (CPR). A patient deterioration and escalation policy was in place, which instructed staff to arrange transfer of patients to an emergency NHS facility in the event of a complication.
- The medical director undertook annual sepsis training and was the lead for intervention in the event a patient needed assessment and treatment. They ensured other members of the clinical team were conversant in sepsis care as part of the clinical operation of the service.
- Clinical staff used the National Patient Safety Agency (NPSA) five steps to safer surgery when treating patients.
- The service met the AAGBI and BADS guidelines that patients should have access to a 24-hour helpline after discharge.

Nursing and support staffing

Good

Surgery

- A nurse practitioner with current Nursing and Midwifery Council (NMC) registration provided services on demand and the registered manager maintained a record of their current training and competencies.
- Two receptionists provided administrative and customer care support Monday to Friday.
- Clinical teams could be formed of staff who had not previously worked together and who worked at the clinic occasionally. To address the risks associated with this, the medical director ensured the clinical team carried out a briefing at the beginning of each treatment session to ensure there was a clear clinical plan in place. This was a safety process that ensured the clinical team established a working relationship with roles and responsibilities, including a review of their skills.
- The business manager maintained up to date policies for safe staffing, including for recruitment, disciplinaries and lone working. Staff we spoke with demonstrated good knowledge of the lone working policy and we observed arrangements in place to facilitate this in the clinic, including through a locked-door policy. This meant access to the clinic was controlled and staff granted this following positive visual identification.

Medical staffing

- The medical director and owner was a gynaecologist and led surgical care. According to demand, an accredited obstetrician working under practicing privileges and the clinic maintained relationships with other consultants who could provide ad-hoc services. A locum radiographer and a radiologist provided contracted services to the clinic for specific procedures and were always on site for procedures that involved x-rays or other diagnostics. A named radiation protection supervisor was always on site when procedures were undertaken.
- All staff working under practicing privileges were employed substantively elsewhere and the medical director and business manager maintained a record of their revalidation and appraisal evidence to ensure their practice and competencies remained up to date.
- The business manager planned staffing levels and skill mix with the clinical director in advance of each procedure to ensure treatment could be carried out safely.
- The service had an established process for assessing and granting practising privileges for visiting clinicians. The clinical director was responsible for interviewing external clinicians and establishing their accreditation level and evidence of practice and competency. They also carried out checks with the GMC and the NMC. As external clinicians were used occasionally, the clinical director carried out additional six-monthly checks on their registration and accreditation status.
- The clinic did not offer a 24-hour service and out of hours medical advice was provided by the medical director in emergencies by telephone. A buddy system was in place in the event the medical director was unavailable. Prior to discharge a member of the clinical team advised patients of the procedure to follow if they experienced adverse symptoms.
- There was no additional on-call medical cover during procedures as the clinical team's skill mix was established in advance of each elective procedure.

Emergency awareness and training

- All staff had up to date fire and emergency training and could explain the evacuation procedures.
- The fire authority had carried out a premises risk inspection in the previous year and identified no concerns or risks related to fire safety.
- An up to date fire policy was in place and had been reviewed in 2018.

Are surgery services effective?

Good

We rated effective as **good.**

Evidence-based care and treatment

- The medical director was the lead for clinical policy updates and based these on the latest guidance from the Royal College of Obstetricians and Gynaecologists and the National Institute for Health and Care Excellence (NICE).
- The clinical director established care and treatment pathways in line with guidance and standards from the Royal College of Obstetricians and Gynaecologists. They reviewed these annually or when national updates were issued by the appropriate body.
- The clinical team carried out routine preoperative tests in line with NICE guidance NG45. This meant patients had appropriate preoperative checks carried out prior to each procedure.

- All clinical staff employed by or working in the service also practiced in NHS services. This meant they had ongoing access to the latest best practice standards, which they implemented in this service. They used case reviews from the clinic, their NHS work and from national publications to review their practice. This meant patients were treated and cared for by professionals with up to date knowledge of best practice guidance and standards.
- The medical director had undertaken training from the Radiological Protection Centre in compliance with the Ionising Radiation (Medical Exposure) Regulations 2014.They had access to a radiation protection advisor and we saw up to date inspection records of radiological equipment. This meant procedures met national safety standards.
- Providing evidence-based care and treatment formed the basis of the service's mission statement, which the team ensured by providing medical treatment led only by accredited professionals carried out treatment.

Pain relief

- The operating doctor assessed preoperative pain and monitored this during each procedure. We saw this was recorded in clinical notes.
- A nurse monitored pain in the recovery room and patients were prescribed pain relief if needed.
- Staff used the post-treatment patient survey to capture feedback on pain management during their treatment. This meant patients received care, treatment and recovery that was attentive to their pain needs.

Nutrition and hydration

- The service provided day case procedures, which meant there was limited need for a formal catering provision or nutrition monitoring. However snacks and drinks were available and staff prepared these for patients to have in the recovery area.
- All surgical procedures were carried out under local anaesthetic and as such there was no requirement for starve times.

Patient outcomes

- The service benchmarked practice against similar services and national guidance in relation to unblocking fallopian tubes.
- The clinical director led patient case reviews with the clinic team and external clinicians who had provided care and treatment. This was a strategy to ensure treatment had met its planned goals and to review the competencies and skill mix of the team that had carried out the procedure.
- There had been no instances of unplanned or emergency patient transfers to other facilities or hospitals between October 2016 and February 2018. During this period there had been no unplanned readmissions and no unplanned returns to the operating theatre.

Competent staff

- Procedures were in place to ensure clinical staff only carried out procedures for which they were competent, assessed and accredited. The medical director maintained a continual record of the roles and clinical work of clinicians in their substantive NHS practices and ensured this met the needs of the patient group.
- The business manager used a staff performance and appraisal policy to structure supervisions and professional development plans.
- All permanent staff had undergone an appraisal in the previous 12 months, in line with the provider's policy. We spoke with three members of staff about their experiences of appraisal, all of whom were positive about this and said it helped to identify their strengths and weaknesses as well as to establish a plan for ongoing training. For example one member of staff was liaising with an external marketing agency to develop their skills in this area. The business manager was supportive of staff who wished to continue their professional development and helped to secure opportunities for training.
- The business manager used a structured appraisal template to review progress in the preceding year and to identify if all aspects of the individual's employment were up to date. We reviewed one recently completed appraisal and noted a focus on the individual's achievements, such as an increase in knowledge and confidence. Staff also carried out self-reflection and worked with the manager to identify areas of challenge and for development. For example one individual identified a need for a greater understanding of national standards in marketing, including the use of analytics.
- The medical director had an agreement in place with a locum agency to ensure they underwent appraisals and were revalidated as required. They worked in excess of

30 days per year in a clinical capacity in an NHS surgical environment to ensure they maintained clinical skills. They also undertook at least 50 days of personal professional development annually.
- The medical director demonstrated a track record of undertaking training accredited by recognised specialist bodies, including the Royal College of Obstetricians and Gynaecologists, the British Society for Colposcopy and Cervical Pathology and the British Maternal and Foetal Medicine Society. They had completed training from the Royal College of Radiologists in advanced transvaginal 3D ultrasound technique and virtual hysteroscopy.
- The medical director had been assessed as competent by the British Society for Gynaecological Endoscopy in laparoscopic surgery and by the Radiological Protection Centre in the management of ionising radiation.
- An established induction process was in place. This included clinical and non-clinical inductions to cover clinical policies, processes and awareness. This meant staff were able to provide safe, effective care in line with service and care standards.

Multidisciplinary working

- The clinic operated independently and was not part of a specialist care or treatment network. Clinical staff demonstrated they had the skills and experience to meet patient needs.
- An escalation policy was in place in the event a patient deteriorated during a procedure and staff needed to transfer them to an emergency department.

Access to information

- Staff, including those providing ad-hoc services, were required to adhere to a confidentiality policy.
- Systems were in place to ensure clinicians had access to information including care and risk assessments and medical histories prior to providing treatment.
- The service shared information with other clinical services, when patients had consented to this, in line with NICE quality statement 12 in relation to providing coordinated care.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- We reviewed consent processes with staff and through looking at a sample of patient records. We found evidence staff adhered to the service's consent policy including through documenting when consent took place and ensuring this was signed by the patient, including for sterilisation procedures. There was also evidence staff provided a cooling-off period following the decision to undergo surgery.
- We spoke with one patient who had visited the clinic for a number of treatments. They said they fully understood the consent process and felt clinicians had always been very open with them in discussing the likely outcomes of treatment.
- Where clinical staff carrying out pre-treatment assessments and consent discussions were concerned about a patient's mental capacity, they secured additional professional advice. Patients who lacked capacity who had an appointed carer were required to satisfy clinical staff that they understood their treatment and aftercare before procedures could take place.
- Staff demonstrated understanding of their responsibilities under the Mental Capacity Act (2005), including in the consent process. The doctor who carried out the treatment plan pre-assessment included a mental capacity assessment and postponed treatment if the patient did not understand the procedure or was unable to provide consent. Clinical staff we spoke with said they would challenge the treating doctor if they felt a patient had diminished capacity to consent to treatment.

Are surgery services caring?

Good

We rated caring as **good.**

Compassionate care

- A dignity and respect policy was in place and staff adhered to this in practice, such as by using curtains when patients were changing or in the recovery area.
- All 10 of the comment cards we received included comments on the kindness and professionalism of staff. Eight patients noted staff had treated them with privacy and dignity and four patients noted staff had understood their feelings.
- A privacy and decency policy was in place and was in date. This outlined baseline standards for staff in the standards of their interactions with patients. Feedback we received from patients through comment cards indicated staff adhered to this policy consistently.

- Staff carried out a rolling patient survey, which each patient was asked to complete before leaving the clinic. Between September 2017 and December 2017 12 patients completed the survey. All of the responses were positive and four rated the overall service as 'excellent'.
- Non-clinical staff had customer service training and the business manager ensured this was updated annually or as a result of specific learning from patient feedback.
- Training and policies for compassionate care reflected the standards set out in National Institute for Health and Care Excellence (NICE) quality statement 15 in relation to dignity and kindness.

Understanding and involvement of patients and those close to them

- Staff involved patients in all stages of their care and treatment in line with NICE quality statement 15. This began at the pre-assessment stage when the clinical director reviewed each patient's medical history and discussed the likelihood of success of their requested treatment.
- Where different treatment options were available staff discussed these with patients to help them make an informed choice.
- One patient we spoke with said they felt the doctor had taken the time to listen to them and had clearly understood their needs. They also told us they had received lots of information about their treatment and assessment. Comments we received on comment cards also reflected this and five patients noted they felt involved in their treatment plan.
- All treatment included an aftercare package that included outpatient support, access to telephone advice and printed information given before discharge.
- One patient told us they had always received one-to-one feedback after each treatment from the doctor and or the nurse. They said this, along with the 24-hour telephone advice line they had access to, ensured they felt confident staff fully involved them in their care.

Emotional support

- Staff recognised the nature of services provided meant patients often found treatment and aftercare to have an emotional impact and reflected this in training. When scheduling appointments the team ensured no more than three patients would be in the waiting room at any given time. This was a strategy to ensure standards of privacy and to maintain a quiet, calm environment.
- Patients noted in their survey responses that staff were kind and caring in their service and treatment delivery. One patient noted how the nurse had spent time speaking with them to calm their nerves about the treatment.
- From our discussions with staff we found the team had an approach of natural empathy with patients who were trying to get pregnant and provided appropriate emotional support when needed. For example staff said they would sit and have a drink with patients who were upset and listen to them.
- Clinicians offered patients time to discuss the implication of sterilisation procedures and could arrange formal counselling on request.

Are surgery services responsive?

Good

We rated responsive as **good.**

Service planning and delivery to meet the needs of local people

- Clinical staff provided treatment that unblocked fallopian tubes with x-ray guidance and under local anaesthetic. This was offered as a key element of the provider's core treatment provision. This approach was a less invasive treatment than other methods of unblocking fallopian tubes and was typically carried out in patients who wished to get pregnant naturally.
- The clinical team offered a well women clinic that included consultations for a range of specialist conditions, including infertility, cervical smears, vaginal wall surgery, labioplasty, hymenoplasty, hysteroscopy, polypectomies & biopsies, colposcopy and biopsies. The clinic also offered diagnostic procedures for hysterosalpingogram and transcervical tubal catheterisation, sigmoidoscopy, cystoscopy and ultrasound.
- The business manager planned appointment times to manage pressure on the service and minimise the risk of delays.

- The service had an active service level agreement with a laboratory that ensured clinical samples were handled and analysed in line with national standards.

Access and flow

- Patients accessed the service by self-referring or on referral from another clinician. The team carried out procedures by prior arrangement and were available Monday to Saturday from 10am to 6pm.
- Outpatient consultations were by appointment only and each patient was allocated up to 30 minutes.
- An on-call system was in place when the clinic was closed, which meant patients had access to clinical advice, including for emergencies. The surgeon provided advice by telephone in urgent cases and ensured patients attended their nearest NHS service in the event of urgent need. Where the surgeon was unavailable they nominated someone to provide this service.
- There was no waiting list for services and the wait for treatment related only to the consent and cooling-off period and the availability of appropriate specialists.
- The service was not able to offer unplanned emergency surgery procedures and instead referred patients to their nearest NHS hospital.
- Between October 2016 and February 2018 there had been no cancelled surgical procedures.
- Patient comment cards and a patient we spoke with commented on the ease of access to the service, with flexible appointment times.
- Patients accessed the consultant radiography service through a GP referral.

Meeting people's individual needs

- All areas of the clinic were accessible by wheelchairs and by those with reduced mobility.
- Members of the staff spoke three languages other than English and supported patients with interpretation if needed. Where a patient needed language support at a more advanced level or in another language, the service had an established relationship with a translation service. This was a chargeable service available with patient consent.
- Clinical staff followed up with patients after their procedure unless the patient declined this.
- The clinic provided a highly individualised service for specific, clearly defined conditions. Treatment was only provided after a preoperative assessment was completed, in line with National Institute of Health and Care Excellence quality statement 15. We saw evidence clinicians consistently adhered to consent processes within the preoperative assessment although there was no defined cooling off period.
- Patients noted clinical staff provided details of risks and potential complications and said they were given post-procedure instructions and information to take away.
- Private spaces were available for patients to have time alone and for confidential discussions with clinical staff.

Learning from complaints and concerns

- There was an up to date complaints policy in place and information on how to complain was displayed prominently in the waiting area. This information was also available on the service's website.
- The complaints policy included information for patients on referring their case to the Independent Healthcare Sector Complaints Adjudication Service (ISCAS) in the event they were not satisfied with the provider's response.
- The service reported no formal complaints between December 2014 and February 2018. This represented a four year period with no complaints, which reflected high levels of patient satisfaction.
- Staff demonstrated good understanding of the complaints policy and said the attentive, small-scale nature of the service meant they could address minor concerns as they arose. For example one patient in 2017 had voiced displeasure over the availability of clinic times. This was raised as a minor concern and not a complaint. The business manager had resolved this immediately and had discussed the cause of the issue in the next whole-team meeting.
- The business manager identified opportunities for learning from communication with patients and shared these with staff as part of meetings and training. For example one patient had approached reception staff aggressively with a demand to be seen by a clinician immediately. To address this, the manager met with the patient and explained why the clinic could not provide treatment on a walk-in basis. Through this discussion they identified that the patient had pre-existing health concerns, which meant they would need additional clinical assessment. The manager explained why this

was the case and offered the patient the next available appointment with a doctor. They used this situation to ensure staff had the knowledge and skills to interact with people exhibiting different personalities.

Are surgery services well-led?

Good

We rated well-led as good**.**

Vision and strategy for this core service

- The service vision and strategy centred on providing high quality care and treatment that was responsive to the needs of patients. All members of the permanent team had contributed to the development of the vision and strategy, which included the security of patient information and future sustainability of the service.
- The permanent team had established a mission statement, which they used as a framework for care and treatment. This acknowledged that treatments provided were less invasive than those typically available in the UK, the Middle East and the Gulf region and as such offered patients an alternative treatment option.

Governance, risk management and quality measurement

- The service did not have oversight of the inconsistencies regarding the pregnancy rule in two of the policies we reviewed.
- The medical director and business manager maintained a tracking document for risks and updated these monthly.
- Information management systems were in place to protect patients against breaches of confidentiality and to prevent data loss. This included a back-up server for electronic records and controlled access to paper records in the clinic.
- Where the service shared patient records with GPs or with the patients concerned, this was given by hand in the clinic, delivered by secure post or e-mailed in a password-protected file.
- The clinic was registered with the Information Commissioner's Office to ensure data privacy standards were maintained in line with national best practice standards.
- The service complied with the international payment card industry data security standard in relation to processing payments.
- There was a duty of candour policy in place with evidence of appropriate reviews. The service had not reported any incidents or complaints that applied the duty of candour. However, all of the staff we spoke with demonstrated a good standard of knowledge of their responsibilities and the medical director had established reporting procedures to document any future instances.
- All policies relating to clinical governance and quality assurance were up to date and readily accessible, including for professionals who provided occasional services in the clinic. This included policies for whistleblowing, confidentiality, information governance and the Caldecott principles, acceptable use of e-mail and the internet and an overarching governance and monitoring policy.
- All staff who worked under practising privileges held indemnity insurance in accordance with the Health Care and Associated Professions (Indemnity Arrangements) Order 2014.

Leadership / culture of service related to this core service

- The clinical director provided leadership with support from the business manager.
- The service was provided by a small team of four people, which meant there were well-established close working relationships. This meant each individual had readily available support from their colleagues and senior staff.
- Permanent staff and those who worked occasionally in the clinic described a friendly, professional and positive working environment. Each person said they felt valued as a team member and demonstrated commitment to patient outcomes and the success of the service.
- The senior team arranged an annual social event for everyone involved in the running of the service. All of the people we spoke with said this was a positive opportunity for team building and helped to maintain their sense of commitment to the service.

Public and staff engagement (local and service level if this is the main core service)

- The medical director and business manager led quarterly staff meetings that included clinicians who

worked for the clinic under practicing privileges. Staff told us this was a productive strategy for engagement and said it ensured they had a voice in the running of the service. One individual said they felt they were encouraged to talk about ideas for improvement and development and to make contributions to the business development plan.

- The team used a monthly marketing meeting to improve the reach and awareness of the service. This included the marketing lead and an external specialist who worked to increase the profile of the clinic.

Innovation, improvement and sustainability (local and service level if this is the main core service)

- Although the service demonstrated how they had developed core treatment to meet the needs of a specific group of patients, staff acknowledged that there were financial limitations on the service that meant they could not deliver a full range of infertility services. However an improvement plan was in place, which included sourcing an ultrasound machine for 3D imaging in fertility monitoring.
- A business continuity plan was in place and had been recently reviewed.
- The permanent team had established a business development plan that included increased marketing, investment in reproductive technology and the formation of a strategic management team.
- The senior team acknowledged financial pressures in the organisation but there was no evidence of examples where these had compromised patient care. The team was focused on increasing revenue to be able to offer a more sustainable service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- Review their policies to ensure there is consistency with the pregnancy rule so that patients that may be pregnant are safe from risk.

Action the provider SHOULD take to improve

- Ensure draft policies are reviewed against best practice prior to ratification.
- Audit medicines management procedures to ensure stock control is effective.
- Record and audit surgical outcomes.
- Replace fabric curtains in clinical areas with disposable alternatives.
- Ensure the system used to carry out safety checks on emergency equipment includes a check of sterility of equipment.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must review their policies to ensure there is consistency with the pregnancy rule so that patients that may be pregnant are safe from risk.