A.R.G.C. Limited

Assisted Reproduction and Gynaecology Centre

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

Summary of findings

Overall summary

This is the first time we rated this service. We rated it as good because:

- The service had enough staff to care for patients and keep them safe. Staff understood how to protect patients from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to patients, acted on them and kept good care records.
- Staff provided good care and treatment, gave patients enough to eat and drink, and gave them pain relief when they needed it. Managers monitored the effectiveness of the service and staff worked well together for the benefit of patients. Key services were available seven days a week.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders understood their accountabilities and staff were clear about their roles to run the service. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service engaged well with patients and all staff were committed to improving services continually.

However:

- Safeguarding training did not follow professional guidance. At the time of inspection, the registered manager who was the safeguarding lead, did not know how many staff had completed safeguarding training, at what level the training was, and that this training needed to be routinely refreshed.
- We did not receive evidence that incidents and risks were managed at a senior level.
- We did not receive evidence to demonstrate how many staff had completed mandatory training.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good	

Summary of findings

Contents

Summary of this inspection

Background to Assisted Reproduction and Gynaecology Centre

Assisted Reproduction and Gynaecology Centre provides private fertility treatment for people in central London and the surrounding areas. Most fertility treatments that need to be licensed with the Human Fertilisation and Embryology Authority (HEFA) do not come within the scope of registration with the Care Quality Commission (CQC). If a service is registered with CQC and licensed with the HFEA, we will only inspect and rate the parts of the service that are within CQC scope. This does not include treatments to assist conception and those that are licensed by the HFEA.

The service is registered with the CQC for the regulated activities of diagnostic screening procedures, surgical procedures and treatment of disease, disorder or injury. The treatments that fall within the scope of practice are hysteroscopy, with or without small cyst aspirations. This is a minimal invasive procedure that uses sound waves (ultrasound) to pinpoint a cyst and guide a thin needle into the cyst to remove fluid. A hysteroscopy is a procedure used to examine the inside of the womb (uterus). It is carried out using a hysteroscope, which is a narrow telescope with a light and camera at the end.

The service is located in a three storey Grade I listed building in a residential area. Facilities include a seated reception area, consulting rooms, ultrasound scanning rooms, an operating theatre and recovery area and administration rooms.

The service is open seven days a week and runs a consultant on-call out-of-hours system for patients.

The service is led by the medical and deputy director and registered manager who was the clinic manager. They were supported by a range of clinical staff including consultants, anaesthetists, embryologists, nurses and a healthcare assistant.

The service was last inspected in 2013 and met the standards required. This is the first inspection under our new rating system.

How we carried out this inspection

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on the 27 January 2022.

The team that inspected the service comprised a CQC lead inspector and an inspection manager. During the inspection we spoke with the registered manager, medical director and another two members of staff. We did not speak with any patients during the service so have been unable to rate the caring section. We reviewed a range of policies, audit reports, staff files, and patient records.

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

Summary of this inspection

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service 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 staff undertake safeguarding refresher training every three years as a minimum, in line with the Intercollegiate best practice guidance. (Regulation 17)
- The provider must improve their governance systems for the oversight of risks and incidents. (Regulation 17)

Action a service 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 SHOULD take to improve:

- The provider should improve the system they have for the oversight of mandatory training.
- The provider should ensure patients use independent translation services and not family members for those patients who did not speak English.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Good	Insufficient evidence to rate	Good	Requires Improvement	Good
Overall	Good	Good	Insufficient evidence to rate	Good	Requires Improvement	Good

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Good

We rated it as good.

Mandatory training

The service provided mandatory training in key skills to all staff, but we were not sure everyone had completed it.

We did not receive evidence all staff had received and kept up to date with their mandatory training which included basic life support (BLS), mental health capacity, infection prevention and control, fire, patient confidentiality and safeguarding.The registered manager told us an external provider was engaged to deliver mandatory training subjects, with two-three sessions set aside per year for this. Certificates were provided on completion. However, during the inspection, the manager was unable to provide the information as to how many staff had completed mandatory training. After the inspection we requested this as part of our additional data request, but never received the information. On further questioning the registered manager told us all staff had completed their mandatory training but did not provide evidence to demonstrate this.

We reviewed four staff records which showed they had completed BLS, and four anaesthetist records which indicated they had received training in advanced life support (ALS).

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. However, we were not assured all staff had received refresher training in this subject, and there were no systems to ensure staff received regular training updates.

The registered manager was certified level three safeguarding trained and was the lead for the service. During the inspection, they were unsure of what level other staff were trained to, and they did not have any awareness of the Intercollegiate guidance on training levels. The Intercollegiate guidance provides a clear framework which identifies the competencies required for all healthcare staff and the level of safeguarding training they are required to undertake. The guidance also states staff should receive refresher training every three years as a minimum. There were no systems to ensure staff routinely undertook refresher training. Further, the registered manger was providing the training to staff themselves, despite not having been trained as a deliverer of training.

Good

Diagnostic and screening services

We saw evidence from three staff records they had completed level two safeguarding training, One staff members records showed safeguarding training had been completed over four years ago. The registered manager told us they had received regular refresher training.

After the inspection, the registered manager told us all consultants and anaesthetists had completed safeguarding level two training and most nurses had completed safeguarding training to level two or three, and those who had not were due to complete safeguarding level two training by the end of February 2022. However, we did not see the evidence for this, and our concerns relate to the lack of understanding at a senior level to the Intercollegiate guidance and the ongoing refresher training staff were required to complete.

Staff we spoke with, knew how to identify adults and children at risk of, or suffering, significant harm and were able to provide examples, such as not seeing patients at appointments unless their partners were fully engaged with all appointments and treatment. This was to ensure women were not being coerced into treatment. Staff knew how to make a safeguarding referral and who to inform if they had concerns.

We were told safeguarding was discussed at local team meetings and during governance meetings, although we were not provided with any minutes of such meetings to verify this.

Cleanliness, infection control and hygiene

The service controlled infection risks well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and had suitable furnishings, which were clean and well-maintained.

The service had Covid-19 infection control protocols in place for patients who visited. Temperature checks were carried out on people as they arrived at the service and forms were completed to indicate their well-being status. Patients were asked to clean their hands and wear a mask while at the service. The waiting area accommodated social distancing and appointments were arranged to ensure the service was not too busy. All staff had been vaccinated and lateral flow tests were completed on a routine basis.

Staff followed infection control principles including the use of personal protective equipment (PPE), and were guided by relevant policies. Clinical staff wore scrubs, were bare below the elbows and wore disposable masks, head coverings and shoe coverings when necessary. Hand hygiene audits were routinely completed for compliance and those we reviewed showed a consistent high achievement rate.

Staff cleaned and prepared equipment after patient contact. Equipment we viewed in the operating theatre appeared suitably clean. Staff completed infection control checklists at the start of the day.

There were designated staff with responsibilities for the oversight of infection prevention and control and there was an infection control lead within the service.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

Good

Diagnostic and screening services

The service was located in a Grade I listed building, which meant it was subject to regulations to protect the historical and architectural significance. The design of the environment followed national guidance as far as it was able. Entrance to the building was security controlled by staff.

There was a spacious reception room and the area in which the cyst aspiration procedures were carried out was suitably laid out and appropriate for use. There was good ventilation and the air quality in the room was controlled to maximise safety.

A recovery area was available for women to rest after their procedure. Trolley areas were separated by clean paper screens. Observational equipment was readily available for nursing staff to check the pulse and heart rate after procedure.

Cyst aspiration equipment was safely managed, including the cleaning and sterilisation after use. This was undertaken by an off-site provider under a service level agreement. Staff reported that they had enough hysteroscopes to conduct the required level of work.

Staff carried out and recorded daily safety checks of specialist equipment which included resuscitation equipment, and these items were also subject to safety checks at regular intervals. We saw the resuscitation algorithm was displayed during our visit.

There was up to date portable appliance testing with equipment clearly labelled indicating the date.

There was a backup generator to ensure business continuity in the event of power failure and this was routinely maintenance checked.

Staff disposed of clinical waste safely using the correct colour coded clinical waste disposal bags and a specialist waste company collected daily. Sharps bins were correctly used and stored.

An external safety fire service checked the fire alarms on a weekly basis and the service conducted fire safety drills every six months.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.

Staff completed risk assessments for each stage of the patients journey for hysteroscopy and cyst aspiration treatments. There was a starting treatment checklist which covered the patients' medical history as well as mental health assessments. Individual risks were assessed by the consultant and advice given.

Pre-operative and post-operative assessments as well as discharge assessments were completed for all cyst aspiration treatments using national recognised tools, for example to carry out patient observations such as blood pressure and cardiac monitoring and when to escalate.

Conscious sedation was used for all hysteroscopy and cyst aspiration procedures. A qualified anaesthetist completed all relevant assessments before and during the treatment. The anaesthetist stayed on site until the patient had fully recovered.

Good

Diagnostic and screening services

Staff knew and dealt with specific risk issues. Patients completed a separate consent form in relation to hysteroscopy procedures where the risks were clearly detailed, and patients were given a comprehensive leaflet explaining the whole procedure. Unexpected findings not fertility related were referred to external gynaecologists or the patients GP.

Staff responded promptly to any sudden deterioration in a patient's health. The service did not see or treat any acute high risk medical patients. Due to the nature of the treatments, patients had to be generally fit and healthy and of a young age to start any of the fertility treatments. All staff had completed basic life support training and senior staff were either immediate life support or advanced life support trained. In the event of an emergency, the service would call 999.

There was a management of sepsis policy which provided detailed escalation guidance for staff to follow.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix

Nursing staff

The service had enough nursing and support staff to keep patients safe. There was a total of 17 registered nurses and one health care assistant. The nurses worked on a rotational shift basis from 6.15am to 4.45pm and 7.30am to 6.30pm. The service was open seven days a week. Staffing levels could be adjusted daily according to the needs of patients and the level of activity. There was a nursing manager and deputy who had oversight of nursing staff.

The service did not use any bank or agency staff. Although there had been some sickness absence as a result of Covid-19, the service was able to backfill shifts from within. There was a low staff turnover rate, with most staff having worked at the service for many years.

Nursing staff were given their rotas in advance and there were no nursing vacancies at the time of our inspection.

Medical staffing

In total there were four consultants who worked within the service with two consultants completing the cyst aspiration treatments. There was a rota of six anaesthetists who worked for the service and held practising privileges with the service.

For each hysteroscopy/cyst aspiration treatment there was a consultant, anaesthetist and registered nurse. For the recovery stage a registered nurse cared for the patient on a one to one basis with the anaesthetist having oversight.

The service made sure all medical staff with practising privileges had valid professional registrations, medical indemnity insurance and had completed appraisals.

Medical staff met regularly to ensure everyone was up to date with patient care plans.

Records

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.

Good

Diagnostic and screening services

Patient records were in paper format and were completed for each patient at each attendance. We looked at three sets of patient notes where the patient had undergone a diagnostic hysteroscopy. Patient notes were detailed with the expected level of information, including any potential risks and consent, and all staff could access them easily.

All communication with the patient was recorded clear and concise. There were clear timelines of notes with dates and signatures of staff, so when patients transferred to a new team, there were no delays in staff accessing their records.

Records were stored securely, and staff had completed data protection training. There were policies and procedures for staff to follow for the safe keeping of staff records.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

Staff followed systems and processes when safely prescribing, administering, recording and storing medicines. There were good checklists in place to make sure there was an accurate updated record of administration of medicines and medicine stock.

Staff stored and managed all medicines including medical gases and prescribing documents safely and safe systems were used for the recording and storage of controlled drugs.

There was access to a reversal agent in the event that a patient reacted to sedation. Pain relief was also available and was given when required and after assessing the level of pain.

Incidents

The service did not always managed patient safety incidents well. Although staff recognised incidents and near misses and reported them appropriately, we were not sure managers investigated incidents and shared lessons learned with the whole team and the wider service, as we did not see evidence of this.

Staff knew what incidents to report and how to report them. Staff raised concerns and reported incidents and near misses in line with the service's policy. There had been no recent near misses in the past six months. There had been no reported incidents in relation to cyst aspiration procedures in the past twelve months.

There was an incident reporting policy which provided guidance to staff on how to escalate and who to report an incident to. Incidents were investigated by the medical director and registered manager. We were told incidents were routinely discussed during senior governance meetings and staff received feedback from investigation of incidents, both internal and external to the service. However, we did not see evidence of the full governance meeting minutes to corroborate that this happened.

We did see there was a duty of candour policy in date. The manger was able to describe how this meant being open and transparent to the patient when things went wrong.

Are Diagnostic and screening services effective?

Good

We rated it as good.

Good

Diagnostic and screening services

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Policies we reviewed were in date and accessible to all staff, for example, sepsis management, infection prevention control and management of medicines. Policies and standard operating procedures (SOP) were reviewed annually by departmental heads and in conjunction with the medical director and clinic manager.

The service had an audit programme to monitor performance and assurance for safety, but we did not see evidence in the form of governance meeting minutes to see if results were discussed at a senior level and action taken.

Nutrition and hydration

Staff gave patients food and drink when needed.

Patients waiting to have hysteroscopy treatment were seen early in the morning with reporting time to the reception of 6.30am. Patients were provided with written instructions of when to fast before their appointment time.

Patient's weight and height were taken to assess their body mass index (BMI) as part of the medical history during the first consultation.

Post procedure patients were offered a choice of beverages and snacks. There was a kitchen area within the service and water was available throughout the service.

Pain relief

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

Staff assessed patients' pain using a recognised tool and gave pain relief in line with individual needs and best practice. Patients received pain relief soon after requesting it.

Staff prescribed, administered and recorded pain relief accurately in patient notes.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients. The service had been accredited under relevant clinical accreditation schemes.

Patient outcomes were related to fertility treatments and procedures and were registered with the Human Fertilisation and Embryology Authority (HFEA) and were published on their website.

Although we saw a programme of audits had been completed, we did not receive evidence to demonstrate oversight at a senior level.

Good

Diagnostic and screening services

Competent staff

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

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Managers gave all new staff a full induction tailored to their role before they started work. New staff worked in a supernumerary capacity for three months and had an assessment of competencies as part of the probationary period. Additional training would be provided if any area had not yet been achieved.

We were told managers supported staff to develop through yearly, performance reviews where additional learning could be identified. Competencies were checked annually as part of their appraisal process. Staff received regular annual appraisals. We saw evidence of three nurse appraisals recently completed.

We reviewed two registered nurses' files and found the necessary checks had been completed, for example, evidence of disclosure and barring service (DBS), evidence of qualifications, references, and staff competency checks such as, IPC, bloods and preparing recovery.

Managers supported medical staff to develop through regular, constructive clinical supervision of their work through revalidation and appraisal. We reviewed two consultants' records and saw an appraisal had been completed and certification. The medical director was registered with the General Medical Council (GMC) and was the responsible officer.

Consultants and anaesthetists with practicing privileges received external appraisal within their respective NHS work. Doctors in private practice apply for privileges to be granted at a facility, subject to suitability checks, history and appropriate indemnity cover. The service gained assurance with regular checks and we saw evidence that these checks had been completed for four staff members files.

Managers said they made sure staff attended team meetings or had access to full notes when they could not attend.

Multidisciplinary working

Doctors, nurses and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff held regular and effective multidisciplinary meetings to discuss patients and improve their care. Patients could see all the medical professionals involved in their care at one-stop appointments.

Nurses conducted handovers for their shifts to provide up to date information on patient care. The service worked with other agencies in such instances, when they had to make referrals.

Health promotion

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

The service promoted health and wellbeing by providing information on how the patient could prepare their body to get the best results from treatment. Such information included promoting healthy eating habits avoiding alcohol and smoking and reducing caffeine as well as how to achieve a normal body mass index (BMI). This information was available on the services website.

Good

Diagnostic and screening services

Seven-day services

Key services were available to support timely patient care.

The service was open seven days a week and patients were able to make contact and seek help if required during opening hours up until 6pm. For out of hours contact, patients were redirected to one of the four consultants.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff made sure patients consented to treatment based on all the information available and clearly recorded consent in patient records.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care and this started at the patient's initial consultation.

Staff made sure patients had all the information to make an informed decision and this included the risks. For example, there was a specific separate consent form for hysteroscopy procedures, and this provided the complications of the procedure.

All records we reviewed demonstrated consent had been sought prior to any treatment starting with information being provided at each stage of the patient's journey.

Are Diagnostic and screening services caring?

Insufficient evidence to rate

We did not have enough evidence to rate the caring domain.

There were no patients having treatment under the regulated activity on the day of inspection. We asked the registered manager to approach patients having a procedure under the regulated activity, so that we may speak with them about their experiences. As we did not get any response to this, we could not speak with anyone who had been treated or any relatives or carers. We therefore cannot report fully on the caring key question.

The service engaged with patients for their feedback and we reviewed the latest results of their patient satisfaction survey from January 2020 to January 2021. Patients had scored the service above 90% for all questions asked, such as, convenience of appointments, speed of attention and overall standard of care received. For the question 'would you recommend this clinic?' the service scored 100%. The return of completed forms they had received so far was 50 and was less than the amount in the previous year, but the pandemic could have contributed to this. The service received e-mails and personal letters specifically thanking them for their efforts and this had not decreased from the previous year.

The Human Fertilisation and Embryology Authority displayed patient feedback on their website and the feedback we reviewed was good.

Good

Diagnostic and screening services

The fees patients were expected to pay, were set out clearly from the start before any treatments went ahead.

Are Diagnostic and screening services responsive?

Good

We rated it as good.

Service delivery to meet the needs of local people

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

Managers planned and organised services, so they met the changing needs of the local population.

The service minimised the number of times patients needed to attend the hospital, by ensuring patients had access to the required staff and tests on one occasion. Clinics were run seven days a week an opened early at 6.15am for procedures to start at 7am. This enabled the service to fit around the needs of people. There were no waiting lists for cysts aspirations.

Facilities and premises were appropriate for the services being delivered. Although the building was Grade I listed, the layout was spacious to accommodate enough consultation, theatre and recovery rooms.

There was a three week waiting list for initial appointments, but this was dependant on the patient's preference to see a consultant. Patients were prioritised but appointments were planned in advance due to the nature of the treatment.

Managers monitored and took action to minimise missed appointments and managers ensured that patients who did not attend appointments were contacted.

Meeting people's individual needs

The service was not always inclusive and did not fully account for patients' individual needs and preferences. They coordinated care with other services and providers.

Due to the limitations placed on the structure of the building, there was no access for wheelchair users. The service did provide information to patients on those fertility clinics that could provide access when they could not accommodate them.

There was no informal arrangement with an external company for the use of translation services which is best practice. It was up to the patient to make these arrangements and they were asked to do so if communication was a problem. However, many staff spoke different languages at the service, such as Arabic, Italian, French, Spanish and Russian.

The service saw many international patients and offered an introductory consultation via teleconferencing. Their website provided this information in Arabic as well as English.

Patients were offered independent counselling services when they first registered with the service.

Good

Diagnostic and screening services

Access and flow

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

Waiting times were monitored by the manager and staff made sure patients did not stay longer than they needed to. Appointments were planned so enough time was allowed for the discussion and planning of treatment.

The service was open for 365 days a year, so monitoring could be taken at weekends and bank holidays.

The Covid-19 pandemic had impacted new consultation appointments, but the service was back to normal and managing the slight waiting times for these new consultations.

When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible. There had been no cancellations for hysteroscopy procedures or cyst aspiration in the past six months.

For hysteroscopy treatments, patients were seen early in the morning for the pre-operative checks as the procedure started at 7am and took 30 minutes. Recovery was usually quick due to the procedure being low risk, but there were four recovery beds to accommodate patients and the service was able to book the right amount of patients to make sure there was no overflow and lack of recovery beds.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

The service had a detailed complaints policy with structured systems on the complaints process. Patients were provided with details of how long their complaint would take to investigate.

The service displayed information about how to raise a concern in patient areas. If a patient complained during their visit staff would try to resolve it. If it could not be resolved the patient could raise a formal complaint.

The clinic manager investigated complaints, and these were singed off by the medical director. Complaints were discussed during governance meetings to identify any themes and trends and complaint feedback was shared with staff during local team meetings.

We reviewed two complaints and saw the formal complaints process was being followed.

Are Diagnostic and screening services well-led?

Requires Improvement

We rated it as requires improvement.

Good

Diagnostic and screening services

Leadership

Leaders did not always understand and manage the priorities and issues the service faced. However, they were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

The service was led by the medical director and supported by a deputy medical director and the CQC registered manager who was also the clinic manager. Respective departments had their own leads, for example, there was a nurse manager and deputy nurse manager.

We were told the medical director and clinic manager regularly met with the leads and their team to ensure there was continued oversight of performance and quality. We requested meeting minutes of governance meetings, but only received the summary agenda for two meetings, which were not sufficiently detailed to enable the reader to know what had been discussed. We found incidents and risks were not discussed as set agenda items and could not be certain that these important areas were routinely considered.

The clinic manager did not have a full understanding of their responsibilities for the provision of safeguarding training or the associated competencies required for all healthcare staff. Systems for oversight of mandatory and safeguarding training were not sufficiently developed.

Staff fed back that their managers were supportive and visible, and they worked as a close knit unit with good direction from the leaders.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.

The quality management review 2021 identified the changes the service made due to the Covid- 19 pandemic and this had resulted in an approved Covid strategy which had been implemented.

The services statement of purpose states its aims to assist couples to achieve a pregnancy in a safe and caring environment with state of the art equipment and highly trained staff. Couples would be treated in a kind and professional manner ensuring their privacy and confidentiality. They would be offered a full explanation of the treatment they were undertaking and be kept fully informed at all times. No procedures would be undertaken without the full written consent of the patient and opportunity would be given for questions and discussion.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff told us there was a good culture within the service, one of openness and honesty and there was a good team spirit. Staff said the service was a good place to work. Staff described how they had forged close friendships with other staff members and how they felt part of a family unit.

Good

Diagnostic and screening services

The service promoted equality and diversity and staff provided feedback on their development. The deputy nurse manager described how they had been promoted and developed since they had started.

Governance

Leaders did not always operate effective governance processes, throughout the service. Although staff at all levels were clear about their roles and accountabilities, we were not assured they had regular opportunities to meet, discuss and learn from the performance of the service.

We were told there was a governance structure embedded in the service where all staff were clear about their roles and responsibilities. The medical director and clinic manager understood their accountabilities.

We were told senior people from each department, for example the medical director, the clinic manager, embryologists and consultants attended regular governance meetings where they discussed risks, incidents, patient outcomes, safeguarding, complaints and performance. We were told each of these departments had their own team meetings where they discussed audit findings and local relevant information. They each had their own standard operating procedures to adhere to. We asked to see the minutes from governance meetings, but only received two meeting summaries which were limited in the level of detail around the discussion and decision making. There was a lack of evidence to demonstrate strong and effective monitoring and governance within the service.

There was an audit programme, which included monthly local audits. We were told results fed into the governance meetings where themes and trends could be identified and acted upon. Although we did review audits that had been conducted at a local level, the only evidence we received that audit findings were discussed at a senior level was through the agenda summary sent to us. This did not show the finer details of the discussions such as themes and trends, improvements or deterioration, action taken and roles of accountability.

A quality management review gave oversight on quality indicators, third party agreements, staffing volume and scope of work and patient feedback. The quality management review we looked at described for example how all of the third party agreements had been renewed and how the service had ensured they had a good supply of alternative suppliers to avoid any disruption during the pandemic.

Management of risk, issues and performance

The registered manager did not use systems to manage performance effectively or identify and escalate relevant risks and issues.

There was a system for the management of risks through completed risk assessments. A risk tool was used to determine the level and severity of the risk and therefore each risk assessment had a rating and grade criteria, for example, rare, unlikely, possible, likely, and almost certain applied to them. We saw risk assessments such as health and safety and risk assessments related to Covid 19. The registered manager told us risks assessments were reviewed annually or more regular dependent on the risk.

We were told non clinical risks were reviewed by the medical director and clinic manager at regular quarterly intervals. We asked for evidence of governance meeting minutes to demonstrate this. We received the last two governance meeting agenda/summaries but there were no details to show that risks were discussed during these meetings. Therefore, we did not receive evidence to demonstrate there was a strong oversight of risks and they were regularly reviewed.

Good

Diagnostic and screening services

There was a detailed schedule of audits to ensure quality performance such as medicine management, controlled drugs, obtaining consent and recording keeping to name but a few. Only one of the agenda/summary's provided showed that audit outcomes were discussed at a senior level, but we did not receive the level of detail required to demonstrate there was good oversight.

There was a business continuity plan should the service experience unexpected disruption. For example, there was a backup generator in the event of a power failure.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The service had up to date policies in relation to general data protection regulation and patient's personal information was securely stored in line with the guidance.

The service used a secure business messaging app that connected staff to the information they required quickly. The app was used as a communication tool to get forward messages to al staff quickly and efficiently.

The service conducted audits in record keeping and patient confidentiality and the audits we reviewed showed consistent compliance over continued period of time.

Engagement

Leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services.

The service was using more IT solutions to engage with patients. For example, the service was using teleconferencing consultations for patients overseas. The service had an easily accessible website which was informative and provided contact details if patients wishes to make contact with them. Patients were also directed to the HFEA website to leave feedback which was displayed on their website.

Staff engaged through monthly team meetings where updated information on the service was provided. Due to the small size of the service staff could regularly speak to the clinic manager if need be and staff said they were accessible and had an open door policy.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The service has pioneered a number of techniques in the country which have since become accepted practice.

Routine audits provided oversight of performance and identified themes and trends for continued improvement.

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
Surgical procedures Diagnostic and screening procedures Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service must ensure staff undertake safeguarding refresher training every three years as a minimum, in line with the Intercollegiate best practice guidance. (Regulation 17) • The provider must improve their governance systems for the oversight of risks and incidents. (Regulation 17)