The Birth Company Limited

The Birth Company

Inspection report

Alderley Edge Medical Centre
Talbot Road
Alderley Edge
SK9 7HR
Tel:

Date of inspection visit: 28 April 2021 and 30 April 2021
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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	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Inspected but not rated
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

We rated this location as Requires Improvement because:

- The service did not always provide mandatory training in key skills to staff or made sure that all staff completed it. Staff did not have the required level of training to enable them to always recognise and report abuse. Policies to keep people safe lacked detail and were not clear. The service did not always control infection risk well or use sufficient control measures to protect women, themselves, and others from infection. They did not use systems or processes to manage or store medicines. Managers did not always investigate incidents or share lessons learned.
- Managers did not always monitor the effectiveness of care and treatment to make improvements and achieved good outcomes for women. They did not always make sure staff were competent as staff records revealed gaps in pre-recruitment checks.
- The service was not always inclusive and did not always take into account women's individual needs. For example, it did not identify, meet, or support the information and communication needs for women with a learning disability, impairment, or sensory loss.
- Managers did not always understand and manage the information available to them to support improvements. They did not operate effective governance processes or have systems to manage performance effectively to enable them to make decisions and improvements. They did not always discuss shared learning from audits or incidents. The service did not always engage well with women to plan and manage services.

However:

- The service had enough staff to care for women and keep them safe. Staff assessed risks to women, acted on them and kept good care records. Staff collected safety information.
- Staff provided good care and treatment. They worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity, and helped them understand their conditions. They provided emotional support to women and those that accompanied them.
- The service planned care to meet the needs of local people and made it easy for them to give feedback. People could access the service when they needed it and did not have to wait too long for their results.
- Staff felt supported to develop their skills. Staff felt respected, supported, and valued. They were focused on the needs of women receiving care. Staff were clear about their roles and accountabilities. Staff were committed to improving services.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires Improvement 	We rated this service as requires improvement. See the Overall summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to The Birth Company

The Birth Company, opened in Alderley Edge in 2017, offers diagnostic pregnancy, gynaecological and fertility ultrasound scans to self-funding women over 18.

The Birth Company is located on the third floor of a newly refurbished medical centre and has a purpose-built facility for ultrasound and medical examination. The building is wheelchair accessible and has free on-site parking. The service has a reception area with two waiting areas with adequate seating. There are two identical scanning rooms, a meeting room and a staff room. The service has its own toilets.

This service has a sister clinic located in London.

The Birth Company offers a range of ultrasound diagnostic screening scans to pregnant mothers in relation to different stages of pregnancy:

- early pregnancy scans/ viability scan/ dating ultrasound scan at 6 to 10 weeks' gestation
- Harmony, Panorama or SAFE Non-Invasive Prenatal Testing (NIPT) from 10 weeks' gestation, which is a blood screening test for three targeted chromosomal conditions of Down's syndrome (T21), Edward's syndrome (T18) or Patau's syndrome (T13)
- nuchal translucency scans (prenatal screening scan to detect cardiovascular abnormalities in a fetus) at 11 to 14 weeks' gestation
- reassurance scans / early anatomy scans at 12 to 24 weeks' gestation
- sexing scan, gender scan from 16 weeks' gestation
- anomaly scan / anatomy scan / morphology scan at 18 to 24 weeks' gestation
- cervical / cervix length scan at 14 to 36 weeks' gestation
- fetal wellbeing / growth scan, includes doppler scan and presentation at 23 to 40 weeks' gestation
- 3D/4D scan (HD live) at 26 to 32 weeks' gestation.

The service also carries out general gynaecology scanning and assists In vitro fertilization (IVF) clinics abroad for patients who are undergoing fertility treatment. It performs gynaecological scans, follicle tracking and endometrial lining scans.

During the pandemic, the service stopped offering non-essential investigations such as fertility assessment, sexing scans and 4D scans.

The Birth Company is registered for the following regulated activities:

- Diagnostic and screening procedures.
- Maternity and midwifery services.
- Treatment of disease, disorder or injury.
- Family planning.

We inspected diagnostic and screening services provided by this clinic.

The service has had the same registered manager since 2017.

This is the first time this location has been inspected.

Summary of this inspection

We carried out a transitional monitoring call with the service on 12 February 2021. The transitional regulatory approach is a consistent and structured approach to monitoring and relationship management, with clear areas of focus based on a streamline set of Key Lines of Enquiry, through the Transitional Monitoring Activity. Information gathered during this call prompted the need for us to inspect the service.

How we carried out this inspection

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology. One inspector and one inspector manager carried out the inspection on 28 April 2021, with offsite support from an inspection manager and a head of hospital inspection.

We spoke with two members of staff, the sonographer and administrator. We spoke with four women who had used the service and reviewed feedback on website browser platforms and social media. We reviewed the centralised booking system and saw women's records on the system including booking, registration and consent forms. Following the inspection on 30 April 2021, we spoke with two further members of staff, the registered manager and nominated individual.

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

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations.

Action the service MUST take to improve:

We told the service that it must take action to bring services into line with three legal requirements.

- The service must provide care and treatment in a safe way, assess risks to women and do everything practicable to remove or reduce risks. Regulation 12(1)(2)(a)(b).
- The service must ensure that mandatory training in key skills is available, particularly safeguarding, to all staff. Regulation 12(1)(c).
- The service must assess, prevent and control the risk of infection by maintaining comprehensive cleaning records to show that cleaning has been completed between each woman. Regulation 12(2)(h).
- The service must have established systems and processes and operative effectively and assess, monitor and improve the quality and safety of the service and assess the risks Regulation 17(1)(2)(a).
- The service must ensure they have effective communication systems to share the learning from incidents and audit results. Regulation 17(2)(a).
- The service must ensure they have effective policies which are fit for purpose and which are regularly reviewed in line with national guidance. Regulation 17(2)(a).
- The service must have effective systems and processes to assess, monitor, and mitigate current risks. Regulation 17(2)(b).
- The service must monitor the effectiveness of care and treatment and use their audit findings to assess, monitor and improve the quality and safety of the service. (Regulation 17(a)(f).

Summary of this inspection

- The service must have effective governance systems to make sure staff are trained in key skills to ensure provision of a safe service. Regulation 17(2)(f).
- The service must have effective recruitment process to meet the CQC regulation requirements in employing fit and proper persons to carry out the regulated activities. Regulation 19(1)(a)(b)(c)(2).

Action the service SHOULD take to improve:

Action the 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.

- The service should ensure they identify, meet, and support the information and community needs for women with a learning disability, impairment or sensory loss and make reasonable adjustments under the Equality Act 2020.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic imaging

Safe	Requires Improvement
Effective	Inspected but not rated
Caring	Good
Responsive	Good
Well-led	Requires Improvement

Are Diagnostic imaging safe?

Requires Improvement

Mandatory training

The service did not always provide mandatory training to cover all key skills to staff. However, the service made sure that staff completed the modules that were provided.

During our inspection we did not see accurate up to date mandatory records for all staff.

Internal mandatory training for non-clinical staff did not include all modules to ensure they were able to provide safe and effective care. For example the training did not include infection, prevention and control, information governance, consent, mental capacity act, equality and diversity, health and safety at work, moving and handling or incident reporting training.

External mandatory training for clinical staff did not include equality and diversity and incident reporting training.

The service did not have a mandatory training policy which meant there was no guidance to staff on which modules and key skills were mandatory and how often training should be completed.

However, staff told us managers alerted them to complete training and were given protected time to complete mandatory training. Team meeting minutes showed that staff were reminded to complete their mandatory training.

Safeguarding

Staff did not have the required level of training to enable them to always recognise and report abuse.

Managers did not ensure that safeguarding training included female genital mutilation (FGM). This meant that staff were not trained to identify or recognise safeguarding risks during transvaginal scans.

The service had adult and children safeguarding policies, but they lacked detail and did not provide clear guidance for staff.

Requires Improvement

Diagnostic imaging

The service did not have access to anyone trained to level 3 in safeguarding children or adults and this included the safeguarding lead.

However, staff knew how to escalate any safeguarding concerns and the policy did contain local authority safeguarding contacts. Following the inspection, sonography staff completed FGM training.

Cleanliness, infection control and hygiene

The service did not always control infection risk well or use sufficient control measures to protect women, themselves, and others from infection. However, they kept equipment and the premises visibly clean.

Although the service, equipment and furnishings were visibly clean, the cleaning records did not show that all areas and equipment were cleaned regularly. This included the cleaning of transvaginal probes which meant that women could be at an increased risk of infection.

Staff did not perform rapid lateral flow testing for COVID-19 infection in line with government recommendations for regular testing of staff. We raised this with the registered manager, who was unaware staff could spread infection after being vaccinated. Following the inspection, the service had implemented twice weekly lateral flow testing.

The service did not complete quality checks or hand hygiene audits.

The service did not have effective policies or procedures referencing infection, prevention and control. They lacked detail, did not reflect current operational procedures, were contradictory and did not provide clear guidance for staff.

Staff followed infection control principles including the use of personal protective equipment (PPE).

We observed women being encouraged to sanitise their hands and saw sanitisers and washing facilities in each scanning room.

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.

The service had suitable facilities to meet the needs of women. There was clear signage and free onsite parking. Fire extinguishers were accessible, stored appropriately and there were clear fire exit signs.

Staff completed daily checks of stock and equipment to ensure there was sufficient stock to safely care for women.

Ultrasound scanning machines were serviced and tested by an external company. Electrical equipment had been safety tested within the last 12 months.

Staff managed and disposed of clinical and non-clinical waste in a way that kept people safe.

Assessing and responding to patient risk

Requires Improvement

Diagnostic imaging

Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.

Managers completed risk assessments for women. These were based on the information received from the booking and registration forms completed at the time of booking and the COVID-19 questionnaire which was submitted 24 hours in advance of the appointment. Managers reviewed the risks of COVID-19, ectopic pregnancies, miscarriages, smoking or allergies to latex.

Staff told us they would always ask women for the reason of the scan to make sure women did not have an underlying reason such as bleeding or abdominal pain.

Staff knew what to do and acted quickly when there was an emergency. All staff had completed either basic or advanced life support training and had access to a first aid box and a defibrillator.

The service had clear protocols and staff knew what actions to take if unexpected results were

identified on the ultrasound scan.

Staff advised women about the importance of attending their NHS scans and appointments in addition to this service.

Staffing

There were sufficient numbers of staff with the right qualifications, skills, training, and experience to keep women safe from avoidable harm and to provide the right care and treatment.

The service had enough staff to provide the right care and treatment.

Records

Staff kept detailed records of women's care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.

The service had a data retention policy to manage the retention period, storage, and disposal of women's personal data in line with national guidance.

Women's records were stored electronically, and all staff could access them easily.

The service provided women with an electronic copy of the ultrasound scan report and images, or diagnostic test results, by email to enable them to share with their midwife, consultant or GP.

The service provided information which showed they had sufficient information technology systems to ensure personal information was transmitted securely.

Medicines

The service did not use systems or processes to manage or store medicines.

Requires Improvement

Diagnostic imaging

The medicine, emergency and resuscitation policies did not reflect the current practice that medicines were no longer stored at the clinic.

The medicine policy stated the service kept a supply of Misoprostol 20 microgram tablets for women who had had an early miscarriage.

The emergency and resuscitation policies stated EpiPen's were available in the clinic, however, on checking the first aid box we did not see any EpiPen's.

Staff told us the Misoprostol and EpiPen's had been disposed of safely and appropriately at the local pharmacist because their usage dates had expired.

Following the inspection, managers informed us they had purchased an EpiPen which was stored in a locked cupboard.

Incident reporting, learning and improvement

The service did not always manage safety incidents well. Managers did not always investigate incidents or share the lessons learned with staff. However, when things went wrong, staff apologised and gave women honest information and suitable support. Managers ensured that actions from women's safety alerts were implemented and monitored.

The service did not have an effective incident reporting policy and staff did not complete training on how and when to report incidents.

The reporting accidents at work policy was not clear for staff to follow as it asked staff to complete an accident/incident log for logged incidents, but the document is actually called an error log. Managers did not always complete investigations on the incidents recorded.

Team meetings minutes did not show that incidents on the error log were discussed for learning and improvement however, staff told us lessons learned from incidents would also be shared via a messaging app and in team emails.

The service had a policy which covered duty of candour which meant that staff were guided to know when and how to apply duty of candour. However, staff we spoke with were not able to provide a definition of duty of candour.

Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.

Managers ensured that actions from safety alerts from Independent Doctors Federation were implemented and shared with staff.

Are Diagnostic imaging effective?

Inspected but not rated

Evidence-based care and treatment

Requires Improvement

Diagnostic imaging

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women subject to the Mental Health Act 1983.

Staff were able to access policies, procedures and protocols which had been developed in line with national guidance and best practice, for example from National Institute for Health and Care Excellence (NICE), British Medical Ultrasound Society (BMUS), Society and College of Radiographers (SCoR).

Staff protected the rights of patients subject to the Mental Health Act 1983 and followed the Code of Practice. Sonography staff completed mental health and mental capacity training. We were informed by the registered manager the service had not seen anyone subject to the Mental Health Act 1983.

Nutrition & hydration

Women had access to a water dispenser machine in the waiting area.

Staff gave women appropriate information about drinking water before transabdominal ultrasound scans to ensure they attended with a moderately full bladder. This enabled the sonographer to gain effective ultrasound scan images.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain during transvaginal scans.

The service did not undertake pain assessments however, staff told us that women were made to feel comfortable during their appointment.

The website provided additional information on transvaginal / internal scans, advising women to let their sonographer know if they had any worries about discomfort before or during the scan or ask to take a break at any point.

Patient outcomes

Managers did not always monitor the effectiveness of care and treatment to make improvements and achieved good outcomes for women.

Managers collected some audit data of performance metrics however, they did not use these results to understand performance, make decisions and improvements or achieve good outcomes for women.

Managers did not share or make sure staff understood information from the audits. Staff we spoke with did not have an awareness of audit results. Although team meeting minutes showed evidence that audits were discussed, it did not show that audit results were discussed for learning and improvement.

They did not have an audit schedule to monitor and check improvements over time. For example, they did not complete audits for hand hygiene, cleaning, scan times, reception waiting times, numbers of gender or health inaccuracies.

However, the service did perform peer reviews to ensure the accuracy and quality of the ultrasound scan images and written reports.

Requires Improvement

Diagnostic imaging

Staff had available information technology to collect patient outcomes. The scanning machine was able to collect sonography data.

Competent staff

The service did not make sure staff were competent for their roles. However, managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Managers did not have a clear recruitment process to meet the CQC regulation requirements in employing fit and proper persons to carry out the regulated activities. Staff records revealed gaps in pre-recruitment checks with regard to references, qualifications, employment history, and information about physical or mental health conditions.

Managers gave all new staff an induction tailored to their role and an employee handbook to support them in their role. They supported staff to develop through yearly, constructive appraisals of their work. In addition sonography staff received clinical supervision and peer review audits completed for ultrasound reports and images.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Administrative staff received three monthly objective settings meetings which identified any learning requirements.

Sonography staff attended webinars, national conferences and meetings with the Fetal Medicine Foundation, the International Society of Obstetrics and Gynaecology and the British Medical Ultrasound Society.

The service had a disciplinary policy to manage poor staff performance and support staff to improve.

Multidisciplinary working

Staff worked together as a team to benefit women. They supported each other to provide good care.

Staff held regular and effective multidisciplinary meetings.

They communicated effectively with the sister location with regular teleconference calls, emails and using a messaging app. They spoke positively of the integrated IT and telephone system which allowed for cross location cover and peer support.

Staff told us if any concerns were identified from a scan, they would write a referral in the report and advise the women to contact their midwife, GP or early pregnancy service or local NHS trust.

Seven-day services

Services were available to support timely care.

The service was open five days a week and did not provide emergency care and treatment.

The website was designed to take online bookings 24 hours a day.

Requires Improvement

Diagnostic imaging

Health Promotion

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

The website had relevant information promoting healthy lifestyles.

Consent, Mental Capacity act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. However, not all staff had received training in consent.

The service did not have an effective consent policy which reflected current operational procedures.

Staff did not complete training on consent as part of the internal mandatory training.

Although sonography staff had completed external training on the Mental Capacity Act (2005) the service did not have a policy to help staff manage women who lacked capacity, experienced acute anxiety or mental ill health. Managers told us that the service only saw 'medically fit women' and had not seen anyone who lacked capacity or a need relating to their mental health.

Although staff gained consent from patients in line with legislation the registered manager told us that checking consent in line with national guidance was "not relevant to the service".

The service completed audits to check consent forms had been saved correctly.

Are Diagnostic imaging caring?

Good

Compassionate care

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

We saw positive examples of when staff provided compassionate care to women. They were discreet and responsive and took time to interact with women in a respectful and considerate way. Sonography staff introduced themselves to women at the start of the scan appointment.

All women we spoke with described a positive experience and said staff treated them well and with kindness.

The service had a changing area in the corner of each scan room which had a frosted glass privacy screen to maintain the privacy and dignity of women whilst undressing and redressing after a scan.

Staff took account of women's personal needs. Women we spoke with said staff were very caring towards them if they had a history of miscarriages or terminations.

Requires Improvement

Diagnostic imaging

Emotional support

Staff provided emotional support to women, families, and carers to minimise their distress. They understood women's personal needs.

Staff gave patients help, emotional support and advice when they needed it. Staff had been trained to provide chaperone support if required.

We saw positive examples of emotional care from thank you cards, online feedback from women who had used the service. We heard a positive example of when staff kept in regular contact with a woman with a potentially life-threatening condition.

Sonography staff had received training to deliver bad news in the event of a miscarriage, need for a termination or a high probability of a chromosome abnormality result from Non-Invasive Prenatal Testing (NIPT).

Staff could signpost women to receive specialist help and advice from a number of services and provide leaflets for women in the event of a miscarriage.

Understanding and involvement of patients and those close to them

Staff supported and involved women, families, and carers to understand their condition and make decisions about their care and treatment.

The service understood and involved service users in their care by providing clear information about scan packages and costs on the website.

Staff made sure women understood their care and treatment and supported them to make informed decisions about their care. Women were guided to choose the right scan or package for them depending on the stage of their pregnancy.

Staff told us they took time to explain the scan procedure to women, answer any questions and provide realistic timescales for scan or blood results. Women understood when and how they would receive their scan results. The service was able to send ultrasound scan images directly onto women's mobile phones for them to share on social media platforms.

Although women could give feedback on the service, managers could not provide examples of how they used patient feedback to make improvements.

Are Diagnostic imaging responsive?

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 and the communities served.

Requires Improvement

Diagnostic imaging

Facilities and premises were appropriate for the services being delivered.

It was easily accessible by public transport with Alderley Edge railway station five minutes' walk away and had car parking spaces.

Meeting people's individual needs

The service made reasonable adjustments to help women with limited mobilities access the service, however, it did not always take into account all women's individual needs in line with the Equality Act 2010. The service directed women to other services where necessary.

Managers made sure women could get help from interpreters when needed. Women were asked if they required a translator on the registration form which was completed at the time of booking.

The service made reasonable adjustments to help women with limited mobilities access the service. There was an electric door at the main entrance to the building, accessible toilets on the ground floor and a lift available to reach the third floor. The entrance door to the service was wide enough for wheelchair (and pushchair) access. The couches in the scanning room could be lowered if required.

The service could signpost women to a number of specialist pregnancy, miscarriage, and fertility charities as well as a genetic counselling team and a psychologist or a psychotherapist who specialised in fertility, pregnancy, and parenthood.

Although the service had an equality and diversity policy, training records showed staff had not completed equality and diversity training.

The service did not have a policy to help guide staff to identify, meet or support the information and communication needs of patients with a disability, impairment such as aphasia, autism or a mental health condition, or sensory loss such as deaf, blind or deafblind. This was not in line with making reasonable adjustments under the Equality Act 2010. The booking, registration or consent form did not ask women if they required any reasonable adjustments to attend the service. The website did not promote making any reasonable adjustments to meet women's individual needs.

Access and flow

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

Women could access the service when they needed it and were able to book same day appointments for urgent concerns. Bookings could also be made online 24 hours a day, by email or telephone.

The service did not have a waiting list for appointments, and we observed appointments to run on time.

Women had timely access to test results and diagnosis and the service had a process to chase up outstanding blood results.

Learning from complaints and concerns

Requires Improvement

Diagnostic imaging

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously and investigated them. The service included women in the investigation of their complaint. Managers shared lessons learned from informal complaints with all staff. However, the complaints guidance contained incorrect information.

Women could provide feedback and raise concerns about care on website browser platforms, social media platforms and patient questionnaires and managers responded to all positive and negative feedback on website browser platforms.

The service clearly displayed complaints guidance information about how to raise a concern in the waiting area however, the guidance incorrectly states women should approach the Care Quality Commission (CQC) if they were unhappy with the outcome of a complaint instead of the Independent Sector Complaints Adjudication Service (ISCAS). Following the inspection, the service confirmed this had been amended.

Although the service has had no formal complaints, managers told us they were proactive in managing and acknowledge informal complaints and would be able to recognise themes and trends. They were not able to provide examples of what had been improved, or lessons learned, as a direct result of women's feedback or informal complaints.

Following the inspection, managers shared with us an example of how the service had improved as a result of an informal complaint.

Are Diagnostic imaging well-led?

Requires Improvement

Leadership of the service

Managers had the clinical skills and abilities needed for the service. They were visible and approachable for women and staff. However, they did not always understand and manage the information available to them to support improvements.

The registered manager and managing director were responsible for the line management of staff. Staff we spoke with told us they were supportive and encouraged their development.

Managers were available across both locations to provide clinical advice and guidance.

However, we were not assured that managers had robust oversight of the performance of the service.

Vision and Strategy

The service did not have a formally documented vision for what it wanted to achieve and a strategy to turn it into action.

There was no formal vision or strategy. We were told the service intended to employ a second sonographer or a midwife to enable them to offer more appointments and services.

Requires Improvement

Diagnostic imaging

Culture

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

Staff we met were warm, friendly and welcoming. They spoke positively about their roles and demonstrated pride in their work and managers were proud of them.

The website displayed a strong emphasis of care for women.

The service had a whistle blowing policy which encouraged staff to raise any concerns with managers.

Managers responded positively and took immediate actions as a result of some of the concerns we found on inspection and showed willingness to learn and improve.

Governance

Managers did not operate effective governance processes. Staff did not have regular opportunities to meet, discuss and learn from the performance of the service. However, staff at all levels were clear about their roles and accountabilities.

Managers had limited oversight of the concerns that we identified during the inspection. They were not aware of the risks and challenges which could cause potential harm to women who use the service. For example they did not ensure that safeguarding training included female genital mutilation (FGM), did not complete pre-recruitment checks, did not have adequate cleaning records and did not keep accurate up to date mandatory records for all staff.

The service did not have effective policies and procedures to provide clear guidance for staff. Managers did not always regularly check or update policies and procedures in line with national guidelines or best practice. Policies were not always clear, lacked detail and did not always reflect current operational procedures.

The service did not have a specific policy for mandatory training. We did not see the Mental Capacity Act, Deprivation of Liberty Safeguards or the Equality Act 2010 referenced in any of the policies we reviewed.

Managers did not discuss quality and safety performance issues at team meetings. They did not discuss or share learning from incidents or audit outcomes to improve the quality of care and treatment of women attending the service. We did not see any shared learning from incidents or audit results or patient outcomes in the minutes of meetings we reviewed.

Management of risks, issues, and performance

Managers did not have systems to manage performance effectively. They did not have systems in place to ensure risks were identified, escalated, and then mitigated to reduce their impact. However, they had plans to cope with unexpected events.

Managers did not have knowledge or oversight of the service's main risks and they did not understand the challenge of risks in terms of quality, improvements, and performance.

Requires Improvement

Diagnostic imaging

The risk register was not reviewed regularly or up to date and we found there was a lack of oversight of current clinical and non-clinical risks. Risks were not discussed at team meetings.

However, the service had a business continuity plan and valid insurance covering both public and employer liability, including professional indemnity insurance for registered professional staff.

Information management

Managers did not always analyse the data they collected to ensure they understood their performance to enable them to make decisions and improvements. However, staff could find the data they needed, in easily accessible formats. Data or notifications were consistently submitted to external organisations as required.

The information systems were integrated and secure.

Staff did not complete information governance training however, staff used password protection to prevent unauthorised access to data.

Staff reported sufficient numbers of computers and ultrasound machines in the service. They spoke highly of the integrated information technology database and telephone system which was linked to the sister location in London.

The service had a centralised appointment booking system and could ensure that personal information was transmitted securely.

Engagement

Managers did not always actively and openly engage with women to plan and manage services. However, they collaborated with partner organisations to help improve services for women.

Managers sought feedback from women's experiences every six months. However, they told us they did not use this information to plan and manage services.

Staff told us managers were approachable, supportive, and used the messaging app, emails, and team meetings for engagement. They were involved in the day to day running of the service.

The service collaborated with the sister clinic to help improve sonography scans and reports at provider level. In addition, they collaborated with a consultant in fetal medicine at a local NHS hospital.

Learning, continuous improvement and innovation

All staff appeared to be committed to continually learning and improving services. Managers told us they encouraged innovation and participation in research. However, they were unable to provide examples of service improvements.

Managers were not able to provide examples of service improvements resulting from incidents, women's feedback, or audits.

Staff felt confident to suggest improvements to the service such as;

Requires Improvement

Diagnostic imaging

- closing off online appointment slots to avoid women being able to book at short notice
- a system in place to check if new bookings had been made overnight
- the creation of signs showing when the reception area and toilet facilities had last been cleaned.

Managers told us the service was planned to be sustainable and environmentally conscious and did everything electronically to be paper light.

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 service must provide care and treatment in a safe way, assess risks to women and do everything practicable to remove or reduce risks. Regulation 12(1)(2)(a)(b). • The service must ensure that mandatory training in key skills is available, particularly safeguarding, to all staff. Regulation 12(1)(c). • The service must assess, prevent and control the risk of infection by maintaining comprehensive cleaning records to show that cleaning has been completed between each woman. Regulation 12(2)(h).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service must have established systems and processes and operative effectively and assess, monitor and improve the quality and safety of the service and assess the risks Regulation 17(1)(2)(a). • The service must ensure they have effective communication systems to share the learning from incidents and audit results. Regulation 17(2)(a). • The service must ensure they have effective policies which are fit for purpose and which are regularly reviewed in line with national guidance. Regulation 17(2)(a). • The service must have effective systems and processes to assess, monitor, and mitigate current risks. Regulation 17(2)(b).

This section is primarily information for the provider

Requirement notices

- The service must monitor the effectiveness of care and treatment and use their audit findings to assess, monitor and improve the quality and safety of the service. (Regulation 17(a)(f).
- The service must have effective governance systems to make sure staff are trained in key skills to ensure provision of a safe service. Regulation 17(2)(f).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed • The service must have effective recruitment process to meet the CQC regulation requirements in employing fit and proper persons to carry out the regulated activities. Regulation 19(1)(a)(b)(c)(2).