Midlands Ultrasound & Medical Services (MUMS) Limited

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	Inadequate
Are services safe?	Inadequate
Are services effective?	
Are services caring?	Good
Are services responsive?	Requires improvement
Are services well-led?	Inadequate

Summary of findings

Letter from the Chief Inspector of Hospitals

Midlands Ultrasound and Medical Services (MUMS) Limited is a private clinic that has been in operation since November 2003 and provides diagnostic and screening services to pregnant women in the Solihull area of the West Midlands. The service provides a total pregnancy care package, during which they take on the responsibility of managing all medical and midwifery elements of pregnancy care including taking relevant blood tests, ultrasound examinations, screening for conditions which might complicate the pregnancy as well as undertaking the delivery of the baby in a hospital setting and postnatal care.

MUMS Limited also offers gynaecological services, including advice regarding for example ovarian cysts or endometriosis (a condition where tissue that behaves like the lining of the womb (endometrium) is found in other parts of the body). The practice also offers physiotherapy services to support gynaecological care.

The service uses the latest technology 3D and 4D ultrasound machines which can give the highest resolution images for use in obstetrics and gynaecology. A 3D ultrasound takes thousands of pictures or photos of the baby and provides a three-dimensional image of the baby while a 4D ultrasound test is a way of reproducing a moving image of the baby inside the womb.

The service was previously inspected in January 2013, where we found the service met all the standards inspected under the Health and Social Care Act 2008 (Regulated Activities).

We inspected this service using our comprehensive inspection methodology. We carried out a short-notice announced inspection on 10 January 2020. We gave one weeks' notice of our inspection to ensure the availability of the registered manager and that clinics were running.

To get to the heart of womens' 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.

Services we rate

We have not previously rated this service. We rated it as Inadequate overall.

We found areas of practice that were inadequate:

- Staff did not have training in key skills, and medicines were not always managed well. The service did not manage safety incidents or learned from them. Staff did not collect safety information or use it to improve the service.
- Leaders ran services without reliable information systems and did not support staff to develop their skills. Staff did not understand the service's vision or values and did not know how to apply them in their work. Staff were not clear about their roles and accountabilities. The service did not engage with women and the community to plan and manage services.

We found areas of practice that require improvement:

- The service did not always have staff on site to support deteriorating women, and record keeping standards were not monitored.
- Managers did not monitor the effectiveness of the service or made sure staff were competent. Consent was not routinely obtained.
- The service did not always take account of women's individual needs or make it easy for people to give feedback.

We found good practice:

Summary of findings

- The service had enough staff to care for women and keep them safe. They understood how to protect women from abuse and managed safety well. The service controlled infection risk well. Staff assessed risks to women and kept good care records.
- Staff provided good care and treatment, gave women enough to eat and drink, and gave them pain relief when they needed it. Staff worked 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. Key services were available six days a week.
- Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of local people, who could access the service when they need it and did not have to wait too long for treatment.
- Staff felt respected, supported and valued. They were focused on the needs of women receiving care.

We found the following issues that the service provider needs to improve:

- There were no staff training records or processes to confirm staff had the right qualifications, skills, training, competencies and experience. Staff had not received any additional training since induction which ranged from five to 12 years.
- There were no systems in place to ensure an effective recruitment and selection process, with four out of eight staff records reviewed missing key documents including Disclosure and Barring Service checks.
- Policies and procedures which included medicines, consent, incidents and complaints were dated 2008 and were significantly past their review date. They did not reflect current guidance or legislation.
- There was no system to record and monitor incidents and complaints. There were no team meetings to ensure staff had up to date information and the opportunity to share and learn from incidents and complaints.
- There was no systematic programme of clinical/internal audit to monitor quality and safety of the service.
- There were no processes to manage current or future performance.
- The service did not have a risk register to manage any identified risk.
- The provider did not have a process to account for medicines held. We were also not assured that those staff administering medications were qualified as staff records were incomplete.
- The provider did not have an effective recruitment and selection procedures. Records seen did not have any Disclosure and Barring Service checks or references to ensure they were of good character. We reviewed eight staff records and found four were missing these key documents.
- We did not see any records to ensure that employees had the appropriate qualification(s), competence, skills and experience required. We saw no records kept verifying this.
- The provider did not have processes in place to ensure that staff complied with the European Working Time Directive as most staffs first employment was NHS services.
- The provider did not have a system in place to assess the competence of employees before they work unsupervised in a role. There was no evidence of any supervision until the person was deemed competent to carry out their role.
- The provider did not have a system to monitor the quality of scans taken to ensure staff were competent in their role.

Following this inspection, we told the provider that it must take actions to comply with the regulations. We also issued the provider with a warning notice that affected the diagnostic imaging service. Details are at the end of the report.

On the basis of this inspection, the Chief Inspector of Hospital has placed the service into special measures.

Services placed in special measures will be inspected again within six months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within six months if they do not

Summary of findings

improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further six months, and if there is not enough improvement we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Heidi Smoult
Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	We rated this service as Inadequate because it was not safe, effective or well led. We rated responsive as requires improvement and caring as good.

Summary of findings

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Inadequate

Midlands Ultrasound & Medical Services (MUMS) Limited

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Midlands Ultrasound & Medical Services (MUMS) Limited

Midlands Ultrasound and Medical Services (MUMS) Limited is a specialist consultant-led medical practice based in Solihull, West Midlands. The service opened in 2003 as a screening centre for obstetrics and gynaecology. The service primarily serves the communities of Solihull, Chelmsley Wood, Leamington Spa, Redditch, Bromsgrove Coventry, Worcester, Sutton Coldfield, Birmingham, Warwickshire and West Midlands area.

The service has had a registered manager in post since October 2010.

The service offers early pregnancy scans, 4d scans, gender scans, well-being and growth scans and Nuchal and non-invasive prenatal testing (NIPT). Nuchal testing is a sonographic prenatal screening scan (ultrasound) to detect chromosomal abnormalities in a foetus while NIPT is a blood test used to screen for Down Syndrome and a few other chromosomal conditions. Other services offered include private delivery by induction of labour or caesarean section, blood testing, smear testing and gynaecology and fertility ultrasound scans as well as chorionic villus sampling (CVS), (a test offered during pregnancy to check if the baby has a genetic or chromosomal condition) and amniocentesis (a process in which amniotic fluid is sampled using a hollow needle inserted into the uterus, to screen for abnormalities in the developing foetus).

The service was previously inspected in January 2013, where we found the service met all the standards inspected under the Health and Social Care Act 2008 (Regulated Activities).

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 10 January 2020 where we rated the service as Inadequate overall.

Our inspection team

The team that inspected the service comprised of two CQC lead inspectors. The inspection team was overseen by Bernadette Hanney, Head of Hospital Inspection

Information about Midlands Ultrasound & Medical Services (MUMS) Limited

Midlands Ultrasound and Medical Services (MUMS) Limited provided a total pregnancy care package, during which they managed all medical and midwifery elements of pregnancy care including taking relevant blood tests, ultrasound examinations, screening for conditions which might complicate the pregnancy as well as undertaking the delivery of the baby in a hospital setting and postnatal care. Some aspects of the maternity service were provided under practising privileges arrangements with a service level agreement in place at a nearby hospital, this did not inform part of this inspection.

The service offered diagnostic pregnancy ultrasound scans, including:

- Early pregnancy scans performed from six weeks' gestation.
- Non-invasive prenatal tests (NIPT) from nine weeks of pregnancy onwards.
- Nuchal scans performed between 11 weeks and two days and 13 weeks and six days.
- Reassurance scans between 14 and 18 weeks' gestation.
- Foetal sexing scans from 15 weeks' gestation.
- 20-week anomaly scans between 18 and 24 weeks' gestation.
- 4D scan packages performed from 24 to 32 weeks' gestation.
- Growth scans and foetal wellbeing performed from 18 to 42 weeks' gestation.

Summary of this inspection

Additional services provided included:

- Induction of labour (usually after 37 weeks' gestation).
- Caesarean section.
- Gynaecology ultrasound for women with gynaecological problems.
- Vaginal rejuvenation ThermiVa Care (for the detection of gynaecological problems including cancers).
- Fertility scans, cervical smear tests, coil fitting/ checking and ovarian cancer screening could be offered on request.
- A range of blood testing which included for example: beta human chorionic gonadotropin (BHCG) (a hormone produced by the placenta during pregnancy, and typically detected in the blood), glucose tolerance testing and infection screening.
- Chorionic villus sampling (CVS) (a test offered during pregnancy to check if the baby has a genetic or chromosomal condition) and amniocentesis (a process in which amniotic fluid is sampled using a hollow needle inserted into the uterus, to screen for abnormalities in the developing foetus).
- Group B Streptococcus testing (a life-threating infection in new-born babies in the UK).
- Maternity reflexology which included: fertility, maternity and post-natal reflexology.

Facilities include two scanning rooms and a seated waiting area. The service was registered to provide the following regulated activities:

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

All women accessing the services self-referred to the clinic and were seen as private (paying) women. The provider runs five clinics a week from their office in Solihull which are by appointment only. The standard opening times are Monday 8am to 7.30pm, Tuesday to Friday 8am to 5pm and Saturday from 8.30am to 3pm.

During our inspection, we visited the registered location in Solihull and we spoke with seven staff including sonographers, sonographer assistants, administration staff, and senior managers. We observed the environment and care provided to women and observed three ultrasound scan procedures. We spoke with two women and their partners and reviewed three care records and consent forms. We also looked at a range of performance data and documents including policies, meeting minutes, audits and action plans.

At the time of our inspection, MUMS employed two consultant gynaecologists, two foetal medicine specialists. A further 12 staff had interchangeable roles which included: sonographers, midwives, ultrasound assistants, administrators, receptionists and an accounts manager. One of the consultant gynaecologists was also the registered manager.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the services second inspection since registration with CQC, which found that the service was not meeting all standards of quality and safety it was inspected against.

Track record on safety (August 2018 to August 2019)

- Zero Never events.
- Zero Clinical incidents.
- Zero serious injuries.
- Zero incidences of hospital acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- Zero incidences of hospital acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- Zero incidences of hospital acquired Clostridium difficile (c.diff).
- Zero incidences of hospital acquired E-Coli.
- Six complaints.

Services provided at the service under service level agreement:

- Clinical and or non-clinical waste removal.
- Maintenance of medical equipment.
- Pathology and histology.

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?

Inadequate

We have not previously rated this service. We rated it as Inadequate because:

- The service did not provide mandatory training in key skills and did not make sure everyone completed it.
- Staff did not have training on how to recognise and report abuse.
- While the equipment and the premises looked visibly clean, the service did not have cleaning schedules to verify areas were regularly cleaned.
- Staff were not trained to deal with deteriorating women and risk information given by staff was not always in line with PHE guidance. Staff who could deliver first aid were not always on site.
- The service did not ensure staff had the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment.
- There was no process to ensure standards were maintained, or consent was gained prior to sharing information.
- The service did not use systems and processes to safely record medicines. Staff did not record the temperature of stored medicines to maintain their safety.
- The service did not manage safety incidents well. Staff did not recognise incidents and near misses and did not report them appropriately.
- The service did not monitor results to improve safety. Staff did not collect safety information or share it with staff, women and visitors.

However:

- Staff understood how to protect women from abuse.
- The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff completed and updated risk assessments for each woman. Staff identified women at risk of deterioration.
- 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.

Summary of this inspection

- Staff prescribed, administered and stored medicines safely.
- Staff said that when things went wrong, staff apologised and gave women honest information and suitable support.

Are services effective?

We do not rate effective.

- The service did not have processes to review policies to ensure guidance was current. Managers did not ensure that staff followed guidance.
- Staff did not monitor the effectiveness of care and treatment. They did not use the findings to make improvements.
- The service did not have processes to ensure staff were competent for their roles. Managers did not generally appraise staff's work performance or held supervision meetings with them to provide support and development.
- While staff understood the importance of obtaining informed consent this was not routinely.

However:

- The service provided care and treatment based on national guidance and evidence-based practice.
- Staff knew how to protect the rights of women subject to the Mental Health Act 1983.
- Staff gave women enough food and drink to meet their needs.
- Staff assessed and monitored women to see if they were in pain.
- Doctors, nurses and other healthcare professionals worked together as a team to benefit women. They supported each other to provide good care.
- Key services were available six days a week to support timely care.
- Staff gave women practical support and advice to lead healthier lives.
- Staff understood when to assess whether a woman had the capacity to make decisions about their care.

Are services caring?

Good

We have not previously rated this service. We rated it as Good because:

- Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to women, families and carers to minimise their distress. They understood women's personal, cultural and religious needs.

Summary of this inspection

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

Are services responsive?

Requires improvement

We have not previously rated this service. We rated it as Requires improvement because:

- While the service planned and provided care in a way that met the needs of local people and the communities served, it did not have processes of providing shared learning from feedback.
- Staff did not always make reasonable adjustments to help women access services, with limited access to interpreting services and written information available in few languages.
- The service did not monitor waiting times.
- Women were not given the opportunity to give feedback and raise concerns about care received. The service did not share lessons learned with all staff in the service.

However:

- The service was inclusive and took an account of women's individual needs and preferences.
- People could access the service when they needed it and received the right care promptly.

Are services well-led?

Inadequate

We have not previously rated this service. We rated it as Inadequate because:

- Leaders did not have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced.
- The service had a statement of purpose of what it wanted to achieve but did not have a strategy to turn it into action. Leaders did not have processes to apply the aim of the statement of purpose or how to monitor progress.
- Leaders did not always operate an effective governance processes. Staff at all levels were not clear about their roles and accountabilities and did not have regular opportunities to meet, discuss and learn from the performance of the service.
- Leaders and teams did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues and identified actions to reduce their impact. They did not have plans to cope with unexpected events and staff did not contribute to decision-making to help avoid financial pressures compromising the quality of care.

Summary of this inspection

- The service did not collect any data so that it could be analysed. Staff did not have access to data so that they could understand performance, make decisions and improvements. Information systems were secure.
- Leaders and staff did not actively and openly engage with women and staff to plan and manage services.
- Leaders did not have an understanding of quality improvement methods or the skills to use them. Staff were not committed to continually learning and improving services.

However:

- Leaders were visible and approachable in the service for women and staff.
- 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. The service had an open culture where women, their families and staff could raise concerns without fear.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	N/A	Good	Requires improvement	Inadequate	Inadequate
Overall	Inadequate	N/A	Good	Requires improvement	Inadequate	Inadequate

Notes

We inspect but do not rate effective for diagnostic imaging.

Inadequate

Diagnostic imaging

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

Are diagnostic imaging services safe?

Inadequate

We have not previously rated this service. We rated it as inadequate.

Mandatory training

The service did not provide mandatory training in key skills and did not make sure everyone completed it.

Staff did not receive mandatory training. Mandatory training courses in key skills were not provided to staff in any form, with no mandatory training requirements identified or monitored. The service did not have an up to date mandatory training policy, and training requirements had not been identified.

We reviewed staff records for sonographers and administration staff and found the service had not identified mandatory training requirements, with topics such as manual handling, infection prevention and control, health and safety, fire safety, information governance, and safeguarding not covered. Most staff also had employment in the NHS and received training from their substantive NHS employer. Although, the service had not requested copies of training certificates for assurance of completion of mandatory training. Following our inspection, the provider told us training records were in place for all staff. However, we did not see any additional supporting evidence.

The registered manager and staff spoken with informed us that the ultrasound machine used by the service was an updated version of machines frequently used in the NHS. As such, sonographers at the location were already familiar with the machine before commencing employment. Although, there was no assurance that staff were competent to use the equipment available as we saw no training records for use of equipment. Staff spoken told us the ultrasound manufacturer was available to train sonographers to use the machine, should they require it.

Clinical staff told us they had completed training on recognising and responding to women with mental health needs, learning disabilities, autism and dementia within their NHS role, however, we found no evidence that assurances of this training had been sought by the service. There were no mandatory training modules provided by the service.

Managers did not monitor mandatory training or alert staff when they needed to update their training. Mandatory training was not reviewed or completed on an annual basis by all staff. There was no expectation to complete mandatory training modules. Staff we spoke to told us mandatory training was not discussed at their appraisals.

Safeguarding

Staff did not have training on how to recognise and report abuse. However, staff understood how to protect women from abuse.

The hospital did not have clear systems, processes and practices to safeguard adults, children and young people from avoidable harm, abuse and neglect that reflected legislation and local requirements. The service had an "Adult protection and prevention of abuse" policy. However, the policy was not dated and had no review date which meant we could not be assured the

information was up to date and suitable for use. The registered manager confirmed the service had not made any safeguarding referrals during the reporting period. There was no female genital mutilation (FGM) policy provided for staff on how to identify and report FGM as per national guidance (Department of Health and Social Care and NHS England, FGM mandatory reporting duty, October 2015).

Staff had not received training specific for their role on how to recognise and report abuse. The service did not have training records to show that staff had received the appropriate level of training. However, staff we spoke with were able to articulate signs of different types of abuse, and the types of concerns they would report or escalate. They were able to explain how to raise a safeguarding concern. The registered manager was the designated lead for children's and adults' safeguarding. They informed us they were available to provide support to staff when required which was confirmed by staff spoken with. All staff knew the registered manager was the safeguarding lead within the service.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act. However, information for women was not available in different languages to prevent harassment and discrimination in relation to protected characteristics under the Equality Act.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff told us they had not had to make any referrals recently. However, they told us the process they would follow and who they would inform if they were concerned about the potential abuse of a woman or visitor.

Safety was not promoted through recruitment procedures and employment checks. The provider did not have processes in place to ensure that appropriate checks were undertaken as required. Of the eight staff records seen we saw only one of the eight records had a Disclosure and Barring Service (DBS) check. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups. This was discussed with management who were able to provide us with printed copies for a further three staff members. However, they were unable to inform us of the process to ensure this was routinely done. We reviewed eight personnel files and saw that two of the eight had a curriculum vitae on file, and the service had obtained references for none of the records seen. The records also did not show an employment offer letter, contracts or evidence of induction/training.

Following our inspection, the provider told us all staff had individual files which contained DBS certificates, a curriculum vitae to document previous training and experience, and evidence of attendance at events related to their role. We were also told that non clinical staff had attended safe guarding level 1 training, with level 2 arranged for later in the year. Prevent training had also been arranged with the local safeguarding lead midwife. However, we did not see any additional supporting evidence.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. While the equipment and the premises looked visibly clean, the service did not have cleaning schedules to verify areas were regularly cleaned.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained, however cleaning records were not up-to-date and did not demonstrate all areas were cleaned regularly. The service was visibly clean, tidy and well maintained, with the general cleaning of the service provided by an external cleaning company. However, the records kept by the cleaner did not include a regular cleaning schedule or detail which areas had been cleaned, and it was not clear if all areas were cleaned regularly. There was also no schedule to ensure children's' toys were cleaned regularly and suitable for use. Clinical equipment in scanning rooms were cleaned by sonographers. Cleaning equipment was available and stored securely.

We inspected all scanning rooms throughout the service and found them to be clean and tidy, have handwashing facilities and a supply of personal protective equipment (PPE), which included latex-free gloves and aprons. However, there were no signed or dated daily cleaning schedules in place throughout all areas.

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

follow infection control practices. This included wearing the correct personal protective equipment (PPE), such as gloves and aprons. We saw staff wearing gloves for all contact, and routinely sanitised their hands using either hand gel or handwashing facilities. During our inspection, we observed clinical staff were arms bare below the elbows and adhered to the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. This was in line with the National Institute for Health and Care Excellence (NICE) quality standard (QS) 61, statement three. This standard states people should receive healthcare from staff who wear gloves or decontaminate their hands immediately before and after every episode of direct contact or care.

We did not see training records to confirm staff had received mandatory infection prevention and control (IPC) training. Although we observed staff using either hand gel or washing their hands at the appropriate time, no handwashing compliance audits were conducted therefore we could not be assured of the processes in place to oversee hand hygiene procedures.

While the service had IPC policies and procedures, these had not been reviewed since 2008. This meant we could not be assured the information contained within the policy was up to date and suitable for use.

Handwashing facilities and hand gel sanitisers were available throughout the service. All hand wash sinks were compliant with Health Building Note 04-02 (HBN) to allow correct hand hygiene and could be operated without the use of hands and had separate hot and cold taps. There were facilities for the disposal of clinic waste where appropriate, and the service had an agreement with a third-party disposal company.

We observed three clinics and noted the couch in the treatment room used by women was covered with a disposable cloth which was changed between women and the couch wiped with an antibacterial wipe before laying out a new disposable cloth.

The service had processes for dealing with blood and body substance spills, and a spill kit was available at the location. At the time of our inspection, staff informed us there had been no need to use this to date.

In the 12 months before the inspection there had been no incidences of healthcare acquired infections at the location.

Staff cleaned equipment after contact and labelled equipment to show when it was last cleaned. Staff followed best practice guidance for the routine disinfection of ultrasound equipment (European Society of Radiology Ultrasound Working Group, Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group (2017)). The ultrasound probes were decontaminated using three step disinfectant wipes between each woman and at the end of each day. We observed staff cleaning equipment such as probes during the inspection.

We saw no evidence of an annual risk assessment for Legionnaires' disease was undertaken. Legionnaires' disease is a serious pneumonia caused by the legionella bacteria. People become infected when they inhale water droplets from a contaminated water source such as water coolers and air conditioning systems.

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.

Women could reach emergency pull cords in areas where women were left alone, such as toilets.

The design of the environment followed national guidance. Diagnostic services were located across the ground floor within the service and included a reception desk and waiting area, a small administration office, a consulting room, a phlebotomy room, a gynaecology consulting room with ultrasound scanner, and a pregnancy ultrasound scanning room. The first floor had two offices, a consulting room and a staff room/kitchen. The reception and waiting areas were clear of clutter and contained a suitable number of chairs to meet women's needs.

There was clear signage and visual prompts to assist women and visitors attending the department. Women were asked to wait in the waiting area until they were called through to the relevant diagnostic imaging suite.

The service did not have a property file containing key documentation. The health and safety policy was out of date and had not been reviewed to ensure it was

compliant with up to date regulations. The managerial staff at the service had not undertaken a range of environmental risk assessments, or risk assessments on all new or modified imaging equipment.

Staff carried out daily safety checks of specialist equipment. The service had an equipment quality assurance (QA) programme in place, with all sonographers involved in daily, weekly and monthly QA processes. The service maintained a record of quality assurance testing and we saw evidence that quality assurance testing was completed at regular intervals in line with the Institute of Physics and Medical Engineering.

Servicing and maintenance of the premises and equipment was carried out using a planned preventative maintenance (PPM) programme. The service completed PPM checks regularly and in line with manufacturer's guidelines. Diagnostic imaging equipment used by the service was serviced regularly as required and maintained by a recognised service team. We saw evidence the ultrasound equipment had the necessary acceptance checks and critical examination reports to demonstrate the outcome of testing safety features and warning devices. The ultrasound scanner had just been serviced before the inspection with no issues or concerns identified. The service had a service contract with an external engineering company; and if faults arose, staff were able to call out engineers to assess and perform repairs. Staff explained that when they had called the company the service was efficient and quick.

Staff disposed of clinical waste safely. There was correct segregation of clinical and non-clinical waste into different coloured bags. This was in line with the Health Technical Memorandum 07-01, 'Control of Substance Hazardous to Health, and the Health and Safety at Work Regulations'. Sharps bins were labelled, the bins were not overfilled and were closed when not in use.

Assessing and responding to risk

Staff were not trained to deal with deteriorating women and risk information given by staff was not always in line with PHE guidance. Staff who could deliver first aid were not always on site. However, staff completed and updated risk assessments for each woman. Staff identified women at risk of deterioration.

Staff completed risk assessments for each woman on arrival and updated them when necessary and used recognised tools and staff knew about and dealt with any specific risk issues. The service only provided ultrasound scans to women over 16 years of age. The service did not offer emergency tests or treatment. We saw staff encouraged and advised women to attend scans as part of their NHS maternity pathway and we observed women stating that they were receiving appropriate antenatal care from an NHS provider. We did not observe staff asking women if they had brought their NHS pregnancy records with them to their appointment. This meant the sonographers may not have access to women's obstetric and medical history, if required. It also meant that staff could not contact the most relevant medical provider if a concern was detected.

Staff spoken with explained the processes and actions to take if potential abnormalities were identified on ultrasound scans; this included referring women to appropriate NHS antenatal healthcare providers. We saw literature on display which contained contact numbers for local hospital antenatal care providers. If the sonographer suspected higher-risk conditions or concerns (such as, placental abruption or an ectopic pregnancy) they were instructed to immediately dial 999 for emergency assistance. This was confirmed by staff spoken with. Sonographers at the service told us they could contact the registered manager for advice and support when required.

Staff had access to a first aid box on site. While the service had a resuscitation policy, this was not dated and had not been reviewed which meant that we could not be assured that the information was up to date. The provider did not have a process in place to ensure there was a staff member trained in first aid to always be on duty, and personnel files showed staff had not completed first aid at work. Staff told us that should they have concerns about a woman's condition during their appointment they would telephone the emergency service for support. Following our inspection, the provider told us two members of staff had attended a first aid course. However, we did not see any additional supporting evidence.

The service reported there had been no unplanned urgent transfers of a woman to another health care provider, and no appointments had been cancelled for a non-clinical reason in the reporting period.

While the service did not have processes in place in the event of an unusual or unexpected circumstance such as a cardiac or respiratory arrest or if a woman should lose consciousness when attending the clinic, staff explained the procedures they would take which included the commencement of basic life support until the paramedic crew arrived. The clinic did not have facilities for advanced resuscitation. All sonographers told us they were trained in basic life support (BLS) techniques, however there was no evidence available to support this.

We observed that information provided for women who utilised the service was clear as to the limits of diagnostic services provided. We saw that scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for 'as low as reasonably achievable' (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency of ultrasound waves. This meant that sonographers used minimum frequency levels for a minimum amount of time to achieve the best result.

Information however, provided by the service to women contradicted Public Health England (PHE) guidance. PHE advise that although there is no clear evidence that ultrasound scans are harmful to the foetus, parents-to-be must decide for themselves if they wish to have ultrasound scans and balance the benefits against the possibility of unconfirmed risks to the unborn child. Although safety information given in the service brief was contextualised by various ultrasound methods and research sources, some of the language used was sometimes definitive; for example, "… there is no risk to your baby".

Treatment for conditions diagnosed within the clinic and the delivery of babies were provided in a hospital setting. The consultant medical staff had admitting rights to several hospitals within the area. These treatments included:

- Medical treatment for complications of pregnancy such as hypertension, diabetes and other medical conditions.
- Surgical treatment for complications of pregnancy such as caesarean section delivery, assisted vaginal delivery and perineal repair following obstetric trauma.
- Medical treatment for common gynaecological conditions such as hormone therapy, antibiotic treatment and analgesia. The medical staff within the clinic could issue private prescriptions.
- Surgical treatment for gynaecological conditions such as laparoscopy (a type of surgical procedure that allows a surgeon to access the inside of the abdomen (tummy) and pelvis without having to make large incisions in the skin), abdominal hysterectomy, ovarian cystectomy (a minimally invasive surgical procedure that uses laparoscopy to remove an ovarian cyst while still preserving the ovary so women can remain fertile), oophorectomy (the surgical removal of an ovary or ovaries), vaginal hysterectomy, perineal surgery for cysts and vaginal prolapse.

Qualified allied health professional staffing

The service did not ensure staff had the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment.

We found no evidence that allied health professionals were appropriately trained or had the skills and experience to deliver safe care. The service however had enough staff of relevant grades to keep women safe. The service did not have an up to date mandatory training policy, and training requirements had not been identified. We reviewed staff records for sonographers and administration staff and found the service had not identified mandatory training requirements, with topics such as manual handling, infection prevention and control, health and safety, fire safety, information governance, and safeguarding not covered. Most staff also had employment in the NHS and received training from their substantive NHS employer. Although, the service had not requested copies of training certificates for assurance of completion of mandatory training.

The service was staffed daily, Monday to Saturday. The registered manager was responsible for the day-to-day running of the service. There were four scan assistants and four administration assistants employed at the service. Scan assistants/administrators were responsible for managing enquiries, appointment bookings, supporting the sonographers during the ultrasound

scans, and helping to support women and make them comfortable. Day-to-day management of scan assistants was undertaken by the practice manager. Three sonographers worked for the service on a self-employed basis. All sonographers held substantive posts in the NHS and had previous obstetrics and gynaecology experience.

Managers calculated and reviewed the number and grade of staff needed for each shift. The manager could adjust staffing levels daily according to the needs of women, and the number of staff on all shifts matched the planned numbers. Sonographers and support staff were flexible dependent on the number of bookings and expected demand on the service, and typically each worked several days a week. The service had an electronic appointment system which staff used to develop a rota for sonographers which was planned two to three weeks in advance, with scans booked around the availability of sonographers. All staff we spoke with felt that staffing was managed appropriately. Staff told us that the service operated with a minimum of a scan assistant and a qualified sonographer on duty per clinic. The practice manager was available to provide additional support as required.

Staff told us there was a low rate of sickness and turnover, the service had no current vacancies and no issues in recruiting to vacancies if they became available. Data provided by the service showed a 50% sickness rate for receptionists, which was high due to two members of staff being on long term sick leave. The sickness rate was inflated due to the small numbers of staff within the service.

The pool of staff available at the service was adequate to cover absenteeism, such as holidays and sickness cover.

Managers did not use bank and agency staff.

Medical staffing

The service did not ensure staff had the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment.

We found no evidence that medical staff were appropriately trained or had the skills and experience to deliver safe care. The service however had enough medical staff to keep women safe. We reviewed staff records and found the service did not have processes in place to ensure consultants had professional indemnity insurance, scope of practice, professional registration with the General Medical Council and evidence of revalidation or the right qualifications, skills, training and experience. The service had four consultants who regularly worked at the service but were not directly employed as they worked under practicing privileges. Practicing privileges were granted to consultants who treated women in the service, that carried out procedures they would normally carry out within their scope of practice within their substantive post in the NHS.

Care was consultant-led. Staff informed us that should they required access to expert medical advice they could contact the registered manager.

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. However, there was no process to ensure standards were maintained, or consent was gained before sharing information.

Notes were comprehensive and all staff could access them easily. All women had a hospital maternity information system entry made as appropriate. During the inspection, we observed written information was appropriately stored with no issues or concerns identified. However, the provider did not have a record audit in place to regularly check the accuracy of the data entered. This meant we were not assured the provider had systems and processes in place to oversee the storage or recording of written information.

The service had a record keeping policy which was undated and not reviewed to ensure the content was up to date and suitable for use. The policy outlined the procedure staff should take which included:

- Ensuring that all files or written information was not left unattended where it could be read by unauthorised personnel and that files were stored in a secure manner in a locked cabinet and only accessible by staff who had a need or right to do so.
- Ensure that all records were signed and dated.
- Regularly check on the accuracy of any data being entered in to a computer and when using computers always observe strict security and confidentiality.

Diagnostic imaging

During the inspection, we observed three clinics, and where identified, reports were sent to the woman's GP. However, we noted that staff did not ask for the woman's consent to contact their GP or NHS antenatal healthcare provider should a potential anomaly or concern be identified. This was not in line with company policy and was brought to the attention of senior staff who confirmed they would address this with staff.

While the service had an information governance policy this had not been reviewed since 2008. This was brought to the attention of senior staff who confirmed that they would arrange for all policies to be reviewed and updated.

The registered manager was the information governance lead for the service and we saw that all staff at the service had received updated information regarding governance, however not by formal training.

Pre-scan questionnaires and consent forms at the service ensured sufficient information was obtained from women before their scans; for example, in relation to number of weeks pregnant, and number of previous pregnancies. Women were also required to declare medical conditions that might affect their scan.

Sonographers completed ultrasound reports, with the support of scan assistants. A copy of the image/report was provided to the woman to take away. The service retained a copy of the scan report, in case they needed to refer to the document in future. The service retained a digital copy of scan images for a period of 30 days, in order to rectify any issues following the scan.

When women transferred to a new team, there were no delays in staff accessing their records. The service received referrals through a secure email, telephone call from the referring consultant or hospital or by post. Appointments were booked in advance, and women were sent appointment letters, or contacted by phone if short notice. The service provided referrers with electronic diagnostic imaging reports which were encrypted. Staff told us there were no issues with delays in receiving scan results from other hospitals or providers.

Records were stored securely. Throughout the service, care was taken to ensure that computer screens were not accessible or in view of unauthorised persons. Computers were locked when not in use. Computer access was password protected and staff used individual log-ins.

Paper documentation such as referral requests were stored securely and destroyed as appropriate. Staff had not received training on information governance as there was no mandatory training programme in place.

Medicines

The service did not use systems and processes to safely record medicines. Staff did not record the temperature of stored medicines to maintain their safety. However, they prescribed, administered and stored medicines safely.

Staff did not follow systems and processes when safely recording medicines. The service did not have processes for the administration and management of medicines. They did not keep a running total of the stock which meant there was a risk of medicines being used and not accounted for. Following our inspection, the provider told us they had bought a drug record book to allow for staff to take stock. However, we did not see any additional supporting evidence. The service did not have a medicines policy which outlined suitable arrangements for the recording, safe-keeping, handling and disposal of medicines. However, medicines were supplied and stored securely. All medicines were kept in locked cupboards with only appropriate staff having access to keys. All medications were prescribed by the registered manager who was a consultant in fetal medicine.

Staff did not store or manage medicines safely. Staff did not monitor and record temperatures of stored medicines as they were not recorded as part of the daily checks by staff. Medicines should be stored in line with manufacturers' recommendations and meant that we were not assured of the processes to manage the storage and administration of medicines appropriately. However, the service had appropriate lockable storage facilities for medicines, such as cupboards. Keys to the medicine cupboards were stored in accordance with national guidance and held by senior staff to prevent unauthorised staff from gaining access. They were able to describe processes for monitoring stock levels of medicines stored in cupboards and ensuring that all stock was within its expiry date.

There were no controlled drugs (CDs) kept or administered by the service.

Incidents

Inadequate

Diagnostic imaging

The service did not manage safety incidents well. Staff did not recognise incidents and near misses and did not report them appropriately. However, staff said that when things went wrong, staff apologised and gave women honest information and suitable support.

Staff did not always know what incidents to report and how to report them. Staff understood their responsibilities to raise concerns, to record safety incidents and to report them internally and externally. However, there was no evidence to confirm all members of staff had received appropriate training and information about accidents and incidents at work and how to avoid them. Staff informed us they had not received updated training since induction which was between six and 12 year before starting employment with the service. Staff told us they were aware of what constituted an incident, and the types of issues they should report and record as incidents, however we were not assured they would identify all reportable safety incidents. There was a limited reporting culture and staff were not encouraged to report 'near-miss' situations.

The service had no serious incidents or never events, however staff were aware of the incident reporting process, and raised them in line with the service policy which was out of date. The service had a prevention of accidents policy which was undated and did not have a review date. This meant that we could not be assured that the content of the policy was up to date.

The policy identified that the service maintained three separate records when reporting accidents. These included:

- An accident book which recorded all accidents, whether they were notifiable and regardless of to whom they happened.
- An accident/incident report which was completed by the person suffering from the accident or by a member of staff. These forms were counter-signed by a witness.
- Notifiable accidents using the Health and Safety Executive report form. This should be completed within 10 days of the incident or accident. The local authority and local health commission were also notified.

The registered manager was responsible for conducting investigations into all incidents at the service.

The service reported there had been no never event or serious incidents from August 2018 to August 2019. Never events are serious safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious harm or death but neither need have happened for an incident to be a never event.

The registered manager explained the process they would undertake if they needed to implement the duty of candour following an incident. There had been no incidents from August 2018 to August 2019 which required the use of the duty of candour.

The service used an incident book for reporting incidents. During the reporting period there was one incident reported which related to a fall by a member of staff.

Staff understood the duty of candour. They explained how they would be open and transparent and gave women and families a full explanation if things went wrong. From April 2015, healthcare providers were required to comply with the Duty of Candour Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify women (or other relevant persons) of certain notifiable safety incidents and reason able support to the person. Staff said they were open and honest with women and applied this to all their interactions. Staff said they would discuss any identified concerns with the woman and provide a full apology. Staff were familiar with the terminology used to describe their responsibilities regarding the duty of candour regulation. Staff described a working environment in which any errors in a woman's care or treatment were investigated and discussed with the woman and their relatives.

Managers investigated incidents thoroughly, however staff did not always receive feedback from investigation of incidents. Staff told us if they reported an incident, they would discuss it with their manager, however we found no evidence of learning from incidents. The service did not hold daily huddles, or frequent staff team meetings where this information could be shared. There were also no minutes following team meetings to allow learning to be shared.

Diagnostic imaging

Safety Thermometer (or equivalent)

The service did not monitor results to improve safety. Staff did not collect safety information or share it with staff, women and visitors.

The service did not have processes to continually monitored safety performance.

Safety Alerts

The service had an emergency and crisis situation policy. The aim of the policy was to ensure the safety and well-being of women, staff and visitors. However, the policy was not dated and had not been reviewed to ensure the content was up to date and suitable for use.

The policy highlighted the processes to take place in the event of imminent danger to women, staff and visitors as a result of for example, power cuts, bomb alerts, floor, fire or damage to the building. During the inspection, staff informed us they had not undertaken fire safety training and no fire and evacuation drills were held. We did not see any fire safety training records which was brought to the attention of senior staff. However, staff did say that in the event of a safety alert, they would phone the appropriate service such as the fire brigade.

Are diagnostic imaging services effective?

We inspected but did not rate effective.

Evidence-based care and treatment

While the service provided care and treatment based on national guidance and evidence-based practice, they did not have processes to review policies to ensure guidance was current. Managers did not ensure that staff followed guidance. Staff knew how to protect the rights of women subject to the Mental Health Act 1983.

While staff followed policies to deliver high quality care according to best practice and national guidance, there were no processes to review and ensure information was correct and up to date. The service had policies and protocols in place. However, all policies and protocols we reviewed did not contain a next renewal date and were either undated or had a last review date of 2008. This meant that we were not assured that policies were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS). This was brought to the attention of senior management who confirmed that they would arrange for all policies to be reviewed and updated.

Scans were conducted according to BMUS recommendations for 'as low as reasonably achievable' (ALARA) principles for safety in ultrasound scanning.

The service did not have an audit programme in place to provide assurance of the quality and safety of the service. Clinic and local compliance audits were not undertaken regularly; for example, experience, cleanliness, health and safety, ultrasound scan reports, equipment, and policies and procedures.

Staff protected the rights of women subject to the Mental Health Act and followed the Code of Practice. The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief and sexual orientation when making care and treatment decisions. Staff told us that they would escalate any concerns and seek further guidance if necessary.

Nutrition and hydration

Staff gave women enough food and drink to meet their needs.

Staff made sure women had enough to eat and drink, including those with specialist nutrition and hydration needs. While women attending the service were not routinely provided with food or drinks, as they were only there for a short period, to improve the quality of the ultrasound image, some women were asked to drink extra fluids on the lead up to their appointment. Women who were having a gender scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. Drinking water was available on site. However, due to the nature of the service, food and drink was not routinely offered.

Pain relief

Staff assessed and monitored women to see if they were in pain.

Women were asked by staff if they were comfortable during their appointment, however no formal pain monitoring was undertaken as women were generally in the service for short periods. Staff described how they would offer support to women who reported being in pain by referring them to a consultant.

Outcomes

Staff did not monitor the effectiveness of care and treatment. They did not use the findings to make improvements.

The service did not participate in relevant national clinical audits and did not have a comprehensive audit programme. The registered manager had overall responsibility for governance and quality monitoring. Information about the outcomes of women's care and treatment was not routinely collected or monitored, with no regular clinical audits undertaken or appropriate action taken to monitor and review the quality of the service. This included information about the number of ultrasound scans completed including the number of rescans, and the number of referrals made to other healthcare services. This meant we could not be assured that the manager had enough information to improve the care and treatment of women using the service.

Staff confirmed the quality of diagnostic images was not regularly audited by the service and the outcomes were shared with staff. This included peer reviews of radiologists work to improve standards and education, which were also not performed. The Royal College of Radiologists recommends that there should be regular discrepancy audits and multidisciplinary (MDT) meetings to discuss cases and discrepancy errors that have been reported for learning and reflective purposes

The provider did not have processes to oversee procedures undertaken by the service such as:

- False negative scan report (For example: Down syndrome pregnancy identified after a low risk report or fetal malformation not identified by scan).
- False positive scan report (For example: a problem is identified which is not present, false diagnosis of a miscarriage, ectopic pregnancy or fetal abnormality).
- Failure of blood samples or microbiology samples to reach the appropriate laboratory.
- Failure to give results to women when anticipated.
- Miscarriage following amniocentesis or chronic villus sampling (CVS). CVS is where the cells from the placenta are removed from inside the womb using a needle.
- Incorrect information or results being given or sent out from the practice.
- Women reporting dissatisfaction with some aspect of the service either verbally or in writing.

Staff informed us that there was a rescan guarantee for when it was not possible for the sonographer to confirm the gender of the baby at the time of the appointment. If the woman received incorrect information with regards to their baby's gender, they were offered a complimentary 4D baby scan.

The provider did not have regular team meetings and did not collect feedback. Staff spoken with confirmed they had not attended a team meeting for several months. As all sonographers at the service were substantively employed in the NHS, they struggled to attend clinic team meetings and we did not see processes to ensure they were kept up to date with what was happening within the service.

The service ensured that all private women delivered their babies in a hospital setting. Home births were not provided by the service.

Screening for Trisomy 21 (also known as Down syndrome, a genetic condition caused by an extra chromosome) was audited and data fed back to the team within the foetal medicine foundation audit programme.

Competent staff

The service did not have processes to ensure staff were competent for their roles. Managers did not generally appraise staff's work performance or held supervision meetings with them to provide support and development.

We found no evidence that staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. The provider did not have processes to ensure that all clinical staff were registered with their relevant society or council and upheld and abided by their code of practice. Staff confirmed they had not been assessed to ensure they were competent in their role.

There was no competency folder in place to demonstrate staff had been appropriately assessed. We reviewed staff records for sonographers and administration staff and found the service had not identified mandatory training requirements, with topics such as manual handling, infection prevention and control, health and safety, fire safety, information governance, and safeguarding not covered. We found no evidence that poor or variable staff performance was identified through complaints, incidents, feedback and appraisals. Staff were not supported to reflect, improve and develop their practice through education by their manager. The service did not operate a comprehensive mandatory and statutory training programme which ensured relevant knowledge and competence was maintained and updated throughout the lifespan of employment with the service. There was no system to ensure staff were supervised while developing their competency. Following our inspection, the provider told us supervisory sessions had taken place and all staff had been assessed as competent, with records kept within staff files. However, we did not see any additional supporting evidence.

Managers did not make sure staff received any specialist training for their role. Staff spoken with said they had been trained in the use of specialist equipment, however during our inspection we saw no evidence of equipment training. Records seen did not identify if sonographers were registered, if applicable, with a professional regulatory body such as the Health and Care Professions Council (HCPC), the Nursing and Midwifery Council (NMC) or the British Medical Ultrasound Society (BMUS). The service did not have a comprehensive induction programme for new staff which covered areas such as the services' policies and procedures, the organisation and worker role, safe working practices, first aid, fire safety, confidential, women's rights and dignity and choice. We reviewed staff files and did not see evidence that staff had completed a local induction, which included mandatory and role-specific training.

We looked at eight staff files and found that only four files had a Disclosure and Barring Service (DBS) check. The staff files also did not contain evidence of a curriculum vitae, recruitment, interview and selection processes, references from previous employment, picture identification and employment contract. This meant that we could not be assured that there were processes for the recruitment and review of staff records. We could also not see evidence of sonographers undertaking continuous professional development and additional formal qualifications. The provider did not have processes to review/audit the work of the sonographers to ensure the quality was appropriate. Following our inspection, the provider told us they had developed a quality assurance system and records were maintained in staff files. However, we did not see any additional supporting evidence.

The service did not formally appraise self-employed staff and were not generally supported to develop through yearly constructive appraisals of their work. Data provided by the service before to the inspection showed no staff had received their appraisal. This was raised as a concern during the inspection, and staff told us they had completed 50% of appraisals which we saw evidence of completion, with the remaining staff planned for later in the year. Following our inspection, the provider told us all staff had received their appraisal. However, we did not see any additional supporting evidence.

The sonographers did not receive competency assessments from the clinical lead. The registered manager did not check staff's registration, indemnity insurance and revalidation status on an annual basis.

Multidisciplinary working

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

Staff worked across health care disciplines and with other agencies when required to care for women. Staff worked closely with referring consultants, which ensured a smooth pathway and prompt diagnosis for women. Staff told us they had good working relationships with consultants. Staff were able to provide examples of how good working relationships with sonographers and consultants improved the outcomes for women. We saw positive working relationships between all staff within the service. A sonographer we spoke with told us they had good working relationships with the consultants. We heard positive feedback from staff of all grades about the excellent teamwork. If a possible anomaly or concern was detected, the service had pathways to refer women to their primary antenatal care providers; for example, their GP or local NHS trust.

However, the service did not have regular team meetings and there were limited opportunities to share information, specific to the service or the wider health community. We did not see any evidence to say if they were well attended, as there were no minutes available.

Seven-day services

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

The service was not open seven days a week as it ran according to demand. The service was open Monday to Saturday, with clinics which typically ran Monday 8am to 7.30pm, Tuesday to Friday 8am to 5pm and Saturday 8.30am to 3pm. This offered flexible service provision for women and their companions to attend around work and family commitments. The service had capacity to extend service provision as and when the need arose; and ran additional clinics on Friday evenings, if needed. Consultants were on site during core opening times. Appointments were flexible to meet the needs of women. Appointments were offered at short notice if there was availability.

Health promotion

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

The service promoted opportunities for healthy living. The service had relevant information promoting healthy lifestyles and support across the service. There were health promotion information and materials, including information leaflets on how to keep the baby healthy.

Consent and Mental Capacity Act

While staff understood the importance of obtaining informed consent this was not routinely obtained. Staff understood when to assess whether a woman had the capacity to make decisions about their care.

Staff did not always gain consent from women for their care and treatment in line with legislation and guidance. Women's consent to care and treatment was not always sought in line with legislation and guidance. Staff informed us they obtained consent before undergoing ultrasound scanning. Staff spoken with confirmed they documented consent, and that they would verbally check the woman was still happy to go ahead with the scan. We looked at three electronic records and found no evidence of consent being obtained. This was brought to the attention of the registered manager who confirmed they would address this with staff.

The provider did not provide staff with training in relation to consent, and the Mental Capacity Act (2005), although staff confirmed they had received this as part of their induction training which ranged from six to 12 years ago. There was no evidence of staff receiving a refresher course.

There was a Mental Capacity Act (2005) policy which had not been reviewed since 2008 which meant that we could not be assured the information contained within was suitable for staff to follow.

During our inspection, we saw that the sonographer checked information women had provided, asked questions to clarify any issues, but did not see the woman's verbal consent before the sonographer commenced with the ultrasound scan. Following our inspection, the provider told us they had created a consent form for all patients, and staff could record verbal consent in patients' medical records. However, we did not see any additional supporting evidence

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. Staff we spoke to had a good understanding of the need to assess capacity to make decisions when necessary. Women told us they had been given clear information about the benefits and risks of their scan in a way they could understand, and said they were given enough time to ask questions if they were not clear about any aspect of their scan. However, no verbal or written consent was recorded during these discussions.

When women could not give consent, staff made decisions in their best interest, taking into account women's' wishes, culture and traditions. Staff were able to explain the best interests' decision-making process and gave examples of when staff recognised women's needs for extra support when consenting to treatment, such as when woman had a learning disability or were living with dementia. Staff told us they would involve the woman's relatives and carers to provide further information about the woman's wishes. There was multi-disciplinary involvement in reaching a best interest decision for the woman.

Inadequate

Diagnostic imaging

Staff made sure women consented to treatment based on all the information available. Women told us they had been given clear information about the benefits and risks of their scan in a way they could understand. Women said they were given enough time to ask questions if they were not clear about any aspect of their treatment.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 and the Children Acts 1989 and 2004 and they knew who to contact for advice. They knew how to support women experiencing mental ill health and those who lacked the capacity to make decisions about their care. Medical staff supported women to make decisions in line with relevant legislation and guidance.

Are diagnostic imaging services caring?

Good

We have not previously rated this service. We rated it as good.

Compassionate care

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

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. Women said staff treated them well and with kindness. We observed caring interactions with women throughout the service. We saw staff being caring and compassionate with women and their companions. We observed staff providing a culture of kindness, dignity and respect, and women praised staff for their kindness and understanding of their needs. During our inspection, we spoke with two women and their companions. All women and companions we spoke with during our inspection described the service positively. For example, they said the service was "wonderful".

However, the service did not collect feedback from women to ensure they were content with the service they experienced. Staff told us that women could leave feedback on social media. We saw examples which included "can not fault this place, from the moment I called I felt like they could not help me enough" and "…it was the nicest, warmest, friendliest experience I have ever had."

Staff followed policy to keep care and treatment confidential. Women we spoke to told us their privacy and dignity was always maintained. The scanning rooms afforded women privacy and dignity with a privacy curtain should women wish to use it. The scan room had wall-mounted monitors. This meant that the woman and their companion could easily view ultrasound images, should women opt to use the privacy curtain.

The service had adopted the values and principles of privacy and dignity as set out by the Department of Health and Social Care. The service was especially conscious of the need to preserve each individual woman's dignity by ensuring, wherever possible, that each woman had the choice to be examined by another woman. Where this was not possible a female chaperone was always in attendance.

Staff understood and respected the individual needs of each woman and showed understanding and a non-judgmental attitude when caring for or discussing women with mental health needs. Staff responded well to people's questions and concerns. Staff quickly recognised when someone might need some extra reassurance or support and provided it tactfully. Staff were aware of how women's behaviour may be affected by their health and showed compassion and understanding during their interactions.

Emotional support

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

Staff gave women and those close to them help, emotional support and advice when they needed it. We spoke with women and relatives who all felt that their emotional wellbeing was cared for. Staff had a good awareness of women with complex needs and those women who may require additional support should they display difficult behaviours during their visit to the service. Women told us staff were very helpful, and were able to answer any questions they had, without feeling rushed.

Inadequate

Diagnostic imaging

Staff supported women who became distressed in an open environment and helped them maintain their privacy and dignity. Staff provided emotional support to women to minimise their distress. The scan assistants acted as chaperones during ultrasound scans to ensure women felt comfortable and received the level of emotional support they required.

Staff had not received training on breaking bad news, however demonstrated empathy when having difficult conversations. We observed scan assistants and sonographers during ultrasound scans who were very reassuring and interacted with the woman and their companions in a professional, respectful, and supportive way. Staff spoken with confirmed that they had not received training but felt that this would help them to understand and appreciate parents needs and feeling when receiving challenging news, and to offer appropriate emotional support. Staff told us that if possible anomalies were identified, or concerns arose, women would be counselled (by the sonographer, supported by the scan assistant) in the scan room. Staff said that any woman awaiting appointments would be informed that scans might be delayed.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. Staff provided emotional support whilst caring for women and were allowed time to provide any emotional support women needed. Staff supported women through their investigations, ensuring they were well informed and knew what to expect. Staff told us that should a woman require counselling this would be through closely allied NHS services in foetal medicine or bereavement.

Understanding and involvement of women 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.

Staff made sure women and those close to them understood their care and treatment. Staff talked with women, families and carers in a way they could understand, using communication aids where necessary. Staff involved women and those close to them in decisions about their care and treatment. Women we spoke to said they felt involved, and had been given the opportunity to ask questions, and felt comfortable and reassured. All women told us they were provided with a good, clear explanation and were provided with written information about their condition and the type of scan they were due to have. We observed that women and their companion were provided with detailed descriptions of scan images. For example, one woman stated that the sonographer had provided more information than their local NHS hospital. Staff adapted the language and terminology they used when discussing the procedure to the needs of individual women and their companions.

Women and their families could not always give feedback on the service and their treatment. While women were able to leave comments and write reviews of their experience on the service's social media pages, the service did not routinely ask or collect satisfaction or experience information. Staff told us they had previously introduced electronic and paper-based surveys, however they had not been run for several years. As such the service were unable to identify any areas for improvement or act on feedback from women.

Staff supported women to make informed decisions about their care. Women told us they were very satisfied with the care they received and the staff who provided it. They felt involved in their ongoing treatment and staff took the time to explain the procedure and what would happen during their scan. Women we spoke to said they had plenty of opportunity to ask questions and staff listened to them and were happy to answer any questions they had. They had been kept 'well-informed' of their treatment plan and that they felt able to raise any concerns with staff. Staff checked women's understanding before they asked them to make decisions.

Are diagnostic imaging services responsive?

Requires improvement

We have not previously rated this service. We rated it as requires improvement.

Service delivery to meet the needs of local people

Inadequate

Diagnostic imaging

While the service planned and provided care in a way that met the needs of local people and the communities served, it did not have processes of providing shared learning from feedback.

The service had an open culture with access to social media from which they received feedback. This enabled the service with the opportunity to address issues as they arose and make decision on important changes. However, senior staff said that they did not have a process of checking and providing shared learning from feedback left on social media.

Managers planned and organised services so they met the changing needs of the local population. The service provided a range of medical and midwifery services including taking relevant blood tests, ultrasound examinations (including wellbeing, viability, growth, presentation, and gender scans) screening for conditions which might complicate the pregnancy as well as undertaking the delivery of the baby in a hospital setting and postnatal care.

Services were delivered to meet women's needs, offering appointments after working hours during the week, and at weekends. The service provided payment details in a booking confirmation email before their appointment. Ultrasound scan prices were detailed on the service's website.

Facilities and premises were appropriate for the services being delivered. All scanning rooms were located on the ground floor of the practice and were accessible to those using mobility aids. The scanning rooms were large with ample seating, and children of all ages were welcome to attend. The reception area could be accessed via the practice's main entrance, which was a short distance from the car park. The service had appropriate facilities to meet the needs of women waiting for their scans, which included comfortable seating, access to bathrooms, water dispensers and reading material.

The service had systems to help care for women in need of additional support or specialist intervention. Appointment letters contained information required by the woman such as contact details for the service and information about their ultrasound scan, including whether they needed a full bladder before their examination. There was also a link to a 'frequently asked questions' section on the service's website. Women who required additional support, for example women living with dementia or a learning disability, were able to bring a carer/relative.

Meeting people's individual needs

Staff did not always make reasonable adjustments to help women access services, with limited access to interpreting services and written information available in few languages. However, the service was inclusive and took an account of women's individual needs and preferences.

Staff made sure women living with mental health problems, learning disabilities and dementia, received the necessary care to meet all their needs. Reasonable adjustments were made by staff to ensure women in these groups could access the care they needed and received scans in a timely and safe way. Women were able to have early or late bookings to support their individual needs. All staff we spoke to said they take great pride in their work, especially when they are able to accommodate women with mental health problems, learning disabilities or dementia.

Staff understood and applied the policy on meeting the information and communication needs of women with a disability or sensory loss. Women received detailed written information to read and sign before their scan appointment. Key information about what different ultrasound scans involved were available on the service's website. However, this could not be accessed in any recognised world language.

The service did not provide translation services or sign language interpreters including British Sign Language as well as other spoken languages. The service did not have a contracted telephone interpretation service for staff to use during appointments with non-English speaking women. Senior staff informed us that they would utilise the services of the women's companion or if applicable use the translation service on their mobile telephone.

Staff described that if they had a woman who was deaf attend the service for an ultrasound scan this would be identified at the time of booking. Staff described how what communication techniques they would use such as being mindful to face the woman when speaking and clearly articulate words (for lipreading).

Diagnostic imaging

Information on the service's website could not be accessed in (changed to) any language. The service did not offer a 'read out loud system' to allow the visually impaired to gain information with ease. The service did not have a contracted (telephone) language interpretation service, that could be utilised for consent taking processes, if needed.

There were procedures in place to make sure women were aware of fees payable. Staff told us they would provide quotes and costs and aimed to ensure that women understood the costs involved. The service's website also clearly described the different payment options available.

The service was located on the ground floor, with direct access from the street; and off-street parking was available. Accessible bathroom facilities were situated adjacent to the clinic and waiting area. There was a reception area with ample seating for women awaiting appointments, and their companions.

The scan room was large and airy, with ample seating. We observed the scan room provided a relaxing and calming environment for women and their companions. There was an adjustable medical bed in the scan room, which staff used to support women with limited mobility.

We saw that children were welcomed in the clinic, and toys were provided in the waiting area to entertain them.

While the service had an equality and diversity policy, all policies seen were either undated or dated 2008 which meant that we were not assured that the information contained therein was up to date and suitable for use. Staff had not completed any equality and diversity training at the time of the inspection.

Access and flow

People could access the service when they needed it and received the right care promptly. However, the service did not monitor waiting times.

Managers did not monitor waiting times; however women could access services when needed and received treatment when they need it. Staff told us the service offered access to appointments in a timely manner for all women. All women self-referred to the service. This was arranged following a telephone discussion with the service and should there be no capacity on a particular occasion this was discussed with an alternative appointment made. Women told us they were able to book appointments at times that suited them.

There was no process in place to monitor waiting times, with no audits carried out by the service around access or demand and capacity. Managers told us they always ensured women could access services when needed, and often women expected to be seen the same day, which they were able to provide.

The service prioritised referrals for procedures/ examinations by having discussions with the woman regarding their requirements.

The service opened according to demand, and typically ran Monday 8am to 7.30pm, Tuesday to Friday 8am to 5pm and Saturday 8.30am to 3pm. The service had capacity to extend service provision as and when the need arose.

At the time of our inspection, there was no waiting list or backlog for appointments. Staff told us the service carried out approximately 350 scans a month, however were unable to provide a detailed breakdown over the past 12 months as this was not routinely monitored.

Managers and staff worked to make sure women did not stay longer than they needed to. Appointments generally ran to time; reception staff would advise women of any delays as they signed in. Staff told us they would keep women informed of any ongoing delays. We heard women speaking positively with staff about the availability of scans and confirmed they had received they had received suitable appointments in a timely fashion.

Managers worked to keep the number of cancelled appointments to a minimum and made sure they were rearranged as soon as possible. At the time of inspection, the service did not formally monitor rates of non-attendance. However, staff we spoke with said that if a woman suffered a miscarriage before their appointment, the service would refund the deposit payment immediately. There had been no cancelled procedures or examinations from August 2018 to August 2019.

Learning from complaints and concerns

Inadequate

Diagnostic imaging

Women were not given the opportunity to give feedback and raise concerns about care received. The service did not share lessons learned with all staff in the service.

Women, relatives and carers did not know how to complain or raise concerns, and the service did not clearly display information about how to raise a concern in waiting areas. The complaints policy provided by the service was not dated and did not have a review date. This meant that we were not assured that the information was up to date and suitable for use. The policy however outlined the procedures for accepting, investigating, recording and responding to local, informal, and formal complaints about the service. Records seen did not identify that staff had completed a mandatory training course on customer care and dealing with complaints.

The clinic reception area did not have information of how women could make a complaint. We did not see information about how to complain on displayed in the clinic reception area and information on how to make a complaint was not available on the service's website.

Staff understood the policy on complaints and knew how to handle them. Managers investigated complaints and identified themes. Staff described their approach to complaints and said they tried to meet all complainants on the day while they were still in the service, to try to understand their complaint and resolve as much as possible. The registered manager described that there was a minimum of one scan assistants and a sonographer on duty at all times; this helped to ensure there was enough staff to interact personally with every client.

The registered manager had overall responsibility for reviewing and responding to complaints, which were collated in a complaints log. The manager described that the complaints and concerns received were usually minor in nature and most often communicated to the service through social media channels. There had been six formal complaints from August 2018 to August 2019. During the inspection we reviewed all of these complaints, with common themes including poor experience and poor communication. We saw complaints were responded to in writing within five days and women offered the opportunity to attend the service for a face to face discussion.

The policy stated that it was the service's aim to ensure that all had the right to express their thoughts and feelings about the way the clinics were run. The service had a complaints procedure which included:

- Informing a staff member who would endeavour to resolve the difficulty informally.
- Should this action not be complainant's satisfaction, they could refer the complaint to the registered service provider either verbally or in writing. The provider would:
- Acknowledge the complaint within two working days of receipt of complaint.
- Investigate the complaint and respond in writing within a period of 20 days.
- Write to you to let you know of the progress made where the investigation takes longer than 20 days, and the reason for the delay.

Staff knew how to acknowledge complaints, however did not receive feedback from managers after the investigation. The service did not have processes in place for regular team meetings which meant that there was no opportunity to discuss complaints and concerns to encourage shared learning.

Are diagnostic imaging services well-led?

Inadequate

We have not previously rated this service. We rated it as inadequate.

Leadership

Leaders did not have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced. However, they were visible and approachable in the service for women and staff.

Leaders did not have the right skills and abilities to run a service providing high-quality sustainable care. They did not have a good awareness of the service's performance and needs.

The service was led by the registered manager and practice manager who staff told us were very approachable. We found staff were enthusiastic and proud to work within the diagnostic service.

Inadequate

Diagnostic imaging

Across the service, staff told us they could approach managers, including the registered manager with any concerns or queries. Staff throughout the service told us they felt supported, respected and valued. The sonographers reported to the registered manager for matters of administration and clinical needs. We saw the team was committed and determined to tackle issues as they arose. The registered manager was supported by a practice manager and accounts manager regarding the day to day management of the service. Staff spoken with confirmed that the management team had detailed knowledge and took prompt action to address any problems. Staff knew the management arrangements and told us they felt well supported.

We saw that the registered manager and the service's managerial team interacted well with staff and were friendly and approachable.

Vision and strategy

The service had a statement of purpose of what it wanted to achieve but did not have a strategy to turn it into action. Leaders did not have processes to apply the aim of the statement of purpose or how to monitor progress.

The service did not have a strategy or vision developed together with input from staff, with no strategic objectives identified for 2020. The service did not have a detailed business strategy which outlined what it wanted to achieve over the upcoming year.

The service's statement of purpose said it aimed to "provide all clients with the highest professional clinical standards in all areas of practice, using the latest scanning techniques and equipment." Staff we spoke with were not aware of either the statement of purpose or of the ethos identified on the service's website.

The service did not have any identified values, which underpinned their ethos which was "to provide the best possible support for informed choice and treatment for you and your baby's health located in a professional and comfortable setting."

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. The service had an open culture where women, their families and staff could raise concerns without fear.

Managers across the service promoted a positive culture that supported and valued staff. We spoke with four members of staff who all spoke positively about the culture of the service. Staff felt supported, respected, and valued, and all said they were happy working for the service. Staff described the culture within the service as being open and honest and felt they were listened to by senior managers.

Staff said there was a high staff retention rate amongst all staff. Staff said they felt valued by managers and colleagues.

All staff we met were welcoming, friendly and helpful. They were very proud of where they worked, enthusiastic about the care and services they provided, and said they were happy working for the service. We observed staff practice and saw that they were polite and professional with all women and families.

We saw that the culture of all the areas we visited during our inspection centred on the needs and experiences of the women. For example, if a mistake happened this was handled in a sensitive and open way. Staff felt empowered to make decisions and to challenge if required to ensure care constantly improved.

Any incidents or complaints raised had a 'no blame' approach to the investigation. Staff we spoke with said they were open and honest with women in circumstances should an error occurred, and apologies would always be offered. The manager explained the process they would take to rectify any errors, however no incidents had been recorded in the reporting period.

The registered manager was aware of the duty of candour regulation; however, they had not had any incidents which met the criteria where formal duty of candour had been required to be implemented.

Equality and diversity training was not incorporated into the service's induction and mandatory training programme.

Governance

Inadequate

Diagnostic imaging

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

The service did not have governance systems that ensured there were structures and processes of accountability in all areas to support the delivery of good quality services.

During our inspection we reviewed five policies which included medicines, consent, incidents and complaints. They were either undated or dated 2008 and were significantly past their review date. All policies seen did not reflect current guidance or legislation. For example, we did not see procedures for obtaining consent to care and treatment which reflected current legislation and guidance for staff to follow. The practice manager told us policies and procedures for the service were initially provided by an external HR and workforce company and had not been reviewed since they were last updated in 2008. Following our inspection, the provider told us all of their policies and procedures had been reviewed, updated and staff had been asked to review. However, we did not see any additional supporting evidence.

The management team did not attend management or clinical governance meetings and there was no forum to discuss complaints, incidents, audits, risks or to share information. The registered manager had overall responsibility for clinical governance and quality monitoring which included investigating incidents and responding to complaints.

All staff from the service attended team meetings, however they were intermittent which meant that staff were not provided with the opportunity to share lessons learnt regarding complaints and incidents. Following our inspection, the provider told us they had scheduled monthly team meetings. However, we did not see any additional supporting evidence.

The service did not have any audit results to improve the service. We saw that feedback was not collected and service changes were not routinely discussed and reviewed.

Governance processes were not effective to ensure all staff received an appraisal. At the time of our inspection, 50% of staff had received an appraisal with the remaining staff due to receive theirs over the next few months. While this programme was on going, staff confirmed they had not received an appraisal for several years until recently.

There was not an effective recruitment, training or performance review processes, and the registered manager did not ensure staff were appropriately qualified and trained to deliver good quality care. The registered manager did not identify training needs of staff through appraisal or support completion of specialist training to support care.

There was no systematic programme of internal audit used to monitor compliance with policies such as hand hygiene, health and safety and pathways. Audits were not completed which meant results were shared to drive improvements.

Managing risks, issues and performance

Leaders and teams did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues and identified actions to reduce their impact. They did not have plans to cope with unexpected events and staff did not contribute to decision-making to help avoid financial pressures compromising the quality of care.

The service did not have clear and effective processes in place for identifying, recording and managing risks. The service did not maintain a risk register to identify the severity and likelihood of risks causing harm to women or staff. Following our inspection, the provider told us they had developed a risk register but no significant risks had been identified. However, we did not see any additional supporting evidence.

During the inspection we did not see up to date health, safety and environment risk assessments such as fire, health and safety, legionnaires' disease, and the Control of Substances Hazardous to Health Regulations (COSHH) risk assessments. The aim of these risk assessments would be to detail any identified risks together with mitigating/control measures, the individual responsible for managing the risk and the risk assessment review date.

The service had a major incident planning policy which for example, outlined actions staff needed to take in the

event of extended power loss, a fire emergency, or severe weather conditions. However, the policy was not dated which meant that we were not assured if the information contained therein was up to date and suitable for use.

The manager and staff told us there had not been any recent training or practice events to ensure staff were aware of their responsibilities in the event of a major incident. The service did not have a business continuity plan that may provide guidance on maintaining services and dealing with business interruptions, which might disable services or require special arrangements to be put in place to allow them to continue. Staff confirmed they had not carried out a fire drill for several years.

The service did not have processes to monitor performance so that it could benchmark itself against other similar services.

There was no audit programme which would provide assurance of the quality and safety of the service.

The service did not undertake any sonographer peer review audits as recommended by the British Medical Ultrasound Society. There was no process to ensure sonographers had completed competency assessments.

They did not have the results of feedback, complaints or audits to help identify any necessary improvements and ensure they provided an effective service.

Managing information

The service did not collect any data so that it could be analysed. Staff did not have access to data so that they could understand performance, make decisions and improvements. Information systems were secure.

The service did not have key performance measures. During the inspection, we found no evidence of information to enable managers to assess and understand performance in relation to quality, safety experience, human resources, operational performance and finances. Key performance, audit, and feedback data was not collated and reviewed to improve service delivery or to drive forward changes in practice. Senior staff spoken with had an overview of the service but could not provide evidence of performance and where further improvements were needed to address these.

The service had a data protection policy in place, which incorporated the Data Protection Act 1998. Administration staff spoken with confirmed they had received training on the general data processing regulation (GDPR) which came into effect in May 2018. However, we reviewed staff records and found no evidence that the service monitored compliance with information governance, with the service unable to provide data on the number of staff who had received the appropriate training.

Staff were able to access electronic records appropriate to the needs of the investigation being completed. Staff had access to up-to-date, accurate and comprehensive information on care and treatment. Electronic records were kept secure to prevent unauthorised access to data, however, authorised staff demonstrated they could be easily accessed when required. The service was aware of the requirements of managing personal information in accordance with relevant legislation and regulations. General Data Protection Regulations (GDPR) had been reviewed to ensure the service was operating within the regulations.

During the inspection we saw appropriate use of computers with no screens detailing identifiable information left unattended. There were sufficient computers available to enable staff to access the system when they needed to. Computers were available in all the areas we visited. All staff had secure, personal login details and had access to email and all service information technology systems.

Engagement

Leaders and staff did not actively and openly engage with women and staff to plan and manage services.

The service did not seek feedback from relatives and carers of women who had attended the service to help share and improve the service. Women and visitors were not actively encouraged to provide feedback, although women could provide feedback using the service's social media pages. While women were able to leave comments and write reviews of their experience on the service's social media pages, the service did not routinely ask or collect satisfaction or experience information. Staff told us they had previously introduced electronic and paper-based surveys; however, they had not been run for

several years. Staff told us that they did not regularly reflect on information and feedback gathered from women and their companions to improve quality of care and service delivery.

During our inspection, we saw staff were not engaged in the service and were not empowered to help improve services. Staff did not attend regular team meetings and were unable to learn from each other or share information. Staff told us that managers were approachable, and they felt comfortable to raise any concerns with them. Information was not shared consistently, usually face to face on an ad-hoc basis.

Learning, continuous improvement and innovation

Leaders did not have an understanding of quality improvement methods or the skills to use them. Staff were not committed to continually learning and improving services.

Staff did not continuously strive to implement changes or improvements for the benefit of the service. There was no processes for staff to improve the service by sharing learning from things that went well, and things that went wrong. This included a lack of regular team meetings. Staff we spoke with could not provide examples of improvements or changes made to processes based on feedback and staff suggestions.

We did not find any evidence or oversight that sonographers and scan assistants undertook continuous professional development.

The service continued to monitor and upgrade the ultrasound scanning machines where necessary as improvements were released by manufacturers.

New technology had been introduced to improve the service such as non-invasive prenatal testing (NIPT).

The provider had improved its service by putting scanned images on memory sticks for women to take away.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure all staff can complete and evidence mandatory training in key skills, including safeguarding, as well as competencies around the roles they undertake. (Regulation 17)
- The provider must ensure there is a robust recruitment and selection process, and all information required by the Health and Social Care Act 2008 to ensure fit and proper people work within the service is recorded and available. (Regulation 19)
- The provider must ensure all policies are reviewed, are in line with current guidance and legislation, changes made if necessary and appropriate review dates set. (Regulation 17)
- The provider must ensure an effective incident reporting system is in place and staff understand how to report incidents including near misses. (Regulation 17)
- Ensure an effective complaints system is in place and staff understand how to record and respond to complaints. (Regulation 17)
- The provider must ensure there is a comprehensive audit programme to review and assess the quality of services provided. (Regulation 17)
- The provider must ensure there are effective systems in place to gain and record consent in line with current legislation and guidance. (Regulation 17)
- The provider must ensure there is a robust system in place to ensure the safe prescribing, administering and recording of medicines. (Regulation 17)

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	S29 Warning Notice

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed