Ooh Baby Baby LTD

Ooh Baby Baby

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Inspected but not rated
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

We rated this service as requires improvement because:

The service did not ensure staff had completed mandatory, and awareness, training to a level appropriate to their role. The service did not always use sufficient infection prevention control measures to protect women, themselves, and others from infection. The maintenance and use of facilities and premises did not always keep people safe. The service did not always identify relevant risks and issues relating to first aid training, pre-scan checks or portable appliance testing (PAT) for electrical equipment.

Managers did not always use systems to manage performance effectively. They failed to operate effective governance processes. The service did not always follow national guidance and evidence-based practice. They did not always identify relevant risks and issues or recognise actions to reduce their impact. They did not complete the necessary pre-employment checks for staff or fit and proper person checks for all directors.

However:

The service had enough staff to care for women and keep them safe. Staff understood how to protect women from abuse, and managed safety well. Staff assessed risks to women, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.

Staff provided good care and treatment. Managers monitored the effectiveness of the service. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.

The service had a strong, visible, person-centred culture. Staff were highly motivated and passionate. Women treated women with exceptional compassion and kindness. They respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided dedicated and personalised emotional support to women and their visitors.

The service planned care to meet the needs of local people, took account of women's individual needs, and made it easy for women to give feedback. Women could access the service when they needed it and did not have to wait too long for a consultation.

Managers promoted a positive culture. Staff felt respected, valued, and were supported to develop their skills. They were clear about their roles and accountabilities and were focused on the needs of women receiving care. Staff engaged well with women to plan and manage services and were committed to continually improving services. The service had implemented a vision for what it wanted to achieve and had aims and objectives to turn it into action.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Community health services for children, young people and families	Requires Improvement 	We rated this service as requires improvement because safe and well led were rated as requires improvement. Caring and responsive were rated as good. We do not rate the effective domain in diagnostic and screening services.

Summary of findings

Contents

Summary of this inspection

Background to Ooh Baby Baby

Ooh Baby Baby is a private baby scanning service. The clinic opened in November 2021 and provides a non-diagnostic and screening service to self-funding women who are over the age of 16. These scans are separate from NHS standard care pathways.

The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures.

The Care Quality Commission (CQC) defines a service providing non-diagnostic baby scans as a "souvenir scan," and an "ultrasound to record sound, pictures, or videos of your baby to keep as a memento. Souvenir scans are not for diagnosing problems with you or your baby."

The service had not been inspected previously.

How we carried out this inspection

The team that inspected the service comprised of a CQC lead inspector, an assistant inspector and an offsite CQC inspection manager. This inspection was overseen by Sarah Dronsfield, Deputy Director of Operations.

Our inspection was unannounced (staff did not know we were coming) to enable us to observe routine activity.

We spoke with the two directors. One of them was the registered manager who was trained as the ultrasound practitioner, the other was the general manager and receptionist. The service also employed a receptionist who worked part time.

They all participated in the service delivery of the regulated activity and are referenced as staff throughout the report. The registered manager and general manager are referred to as managers throughout the report.

We spoke with five women who had used the service and reviewed feedback on website browser platforms and social media.

We observed four baby scan procedures.

We reviewed a range of policies, procedures and other documents relating to the running of the service including consent and scan reports and onward referral letters.

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

Outstanding practice

We found the following outstanding practice:

Summary of this inspection

- There was a strong visible person-centred culture with staff delivering exceptional and personalised emotional care for woman.
- The service offered a gender reveal for siblings called a brother or sister introduction scan. They wanted siblings to feel the excitement of the pregnancy and start the close bond with their new brother or sister.
- The service had a 'pregnancy announcement station," available for women to use free of charge to create their own announcement photograph. This had a letter pin board for people to write their own messages and style it with available baby accessories and logos such as "hello world." They also had messages related to seasons, such as "no more silent nights" and "Santa Clause isn't the only one coming to town" for Christmas."

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

The service must ensure staff complete mandatory, and awareness training to a level appropriate to their role and attain compliance targets within designated timescales. This includes, but is not limited to, emergency first aid training. **Regulation 12(1)(2)(c).**

The service must ensure that the assessment of risk, preventing, detecting, and controlling the spread of, infections, including those that are health care associated is managed in line with national guidance. This includes, but is not limited to, hand hygiene, ensuring all cleaning equipment is clean and substances subject to COSHH regulations are stored securely. **Regulation 12 (2) (h).**

The service must ensure care and treatment is provided in a safe way for women, including assessing the risks to the health and safety of service users of receiving the care or treatment and doing all that is reasonably practicable to mitigate any such risks. This includes, but is not limited to, following the pause and check list issued by The Society and College of Radiographers and British Medical Ultrasound Society (BMUS) and the use of pulse wave doppler. **Regulation 12 (1)(a)(b).**

The service must have effective governance processes to ensure the safe and effective delivery of care. Managers must have oversight of risks and challenges. This includes, but is not limited to, mandatory, and awareness, training completion, infection, prevention, and control measures, and portable appliance testing. Managers must have appropriate processes to identify women attending under the age of 18 years old. **Regulation 17 (1)(2)(a)(b)(c)(f)**

The service must ensure effective governance processes are fully implemented to assess, monitor, and drive improvement in the quality and safety of services provided. Managers must adhere to national guidance and best practice as a non-diagnostic service. This includes, but is not limited to, the use of pulse wave doppler, providing accurate measurements and diagnosis, and peer reviews. **Regulation 17(1)(2)(a)(b)(c)(f)**

The service must have effective recruitment process to ensure that staff are suitably qualified, competent, skilled, and experienced persons to ensure provision of a safe service. Managers must complete the necessary pre-employment checks for staff and fit and proper person checks for directors. **Regulation 19(1)(a)(b)(2)(3)**

Summary of this inspection

Action the service SHOULD take to improve:

The service should ensure there were effective processes in place to check and record women's ID to confirm they were over 16 years of age. **Regulation 12.**

The service should ensure that the guidance within all of their policies and their website is applicable, accurate and relevant to the service. This should include, but is not limited to, the guidance within the clinic training document and the complaints policy. **Regulation 17.**

The service should ensure all equipment is maintained in line with manufacturer's guidance. **Regulation 15.**

The service should ensure there is closed-circuit television (CCTV) signage to comply with General Data Protection Regulations (GDPR). **Regulation 17.**

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Community health services for children, young people and families	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

Community health services for children, young people and families

Requires Improvement

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

Is the service safe?

Requires Improvement

Mandatory training

Managers did not make sure everyone completed training relevant to their role. However, the service provided mandatory training in key skills to all staff.

The mandatory training programme was comprehensive and met the needs of women and staff. Managers monitored mandatory and awareness training and alerted staff when they needed to update their training. The mandatory training policy indicated all staff must complete their training within one month of commencing employment with the service. However, we reviewed training records which showed not all staff were compliant with the awareness training modules such as mental health awareness and prevent training.

The service provided mandatory training in key skills to all staff to ensure provision of a safe service. This training included clinic training, consent, incident reporting, first aid at work, adult and children's safeguarding, health and safety at work and infection control.

There were additional awareness training modules relevant to their role and responsibilities such as female genital mutilation awareness, mental health awareness and prevent training.

Staff were given protected time to complete this training.

Safeguarding

The service did not have effective processes to check and record women's ID to confirm they were over 16 years of age. However, staff understood how to protect women from abuse and the service worked well with other agencies to do so.

Staff we spoke with could give examples of how to protect women from harassment and discrimination. They knew how to recognise and report abuse. They knew how to make a safeguarding referral via the safeguarding incident report form and who to inform if they had concerns. Staff were required to complete level 1 safeguarding adults and children's training during their induction and was a mandatory training requirement.

Community health services for children, young people and families

Requires Improvement

The registered manager, who was also the ultrasound technician, was the nominated safeguarding lead for the service and had completed level 3 safeguarding training for both children and adults. However, the receptionist had not received level 1 safeguarding children training.

The service's website stated that the service offered scans for women under the age of 18 if accompanied by a parental guardian. The online booking system asked women to confirm their date of birth. Upon arrival at the clinic women were asked to complete a consent form and staff were asked to check the women's ID. There was an additional consent document for parents/guardians to complete verifying this information before the scan took place. However, staff we spoke with told us that they did not check ID and there was no provision for recording that this check had taken place. This meant there was a risk women under the age of 16 may receive regulated activities at the service. Following the inspection, the service confirmed they would check proof of identification to check dates of birth of young women attending the clinic.

There was an up-to-date and comprehensive children, young people and adults safeguarding policy which all staff were familiar with and knew how to access.

All staff had received training in female genital mutilation (FGM) at induction. They had access to an FGM risk assessment tool and safeguarding policies on how to identify and report it.

The service displayed information regarding safeguarding from abuse in the unisex toilet. This reflected good practice as it meant women and visitors could discreetly access support from staff if required.

We did not see any other informational posters or leaflets displayed in public areas to signpost service users to safeguarding help and advocacy. Staff informed us that information posters were being produced and plans were in place to display them more widely within the clinic.

Cleanliness, infection control and hygiene

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

There was an infection prevention and control policy, which identified the registered manager as lead for overall infection prevention and control.

The ultrasound practitioner adhered to the infection control principles of bare arms below the elbows, and they regularly sanitised their hands. However, we did not observe any handwashing completed by any staff.

There were no hand hygiene posters above every sink to provide a visual guide to effective handwashing. The service did not conduct hand hygiene audits.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. Although the waiting area seating had fabric covers, this was not in a clinical area and were regularly cleaned. All other seating and furniture were suitable for easy cleaning. The service had adequate supplies of appropriate cleaning materials.

The receptionist conducted regular daily checks and followed the cleaning schedule for the non-clinical areas. A deep clean was conducted each week.

All women we spoke with described the clinic as clean with comments such as "spotless" and "very clean."

Cleaning schedules and audits were signed off by management. They were up-to-date and demonstrated that all areas were cleaned regularly. However, we found dirty cleaning equipment such as a mop head and toilet brush.

The ultrasound practitioner was responsible for cleaning the scan room. During our inspection we observed them changing the paper roll on the scanning couch and cleaning all surfaces with anti-bacterial wipes in between each woman.

Environment and equipment

The maintenance and use of facilities and premises did not always keep people safe. The service had not completed portable appliance testing (PAT) for electrical equipment and did not display closed-circuit television (CCTV) signage. However, staff were trained to use equipment.

The entrance door was recorded continuously by closed-circuit television (CCTV). There was no signage to inform women and visitors that this area was recorded by CCTV which meant the service did not comply with General Data Protection Regulations (GDPR).

The renewal date for portable appliance testing (PAT) of electrical equipment had elapsed in November 2022. Staff informed us that the testing was scheduled for the following week.

The service consisted of a large reception and waiting area with ample seating for women and their families. Staff at reception had a clear line of sight to the entrance door.

The entrance environment was fully accessible, bright, spacious, and well maintained.

The service had a large accessible sonography room which had enough suitable equipment to help them to safely care for women. There was a projector and to ensure women and their guests could see clear ultrasound images. There was enough seating to accommodate up to four guests. The room had a comfortable ambient temperate, with easy access to a unisex toilet across the corridor.

The service kept adequate stocks of personal protective equipment (PPE) such as masks, gloves, and aprons. There were two first aid kits, one stored in the scanning room and one in the kitchen.

Staff carried out safety checks of specialist equipment. For example, we saw an up to date ultrasound machine service and training log.

The service had a fire risk assessment and an adequate fire evacuation plan with signposting information to the fire exists, fire extinguisher and assembly points. The fire exits were clear of obstructions. The fire extinguisher and fire blanket were located in the kitchen and serviced within an appropriate timescale. However, the fire extinguisher was not secured within the appliance mounting bracket.

There was a kitchen used by staff with electrical appliances to make food and beverages. The kitchen was used to store cleaning equipment including a mop, bucket and hoover. The domestic waste bin did not have a pedal system. There was also a CCTV monitor which showed live images from the reception area.

Substances hazardous to health subject to control of substances hazardous to health (COSHH) regulations 2002, were stored in an unlocked low-level kitchen cupboard.

Staff disposed of domestic waste safely.

A legionella risk assessment had recently been conducted.

Assessing and responding to patient risk

The service did not always identify relevant risks. However, staff completed and updated risk assessments for each woman. They knew what to do and acted quickly when there was an emergency.

We reviewed emergency first aid at work certificates for two members of staff which had expired in November 2022. Following the inspection, the service sent evidence of completion of the emergency first aid at work certificates, but this was only for one member of staff.

The service displayed a pause and check list issued by The Society and College of Radiographers and British Medical Ultrasound Society (BMUS). However, we did not observe the ultrasound practitioner following this process in practice.

Staff completed a health and safety training which highlighted potential risks of using the service and actions required to mitigate or act on risks. There was a clear emergency and evacuation procedure, and all staff were trained in basic first aid. Staff we spoke to could demonstrate how they would deal with an emergency situation in the clinic.

Staff signed to acknowledge that a risk assessment had taken place for each woman based on the information shared on their consent form which was a comprehensive document. For example, the form asked for number of weeks pregnant (if known), general health, total number of pregnancies and children and any allergies or skin conditions.

Women consented to the scan on the basis they understood the risks associated with a non-diagnostic scan. They signed to say they had contacted their GP regarding the pregnancy and engaged in an appropriate program of antenatal care. They signed to say they declared any obstetric health history such as previous miscarriages, ectopic pregnancies, and any existing health conditions such as bleeding.

We observed four ultrasound scans. The sonographer completed additional risk assessments during the scan and strongly recommended women attend all NHS antenatal appointments. They asked each woman about previous pregnancies, whether this was their first, history of multiple births, any health issues, worries, concerns, cramps, bleeding, date of last menstrual period (LMP), and when the next midwife appointment was booked. The ultrasound practitioner had access to guidance and scan procedures. However, we did not observe the ultrasound practitioner providing information relating to the risk of using a doppler to listen to the baby's heartbeat, which was not in line with their standard operating procedure or competencies listed.

Staff responded promptly to any immediate risks to women's health and followed clear policy guidance for emergency support. They gave examples of redirecting women to their local NHS care provider.

Staffing

The service had enough staff with the right qualifications, skills, training, and experience to keep women safe from avoidable harm and to provide the right care. Managers gave new staff a full induction.

The service had enough staff to provide the right care and treatment. We spoke with the two directors; one of them was the registered manager who was trained as the ultrasound practitioner, the other was the general manager. The reception duties were covered by the general manager and receptionist who both worked part time.

Community health services for children, young people and families

Requires Improvement

The managers planned staffing rotas at least two weeks in advance. The staff that covered reception worked the same days each week and alternated Friday and Saturday shifts. Staff worked alone when rostered to open up the clinic, however, there was a lone working policy in place which described current arrangements to keep staff safe.

Managers made sure all new staff had a full induction tailored to their role and a high level of support.

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.

Women's records were comprehensive, and all staff could access them easily. The service offered non-diagnostic scans and the patient notes were sufficient for the scans that were being completed.

The service had a record keeping policy which managed the privacy, retention period, storage, and disposal of women's personal data in line with national guidance.

Records were stored securely. The service kept electronic scan records and consent forms. Staff stored paper booking and consent forms in a locked cupboard in the office with restricted access. All records were managed in line with the services record keeping and privacy policy.

Staff had a good understanding of how to maintain the confidentiality of women and ensured conversations were discreet.

Incidents

The service managed safety incidents well. Staff recognised and reported incidents. Managers investigated incidents and shared lessons learned with the whole team. When things went wrong, staff apologised and gave women honest information and suitable support.

The service had an incident reporting policy and staff knew what incidents to report and how to report them.

Staff completed mandatory training on incident reporting and understood the duty of candour. They were open and transparent and gave women and families a full explanation if and when things went wrong.

Staff we spoke with knew what incidents to report and how to report them. However, they confirmed there had been no reportable incidents since the business opened and there were no entries in the accident book.

Managers shared lessons learned from incidents with staff. Staff met to discuss the feedback and were given opportunities to discuss incidents openly.

Community health services for children, young people and families

Requires Improvement

Is the service effective?

Inspected but not rated

Evidence-based care and treatment

The service provided care and procedures mostly based on national guidance and evidence-based practice. Staff protected the rights of women subject to the Mental Health Act 1983. However, managers did not always check to make sure staff were aware of and followed guidance.

Manager worked closely with staff and regularly discussed up to date current and best practice. They monitored a document which staff would sign to evidence they had read understood guidance including any recently updated versions.

Staff were able to show us how they accessed this guidance in the service's policy and procedure folder.

We reviewed all policies and saw they were dated and reviewed regularly.

Staff regularly reviewed guidance and alerts from which to understand best practice.

- The National Institute for Health and Care Excellence (NICE)
- The British Medical Ultrasound Society (BMUS)
- European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)
- UK Health Security Agency

The registered manager told us they had a good working relationship with their previously employed sonographers who provided further discussions around best practice.

We heard many examples of how the service delivered high quality care according to best practice and national guidance.

- They offered a free early reassurance rescan after a minimum of 7 days if it was too early to visualise the baby (no yolk sac or embryo present).
- They bought sterile ultrasound gel to reduce the risk of infection.
- They were aware they have a duty of care to refer women to the local early pregnancy admission unit (EPAU) or NHS service, if they identified any concerns or anomalies.
- They subscribed to the BMUS as low as reasonably achievable (ALARA) protocols by using the lowest possible output power and shortest scan times possible consistent with achieving the required results.

The service displayed their terms and conditions on their website. They had a standard operating procedure (SOP) for pregnancies above and below 14 weeks. These documents clearly stated the main purpose of the scan was to obtain a recreational/ souvenir/ keepsake image as the service offered non-diagnostic baby scans. The provider was registered with CQC as a non-diagnostic service. It stated that ultrasound practitioners could comment on the gender, check the size of the baby, check for multiple pregnancies, detect gross anomalies, and show the position of the fetus and the placenta on the screen.

We reviewed the SOPs, client incident reports and onward referrals which showed that.

- gestational ages were based on the documented length of the crown rump length (CRL)
- exact CRL measurements were provided to women who had requested these to pass onto a different care provider.
- Staff had interpreted the ultrasound appearances of early pregnancy complications and documented "potential cyst" and "miscarriage suspected" on many forms.

This does not adhere with the latest guidance from the Society of Radiographers (SoR) on competencies which clearly defined the competencies required for non-diagnostic (souvenir) scans and stated no accurate measurements or diagnosis should be completed for ultrasound services offering non-diagnostic scans.

In addition, we observed staff using a pulse wave doppler to amplify the baby's heartbeat during the ultrasound scan. The service's website page also refers to packages which include see and "hear" your baby's heartbeat. The SoR guidance stated doppler was not recommended for non-diagnostic scans at any gestational age. The reasons for this is because it is outside of the ultrasound practitioner's scope of practice.

Following the inspection, the service told us they would make sure all future measurements and gestational age were given as approximations to comply with them being a non-diagnostic baby scanning service. They confirmed they would not diagnose, but simply record what they saw and where required make onward referral to an EPU to suggest additional examinations or follow up procedures by the NHS.

The ultrasound practitioner did not always follow the pause and check list issued by SoR. We did not hear them identify women before their scan using their name, address, and date of birth. Staff did not always follow best practice guidance of welcoming women or introducing themselves to women and families.

We did not observe the ultrasound practitioner follow BMUS and SCoR alternative techniques guidelines to obtain better images with scanning women on their sides.

Staff protected the rights of patients subject to the Mental Health Act and followed the Code of Practice. The service had a guide for staff to follow if women experienced acute anxiety or a mental health crisis and staff knew how to direct women appropriately. However not all staff had completed mental health awareness training.

Patient outcomes

Managers monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women.

The manager had overall responsibility for measuring the quality and safety of the service and monitoring trends in performance. The service sent a copy of their schedule of audits completed for 2022 and 2023 and the monthly audits appeared to be the same each month.

The service collected information on the number of women who attended for a non-diagnostic ultrasound scan. They recorded how many different scans had been completed for each woman for example, early and late reassurance scans, gender scan and 4D scans. They kept a detailed record of women who returned for more than one scan.

The service did not complete audits such as hand hygiene, scan times, reception waiting times, numbers of gender inaccuracies.

The service completed regular reviews of the feedback provided on social media, emails and in person. We reviewed this feedback which was recorded in a client feedback log, and it was consistently positive.

Community health services for children, young people and families

Requires Improvement

All women we spoke with described positive outcomes from the appointment in relation to their baby scan and also their well-being.

Managers picked out positive and negatives themes as part of the audit analysis. For example, the positive feedback included.

- Going above and beyond for women
- Cleanliness of the clinic
- Ultrasound practitioner's communication with women and how the scan is performed.
- Women feeling welcome and at ease.
- Large projector screen
- Affordable
- Friendly kind staff

Managers reviewed this feedback every month to assess whether any changes need to be implemented to improve the service. Managers discussed and shared audit outcomes with staff at regular team meetings.

We found examples of when changes had been made to practice.

- The wording in the scan report template was amended to help women understand the information better.
- The layout of the scan report template was improved to an easy to read format.
- The service now provided women with a copy of their baby scan report before they left the clinic.

The service recorded the number of rescans required however, they did not record or audit the reasons why the first scan was not successful for example women were being scanned too early or the baby was not in the best position for scanning.

We reviewed the audit for the number of referrals made to the early pregnancy assessment units (EPAU). Staff would email and sometimes make follow up calls to women to assess the accuracy of the onward referrals. However, they explained calls were not always answered and so outcomes were not always known.

Managers informed us they kept a record of feedback relating to members of staff and shared this feedback with staff. For example, the service had four positive five star reviews in one evening and staff were congratulated to help boost morale and confidence in practices.

There were no national audits which were relevant to the service. This meant this service were unable to benchmark their performance against other similar sized services.

The service did not have a process for peer reviews to ensure the accuracy and quality of scan images and reports. This meant there was limited assurance of the consistency when measuring ultrasound practitioner's performance and this was not in line with British Medical Ultrasound Society (BMUS) guidance.

Competent staff

Managers did not complete pre-employment checks to make sure staff were competent for their roles. However, they appraised staff's work performance and held supervision meetings with them to provide support and development.

Community health services for children, young people and families

Requires Improvement

Managers did not complete the necessary pre-employment checks for staff at the time of employment. We found gaps in recruitment files relating to Disclosure and Barring Service (DBS), references, CVs, and unaccounted employment gaps. This meant the service had not adhered to their recruitment policy and induction processes.

In addition, managers did not complete the necessary fit and proper person checks for all directors to ensure they were of good character and had the qualifications, competence, skills, and experience. This meant the service had not adhered to the Health and Safety Care Act and the CQC regulatory requirements.

The registered manager had completed an ultrasound course in May 2022. However, we were unable to find this course or training provider recorded on their training certificate. They gained experience from shadowing previous employees who were NHS sonographers and had maintained a good working relationship with them for clinical support.

Managers had the right skills and knowledge to meet the needs of women. They gave a full induction to new staff before they started work. There was a clinic training guide which clearly outlined the staff responsibilities, such as how to take bookings and how to set up for the day. It also included infection control, health and safety, consent, and incident report training as part of their induction.

Managers supported the learning and development of staff. They made sure staff received specialist training for their role to develop their skills and knowledge. They completed constructive appraisals which included a review of personally set objectives and personal development plans with related target dates for completion.

The service were researching additional training opportunities to support staff caring for women who had had a history of miscarriages.

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

Multidisciplinary working

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

Staff spoke positively of team working, effective communication and peer support. We observed constructive examples of staff working well together.

Managers held regular team meetings to discuss feedback reviews, performance, safety, and ideas on how to improve the service.

Staff gave examples of when they had referred woman to local early pregnancy assessment unit (EPAU) or NHS services. We reviewed scan reports which were printed out for women to take with them if the scan had identified any issues or anomalies. Managers explained that women would prefer to leave the clinic with a copy of the scan report rather than being formal referred to the local EPAU or NHS service.

Services were available to meet the needs of women.

The clinic was open five days a week including Saturdays.

It did not provide emergency care and treatment.

The appointment times were flexible to accommodate women and the clinic was open until 8pm two evenings during the week.

Community health services for children, young people and families

Requires Improvement

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

Managers were responsive to women if they needed additional advice and support seven days a week.

Health promotion

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

The service planned to display health information in the waiting area. Staff promoted healthy lifestyles during the scan appointments. We saw various books displayed in the waiting area which related to positive birth experiences; however, these were only available in English language.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The registered manager supported primary carers to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

The registered manager understood how and when to assess whether a woman had the capacity to make decisions about their care and knew who to contact for advice.

Staff gained consent from women in line with legislation and guidance. They made sure women consented to treatment based on all the information available. The service had consent forms in multiple languages to help women understand their rights and options.

Women completed an online booking form and a written consent form before their scan to confirm they understood the terms and conditions. They provided consent for the service to share scan results for onward referral reports or use scan images in promotional material.

We reviewed 14 consent forms and found these were completed fully.

Staff received consent training as part of mandatory training. Some staff had recently undertaken a mental health awareness training course. This was in response to some women reporting on email feedback they were suffering pregnancy anxiety.

The service had appropriate safeguarding arrangements, consent forms and guidance for young women aged 16 to 18 who wished to have a baby scan. The service asked for date of birth upon booking. If they were identified as being between 16 and 18, the advice was that they needed to be accompanied by a responsible adult. Following the inspection, the service planned to ask young women for ID for proof of age.

Community health services for children, young people and families

Requires Improvement

Is the service caring?

Good

Compassionate care

The service had a visible person centred culture. Staff were motivated and passionate to treat women with compassion and kindness. They respected their privacy and dignity and took account of their individual needs.

We observed staff delivering personalised care. They were discreet and responsive and took time to interact with women in a respectful and considerate way.

Staff showed kindness, empathy, and compassion to women when they explained their reasons for requesting the baby scan, especially when women had previous miscarriages or when women were trying to conceive.

Women said staff treated them well and with kindness. We spoke to three women who all gave positive feedback "lovely friendly staff" and "make you feel very relaxed."

We reviewed feedback from social media and client feedback log which was overwhelmingly positive. For example, it confirmed staff "go above and beyond to make you feel at ease" and "from the moment you step through the door you are made to feel special." The environment was described as "warm and friendly," and the staff were "so professional, down to earth and lovely."

We spoke with three women who had both used the service before and had returned because of the compassionate care provided at previous appointments.

The service had an equality and diversity policy for staff to use for guidance and information as also available within the health and safety staff training manual. Staff understood and respected individual needs and displayed a non-judgmental attitude. Women we spoke to confirmed staff respected their privacy and dignity.

Staff followed policy to keep patient care and scans confidential. They would share concerns with other healthcare providers with the women's consent.

Staff understood and respected the personal, cultural, social, and religious needs of women and how they may relate to care needs. They gave examples of providing compassionate care to same sex couples and new parents.

However, we did not observe staff being welcoming or introducing themselves to women.

Emotional support

Staff provided emotional support to women when they needed it.

The service was inclusive and accessible to all women.

Community health services for children, young people and families

Requires Improvement

We observed staff offering reassurance to women before, during and after baby scans. They demonstrated empathy when the ultrasound scan did not provide a clear enough picture for a scan picture or when the gender could not be identified due to the position of the baby.

Staff were conscious of the emotional needs for women attending scans. They followed guidance to support women who experienced anxiety or previous miscarriages. For example, they were mindful of providing additional support to women who arrived at the clinic on their own or who had requested multiple reassurance scans.

Staff supported women who became distressed in the clinic and helped them maintain their privacy and dignity by offering them time in an office room.

We saw positive examples of emotional care feedback from women social media and the client feedback log.

We heard of examples when staff provided excellent emotional support. For example, they would ask women who had received unfortunate news if they would like to leave via the back door to avoid going back through the reception area.

We spoke women who had used the service on more than one occasion and said the staff took their time to get to know them. We heard of one example when a family had had a recent male bereavement in the family and staff made their gender reveal extra special because it was going to be a baby boy, they said “it made the gender reveal a very special family moment.”

The service offered additional services to support the woman’s pregnancy such as hypnobirthing and pregnancy massage sessions.

Understanding and involvement of women and those close to them

Staff supported women to understand their condition and make decisions about the next stages of their care and treatment.

The service made sure women understood their treatment by providing clear information about scan options and costs on the website. They were supported to make informed decisions about their care and were guided to choose the right scan depending on the stage of their pregnancy.

Staff made sure women were given the time they needed for the scan, and this included time for questions and answers.

We reviewed feedback from social media and client feedback log which demonstrated that “everything is explained thoroughly so you know exactly what’s happening and what you’re seeing.”

Women we spoke with confirmed that they felt listened to and were given the opportunity to ask questions and did not feel rushed.

Staff talked with women and their visitors in a way they could understand. We observed them actively involving the women and family to make the scan more memorable. For example, they pointed out the baby’s face and limbs and the beating heart.

We observed a woman returning to have a scan after going for a walk / drink and heard staff say “let’s see if this baby has uncurled” in order to identify the gender.

Community health services for children, young people and families

Requires Improvement

The service offered different options for gender reveal. For example, there was the option to find out the gender in the scan room. Staff made this a special experience when revealing a baby's gender by using pink or blue lighting in the scan room. We observed staff writing down the gender in an envelope which was to be passed onto a family member so that it would a surprise for the women and partner during a gender reveal event.

The service also offered a special gender reveal for siblings called a brother or sister introduction scan. They wanted siblings to feel the excitement of the pregnancy and start the close bond with their new brother or sister. We heard one example of when a sibling opened up a gender reveal box and found a blue bear holding the scan picture with the words "you are going to be a big brother."

We read feedback from social media about these scans which demonstrated staff involved a sibling as much as possible during the scan. For example, staff "whispered the gender to him before revealing it on the screen to us" or would tell them "You are going to be a big sister / brother." This scan includes a heartbeat bear for the siblings to "cherish their memory and continue to build their bond at home."

The service offered free rescans if they were unable to identify the gender of the baby on the day due to the baby's positioning.

Women understood when and how they would receive their scan images and results. They had an opportunity to choose the image they wanted immediately after the scan, to be printed out as part of their chosen scan package. Women we spoke with were pleased with their scan image and said the "quality of the scan pictures was amazing."

The service had a 'pregnancy announcement station," available for women to use free of charge to create their own announcement photograph. This has a letter pin board for people to write their own messages and style it with available baby accessories and logos such as "hello world." They also had messages related to seasons, such as "no more silent nights" and "Santa Clause isn't the only one coming to town" for Christmas."

Staff supported women to make informed decisions about the next stages of their care. This included onward referral to NHS services when scan results indicated abnormalities or other unexpected results. This ensured women did not leave the clinic without fully understanding where they would receive help and support going forward. The clinic worked with multiple local NHS hospitals and provided women with a choice of referral hospital if appropriate. Staff were trained to signpost women to specialist support services and charities.

Is the service responsive?

Good

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

The facilities and premises were appropriate for the services being delivered.

The clinic was on the ground floor with good access for women with pushchairs or wheelchairs. There were accessible toilets.

Community health services for children, young people and families

Requires Improvement

The service was located on a row of shops just off the main street in Mexborough town centre. It was easily accessible by public transport and had car parking spaces located at the rear of the building.

Managers monitored and took action to minimise missed appointments. The booking system sent out automatic reminders ahead of appointments and offered a grace period for late attendances caused by unforeseen circumstances. Staff offered flexibility in short notice rebooking in some circumstances, such as COVID-19 isolation.

Managers ensured that women who did not attend appointments were contacted. However, there was a low rate of non-attendance because the service requested a non-refundable deposit payment on appointment booking.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They directed women to other services where necessary.

Women were able to declare any reasonable adjustments they needed to attend the scan appointment safely and comfortably at the booking stage, by telephone or at arrival at the clinic.

Staff adhered to the equality and diversity policy to ensure women with protected characteristics received care free from bias. They gave examples of providing person centred care to same sex couples and couples who had been through in vitro fertilisation (IVF) or intrauterine insemination (IUI) treatment.

Staff gave positive examples of when they made reasonable adjustments for woman in terms of personalising the service to meet their needs. For example, staff would take more care over their choice of words and behaviours during early reassurance scans compared to later reassurance scans where they would create a joyful atmosphere.

We observed the ultrasound practitioner checking the scan images themselves before projecting the image onto the larger display screen. The reason for this was to avoid any obvious gender reveals or if abnormalities were found.

Staff gave positive examples of how they responded and cared for women with a disability or sensory loss. The service was able to print out information in larger font and also used technology to aid communication and translation. They had supported women who arrived in wheelchairs, helped them onto the scan couch and adjusted the back of the couch so that it was comfortable.

The service had consent forms printed in languages spoken by the women in the local community for example Romanian, Polish and Urdu. In addition, they had a list of buzz words in different languages relating to baby scanning words such as baby, pregnant, gender, scan, early, 4d, toilet, pains, hospital, unwell suffering / sick, boy and girl.

Staff were culturally sensitive to women who had different religious faiths. They were aware of women with different faiths arriving to the clinic on their own and made sure they provided adequate support. In addition, they understood the importance of maintaining privacy during the scans for women and made sure that the scan area was the only area exposed on the body for the scan.

The service offered women a range of baby keepsake and gender reveal merchandise which included including balloon, confetti cannon and scratch cards for gender reveals. Heartbeat bears were available which contained a recording of the unborn babies' heartbeat.

The service could signpost women to a number of specialist pregnancy and miscarriage charities.

The registered manager would find an appointment at a nearby baby scan clinic during periods of unexpected leave, especially if women had already planned a gender reveal party.

Access and flow

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

Women were able to book same day online appointments, by email or by phone.

The service did not hold a waiting list for appointments because all patients were offered an appointment within 24 to 48 hours. They provided reassurance scans for women who could not get an early appointment in the NHS, especially during the COVID-19 pandemic.

The registered manager was able to offer short notice bookings for any urgent requests. They were able to offer an evening or weekend appointment outside of the normal clinic hours as and when the need arose. In addition, they were able to adjust the appointment times to accommodate women who required additional time.

The appointment structure meant a rescan could take place quickly especially if the ultrasound practitioner was unable to obtain a clear image due to the position of the baby. Women were advised to have a walk and a drink and were provided an approximate return rescan time.

The service kept delays and waiting times to a minimum.

Staff facilitated fast access to scan images and made these available to women immediately.

Learning from complaints and concerns

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

The service had policy to cover compliments and complaints. Women could raise complaints in person, in writing, by telephone, social media and email.

Staff understood their responsibilities in the logging on any complaint or concern and knew how to respond to and escalate complaints.

The registered manager described how they had overall responsibility for reviewing, investigating, responding to complaints, and providing feedback within four weeks, in line with their policy.

Following the scan, staff would provide information to women to advise them how to get in touch if they required any additional support. Women were encouraged to leave feedback on social media.

The service was proactive in reducing the need for any formal complaints. For example, women were offered free rescans if they were dissatisfied with the scan image quality.

Community health services for children, young people and families

Requires Improvement

We reviewed social media feedback and saw that managers had responded to all positive and any negative comments.

Manager recorded this feedback onto a client feedback log. We reviewed this log, and it contained information such as the date of the visit and what feedback was given. However, there was no information written for against any action taken on this feedback.

Following the inspection, managers shared an updated copy of the client feedback log which showed what action had been taken against relevant feedback. The registered manager said they would use this to identify themes and trends.

We reviewed the complaints received within the last year. The registered manager followed process and investigated them within timescales and duty of candour was provided in line with their policy. The registered manager had responded appropriately, and the complainant was satisfied with the outcome. We saw actions had been taken to improve the service as a result of this complaint.

However, the service did not clearly displayed information about how to raise a concern in the clinic or on their website. The complaints policy did not inform women who to approach if they were unhappy with the outcome of a complaint such as an Independent Sector Complaints Adjudication Service (ISCAS) or mediation service. However, this information was detailed within the staff clinic training document.

We heard several positive examples of how women's feedback had been used to improve the service. For example, staff including the ultrasound practitioner had completed a mental health awareness course after receiving feedback that women were anxious in attending the scan.

The service learned they needed to set clear expectations about the quality of the scan picture following feedback received from women. They amended their consent form and information to state they could not always guarantee a clear scan picture to show the gender and created a false gender policy in the case when gender was incorrect.

Is the service well-led?

Requires Improvement

Managers had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and staff. They supported staff to develop their skills.

During the COVID19 pandemic the service had not been successful with the recruitment or retention of sonographers. As a result, the registered manager had trained as an ultrasound practitioner to perform the baby scans. This meant they needed leadership support from the general manager (second director) who had oversight of the day to day running of the clinic. We were informed the general manager was in the process of applying to become a joint registered manager. This meant there would be two managers responsible for regulatory compliance.

The managers managed the service effectively during the COVID-19 pandemic to ensure the safety of women attending for ultrasound scans. They offered additional capacity for women who could not access NHS services due to reduced availability.

Community health services for children, young people and families

Requires Improvement

We observed visible leadership from both managers. They understood and recognised the challenges of maintaining safety and quality whilst at the same time meeting the demand for requested baby scans.

The registered manager was aware of the role social media played in providing information on the quality of their services, and ensured their website was fully updated and interactive in order to facilitate as many opportunities to engage with women as possible.

We saw examples of how managers had encouraged staff to develop in their role.

Staff we spoke with felt confident to discuss any concerns with managers.

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

Vision and Strategy

Managers had a vision for what they wanted to achieve, with related strategies and objectives to turn them into action. They were passionate about providing a high quality and sustainable service.

Managers had a vision to expand their business to provide holistic services to women who were pregnant or who had recently given birth. They wanted to provide a service that so women could meet and speak about their experiences. They had already arranged events for pregnancy massages and a baby / toddler first aid course. Their objectives for this was to create a survey for women who attended the clinic to research ideas for networking.

One of their visions was to help bereaved parents in the community and they intended to contact local professionals / midwives to give talks at the clinic. They were planning their first bereavement supportive meeting in March 2023.

Staff were dedicated to provide a safe, and comfortable, environment for women for baby scans.

Culture

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

The service provided a positive culture to support women. Women we spoke with reported feeling comfortable to raise any concerns if needed with managers.

Staff we met were warm and friendly. They worked closely with each other, and they reported feeling supported and motivated. They spoke positively about their roles and demonstrated pride and passion.

Managers supported staff to promote their positive wellbeing. The service had a whistleblowing policy which encouraged staff to raise any concerns.

The website and social media displayed a strong emphasis of care for women.

The registered manager offered ongoing support to women over telephone or messaging free of charge following a baby scan.

Community health services for children, young people and families

Requires Improvement

Governance

The registered manager failed to operate effective governance processes. However, staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Managers did not always make sure the guidance within all of their policies and their website was applicable, accurate and relevant to the service. For example, the guidance within the clinic training document referenced.

- radiographers, midwives, or doctors
- details of scans which included hearing the baby's heartbeat.
- retention period for scan images

In addition, the complaints policy did not inform women to approach Independent Sector Complaints Adjudication Service (ISCAS) or mediation service if they were unhappy with the outcome of a complaint.

Staff at all levels were clear about their roles and accountabilities. They had regular opportunities to meet and discuss the results of audit data and feedback.

We reviewed the communication log which was used to share information such as meeting minutes. This provided examples of when managers had updated, and improved processes following feedback from staff or from women. The log showed how they monitored the progress of these actions over time to measure their performance.

The registered manager understood their responsibilities to report statutory notifications to CQC. There had been no incidents requiring a statutory notification in the last 12 months.

Management of risk, issues, and performance

Managers did not always use systems to manage performance effectively. They did not always identify relevant risks and issues or recognise actions to reduce their impact. However, they had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

Managers had limited oversight of the concerns and awareness of all the risks and challenges that we identified during the inspection.

Managers did not ensure staff had completed training relevant to their role in line with their policy. We found gaps in training records relating to children safeguarding, mental health awareness and prevent training. We also found expired emergency first aid at work certificates. This meant the service had not adhered to their training policy which stated staff would be notified two months prior to certificate expiry date to allow enough time to complete it.

Managers did not complete the necessary pre-employment checks for staff at the time of employment. We found gaps in recruitment files relating to Disclosure and Barring Service (DBS), references, CVs, and unaccounted employment gaps. This meant the service had not adhered to their recruitment policy and induction processes.

In addition, managers did not complete the necessary fit and proper person checks for all directors to ensure they were of good character and had the qualifications, competence, skills, and experience. This meant the service had not adhered to the Health and Safety Care Act and the CQC regulatory requirements.

Community health services for children, young people and families

Requires Improvement

Managers did not identify the risks of poor handwashing compliance and dirty cleaning equipment as an infection, prevention, and control measure. They did not ensure electrical equipment had regular portable appliance testing (PAT) or have processes in place to check women were over 16 years of age.

Managers did not identify the risk of acting outside of the Society of Radiographers (SoR) scope of practice when using a pulse wave doppler to amplify the baby's heartbeat during the ultrasound scan. They did not adhere to the non-diagnostic scan guidance issued from SoR which stated no accurate measurements or diagnosis should be completed for ultrasound scans. They did not follow the pause and check list issued by SoR or British Medical Ultrasound Society (BMUS). They did not perform peer reviews to ensure the accuracy and quality of the ultrasound scan images and written reports.

Managers did not display signage to inform women and visitors that the entrance door was recorded continuously by closed-circuit television (CCTV). This meant the service did not comply with General Data Protection Regulations (GDPR).

Following the inspection, managers sent evidence which showed that directors had met the "Fit and Proper Persons Requirement" (FPPR). They also informed us that staff had completed their emergency first aid at work training but only provided certificated evidence for only one member of staff.

Managers sent the DBS certificate for the member of staff who did not have a current DBS. We were informed the other member of staff was in the process of applying for a DBS for this employment.

The service confirmed they would update their systems and processes to reflect the latest guidance issued by Society of Radiographers (SoR). Managers confirmed they would collaborate with similar sized baby scanning unit to set up a process with for regular peer reviews.

Staff regularly completed appropriate environmental and clinical risk assessments which identified actions which had been completed to mitigate risks. These risk assessments were reviewed regularly.

The service had a business continuity policy which outlined procedures for staff to follow in the event of equipment failure, building closure or short notice staff absence. Staff had access to a list of emergency numbers for the building, equipment, and managers. The service had valid insurance covering both public and employer liability.

Information Management

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

Staff reported sufficient numbers of computers, printers, and a reliable ultrasound machine in the service.

The service used paper records to record the consent and onward referrals. These records were comprehensive and were stored in a locked cupboard at the clinic. The registered manager explained they would scan these paper records as electric medical records 30 days after the appointment and would destroy the original paper records.

The registered manager used information technology systems to effectively monitor and improve the quality of care. They collected information stored using the electronic system for audit reviews. Staff were able to effectively retrieve previous scan information for women returning for additional.

Managers managed and saved women's personal data in a safe and secure way.

The service had appropriate policies which related to the record keeping and privacy for the collection and storage of information kept on women. This included the safe use of social media and email information. In addition, the service was registered with the information commissioner's office (ICO).

The terms and conditions information on the website was clear about the services provided and associated costs.

The registered manager was aware of their responsibility to report statutory notifications to the Care Quality Commission (CQC). There had been no incidents requiring a statutory notification in the last 12 months.

Engagement

Managers engaged with staff and women to plan and manage services. They collaborated with partner organisations to help improve services.

There were consistently high levels of constructive engagement with staff and women who use services.

We heard positive examples of how managers proactively engaged with all staff using a handover book, team meetings and messaging applications.

Staff were encouraged to participate in active discussions to help improve the day to day running of the service and shape plans for the future. They said they were given the opportunity to make suggestions for the service.

We heard positive examples of how the service was committed to being part of the local community. They had held a baby and toddler first aid course and a pregnancy massage event for women. They hosted a reassurance and bonding event which included a pop up baby clothes store and a presentation on antenatal pregnancy care.

They had approached local charities and health professionals to help plan events at the clinic and were introducing antenatal classes and coffee mornings for women in the community.

The registered manager encouraged women to share feedback on how they can improve the service. They shared good examples of how this feedback had been used to improve quality of care and manage and plan the delivery of their services.

We reviewed the active social media page and observed that the registered manager was very engaging with women.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. Managers encouraged innovation.

Staff were passionate to learn ways to improve the experience for women. They felt positively rewarded by managers.

We heard of many positive suggestions from staff such as.

- pregnancy diaries
- new merchandise ideas for gender reveals such as scratch cards and blue / pink helium balloons
- attending local baby fayres

Community health services for children, young people and families

Requires Improvement

- second hand baby clothes event at the clinic.

Managers wished to expand their portfolio of services and introduce.

- a hypnobirthing event
- regular antenatal class
- regular coffee mornings
- Talks from local professionals such as midwives
- baby showers, gender reveal and children's parties.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service must ensure staff complete mandatory, and awareness training to a level appropriate to their role and attain compliance targets within designated timescales. This includes, but is not limited to, emergency first aid training. **Regulation 12(1)(2)(c).** The service must ensure that the assessment of risk, preventing, detecting, and controlling the spread of, infections, including those that are health care associated is managed in line with national guidance. This includes, but is not limited to, hand hygiene, ensuring all cleaning equipment is clean and substances subject to COSHH regulations are stored securely. **Regulation 12 (2) (h).** The service must ensure care and treatment is provided in a safe way for women, including assessing the risks to the health and safety of service users of receiving the care or treatment and doing all that is reasonably practicable to mitigate any such risks. This includes, but is not limited to, following the pause and check list issued by The Society and College of Radiographers and British Medical Ultrasound Society (BMUS) and the use of pulse wave doppler. **Regulation 12 (1)(a)(b).**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service must have effective governance processes to ensure the safe and effective delivery of care. Managers must have oversight of risks and challenges. This includes, but is not limited to, mandatory, and awareness, training

This section is primarily information for the provider

Requirement notices

completion, infection, prevention, and control measures, and portable appliance testing. Managers must have appropriate processes to identify women attending under the age of 18 years old. **Regulation 17 (1)(2)(a)(b)(c)(f)**

The service must ensure effective governance processes are fully implemented to assess, monitor, and drive improvement in the quality and safety of services provided. Managers must adhere to national guidance and best practice as a non-diagnostic service. This includes, but is not limited to, the use of pulse wave doppler, providing accurate measurements and diagnosis, and peer reviews. **Regulation 17(1)(2)(a)(b)(c)(f)**

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The service must have effective recruitment process to ensure that staff are suitably qualified, competent, skilled, and experienced persons to ensure provision of a safe service. Managers must complete the necessary pre-employment checks for staff and fit and proper person checks for directors. **Regulation 19(1)(a)(b)(2)(3)**