

Meet the Baby Ltd

Meet The 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?

Inadequate



Are services effective?

Inspected but not rated



Are services caring?

Good



Are services responsive to people's needs?

Requires Improvement



Are services well-led?

Requires Improvement



Summary of findings

Overall summary

We have not inspected this service before. We rated it as requires improvement because:


- Staff had training in key skills but the provider did not have details of what ongoing arrangements were in place to deliver annual mandatory training.
- The service did not control infection risk well.
- The service did not always assess risks to women and act on them.
- The privacy and dignity of women was not always maintained when findings were being relayed to NHS services by telephone.
- Leaders operated governance processes but there was no formal governance framework in place and there were gaps in the system for reviewing policies and procedures. Governance processes could be improved by having a written strategy and ensuring that all policies and procedures had a review date.

However:

- The service had enough staff to care for women and keep them safe, understood how to protect women from abuse, and managed safety well. Staff kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of women and supported them to make decisions about their care.
- Staff treated women with compassion and kindness, respected their privacy and dignity (except on one witnessed occasion when telephoning NHS services), 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, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it.
- Leaders ran services using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and mission statement and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|--------------------|--|---|
| Diagnostic imaging | Requires Improvement  | We have not inspected this service before. We rated it as requires improvement. See the summary above for details |

Summary of findings

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Summary of this inspection

Background to Meet The Baby

Meet The Baby in Warrington (the clinic location) is operated by Meet The Baby Limited. The clinic provides self-referred, privately funded pregnancy scans. The clinic has one scan room, a reception area/waiting room and an area where women can choose their photographs and keepsakes. It is located in central Warrington on the ground floor of a building close to the rail station and is fully accessible. The clinic is registered to provide the following regulated activities:

- Diagnostic and screening procedures

The clinic offers a range of ultrasound scans from six to 32 weeks gestation. Scan options include early pregnancy reassurance scans, conducted by a qualified sonographer; early gender scans from 15 weeks, 3D and 4D gender scans, 4DHD live bonding scans and 2D gender scans. The service states that it does not carry out any diagnostic scans.

The service provides keepsake pictures and DVDs to people who use the service as well as other optional keepsakes such as heartbeat bears and gender reveal balloons and cannons. The clinic employs a registered manager who acts as an ultrasound technician, a receptionist and a sonographer who is able to carry out early reassurance scans, as well as gender identification and bonding scans. The registered manager has been in post since February 2021.

We had not inspected or rated this service before.

How we carried out this inspection

Our inspection was short announced (staff were told that we were coming during the week of our inspection) to ensure that we could speak to the registered manager and a sonographer and to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology.

An inspector carried out the inspection on 31 May 2022 with off-site support from an inspection manager. During the inspection, they met with the registered manager and a sonographer. They also spoke with one woman and their partner.

We reviewed four clinical records and two staff records. We also reviewed policies and procedures held by the provider and other associated records.

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

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:

Summary of this inspection

- The provider must ensure that there are arrangements in place for all staff to undertake annual mandatory training. (Regulation 18)
- The provider must ensure that there is a member of staff with level three children's and adult safeguarding on site when the premises are open. (Regulation 13)
- The provider must ensure that all staff have a good understanding of infection prevention and control practice to ensure that the service is run safely, for example, disposal of clinical waste, handwashing and storage of cleaning chemicals. (Regulation 12)
- The provider must ensure that all clinical waste, particularly offensive hygiene waste such as personal protective equipment (PPE), couch roll and clinical wipes, is disposed of safely in clinical waste bins with foot pedal or no touch operation. The bins should be stored in the same room where clinical waste needs to be disposed of so that clinical waste is not being carried through waiting areas of the clinic. (Regulation 15)
- The provider must ensure that clinical waste stored outside for collection is in a lockable bin or store. (Regulation 15)
- The provider must ensure that handwashing facilities are available in the scanning room. (Regulation 15)
- The provider must ensure that all furniture in the premises is constructed from, or upholstered in, a wipeable material. (Regulation 15)
- The provider must ensure that hazardous cleaning chemicals are kept in a locked cupboard in accordance with the relevant regulations. (Regulation 15)
- The provider must ensure that there are appropriate measures in place to check the age, identity and key pregnancy information and history of the woman. (Regulation 12)
- The provider must ensure that appropriate procedures are in place in the event of a medical emergency. (Regulation 12)
- The provider must ensure that they obtain the appraisals for Sonographers working at the service whose substantive post is elsewhere in the NHS or another provider or that a formal appraisal process and competency framework is developed where these cannot be supplied. (Regulation 18)
- The provider must ensure that there are formal monitoring processes in place to review quality assurance and clinical safety. (Regulation 12)
- The provider must ensure that there is access to independent interpreters to assist women whose first language is not English or who may have a hearing impairment to ensure that a relative does not act as an interpreter where there may be a safeguarding concern. (Regulation 9)

Action the service **SHOULD** take to improve:

- The provider should ensure that all staff have undertaken training in female genital mutilation (FGM). (Regulation 18)
- The provider should ensure that there is an appropriate decontamination policy and relevant training has been undertaken by all staff involved in using and/or decontaminating any transvaginal probe before this is brought into use. (Regulation 15)
- The provider should ensure that regular hand hygiene and infection prevention and control audits are carried out on staff undertaking scans to ensure compliance with infection control and hygiene techniques. (Regulation 15)
- The provider should ensure that the couch in the scanning room is serviced to assure that it remains safe to use. (Regulation 12)
- The provider should consider asking women whether they have a latex allergy before they attend for a scan in order that appropriate measures can be taken to prevent them from coming into contact with latex in the clinic. (Regulation 12)
- The provider should ensure that there is a "pause and check" safety checklist displayed in the clinic as an aide memoire to staff to confirm identity and consent before any procedure is undertaken. (Regulation 12)
- The provider should ensure that appropriate further consent procedures are in place before transvaginal scans are introduced as a service. (Regulation 11)

Summary of this inspection

- The provider should ensure that the privacy and dignity of women is maintained at all times. (Regulation 10)
- The provider should have policies and procedures in place in line with regulated activity, including recruitment. The provider should ensure that all policies and procedures have review dates so that updates can be tracked. (Regulation 17)






Our findings

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Are Diagnostic imaging safe?

Inadequate 

We have not inspected this service before. We rated it as inadequate.

Mandatory training

The service provided training in key skills to all staff and made sure everyone completed it although the provider did not have details about what the arrangements were for delivering annual mandatory training courses going forward.

The mandatory training for new staff was comprehensive and met the needs of women and staff.

The manager and receptionist had completed an online care certificate that covered a number of training courses. The courses included duty of care; working in a person-centred way; communication; privacy and dignity; fluids and nutrition; safeguarding adults; safeguarding children; basic life support; health and safety; handling information and infection prevention and control.

Staff completed awareness sessions on recognising and responding to women living with mental health needs, learning disabilities, autism and dementia as part of the care certificate. However, the care certificate is a generic course to teach people new to care, the fundamental knowledge, skills and behaviours required. The registered manager was unable to confirm what the arrangements for delivering annual mandatory training courses going forward were with dates when specific training needed to be repeated.

In addition, staff had completed training in fire safety and control of substances hazardous to health (COSHH).

The sonographer, who had only recently been employed by the provider, had completed mandatory training whilst working as a locum sonographer. They had supplied evidence of up to date training in mandatory training courses such as infection prevention and control; safeguarding; fire safety; health, safety and welfare; privacy and dignity and resuscitation level 2. They had also completed a learning path for staff returning to the NHS.

Diagnostic imaging

Safeguarding

Staff understood how to protect women from abuse. Staff had training on how to recognise and report abuse and they knew how to apply it. However, there was not always a person trained to level three in adult and children's safeguarding on site when the clinic was open.

Staff received training specific for their role on how to recognise and report abuse. The clinic manager had undertaken level two training in safeguarding children and adults, the sonographer had undertaken level three training in safeguarding children and adults and the receptionist was trained to level one. The courses undertaken had covered female genital mutilation (FGM) and PREVENT, the government strategy, that was developed to assist in signposting organisations where there was a suspicion of an adult or child having been radicalised.

The manager told us that they intended to undertake the level three safeguarding courses but had not had the time. This meant that, when the sonographer was not working in the clinic there was no staff member who was trained to level three in adult and children's safeguarding.

The service had a safeguarding policy in place that had recently been updated and contained details of the local authority safeguarding team and PREVENT.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act.

Staff knew how to identify adults and children at risk of, or suffering, significant harm.

Staff knew how to make a safeguarding referral and who to inform if they had concerns but the registered manager told us that service had never had a need to make any safeguarding referrals.

Staff followed safe procedures for children visiting the service.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. They kept equipment and the premises visibly clean but some furnishings were unsuitable and were not visibly clean. Staff did not manage clinical waste safely.

Clinical areas were visibly clean, but furnishings were unsuitable in the waiting area where they were not covered in a wipeable material and were visibly dirty. The manager was aware that the furnishings were unsuitable, having been told this by the new sonographer and informed us that they were planning to replace them within the next month.

Staff followed infection control principles including the use of personal protective equipment (PPE). The scanning room had ample personal protective equipment and staff wore gloves, masks and aprons when in the scanning room with women.

However, clinical waste was not disposed of safely. The manager was unaware that used PPE was clinical waste and it was not disposed of safely. There was a swing bin in the stock room that had a yellow clinical waste bin liner. The bin was not a clinical standard waste bin that was foot pedal operated or no touch operation. There was no clinical waste bin in the scanning room. Similarly, the waste bin in the toilet area was not a pedal bin.

The manager told us that they would call the council to collect any clinical waste but that they had never had any. There was no lockable clinical waste bin that could be left outside for the collection of clinical waste.

Diagnostic imaging

There were no handwashing facilities in the scanning room. The only hand washing facilities were in the toilet area. The manager was aware of the need for a sink in the scanning room and advised that there were plans to fit one within the next month.

Hand hygiene audits had not been carried out since the sonographer had started working at the premises. However, we noted that staff were bare below the elbows and hand gel was used regularly by the sonographer. Hand sanitising gel was also available for staff, women and visitors to use at the reception desk.

The provider had an infection prevention and control policy and a procedure for bloods and bodily fluids. They had chlorine tablets for cleaning bodily fluids. All other cleaning products were general household cleaning products. However, hazardous cleaning products, although stored in the stockroom, were not kept in a locked cupboard in accordance with the Health and Safety Executive Control of Substances Hazardous to Health (COSHH) guidance.

The manager and receptionist were responsible for cleaning the premises and equipment. There was a cleaning schedule in place and this demonstrated that all areas were cleaned regularly. Staff cleaned equipment after patient contact.

The manager was planning to buy a transvaginal probe for the ultrasound machine to ensure more accurate early pregnancy scans. We advised the provider that they should ensure that there is an appropriate decontamination policy and relevant training had been undertaken by all staff involved in using and/or decontaminating any transvaginal probe before this was brought into use.

Environment and equipment

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

Staff carried out safety checks of specialist equipment. The registered manager had received training in how to check the probe and ultrasound machine calibration which they did on a monthly basis. The manager had not been given any formal training on the use of the ultrasound machine but instead had been trained over the course of a week by another provider.

There were up to date servicing records in place for the ultrasound machine.

All electrical equipment in the clinic was PAT tested (portable appliance testing) annually and this was next due in 2023.

Fire equipment was tested, and staff knew what to do in case of a fire. There were current servicing records in place for the fire extinguisher.

The service had suitable facilities to meet the needs of women and their families. The premises were large enough to accommodate the business with an ultrasound room, large reception/waiting area, a stock room and toilet.

The waiting area was large enough to allow for social distancing between waiting families and appointments were spaced so that there was generally only one woman and family members waiting at one time.

The couch in the scanning room was adjustable and could be lowered and raised. However, there were no servicing records for the adjustable couch.

Diagnostic imaging

The clinic kept a first aid box and the manager had undertaken a first aid course.

The provider kept adequate stocks of personal protective equipment (PPE) such as masks, gloves, aprons and face shields. Customers were asked to wear masks whilst in the premises.

Assessing and responding to patient risk

The service did not always have appropriate arrangements in place to assess and manage risks to women and their foetus. We were not assured that staff knew what to do and would act quickly when there was a medical emergency.

The clinic did not offer diagnostic imaging services. The provider website and consent form advised women that the scans were for non-diagnostic, keepsake purposes only and they did not look for abnormalities.

We were not assured that the service had appropriate arrangements in place to assess and manage risks to women and their foetus. Women were not asked to bring their NHS pregnancy notes with them to the scan. If they did bring them to the appointment the manager did not look at them to check how many weeks pregnant they were and when they last received an ultrasound scan to allow them to make informed decision about whether to receive additional non-clinical exposure to ultrasound. The clinic records system showed when a woman had last received a scan from the provider. The manager told us women were told that they could not receive more than one scan a month from them if they tried to book multiple scans.

Women were not asked to complete a pre-scan questionnaire about their pregnancy history, for example, previous miscarriages, stillbirths or abnormalities. Women were advised that they would not be scanned if experiencing any abdominal pain or vaginal bleeding.

Women were not asked whether they had a latex allergy before being scanned.

The provider only scanned women over the age of 18 years of age, however, women were not asked to bring proof of identity or age with them though a date of birth was asked for at booking.

We did not see any “pause and check” list in the scanning room. This is a list devised by the British Medical Ultrasound Society and Society of Radiographers to ensure that sonographers completed checks during the scan that included confirming the woman’s identity (name, address and date of birth) and consent, providing clear information and instructions and informing the woman about the results. However, the registered manager told us that both they and the sonographer carried out the relevant checks before performing the scan. We raised the matter of the checklist with the manager who agreed to display a copy in the scanning room as a reminder for staff and to reassure women.

The clinic had an adverse outcome procedure in the rare event that a foetal abnormality or other concerns such as no heartbeat were suspected. In such an event, a report was completed by the sonographer to take to the hospital or GP and permission was asked from the woman for the service to contact the local early pregnancy unit to pass on the concerns at the earliest opportunity. We saw a number of completed adverse outcome reports that had all been completed by the sonographer since in post. They contained full information about the concerns of the sonographer, including who they had spoken to at the hospital.

Diagnostic imaging

We saw no reports of concerns completed by the registered manager. The registered manager told us that they were unable to identify abnormalities in general, however, they no longer carried out any early pregnancy scans which did give greater assurance that any abnormalities would be identified by the sonographer who was solely responsible for carrying out any early pregnancy scans.

The sonographer had contacts at the local NHS trust and was developing better patient pathways for women with them when further care and treatment was required urgently.

We were not assured that all staff knew what to do in the event of a medical emergency. For example, the manager told us that a suspected ectopic pregnancy would be a medical emergency. However, we were told they would not call an ambulance to transfer the woman to hospital for immediate treatment and would advise the woman to seek medical treatment as soon as possible.

Staffing

The service had enough staff to provide the right care although there was no induction policy in place for staff.

The service had enough staff to keep women safe. There was no induction policy in place for staff but the manager told us that staff were required to indicate that they had read all the policies and procedures and undertake relevant training. We saw that this had been completed.

The clinic was managed by the registered manager. There was one receptionist and a qualified sonographer who was only recently in post. They were working two shifts per week and carried out all the early pregnancy scans. They worked on a self-employed basis and invoiced for their time. The sonographer was registered with the Health and Care Professions Council (HCPC) as a diagnostic radiographer.

The registered manager was present at every shift and covered the reception when the sonographer was carrying out scans and the receptionist was not present.

The manager (ultrasound technician) only carried out scans on women who were more than 15 weeks pregnant. Early pregnancy scans were booked in on a day that the sonographer was working.

The clinic opening hours were worked around the availability of staff and number of customers using the service. The service did not use any bank or agency staff.

The manager told us that staff did not work alone in the clinic.

Records

Staff kept records of women's care and diagnostic procedures. Records were stored securely and available to all staff providing care.

Consent forms were kept in secure storage for one year, post scan. Notes were made to the reverse of the consent forms by the person carrying out the scan if there was anything of significance, such as the woman was asked to go for a walk to get the baby moving or the gender could not be identified.

Images were deleted from the ultrasound machine manually, every eight weeks.

Diagnostic imaging

Details of the women who had attended for a scan were stored securely on a password protected computer. All staff with access to the records had a separate sign in password.

Medicines

The service did not use any medicines or controlled drugs.

Incidents

The service managed safety incidents well. Staff recognised and reported incidents and near misses. 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.

Staff knew what incidents to report and how to report them. The clinic had an incident policy. This included how to respond to any clinical incidents.

Staff raised concerns and reported incidents and near misses in line with the service's policy.

Managers investigated incidents thoroughly. Women and their families were involved in these investigations. We saw that the critical incident/complaint reporting form was very thorough. It requested a lot of detail about any incident. There was space to record the details of the investigation and space to record learning from the incident.

Staff understood the duty of candour. They were open and transparent and gave women and families a full explanation if and when things went wrong. There was a duty of candour policy in place.

Staff met to discuss the feedback and look at improvements to a client's care. Incidents were reviewed and discussed at team meetings.

Are Diagnostic imaging effective?

Inspected but not rated 

We have not inspected this service before. We inspected the effective domain but do not rate this for diagnostic services.

Evidence-based care and treatment

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

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.

The service provided care based on national guidance and referred people who used the service to the British Medical Ultrasound Society (BMUS) (Guidelines for Professional Ultrasound Practice) for further information on ultrasound.

Diagnostic imaging

The service followed the BMUS guidelines on “as low as reasonably achievable” (ALARA). This meant that ultrasound exposure was kept as low as reasonably achievable and that scans were conducted within minimal timescales and the thermal index or the amount of heat that may be produced, was kept to the minimum level, dependent on the type of scan being conducted.

This information was displayed on the provider website.

Patient outcomes

Staff monitored the effectiveness of care. They used the findings to make improvements. However, there was no formal monitoring in place to review quality assurance and clinical safety.

Managers monitored the effectiveness of care and used the findings to improve them.

The clinic sent an email to all women who used the service to request feedback on their experience. The registered manager collated comments received via the website and social media pages.

Feedback from women was positive, consistent and met expectations.

The manager undertook financial audits but no clinical audits. The service had no formal audit programme in place to review quality assurance and clinical safety such as waiting times, image quality satisfaction, complaints received, incorrect genders identified.

The sonographer had just established a system for a lead sonographer at the local NHS trust to peer review images from the provider to ensure they were of a high quality and also to review referral reports and policies for the proposed transvaginal scans though this had not yet commenced at the time of our inspection.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided support and development. However, they did not have processes in place to carry out or review appraisals for sonographers working in the clinic.

Most staff were experienced, qualified and had the right skills and knowledge to meet the needs of women.

Managers supported staff to develop through yearly, constructive appraisals of their work. The receptionist had an appraisal booked in with the manager, but this was the first appraisal that the manager was to carry out since opening the business. However, there was no formal process for appraisal or supervision of the sonographer, and they did not have a substantive post in the NHS so were not being appraised elsewhere. There was no competency framework in place as part of the appraisal process.

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

Staff had the opportunity to discuss training needs with the manager and were supported to develop their skills and knowledge. Managers made sure staff received any specialist training for their role. The receptionist was undertaking or had undertaken training in epilepsy; management (in order to deputise for the manager); complaints handling; access to science and health and they were undertaking chaperone training, along with the registered manager in order that they could act as chaperones if the service started to offer transvaginal scans.

Diagnostic imaging

The manager had systems to identify poor staff performance and support staff to improve.

Multidisciplinary working

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

We saw that staff worked well together. Women and their families were greeted as they arrived at the service and supported to fill in the paperwork.

The sonographer was working with the local NHS maternity service to refer women with any abnormalities on their ultrasound scans. They were building a relationship with the early pregnancy unit so that they were happy to take telephone referrals from the clinic following a discussion about the concerns.

Seven-day services

Services were available to support timely patient care.

The clinic was open five days a week and the manager told us that they had tried to give as much flexibility as possible in opening hours to enable women to make a convenient appointment time, whether this being in the evening, during a weekday or at the weekend.

At the time of our inspection, the clinic was open five days a week. It was open on Mondays from 10am until 3pm; Tuesday and Thursday afternoons until 8pm; Friday and Saturday from 10am until 5pm.

Health promotion

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

The service had relevant information promoting healthy lifestyles and support in patient areas.

The service had booklets available on diabetes and pregnancy and could offer information on smoking cessation, the flu jab and ante-natal care.

There were signs displayed in the toilet area on how to report domestic abuse.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care. They followed national guidance to gain their consent. Staff followed the service policy and procedures when a woman could not give consent.

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. The service had a Mental Capacity Act policy in place which staff knew how to access. Staff received training in the Mental Capacity Act.

When women could not give consent, they were referred back to the NHS for any scanning procedures because the service did not carry out any procedures without signed consent.

Staff gained consent from women for their care and treatment in line with legislation and guidance. However, the manager had not given consideration to recording further written consent and requesting proof of identity if the service introduced transvaginal scans.

Diagnostic imaging

Staff clearly recorded consent in the person's records. All women received written information to read and sign before their scan.

Are Diagnostic imaging caring?

Good 

We have not inspected this service before. We rated it as good.

Compassionate care

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

Staff cared for people who used the service with compassion. Feedback from people who used the service confirmed that staff treated them well and with kindness.

Ultrasounds were carried out in a separate room. It was not possible to hear general conversation from the room.

Women who received bad news about their pregnancy were spoken to in the scanning room privately and could remain there to ask any questions about next steps and findings. However, we observe one occasion where a woman had received bad news about their pregnancy and the registered manager telephoned the early pregnancy unit and relayed details of the findings within earshot of another family waiting in the clinic.

We observed staff providing compassionate care. They spoke to women and their families in a friendly manner.

We reviewed feedback from many people who used the service. Women were positive about the service they had received.

We spoke with one woman and their partner who told us that they had a very positive experience, had received compassionate care and the sonographer always made time to answer questions and put them at ease when they were nervous.

Emotional support

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

We saw that staff provided emotional support to people who used the service to minimise their distress.

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.

Diagnostic imaging

The manager told us that, if a potential concern was detected during the scan, then this was fully explained to the woman who was kept in the scanning room whilst the form was completed for them to take to an early pregnancy unit. The sonographer, had suggested, and there were plans in place, to convert an area of the waiting room into a quiet room where the sonographer could fully explain any concerns and families could wait for a report and an appointment at the early pregnancy unit to be made for them and to leave when they were ready.

We saw that scans were not rushed and that if good images could not be obtained the woman was advised to go for a walk and then come back for a further attempt. Free rescans were offered where images could not be obtained, or the gender of the baby could not be seen.

Understanding and involvement of women and those close to them

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

Staff involved people who used the service and those close to them in decisions about their care.

People who used the service were given full information on the cost of their scan, packages available and the cost of added extras, such as confetti cannons or balloons.

The clinic website showed the scan packages that were available along with the cost so people who used the service could make a choice about what they wanted. People who used the service were able to choose the photographs they received from all the available computerised images. People who used the service were able to change their mind about the package they received and pay the balance outstanding.

We observed that information was given to women phoning to book an appointment about the best time to have the scan based on the number of weeks pregnant and appointments were made during the optimum window when the best images were likely to be obtained.

Are Diagnostic imaging responsive?

Requires Improvement 

We have not inspected this service before. We rated it as requires improvement.

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 service offered a range of ultrasound scan procedures for private fee paying pregnant women over the age of 18.

Managers planned and organised services, so they met the changing needs of the local population. Clinic opening times meant those people who were working could book an appointment in the evening or at the weekend and there were appointments available on three weekdays.

Diagnostic imaging

Facilities and premises were appropriate for the services being delivered. The treatment room was spacious and provided a suitable and relaxed environment for women and their loved ones to undergo scan procedures whilst maintaining their privacy and dignity.

The premises were located in Warrington town centre and there was ample parking in the vicinity and the clinic was close to a mainline rail station and the bus station. It was convenient for women to travel there by public transport from Warrington and surrounding areas in Cheshire and Merseyside.

Appointments were booked in advance, online or by telephone, and this allowed staff to plan the scan procedures before women attended their appointment.

Managers ensured that women who could not attend appointments were offered a rearranged date at the earliest opportunity.

Meeting people's individual needs

The service was inclusive but did not always take account of women's individual needs and preferences and the provider was not always compliant with the Accessible Information Standards. Staff made reasonable adjustments to help them access services. They directed women to other services where necessary.

The service did not provide separate sessions for women receiving early pregnancy scans. This would have ensured that women who were there for reassurance about their pregnancy, for example those who had suffered previous miscarriages, did not have to share the waiting room with others who were much later on in their pregnancy. The manager told us that the Tuesday evening session was exclusive to early pregnancy scans but it was not possible to separate them on a Saturday as there were so many gender scan customers. We spoke to the manager about this who agreed to try to offer separate early pregnancy clinics when the sonographer was working.

Women receiving an early pregnancy scan, were given a longer appointment to allow time for them to ask any questions.

The service had an equality policy and the sonographer had received equality and diversity training within another role.

The service did not have information leaflets available in languages spoken by the women and local community, but they were able to use Google translate to translate information from the website so women whose first language was not English could make an informed decision. Women were encouraged to attend with someone who could assist with interpreting and allow them to understand the consent form. The service did not have access to an independent translation service.

The service did not have a hearing loop for women with hearing impairments or access to information in braille for women with sight impairments. The manager told us that when people with a hearing impairment attended they would wear visors rather than masks if the person was able to lip read.

The service was accessible for persons with limited mobility on the ground floor of a building with wide doorways and access directly from the street.

The service did not have specific admission or exclusion criteria, but the clinic would not scan women who were unable to give consent or could not be safely scanned. Only women over the age of 18 were scanned.

Diagnostic imaging

Ultrasound scan prices were clearly displayed on the service's website. There was information for prospective clients about what to do before arriving at the clinic, what would happen on arrival and the scan itself. There were also frequently asked questions on the website. Women could also telephone for additional information.

Access and flow

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

All women attending the service were self-referred. They could book their appointments at a time and date of their choice in advance. Appointment bookings were made in person, by telephone or through the provider's website.

Women were given appointments based on their preference. There was no waiting list for appointments, and they could be seen promptly (including the same day in some instances). Women who had to cancel their appointments were given an alternative date and time.

Women were given an appointment time of between 15 and 30 minutes dependent on the type of scan they were receiving but this could be extended if needed.

Learning from complaints and concerns

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

Women, relatives and carers knew how to complain or raise concerns. Information about how to complain and response times was clearly displayed on the website. Complaint forms were available in clinic and included suggestions for improvements.

Staff understood the policy on complaints and knew how to handle them.

Managers investigated complaints and identified themes.

Staff knew how to acknowledge complaints and women received feedback from managers after the investigation into their complaint.

Managers shared feedback from complaints with staff and learning was used to improve the service.

Customers were signposted to other organisations if they remained dissatisfied but were not a member of the Independent Sector Complaints Adjudication Service (ISCAS). The manager said that they would sign up to this service.

The service had received few complaints.

Are Diagnostic imaging well-led?

We have not inspected this service before. We rated it as requires improvement.

Diagnostic imaging

Leadership

Leaders did not always have the skills and abilities to run the service. They did not always understand and manage 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 and take on more senior roles.

The manager was in the clinic when it was open and actively involved in completing scans. However, they lacked an understanding of infection prevention and control knowledge and skills to ensure that the service was run safely. The newly appointed sonographer had provided a lot of guidance and advice on this since their appointment and the manager was beginning to put measures in place to address the shortfalls in infection prevention and control techniques.

We also found gaps in the manager's knowledge and skills around minimising clinical risks to women, monitoring quality and maintaining ongoing mandatory training for all staff.

The manager worked closely with the sonographer to plan improvements to the service. We saw that they worked well together, and the manager was respectful of the suggestions for improvements made by the sonographer.

Vision and Strategy

The service had a mission statement vision for what it wanted to achieve and a strategy to turn it into action was in development.

The provider's mission statement was: "to create and promote accessible ultrasound scans with women's wellbeing and safety at the very core of everything."

The provider's vision was: "to be able to deliver first class care and experience to all at affordable prices."

The provider was in the process of improving the business by planning to introduce transvaginal early pregnancy scans carried out by the sonographer that would produce better images and more accurate scans. There were also discussions around the sonographer becoming a partner in the business.

Culture

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

The registered manager and sonographer were motivated and positive about their work. They told us that there was a friendly, client-focused and open culture and that they worked well as a team.

There were anti-bullying, grievances and whistleblowing policies in place to allow staff to raise concerns without fear.

The provider mission statement set out the commitment of the service to put the customer first.

Governance

Leaders operated governance processes but there was no formal governance framework in place and there were gaps in the system for reviewing policies and procedures. Staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Diagnostic imaging

The registered manager had overall responsibility for clinical governance and quality monitoring though there was no formal governance framework in place or quality assurance audit programme.

The service had systems and procedures in place to ensure that policies referenced current guidelines. However, some policies had review dates and some did not so we could not be assured how often all policies were being reviewed to ensure that they remained current.

Policies and procedures were available to staff. Policies were indexed and were readily available to view in paper and electronic format.

The provider had statutory professional indemnity insurance arrangements, in accordance with British Medical Ultrasound Society (BMUS) guidelines.

The manager told us that they held regular staff meetings. We requested copies of the minutes from the last three meetings but these were not provided.

We did not see a fit and proper persons or recruitment policy but there were staff files for the receptionist and sonographer. This included information such as identification checks, contact details, curriculum vitae (CV's), references and employment contracts and training undertaken.

We saw evidence that the registered manager and sonographer underwent recruitment checks, such as enhanced disclosure and barring service (DBS) checks. There were up to date DBS checks in place for all staff.

Management of risk, issues and performance

Staff used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

There was a comprehensive daily risk assessment in place for the clinic that covered things such as checks on electrical equipment, fire alarm, extinguisher, cleanliness and products available. We saw that this was completed when the clinic was open.

There was a risk register in place in the clinic. This detailed the risk, who might be harmed, the risk controls in place, further action required to mitigate the risk, who carried out the actions, by when and the date complete.

There were five risks on the register, these being about display screen equipment failure, working at height, slips and trips, manual handling and electrical faults.

We saw that the sonographer was involved in current decision making in the business to help avoid financial pressures and to improve the quality of the service being delivered. The manager was receptive to staff contributions to improve the business.

Information Management

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

Diagnostic imaging

Staff received training for information governance and the General Data Protection Regulations.

Computer terminals were password protected, and the scanning machine was also password protected for each sonographer.

Scan images were stored on the scanning machine for no more than eight weeks.

The service had policies on data protection and confidentiality in place.

Engagement

Leaders and staff actively and openly engaged with women and staff to plan and manage services. They collaborated with other organisations to help improve services for women.

Staff routinely engaged with women during their scan procedures to gain feedback about the services.

The registered manager told us client feedback was regularly reviewed. All women were encouraged to provide feedback about the service.

The service was mainly promoted through their website, social media platforms and through word of mouth from people that had used the service.

Staff engagement took place through daily communication and routine staff meetings.

Learning, continuous improvement and innovation

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

The clinic used customer feedback to improve the service and introduced new keepsakes or gender reveal ideas as they came onto the market.

The clinic had invested in high quality scanning equipment to ensure that they were competitive in the market and customer satisfaction remained high.

The clinic was planning to move to transvaginal scans to improve the quality of early pregnancy scans.