Miss Toni Tierney

Meet My Baby Wigan

Inspection report

166 Manchester Road
Ince
Wigan
WN2 2EA
Tel: 07974747676
www.meetmybabywigan.com

Date of inspection visit: 27 June 2023
Date of publication: 27/11/2023

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

Ratings

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

Summary of findings

Overall summary

This was our first inspection of this location. We rated it as good:

- The sonographer had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. The service knew how to manage safety incidents to learn lessons from them.
- The sonographer monitored the effectiveness of the service. The sonographer recognised risks to pregnant women, they worked for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned and provided services in a way that met the needs of local people. People could access the service when they needed it.
- The sonographer had the skills and abilities to run a service providing high-quality sustainable care. They promoted a positive culture that supported and valued women.
- The sonographer cared for women, their families and carers with compassion. They made it easy for people to give feedback and feedback from women confirmed that they were treated well and with kindness. Staff involved patients and those close to them in decisions about their care and treatment and provided emotional support to patients to minimise their distress.
- The sonographer ran the service using reliable information systems. The service had a vision for what it wanted to achieve and workable plans to turn it into action. 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 and local organisations to plan and manage appropriate services and was developing links with partner organisations effectively.

However:

- At the time of the inspection the service did not have a system to peer review images.
- The service did not check proof of age to ensure women were over 18 years of age.

Summary of findings

Our judgements about each of the main services

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

Summary of findings

Contents

Summary of this inspection

Background to Meet My Baby Wigan

Meet my Baby Wigan registered with the Care Quality Commission in 2022 to provide the regulated activity of diagnostic and screening procedures. The provider is registered as an individual to carry out ultrasound baby scanning for keepsakes. The service provides ultrasound baby imaging for pregnant women from the gestation of seven weeks.

There is no requirement to have a registered manager where a provider is registered as an individual. Facilities include a scanning room, waiting area, and toilet facilities. The service had carried out 831 scans between July 2022 and July 2023.

The service enables pregnant women aged 18 years and over to pay privately for a range of abdominal ultrasound scans in 2D, 3D and 4D during pregnancy. The images are recorded and presented as a keepsake for the service user. The scans are not performed for diagnostic purposes and the only screening activity offered is in relation to gender reveals of the unborn baby. 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.

All scans were performed by the provider and the service did not employ any other staff. The provider is referred to as the sonographer throughout the report.

This service has not previously been inspected and no enforcement or compliance actions have been taken against this provider.

How we carried out this inspection

The inspection was announced with short notice to ensure the service was operational on the day of our visit and enabled us to observe routine activity.

We inspected this service using our comprehensive inspection methodology. The inspection team consisted of a lead inspector supported by 2 inspectors on 27 June 2023. The inspection team was overseen by an operations manager.

During the inspection we:

- inspected all five key questions and rated four; (‘effective’ key question is not rated for diagnostic imaging services)
- observed one scanning procedure
- looked at the quality of the environment and observed how staff cared for women and their family members
- looked at 6 service user consent records and booking form records.
- spoke with the provider
- looked at a range of policies, procedures, audits and other documents relating to the running of the service

Summary of this inspection

• spoke with three people using the service

We also reviewed performance information about the service and information provided to us by the service.

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 SHOULD take to improve:

- The service should implement a system for peer review.
- The service should check proof of age to ensure women were over 18 years of age.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Inspected but not rated	Good	Good	Good	Good
Overall	Good	Inspected but not rated	Good	Good	Good	Good

Good

Diagnostic and screening services

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

Is the service safe?

Good

Mandatory training

The sonographer received and kept up-to-date with their mandatory training.

The service used a mixture of electronic online training and face to face training which the sonographer said was an effective mixture to meet their needs.

The mandatory training was comprehensive and met the needs of women. Mandatory training modules included adult basic life support, prevent radicalisation awareness, equality, diversity and human rights, data security awareness, safeguarding adults and children, freedom to speak up, fire safety, infection control and prevention, health, safety and welfare, conflict resolution, manual handling and information governance.

Clinical staff completed training on recognising and responding to women with mental health needs, learning disabilities, and autism.

The sonographer monitored their mandatory training and was aware when they needed to update their training. The service kept electronic and paper records which showed 100% compliance with all relevant mandatory training modules. There was a process in place to track mandatory training compliance and the practitioner proactively booked training that was due to become expired.

Safeguarding

The sonographer understood how to protect women from abuse and worked with other agencies to do so. They had training on how to recognise and report abuse and they knew how to apply it.

The sonographer undertook training specific for their role on how to recognise and report abuse. The service did not provide direct care to children; however, the service did have contact with children attending ultrasound scan appointments with their parent/guardian.

Good

Diagnostic and screening services

Meet My Baby Wigan did not provide ultrasound services to adolescents under the age of 18 years. We saw that the sonographer had completed e-learning training in safeguarding adults' level 3 and safeguarding children level 2 and 3. In addition, the sonographer has completed level 3 designated safeguarding lead training and has a master's degree in coercive control. This meant the safeguarding training was in accordance with national legislation.

The sonographer could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act. The sonographer was aware of the Department of Health's 'Female genital mutilation and safeguarding guidance for professionals' (March 2016). If they were concerned about any woman, they would refer to their local safeguarding team. They were mindful of specific risks and had taken action to make it easier for women to raise concerns. For example, they had telephone numbers in the toilet with contact details for domestic abuse services.

The sonographer was able to give examples of how to identify adults and children at risk of, or suffering, significant harm and were aware of potential signs of physical and psychological abuse and neglect and knew the other agencies necessary to protect them. The sonographer gave appropriate examples of how she had further explored this with women.

The sonographer knew how to make a safeguarding referral and who to inform if they had concerns. There was an up-to-date safeguarding policy which referenced national guidelines and contained contact details for local authority safeguarding teams. In the 12 months prior to the inspection, the service had not reported any safeguarding concerns to the local authority or made any safeguarding notifications to the Care Quality Commission (CQC).

Staff followed safe procedures for children visiting the service. This included ensuring that the child's parent/guardian understood they were responsible for their child during the visit.

The sonographer had an electronic safeguarding template which would be used to document safeguarding concerns and any actions to be taken. The provider's website signposted people to other services for example, National Domestic Abuse, the Men's Advice Line and national LGBT+ Helplines.

Cleanliness, infection control and hygiene

The service controlled infection risk well. The sonographer used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.

The service had an up-to-date infection prevention and control policy in place, which set out staff responsibilities including COVID-19, hand hygiene and personal protective equipment.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. The waiting area was visibly clean and clutter free on the day of our inspection. The practitioner carried out cleaning of the premises and equipment. Cleaning equipment was available and stored correctly. We observed the practitioner cleaning equipment and the scanning couch between women who attended appointments.

At the time of our inspection, we observed the sonographer decanting ultrasound gel from a larger bottle to a smaller one. Although the expiry date of the gel was being monitored, ultrasound gel has been associated with outbreaks of infection in various settings. However, in line with the safe use of ultrasound gel Guidance by the UK Health Security Agency (UKHSA) May 2022, the use of single sterile sachets was not required as no scans were undertaken of non-intact skin or no invasive procedures were undertaken.

However, during the inspection we were told the service planned to introduce the single sterile sachets of ultrasound gel, which they had in stock, to further ensure sterility during ultrasound scan procedures. The sonographer has confirmed that they are now using single sterile sachets of ultrasound gel.

Cleaning records we reviewed were up-to-date and demonstrated that all areas were cleaned regularly. Suitable handwashing facilities were available for the practitioner. We saw that alcohol gel was readily available. The infection prevention and control policy did state that 'handwashing should be done using antibacterial wash as frequent as possible'. The sonographer observed this policy and we saw them washing their hands between scanning appointments. In addition, the practitioner had received hand hygiene training.

The sonographer cleaned equipment after patient contact following the manufacturer's instructions. Equipment was not labelled to show when it was last cleaned for example, using 'I am clean' stickers. However, information about when equipment had last been cleaned was available separately on cleaning schedule records.

Women were asked whether they had any symptoms of COVID-19 prior to attending the clinic.

The sonographer had access to and used appropriate and in date personal protective equipment (PPE). We observed the sonographer using PPE when interacting with women and had their 'arms bare below the elbows' in the clinical area to help prevent the transfer of infection from clothing that could be contaminated.

The sonographer has completed training in infection control, personal protective equipment and dealing with an emergency.

Environment and equipment

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

The premises throughout were fit for the purpose of scanning expectant women. The service was located in a converted retail unit situated on a main road with one scanning room, waiting room and toilet. The décor was lilac and purple walls throughout the waiting room, reception and examination room, with the aim of a soothing and calm environment.

The waiting room had sufficient space for pushchairs and comfortable seating for women and their families to wait for their appointment. The environment in which the scans were performed was spacious and well arranged. The front door of the clinic was locked during the procedure to prevent other women from coming in during a scan.

The design of the environment followed national guidance. For example, the scanning room had laminate flooring which meant that it could be easily cleaned if there were any spillages. Staff had access to a sink close to the scanning room.

The water system is cold water although an additional unit was provided in the bathroom and kitchen area for warm water provision. There was no safety alert signage in place regarding the hot water unit in the patient toilet area. Immediately following the inspection, the provider submitted evidence to show that safety signage was installed in case children tried using the water system.

The examination room was clean, with first aid box, examination couch, ultrasound machine, and a wall-mounted monitor, which projected the images from the ultrasound machine. This enabled the women and their families to view the baby scan more easily.

Good

Diagnostic and screening services

We saw evidence that electrical equipment was safety tested and that visual checks were carried out. The sonographer carried out daily safety checks of specialist equipment.

There was fire signage, fire extinguishers, and a Wi-Fi connected security alarm system. Fire extinguishers were accessible, stored appropriately, and had all been serviced within the date indicated. There is CCTV in the reception area with panic buttons placed in the reception and scanning room; these measures have been put in place to ensure safety of women in line with the provider's lone working policy.

An external company completed the servicing of the ultrasound machine. The service record for the machine confirmed it had been serviced. Where faults arose outside of the planned services, an engineer assessed and carried out repairs.

The service had suitable facilities to meet the needs of women's families. The clinic room had adequate seating available for those accompanying the women to their appointments. There was a toilet leading from the clinic room, which had disabled access and had baby changing facilities.

The service had enough suitable equipment to help them to safely care for women. There was an emergency first aid kit readily available. The records confirmed the kit was checked regularly for broken seals, and expiration dates of contents. The sonographer had undertaken a level 3 qualification in first aid. The scanning couch was height adjustable and had brakes making it safer for women to use. The equipment was kept safe and maintained, through an annual service contract with the equipment provider, which included any maintenance needed throughout the year.

The service had an area that was for the sonographer only. This was included in the service risk assessment and was clearly marked.

The service had systems and processes in place to manage domestic waste. The service did not generate any clinical waste due to the nature of the service.

Women could speak privately to the sonographer. The reception and waiting room area was separate to the scan room which meant that women could speak with the sonographer and view their scan pictures in private. The sonographer limited the number of people allowed in the service at any one time and was able to manage this effectively.

Substances which met the 'Control of Substances Hazardous to Health Regulations' (COSHH) (Health and Safety Executive, 2002), were stored in a locked cupboard in the area marked for the sonographer only. There was clear signage on the cupboard door to alert people to its contents. The cupboard also contained the service's most recent COSHH risk assessment and policy.

The environment and equipment were kept clean by following infection control protocols and health and safety protocols. The ultrasound equipment had been securely fixed to the floor so could be moved by the operator but not removed from the premises. The sonographer told us they followed the manufacturers guidance.

Assessing and responding to patient risk

The sonographer completed appropriate risk assessments and removed or minimised identified risks.

The service sent women information before the scanning appointment which advised them that all scans were souvenirs and keepsakes and were not a substitute for the NHS ultrasound diagnostic imaging scans or NHS pregnancy care. The sonographer made it clear that they did not look for abnormalities and if a woman was experiencing pain or bleeding, they should contact their NHS clinical care team.

Good

Diagnostic and screening services

The service had systems and processes in place to refer or signpost women to their local NHS trust, the early pregnancy unit, their GP or midwife for diagnostic services if the scanning process indicated a concern. The service did not provide diagnostic reports or advice following the baby scan. Women were advised to still attend their routine scans as part of their maternity pathway and to contact their healthcare provider if any concerning information was flagged during their souvenir scan.

The sonographer knew what to do in the event of an emergency and told us they would respond promptly to any sudden deterioration in a patient's health. The service had contact details for local maternity units if the mother preferred the practitioner to contact them on her behalf. Anyone needing emergency medical treatment would be referred through the 999 service. The sonographer had wireless devices so the emergency services could be called immediately in the examination room without leaving the patient.

There was a first aid kit readily available in the clinic and we found that all items were in date. The sonographer would put their first aid training to use until an ambulance arrived.

Due to the nature of service provided, there was no emergency resuscitation trolley on site. The service carried out only low risk baby ultrasound souvenir scans.

The pre-scanning information recommended women who had not had a 20-week anomaly scan to book a weekday appointment. This meant that the service could contact the relevant medical provider if a concern was detected. We reviewed records of women's images which showed the women had been referred on to the local NHS trust due to concerns detected during their baby keepsake scan. The records detailed all relevant information about the services users and the concern.

The sonographer knew about and dealt with any specific risk issues. A risk assessment was completed for each woman on arrival where they were asked about any known allergies.

Information provided to women included information about the scan, its' limitations and the associated risks of frequent scanning. The sonographer said each woman would be assessed and directed to their general practitioner and The British Medical Ultrasound Society website (BMUS) to make an informed choice about the frequency of scanning. The sonographer followed ALARA (as low as reasonably achievable)principles. ALARA means avoiding exposure to radiation that does not have a direct benefit to you, even if the dose is small.

The sonographer 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 although a date of birth was asked for at booking. The service had inclusion and exclusion criteria, for women who could or could not access the service. The sonographer gave an example of when the exclusion policy would be used, for example the service did not accept scan requests for persons under 18 years of age.

Staffing

The sonographer had the right qualifications, skills, training, and experience to keep babies safe from avoidable harm and to provide the right care and treatment.

No other staff were employed in the service nor were bank or agency staff used. The provider was the sonographer. The service had a lone working policy and had a risk assessment to minimise risks associated with lone working.

Good

Diagnostic and screening services

Records

Records of women's care and diagnostic procedures were kept safe. Records were clear, up to date, stored securely and easily accessible.

The service had a records policy in place which detailed staff responsibilities and documentation standards, information governance and the retention of records.

Records were stored securely. Electronic records were password protected. The sonographer had received training in information governance and understood their responsibilities in maintaining information securely.

Women's notes were comprehensive and appropriate for the level of service being provided, including measurements taken when any anomalies were noted, and the referral to the early pregnancy unit. We reviewed six women's records which were clear, legible, complete and easily available.

We saw the audit trail where five women's scans had been referred to NHS services following concerns during a baby keepsake scan. The sonographer tracked the referrals made to the early pregnancy unit by scan date**.**

The sonographer asked women prior to the scan if they had allergies or any medical conditions and these were recorded as part of the consent process.

Scan notes were held securely that only staff could access. Paper records were stored securely and kept in a locked cupboard and would be held for six years. The provider confirmed this information would be shredded to ensure sensitive information was disposed of as per the General Data Protection Regulation 2018 (GDPR).

Scan images and photographs were securely stored electronically and removed after 20 weeks. These could be retrieved in the event of lost or mislaid images. The images were deleted after the six-month period.

The service had an information governance policy. Data collected as part of the service provided was securely stored following GPDR guidelines. The sonographer told us women's data would be kept for six years, in line with policy. Other information was also be held securely either in a locked cabinet or on the computer system which was login protected. Other information that was stored included service user surveys, audits, governance, incidents and near misses.

The sonographer was able to transfer images and scan comments if women required transfer to hospital.

Incidents

The sonographer knew how to manage safety incidents well. They knew how to recognise and report incidents. All incidents would be investigated, and they would identify lessons learnt. If things went wrong, there was a process for the sonographer to apologise to women and to give suitable support.

The sonographer knew what incidents to report and how to report them. The service had not had any serious incidents since the service opened that required reporting. The clinic had an incident policy. This included how to respond to any clinical incidents in line with the service's policy.

The sonographer understood the duty of candour and had appropraite systems and processes in place. Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients of certain notifiable safety incidents and provide reasonable support to that person. The sonographer told us how learning from incidents would be managed by reviewing any incidents and trying to resolve them with

Good

Diagnostic and screening services

women and their families. If something went wrong during the scan, the sonographer told us they would always remain open and honest with the women; by informing them that something had gone wrong, offering support where possible, keeping information truthful and offering an apology in a timely way, in line with their provider's policies and procedures.

The sonographer would report any issues with the scanning equipment to the company who supplied the machine. They knew to record these as formal incidents if a disruption to the service occurred, or a risk was identified to the women or themselves. Safety alerts were monitored by the sonographer.

The sonographer was aware of the requirements for reporting incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

Is the service effective?

Inspected but not rated

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice.

Scans were completed in accordance with recommendations set out by British Medical Ultrasound Society (BMUS) and the sonographer worked to the code of practice set out by the Society of Radiographers.

Foetal measurements were based on BMUS guidelines, and the equipment was calibrated against these guidelines.

The service had a variety of policies in place to plan and deliver high quality care according to best practice and national guidance. The sonographer told us that they reviewed guidance from the British Medical Ultrasound Society and the National Institute of Health and Care Excellence (NICE) and updated the services' policies, procedures, and guidance accordingly.

Policies we looked at included record keeping and consent, referral policy, quality management, lone worker and safeguarding policies. These were in date and referred to up-to-date guidance and legislation. The sonographer explained clearly to women that this was a non-diagnostic scan. Women were reminded of the importance of attending their hospital scans and appointments.

The service was inclusive to all pregnant women who wanted souvenir or keepsake baby scans and there was no discrimination including on the grounds of protected characteristics under the Equality Act. We observed the sonographer advising women to contact their midwife, GP, or other NHS services if they had any concerns or symptoms such as vaginal bleeding or pain following their scan.

Nutrition and hydration

To improve the quality of the ultrasound image women who were having a gender scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. Due to the nature of the service, food and drink was not routinely offered to women. However, there was a fridge containing drinking water in the waiting area, which was accessible to women.

Good

Diagnostic and screening services

Patient outcomes

The sonographer monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women. However, there was no formal monitoring in place to peer review the sonographer's scans for quality assurance.

The sonographer carried out a programme of audits to check improvement over time. There was an internal audit programme to provide assurance of the quality and safety of the service. This included audits of women's experience, infection control, health and safety, equipment, and the quality of ultrasound images.

As the only sonographer in the service, peer review of scans was not possible. We were told that the service had been unable to access an independent peer reviewer for their scans, however they were continuing to try and establish this to provide external oversight of scanning standards.

The service had well-defined pathways for NHS referrals where anomalies were found. Women were asked for consent for the clinic to contact them in the days after an appointment to help staff review and understand outcomes. We saw evidence that where referrals to hospital had been made, these were reviewed and followed up where consent had been provided.

A gender inaccuracy log was recorded and reviewed. The service stated clearly in written and verbal information that gender scans were not 100% accurate. However, if the scan from the hospital differed from the keepsake scan a further scan was offered later and if still different a refund was offered.

Competent staff

The sonographer made sure they were competent for their role.

The sonographer had the right skills and knowledge to meet the needs of pregnant women. The sonographer had completed training to use the ultrasound machine safely and competently from the company who supplied the equipment and with whom they have the service contract with. This training covered the machine controls, additional clinical, interpreting or imaging training was from videos on the internet. The training company were available all year round for further support and guidance and update training.

The sonographer was gaining experience with the number of scans they performed and maintained their competence for this role by regularly undertaking the procedure. They monitored the outcomes of the procedures and kept up to date with evidenced based practice. The sonographer told us they were signed up to receive information from external associations and societies that published best practice in the field of radiology and ultrasounds, such as the British Medical Ultrasound Society. They had a contract with their equipment provider who employed a nurse for specialist queries.

There were no appraisal systems available as the practitioner was a sole trader. They told us how they were trying to access peer support with NHS and other sonographers.

Multidisciplinary working

The sonographer proactively built relationships with other relevant care providers for the benefit of women.

Women and their families and friends were greeted as they arrived at the service and were supported to review and complete additional paperwork. The sonographer worked across health care disciplines and with other agencies when required to support women.

The sonographer had started working with the local NHS maternity service to refer women with any abnormalities on their ultrasound scans and was 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.

Part of the online consent form is a waiver to allow contact with the women's own GP when necessary.

Seven-day services

The service was available, by arrangement, throughout the week to support women.

This service did not provide emergency care and treatment. 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 2pm; Wednesday 6pm-9pm; Friday 6pm-9pm; Saturday 10am until 5pm and Sunday 12.30pm-4pm. The service was flexible if women requested a scan outside of their normal working hours.

Health promotion

The sonographer gave women practical support and advice to lead healthier lives.

The service had relevant information promoting healthy lifestyles and support in the areas women accessed. The service provided clear written information that the imaging service was not a substitute for antenatal care.

The service had information booklets available on diabetes and pregnancy and could offer information on smoking cessation, the flu vaccine and ante-natal care. There were signs displayed in the toilet area on how to report domestic abuse.

Consent and Mental Capacity

The sonographer understood how and when to assess whether a woman had the capacity to make decisions about their care. They followed the service policy and procedures when a woman could not give consent. The sonographer was aware of the importance for gaining consent from women before conducting any ultrasound scan.

There were processes in place to ensure women consented to the scan.The sonographer received training in understanding how to make sure that consent was obtained and how to make sure that women's' capacity was determined, if necessary, to meet the Mental Capacity Act.

The sonographer told us, consent from women for their care and treatment was always sought in line with legislation and guidance. Consent had already been sought as part of the online submission and booking forms prior to appointment. On arriving at the service, the woman would be asked to sign a consent form, then asked verbally for consent before the examination commenced. The sonographer recorded consent in the women's records.

The sonographer would not accept scan requests from girls or young women under the age of 18 years. However, there was no specific process for validating the age of women, which could lead to children under 16 being scanned unknowingly. We were told that the sonographer would challenge anyone if they felt that they were under sixteen years of age.

Good

Diagnostic and screening services

Part of the online consent form is a waiver to allow contact with the woman's own GP if and when necessary.

Is the service caring?

Good

Compassionate care

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

The sonographer took time to interact with women and those close to them in a respectful and considerate way. We observed one scan undertaken and we saw that the sonographer treated the woman well and with kindness. We heard the sonographer introduce themselves by name prior to the scan and they explained the process clearly. During our inspection we spoke with three women and their partners, a child was also present who all told us that they were happy with the way in which they had been treated.

The sonographer followed policy to keep patient care and treatment confidential. The sonographer was able to maintain confidentiality, we observed that clinic doors were closed to prevent scans being observed and conversations being overheard outside of the scanning room.

Emotional support

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

The sonographer gave women and those close to them help, emotional support and advice when they needed it. The sonographer told us they were aware of the anxiety that women may have prior to their scan and they tried to reduce their anxieties by explaining the process and giving them positive information as early as possible during the scan.

We saw that scans were not rushed and that if good images could not be obtained the woman may be 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.

The sonographer told us how she would support women who became distressed. They had received counselling training on breaking bad news and demonstrated a compassionate communication style during the inspection.

The service provided information to women that gave details of where they could go for support if needed. The sonographer told us that when an abnormal finding had been detected during a scan, they would always follow this up with the woman to check how they were and to make sure that they had been followed up by their care provider.

Understanding and involvement of women and those close to them.

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

Good

Diagnostic and screening services

The sonographer made sure women and those close to them understood the scanning process and findings were explained fully. Thirty minutes were given for the scan although they only take approximately ten minutes. The sonographer told us they liked to ensure there was plenty of time for questions and to have a conversation with the person.

The sonographer talked with women, families, and carers in a way they could understand, and the sonographer would access interpreter services should this be required.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. The service had their own patient feedback survey and women used social media as a platform too. The service collected the feedback and comments. We reviewed feedback from women which was consistently positive and complimentary about the care they received. One woman wrote, “I highly recommend the sonographer, she is amazing at what she does nothing is too much trouble. She is so welcoming and goes out of her way to help you, you can clearly see the passion she has. Thanks again for our scans and gender scan.”

And another woman who had used the service wrote, “Thanks so much for our 2 scans. The first at 17 weeks, a gender scan for our wedding gender reveal and at 27 weeks, a bonding scan to also introduce the elder kids. Meet my Baby Wigan is highly recommended by our family and helped build the excitement and experience for all the family and friends.”

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 sonographer planned and organised the service, so they met the changing needs of the local population. This included appointment times in the evening and weekends. Women said their appointment times were suitable and were flexible in response to demand for appointments.

The facilities and premises were appropriate for the service being delivered. The service had systems to help care for service users in need of additional support or specialist intervention. They told us that they did not currently have access to an interpretation service via telephone however they would use an online digital translation application when translation was required urgently.

Meeting people’s individual needs

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

Good

Diagnostic and screening services

The sonographer made sure women living with mental health problems or learning disabilities received the necessary care to meet all their needs. They understood the diversity of womens' needs and when to obtain appropriate support and guidance. The woman was able to identify any additional needs at the point of booking. If they had a particular need such as a phobia, learning disability or physical disability, the sonographer would provide them with a longer appointment time to ensure their needs could be met during a scan.

The sonographer told us how they would make sure women, their relatives and carers could get help to ensure their understanding of any questions being asked or information being given to them. For example, if they required information in different formats. They described having a woman with dyslexia attending the service and how they went through the consent form at a pace with the woman to ensure they understood this.

The sonographer understood and applied the policy on meeting the information and communication needs of women with a disability or sensory loss. During the inspection the sonographer discussed hearing and sight difficulties, they were considering arranging a hearing loop going forward and were aware of the need to speak clearly and to face the woman to enable them to view the mouth to lip read.

Access and flow

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

All women self-referred to the service. They could book their appointment in person, via the telephone, or by using the online booking form via the website. The online booking system generated an automated booking confirmation. Women we spoke with told us the appointment booking system worked well.

The service kept a log of appointments, from July 2022 to July 2023, the service performed 831 ultrasound scans. This included 416 early reassurance scans,192 gender reveal and 223 bonding scans.

The sonographer monitored waiting times and made sure women could access the service when needed. The clinic very rarely cancelled appointments. The sonographer would sort appointments to allow for rescans to take place quickly when required.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service had processes in place to investigate concerns and complaints. The service would include women in the investigation of their complaint.

The service had a complaints policy and the sonographer understood this and knew how to handle them. Information was available on the company website. Feedback could be given on a specific form as well as on social media. At the time of the inspection no negative feedback had been received and no complaints had been received. The sonographer monitored their social media pages daily, which ensured any concerns or complaints were addressed immediately.

Women, relatives, and carers knew how to complain or raise concerns. The sonographer told us if a complaint was received on a face-to-face basis, then the aim would be to resolve the complaint immediately. If the complaint was more complicated, then we were told a response would be given within five working days, in line with the complaints policy. All written complaints would be logged, investigated, and actions undertaken to resolve. We were told that any lessons learned from the complaint and or feedback received, would be adopted with the aim of service improvement.

Good

Diagnostic and screening services

The complaints policy outlined how to deal with a complaint, the escalation process and how complaints would be investigated.

The service displayed information about how to raise a concern in the waiting area including how to feedback on the service to us.

The sonographer could give examples of how they used feedback from women to improve daily practice. One example included the continuing importance to women of their existing practice of not displaying the baby keepsakes, bears or mementos in case a woman experienced difficult news.

Is the service well-led?

Good

Leadership

The sonographer had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were available and approachable for women.

The service was led and managed by the sonographer who operated as an individual and provided day to day management of the service. They understood their role and responsibilities and had the skills and experience to manage the service.

The sonographer was knowledgeable about the types of souvenir scans provided at the location. The sonographer was passionate about the service, with good communication skills and was aware of the risks and challenges within the service. Despite there being no formal qualifications for souvenir ultrasounds, the sonographer had undertaken training provided by the machine supplier and followed this up by extensive online training via tutorial videos. In addition, they used the ongoing support from the trainer of the machine supplier and had qualifications in counselling skills, conflict management, life coaching, and domestic abuse awareness to support them in their role.

The sonographer had awareness of the service's performance, limitations, and the challenges it faced. They were also aware of the actions needed to address those challenges.

The sonographer told us they were keen to extend their skills, they planned to engage with others to promote the interests of souvenir scans, to attend learning events and courses to extend their knowledge and be up to date with best practice.

Vision and Strategy

Meet my Baby Wigan had a vision for what it wanted to achieve and a strategy to turn it into action.

The sonographer told us the basic principles and values they said were essential when delivering or offering a service to people were to ensure the safety of women and pregnant people and their unborn children.

The sonographer developed the service with the vision of providing affordable baby keepsake and souvenir baby images for women.

Good

Diagnostic and screening services

They told us the importance of protecting women who used the service from harm or abuse, to protect them from possible risks of infection, to ensure the equipment and premises were safe, to ensure women and their relatives, friends were treated with respect and had their dignity upheld.

The sonographer was working to develop relationships with local providers to ensure women had access to relevant services, including for those who suffered loss during their pregnancy.

Culture

The service was focused on the needs of women receiving care. The service promoted equality and diversity in daily work. The service had an open culture where women, their partners and families could ask questions and make suggestions.

The sonographer promoted a culture which supported women, their partners, families, and their health during the scan irrespective of cultural background or belief creating a common sense of purpose based on shared values. Women we spoke with spoke positively about the care and attention they received.

The sonographer presented as a very caring person who was open and honest and talked about her own life experiences as a mother. The sonographer was aware of the duty of candour and explained if anything did go wrong, they would be open and honest, offer apologies, report and notify CQC, investigate and adopt lessons learned.

The sonographer actively encouraged feedback from women and their families. We were told this was monitored for trends and issues. We saw examples of feedback being taken seriously and issues being acted on. The sonographer had completed training in equality and diversity.

Governance

The sonographer was clear about their roles and accountabilities and had opportunities to learn from the performance of the service.

The sonographer discussed quality and safety performance issues with us. They were aware of the circumstances when they were required to report and notify CQC if they did not meet the regulations. Examples included changes or incidents affecting the service, any serious injury to a service user, safeguarding alerts and changes to the statement of purpose.

The sonographer had policies in place which had been developed for the safe and effective running of the service. The business had agreements with third party organisations for the delivery of activities that supported the sonography, such as cleaning, waste disposal and information technology. The sonographer described how they would change their practice by learning from alerts or incidents.

The service had monthly cleanliness and hygiene audits in place to monitor cleanliness, infection control and hygiene.

Management of risk, issues and performance

The service generally had systems to identify risks, plans to eliminate or reduce them, and had plans to cope with both the expected and unexpected.

The sonographer understood their responsibilities in relation to risk identification and action required to mitigate the identified risks.

Good

Diagnostic and screening services

The service had a risk register in place. The risks included potential risks to women from receiving ultrasound scans, lone working and environmental risks, accessing the location, financial risk from

competitors and reputational risks. We reviewed risk assessments which provided details of the identified risks and the mitigation in place to minimise the impact.

The service had general, and COVID-19 risk assessments and identified actions which had been completed to mitigate risks.

The service had a business continuity plan and valid insurance covering both public and employer liability.

Information Management

The service collected data to help understand performance, make decisions and improvements. Data or notifications were submitted to external organisations as required.

The clinic had policies for the storage of online records and images. Women's records and scan reports were easily accessible and were kept secure. Paper records were stored in a locked cupboard. All electronic records and systems were password protected.

The service had clear processes for managing information, this included a data protection and retention policy which outlined the purpose for processing personal data, retention periods and disposal methods. Images were saved to the scan machine and held for six years following the scan appointment. Women were informed of the costs online and were told of the scan storage time and how their information was used at their appointment.

The service had processes in place to share information with service users GPs and the local NHS trust in the event of any concerns. The service had clear process in place to raise safeguarding concerns with the local authority safeguarding and in neighbouring counties.

The service compiled audit information to monitor the quality and safety of the service provided to women. This information was used to make improvements to the service in addition to feedback from women.

Engagement

The sonographer actively and openly engaged with women, to plan and manage services. They collaborated with partner organisations to help improve services for women.

The sonographer actively and openly engaged with women, to plan and manage services. The service encouraged women to provide feedback using survey forms provided as well as social media reviews or directly by phone or email. We saw positive examples of feedback that was consistent with comments made by women to us.

The service had a website which provided information to women about the service provided and prices of different scans or scanning packages.

The sonographer collated comments received via the website and social media pages. Outcomes for women were positive and met expectations.

Learning, continuous improvement and innovation

The sonographer was committed to continual learning and to improving their service.

Good

Diagnostic and screening services

The sonographer told us of the systems in place to assess and monitor the quality of the service, such as collecting data via customer satisfaction surveys, complaints and reviews published online. They told us how she would use the information gained via feedback, to improve the service, develop further training plans, new sales strategies, and marketing promotions.

The sonographer had oversight of the service's risks and understood the challenge of risks in terms of quality, improvements, and performance. It was made clear that only souvenir scans were provided. The clinic is modern and clean with the ultrasound machine having updated software, meaning the high-quality imaging can be provided. There is flexibility when cancelling and rearranging scans as the business recognises situations can change.