Meet Your Miracle- Coventry

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location	Good
Are services safe?	Good
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Good

Overall summary

Meet Your Miracle - Coventry is operated by Professional Antenatal Services Limited. It is a small independent health care service providing pregnancy ultrasound scanning services in the West Midlands area. It is an independent single specialty provider of keepsake/ souvenir baby scans using diagnostic ultrasound equipment. The service carries out ultrasound scans in pregnancy for the purpose of bonding and reassurance rather than for clinical purposes or as part of a pregnancy pathway of care.

No screening or medical advice was provided.

Facilities include one scanning room and reception area. A toilet was available. The service operates two further

Summary of findings

locations to the Coventry location. One in Tamworth and one in Nottingham. Both of these units have a single consultation room and a reception/waiting area with a toilet.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced part of the inspection on 2 May 2019.

To get to the heart of patients' experiences of care, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The only service provided by this facility was ultrasound baby imaging for non-diagnostic purposes.

Services we rate

We rated it as **Good** overall.

We found areas of good practice:

- All sonographers were observed as part of a peer observation and manager observations process. The sonographers, including the registered manager carried out scans together and with an external practicing sonographer periodically and annually as part of the personal review procedure/process.
- Staff cared for women with compassion, kindness and respect. They involved women and those close to them in decisions about their care and treatment.
- Women could access services and appointments in a way and time that suited them.
- The registered manager had a vision, where the delivery of quality care was the top priority, and the staff worked to achieve it.
- The service promoted a positive culture.
- The provider monitored scan image quality outcomes.
- The provider understood how and when to assess whether a woman had the capacity to make decisions about their care.
- Services provided generally reflected the needs of the population served and individual needs were taken into account.

We found areas of practice that require improvement:

- Infection risk was not always controlled well. While the equipment and premises were clean, disposable paper towel was not used to cover the examination couch. The service used a cotton towel, and this was not changed between each woman. Staff told us the towel was changed each day. While hand washing facilities were available in the toilet, disposable paper hand towels were not available. Staff and patients shared a cotton towel which was changed daily.
- Two of the four sonographers' disclosure and barring service checks (DBS) had not been checked since 2013. While DBS checks (also called disclosure) have no official expiry date it is considered good practice to review DBSs every three years.
- The service did not have the facility, to provide information to women prior to their ultrasound scan appointment, in any other language but English. In addition, non-English speaking women using the service did not have access to a translation service that could be used during an appointment.

Following this inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	We rated this service as good overall because it was safe, effective, caring, responsive to people's needs and well-led.

Summary of findings

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Good

Meet Your Miracle

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Meet Your Miracle- Coventry

Meet Your Miracle - Coventry is operated by Professional Antenatal Services Limited. The service opened in September 2018. It is a private service in Coventry and primarily serves the communities of the West Midlands area. It also accepts women from outside this area.

The facility provides pregnancy ultrasound scanning services for non-diagnostic purposes. This means the ultrasound is not performed for any clinical reason, such as screening for fetal abnormalities, but to provide the parents-to-be with images and/or recordings of their unborn baby as keepsakes only. The service provides:

- Reassurance scans (from eight weeks gestation).
- Gender determination scans.
- 2D/3D/4D baby scans.
- High Definition live scans.

Professional Antenatal Services Limited registered as a provider with the Care Quality Commission (CQC) in 21 November 2013. They were solely responsible for the service.

The facility offers services to self-pay funded women.

Meet Your Miracle - Coventry has not been previously inspected by the CQC.

Our inspection team

The team that inspected the service comprised; a CQC lead inspector and one other CQC inspector.The inspection team was overseen by Mark Heath, Interim Inspection Manager and Bernadette Hanney, Head of Hospital Inspection.

Information about Meet Your Miracle- Coventry

The service is located on the ground floor of a converted shop building. Facilities include one scan room, a combined reception and waiting area and a toilet. The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures.

During the inspection, we visited all areas of the service. We interviewed the provider, spoke with one member of staff, three women, two relatives and reviewed ten consent forms.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service had not been previously inspected by the CQC.

Activity (January 2018 to January 2019):

- In the reporting period January 2018 to January 2019, there were 2648 scanning procedures performed at the service; of these, 100% were privately funded.
- The service employed six sonographers who provided three whole time equivalent (WTE) cover and seven receptionists who provided three WTE cover.
- It was the service's policy to ensure there was always two staff at the service during opening times. This was usually a receptionist and a sonographer.

Track record on safety (January 2018 to January 2019):

- Zero never events
- Zero clinical incidents
- Zero serious injuries

Summary of this inspection

- Two complaints

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Good

We rated it as **Good** because:

- Staff understood how to protect women who used the service and those who accompanied them from abuse and worked with other agencies to do so. There was a safeguarding policy in place.
- Arrangements were in place to assess and manage risks to women.
- The premises and equipment were suitable for purpose and were looked after. There was a checklist in place to show when the environment and equipment was cleaned.
- The service had enough staff to keep people safe from avoidable harm and abuse, and to provide the right care and treatment.
- Staff had completed mandatory training. There was a system in place to identify training needs and monitor compliance.
- Staff kept minimal records of women's care. The records kept were clear, up to date and easily available to staff providing care.
- The provider understood their responsibility to report, investigate and learn from incidents. There was a system in place to manage incidents.

However:

- Infection risk was not always controlled well, disposable paper towel was not used to cover the examination couch. The service used a cotton towel, and this was not changed between each woman. Disposable paper hand towels were not available in the toilet. Staff and patients shared a cotton towel.
- The provider did not give women a written record of their findings if they found a suspected concern and the woman needed to self-refer to NHS services.

Are services effective?

We do not currently rate the effectiveness of diagnostic imaging services. We found:

- Care and treatment was based on national guidance and good practice standards.
- Staff had the skills, competence and experience needed for their roles.

Summary of this inspection

- The provider understood how and when to assess whether a woman had the capacity to make decisions about their care. They were aware of the importance of gaining consent before performing any ultrasound scan.

Are services caring?

Good

We rated it as **Good** because:

- Staff cared for women with compassion. Feedback from women and those close to them confirmed that staff treated them well and with kindness.
- Staff provided emotional support to women to minimise their distress.
- Staff involved women and those close to them in decisions about their care and treatment.

Are services responsive?

Good

We rated it as **Good** because:

- The services provided reflected the needs of the population served. The service had suitable premises and facilities to meet the needs of women.
- The service generally took account of individual needs.
- Women could access the service when they wanted to.
- Complaints were treated seriously, investigated and measures were taken to resolve them. There was a system in place to monitor complaints received and there was a complaints policy in place.

However:

- There was not a translation service in place that could be used during an appointment for non-English speaking women.
- Information to read and sign prior to ultrasound scan appointment was only available in English.

Are services well-led?

Good

We rated it as **Good** because:

- The manager's vision meant the delivery of quality care was the top priority, and the staff worked to achieve it.
- The registered manager had the right skills, knowledge and experience to run the service.
- The provider promoted a positive culture.
- Effective systems were in place to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.
- Sufficient governance arrangements were in place to ensure good standards of care were maintained.

Summary of this inspection

- There was engagement with women and the public and improvements were made because of comments or complaints received.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

Mandatory training

- **All staff had completed a company induction which included mandatory training in key skills and there was a system in place to identify training needs and monitor compliance.**
- The company induction training covered infection prevention and control, safety and hygiene, information governance, first aid, fire safety and safeguarding adults level 1 training.
- Annual update training was provided via e-learning modules. At the time of inspection all staff were up to date with their training.

Safeguarding

- **Staff understood how to protect women who used the service and those who accompanied them from abuse and worked well with other agencies to do so.**
- All staff had received safeguarding adults and children level 1 training, on how to recognise and report abuse and they knew how to apply it. No other safeguarding training was provided by the organisation.
- The service had a designated person who was the safeguarding lead. They were trained to level 3 which was in line with the recommendations from the Intercollegiate Document adult safeguarding: roles and competencies for health care staff (August 2018). Intercollegiate Document safeguarding children and young people: roles and competencies for healthcare staff (January 2019). However, the safeguarding lead was not always on site but could be contacted during service hours by phone.
- The service did not demonstrate all sonographers were trained to level two safeguarding adults and children. We reviewed sonographer personal records and found 50% of sonographers had completed level two adults and children safeguarding training.
- There was an up-to-date safeguarding policy in place which was up to date and referenced current guidance.
- Staff knew how to escalate concerns appropriately. Staff had a good understanding of their responsibilities with regards to recognising and reporting potential abuse. They were able to describe the steps they would take if they were concerned about the potential abuse of women who used the service or visitors.
- The provider had a folder that contained details of the local authority safeguarding teams. Staff told us they would contact them directly if they had any concerns.
- The service did not provide pregnancy ultrasound scans to women under the age of 18 years. However, children could attend ultrasound scan appointments with their mothers.
- There had been no safeguarding concerns reported to CQC in the reporting period from January 2018 to January 2019.

Cleanliness, infection control and hygiene

- **Infection risk was not always controlled well.**

Good

Diagnostic imaging

- While the equipment and premises were clean, disposable paper towel was not used to cover the examination couch. The service used a cotton towel, over the examination couch. This was not changed between each woman. Staff told us the towel was changed each day.
- There were suitable handwashing facilities for the size and scope of the service. Hand sanitising gel dispensers were available in the scanning room and reception area for staff, women and visitors to use. The provider told us they cleaned their hands with sanitising gel before and after each contact with women who used the service. We did not see any evidence that hand hygiene audits were carried out.
- While hand washing facilities were available in the toilet, disposable paper hand towels were not available. Staff and patients shared a cotton towel which was changed daily. This does not meet infection control best practice. (World Health Organisation guidelines on hand hygiene in healthcare).
- The equipment and premises were visibly clean. There was a checklist in place to show when the environment and equipment was cleaned. Staff cleaned the premises once or twice a week, depending when women attended. We were assured there were processes in place to ensure the premises and equipment were cleaned as required.
- There was no infection prevention and control policy in place. There was no identified infection control lead. However, there had been no incidences of a healthcare acquired infection reported by the service between 1 January 2018 and 1 January 2019.
- Best practice guidance was followed for the routine disinfection of ultrasound equipment (European Society of Radiology Ultrasound Working Group, Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group, 2017). The provider decontaminated the ultrasound transducer with disinfectant wipes between each woman and at the end of each day. The transducer was the only part of the ultrasound equipment that was in contact with women.
- Flooring throughout the service appeared well maintained and visibly clean. The scanning room and reception area were carpeted. However, as no clinical procedures were carried out by the service there was very little risk of infection from blood or other bodily fluid spillages.
- From January to December 2018, there had been no instances of healthcare acquired infections (Source: Routine Provider Information Request).

Environment and equipment

- **The premises and equipment were suitable for purpose and were well looked after.**
- The ultrasound machine used was specifically designed and manufactured for the purpose of obstetric ultrasound scans. It was serviced in line with the manufacturers guidelines to ensure safe operation.
- The maintenance and servicing of the ultrasound machine was carried out in line with manufacturers guidance. The ultrasound machine's performance was also monitored remotely, to ensure it was functioning effectively and optimal levels of output were maintained.
- The provider had received training on how to use the ultrasound machine from the manufacturer. They could also contact them for advice and support when needed. The scanning room had a clear wall space, which the projected images from the ultrasound machine were scanned on to. This enabled women and their families to view their baby scan more easily.
- A first aid kit was available, and all items were in date.
- There was a fire procedure in place and staff were aware of it. A fire extinguisher was available and servicing was in date.
- The portable electrical equipment we saw, which included the computer, telephone and heaters, were last safety tested in February 2019. This was in line with national guidance (Health and Safety Executive, Maintaining portable electric equipment in low-risk environments, September 2013).
- Waste was handled and disposed of appropriately. The service did not have any clinical waste.

Assessing and responding to patient risk

Good

Diagnostic imaging

- **Arrangements were in place to assess and manage risks to women.**
- The service provided pregnancy ultrasound scans for keepsake purposes only. This meant no diagnostic screening was performed for clinical purposes or as part of maternity pathways of care. The terms and conditions for the service clearly advised women that their ultrasound scan was not a substitute for the NHS scans offered during pregnancy and that they should still attend these. Women were made aware of this prior to their appointment and were asked to sign a contract to confirm that they had read and understood the terms and conditions before any scan was undertaken.
- The provider had clear processes in place to escalate unexpected or significant findings identified during ultrasound scans, such as a possible concern. We saw protocols were in place for staff to recommend women to self-refer to NHS services. The provider told us they had not needed to refer any women to NHS services because of potential concerns found. However, they could clearly describe what they would do if needed.
- The registered manager told us they advised any woman who requested a reassurance scan in the early stages of their pregnancy, because they had spotting (light bleeding) or were in pain to seek immediate advice from their GP, midwife, maternity unit or early pregnancy unit.
- Women were requested to provide information about where they were receiving their maternity care as part of the booking process. This meant the service had access to the contact details for the woman's maternity care provider if an unexpected or significant finding was identified.
- The provider told us they would telephone 999 for urgent support if an emergency situation arose on the premises.
- The service accepted women who were physically well and could transfer themselves to the couch with little support. The service did not offer emergency tests or treatment.

Staffing

- **The service had enough staff to keep people safe from avoidable harm and abuse, and to provide the right care and treatment.**
- The service employed six sonographers who provided three whole time equivalent (WTE) cover and seven receptionists who provided three WTE cover.
- Management told us the service would not operate if staffing fell below one receptionist and one sonographer.
- The service ensured all sonographers operating the ultrasound equipment were trained and followed the company policy of scanning for the shortest period possible, never scanning for a period of time longer than 30 minutes (as per the guidelines of the British Medical Ultrasound Society and ALARA (As Low as Reasonably Achievable) is a safety principle designed to minimize radiation doses and releases of radioactive materials).
- There were no staff vacancies at the time of our inspection. The service did not use any bank, agency or locum staff. Substantive staff covered each other's annual leave and sickness leave.

Records

- **Staff kept minimal records of women's care. The records kept were clear, up to date and easily available to staff providing care. However, the provider did not give women a written record of their findings if they found a suspected concern and needed to refer them to NHS services.**
- There were no systems in place to ensure that any relevant information from a woman's visit was integrated into their hospital record and/or communicated to their GP as appropriate. The organisation felt this was not necessary as they did not provide medical advice or referral. The service did not provide scans for the detection of abnormality. If any concerns were raised regarding observations during scans or conversations with women, the service recommended they contact their allocated maternity unit of the hospital they were registered with.
- The registered manager told us they did not provide women with written information if they suspected a concern and needed to refer them to NHS services.

They told us they would advise the woman to contact the relevant healthcare professional. For example, their maternity unit. This was because staff were not trained to diagnose.

Medicines

- The service did not store, prescribe or administer any medicines.

Incidents

- **The provider understood their responsibility to report, investigate and learn from incidents. There was a system in place to manage incidents. When things went wrong, staff apologised and gave women honest information and suitable support.**
- There was a formal system in place to manage incidents. The provider had a management plan which identified what an incident was; An incident should be considered to be any occurrence outside the day to day operation of the business however large or small. Incidents that required communication immediately were identified as:
  - The hospitalisation of any staff member or woman.
  - Failure to trade/provide booked services.
  - Any incident requiring the emergency services to be informed.
  - Any concerns regarding the safeguarding or wellbeing of any individual.
- The management plan also identified how staff could notify the registered manager of any incidents that had occurred. "The Registered Manager must be made aware of any incident that occurs in a timely manner. All communication of incidents can be via email at the end of a working day to summarise incidents and updates." The registered manager told us they would deal with incidents as soon as they occurred due to the small size of the service.
- From 1 January 2018 and 1 January 2019, the provider reported no never events or serious injuries (Source: Routine Provider Information Request). Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- The service had not had any serious incidents between 1 January 2018 and 1 January 2019.
- The service did not have a referral pathway with any hospital. Between 1 January 2018 and 1 January 2019, the service had reported 59 incidences of a suspected concern and had recommended women refer themselves to their local NHS services. The service held contact details for all the hospitals in the area. These details were provided to the woman in any instance of a suspected concern. The service recommended and supported women to contact their allocated hospital's maternity unit to request the appropriate medical support. However, there was no process for following up these cases.
- The service had not made any duty of candour notifications between 1 January 2018 and 1 January 2019. The provider had some understanding of the duty of candour and told us they would always be open and honest with women if anything went wrong. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
- The provider was aware of their responsibility to report any notifiable incidents to the Care Quality Commission (CQC).
- Safety was generally promoted in recruitment procedures and employment checks. Staff had Disclosure and Barring Service (DBS) checks carried out at the level appropriate to their role at the time of their appointment. We saw that the DBS checks had been carried out for all staff. However, two of the four sonographers' disclosure and barring service checks (DBS) had not been checked since 2013. While DBS checks (also called disclosure) have no official expiry date it is considered good practice to review DBSs every three years.

Good

Diagnostic imaging

Are diagnostic imaging services effective?

We do not currently rate the effectiveness of diagnostic imaging services.

Evidence-based care and treatment

- **Care and treatment provided was based on national guidance and good practice standards.**
- Local policies and protocols were in line with British Medical Ultrasound Society (BMUS), Guidelines for Professional Ultrasound Practice, December 2018). The team observed ALARA (As Low as Reasonably Achievable) principle for minimizing radiation exposure 2017.
- The service did not carry out any evidence-based audits or reviews. However, the service wanted to ensure the services were women (patient) led and of a standard which met the expectation of the women who used the service. They sent a link via email to every woman who used the service to provide the opportunity to anonymously provide feedback on the service they had received. This data was reviewed weekly. The feedback process had an option to provide a name and contact information should they wish the company to contact them directly to discuss any concerns.
- There was a protocol in place for the recommending women contact their local maternity service in the event that unexpected findings were found during ultrasound scans, such as a possible concern like unable to detect a pregnancy.
- An appointments protocol was in place, which detailed the procedure for booking women an appointment. This included explaining to women that the ultrasound scans performed at the service were not a replacement for those offered as part of their NHS pregnancy pathway.
- The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of disability, pregnancy and maternity status, race, religion or belief, and sexual orientation, when making care and treatment decisions.

Nutrition and hydration

- Women were told they could eat and drink as normal before their scan. They were also advised to hydrate their body by drinking two extra glasses of water a day, three to four days before their appointment, because this could help improve the quality of the ultrasound image. This information was told to women prior to their appointment.
- Due to the nature of the service and the limited amount of time women spent there, food and drink was not routinely offered. However, hot and cold drinks could be provided if needed.

Patient outcomes

- **The provider monitored scan image quality outcomes.**
- From January 2018 to January 2019, the provider performed 2648 baby keepsake scans. During this period, the service had reported 59 incidences where they had recommended and supported women to contact their NHS services because of suspected concerns.
- The provider told us they reviewed the quality of their scan images. If they were not happy with the quality, they would contact the woman and invite her for a free scan.
- From January 2018 to January 2019, the provider had performed 370 (13.5%) rescans because of the position of the baby.
- The provider participated in sonographer peer review audits. These were undertaken by other members of the scanning team and an external practicing sonographer. This meant their ultrasound observations and report quality were reviewed by a peer. This was in line with professional guidance, which recommends peer review audits are completed using the ultrasound image and written report (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS), Guidelines for Professional Ultrasound Practice, December 2018).

Competent staff

- **Staff had the skills, competence and experience needed for their roles.**

Good

Diagnostic imaging

- All sonographers were observed as part of a peer observation and line manager observations process to monitor their practice. The sonographers, including the registered manager carried out scans together periodically and with an external practicing sonographer at least annually as part of the personal review procedure/process.
- All reception staff received a full company induction, safeguarding level 1 training and two weeks 'on the job' training.
- All eligible staff (those who had been in post for 12 months) had had an appraisal. The staff member we spoke told us these were effective.
- The staff member observed was skilled, competent and experienced to perform the pregnancy ultrasound scans they provided. They had completed training for the ultrasound equipment used.
- Staff had participated in continuing professional development. For example, two of the staff had undertaken a course provided by a university and had been awarded a certificate in ultrasound. Courses attended included a basic ultrasound course in fetal biometry and doppler and essential obstetric ultrasound course run by the Royal College of Obstetricians and Gynaecologists. Additional skills training and assessments were completed across the whole team of sonographers by an external practicing sonographer, who was qualified in early dating and assessment and was a qualified train the trainer. The registered manager (holding a level 3 qualification in delivering, assessment, education and training in lifelong learning) organised and delivered regular training.
- The service referred to the staff that scanned women as sonographers. At the time of inspection, sonography was not recognised as a profession by the Health and Care Professions Council (HCPC) and therefore there was no mechanism whereby an individual could register with the HCPC as a sonographer or be regulated by them as a sonographer.

Multidisciplinary working

- The service generally did not engage in multidisciplinary working. However, they were aware how to refer to local authority safeguarding teams, to benefit women who used the service, when indicated.

Seven-day services

- The service did not provide pregnancy ultrasound scanning for any clinical reason, such as scans offered as part of the NHS antenatal pathway. This meant services did not need to be delivered seven days a week to be effective.
- The service was open every day:
  - Monday 10am–5pm
  - Tuesday 3–9pm
  - Wednesday 10am–3pm
  - Thursday 10am–5pm
  - Friday 11am–3pm
  - Saturday 10am–5pm
  - Sunday 11am–4pm
- Staff worked in a flexible way to meet the needs of women. All scans performed were planned, with appointments arranged in advance.

Health promotion

- The service provided clear written information that the scanning services they provided were not a substitute for antenatal care.

Consent and Mental Capacity Act

- **The provider understood how and when to assess whether a woman had the capacity to make decisions about their care. They were aware of the importance of gaining consent before performing any ultrasound scan.**
- Women were supported to make informed decisions about pregnancy ultrasound scans for souvenir purposes.
- Consent to care and treatment was sought in line with legislation and guidance. Women were asked to read and sign the terms and conditions of the service before any ultrasound scan was undertaken. The terms and conditions clearly stated that the

ultrasound scan was for souvenir purposes only. They also clearly stated that they were not a substitute for the scans offered by the NHS, nor was the sonographer able to offer medical or diagnostic advice. The provider checked that women understood the terms and conditions and scan limitations, before they performed any pregnancy ultrasound souvenir scans.

- The provider understood how and when to assess whether a woman had the capacity to make decisions about their care. They told us they had not had any women who lacked capacity request their services.

Are diagnostic imaging services caring?

Good

Compassionate care

- **Staff cared for women with compassion.**
- Feedback from women we spoke with and reviews submitted confirmed that staff treated them well and with kindness.
- Women's privacy and dignity was maintained during their ultrasound scan. Women with spoke with confirmed this. The provider carried out all ultrasound scans in a private room. This meant that women could speak to them without being overheard.
- Prior to the scan commencing, the sonographer explained the procedure and asked if they were okay to proceed. The door to the ultrasound room was closed when the appointment was in progress. Any woman attending an appointment alone was offered a chaperone.
- We spoke with three women, and two family members about various aspects of their care. Without exception, feedback was positive about their experience, and the kindness and care they received. One woman told us they; "would recommend the service to everyone, the staff were very friendly". Another woman said the staff were; "very professional, very caring."
- The service asked women to provide feedback about their care. They sent every woman a request for feedback. This was sent the day after their appointment. The feedback was anonymous, but the woman was given the opportunity to provide their name and contact details if they would like the service to contact them.
- Between April 2018 and February 2019, the service had 88 responses to their satisfaction survey. Most reviews, (90%) said they would recommend the company to a friend. 74% said the service met their needs extremely well. 22% said the service met their needs very well and 3% said the service met their needs somewhat well. 73% said they rated the quality as very high quality. 22% said they rated the quality as high quality. 3% said the quality was neither high or low. 1% said the quality was low and 1% said the quality was very low quality. Most of the feedback was complimentary about the service. One woman wrote; "I'm so glad I made the decision to come yesterday for a reassurance scan. I have peace of mind and can relax a little until my twelve-week scan". Another wrote; "The lady who carried out my scan was very friendly and patient when answering my questions. She took her time and we didn't feel rushed."

Emotional support

- **Staff provided emotional support to women to minimise their distress.**
- The provider was aware that women attending the service were often feeling nervous and anxious, and they provided additional reassurance and support to these women.
- The provider told us they had identified a potential concern on 59 occasions in the reporting period, between January 2018 and January 2019. They would communicate this sensitively and would ensure they offered support to the woman to contact their maternity service by ensuring the woman had the correct contact details. However, they did not offer follow up care.
- Women were generally advised to have their keepsake pregnancy ultrasound scan once they had had their anomaly scan, which is part of the NHS maternity pathway and its primary purpose is to ensure the baby is growing well without abnormalities. This reduced the risk of the provider identifying any unexpected concern. However, the registered manager told us they received an increasing number of requests for early

scans from women who were extremely anxious and wanted reassurance that they were pregnant. The provider would advise them to contact their GP, midwife or early pregnancy unit for advice if they were experiencing any symptoms of possible miscarriage, such as bleeding and abdominal pain.

- Women were provided with information explaining the procedure prior to their appointment.

Understanding and involvement of patients and those close to them

- **Staff involved women and those close to them in decisions about their care and treatment.**
- The provider communicated with women and those accompanying them so that they understood their care and treatment. The women and their relatives, we spoke with told us they felt fully involved in their care and had received the information they needed to understand their scan procedure. Women told us they were happy with the way they were spoken to. They said things were explained in a way they could understand.
- The women and their relatives we spoke with felt they were given the opportunity to ask questions throughout their appointment.
- Women were encouraged to make their experience a family occasion. Partners, children, other relatives and/or friends were welcome to attend the appointment with the woman.
- There were appropriate discussions about the cost of keepsake pregnancy scans. Women were advised of the cost of their planned scan when they booked their appointment. This information was also available on the service's website.

Are diagnostic imaging services responsive?

Good

Service delivery generally met the needs of local people

- **The services provided generally reflected the needs of the population served. The service generally had suitable premises and facilities to meet the needs of women.**
- The service only provided private keepsake baby scans and did not complete any ultrasound imaging on behalf of the NHS or other private providers. The service offered gender determination scans, and 2D, 3D, 4D and high definition baby images. The provider told us they received an increasing number of requests for early reassurance scans, which they would perform if the woman was well and had no symptoms of possible miscarriage.
- The service was located on the ground floor in a shop building and was accessible to women and those accompanying them. However, the scanning room couch was not adjustable, which meant the service was not able to support women with limited mobility.
- The facilities and premises were generally appropriate for the services delivered. There was a comfortable seating area and toilet facilities for women and those accompanying them.
- Women were provided with appropriate information about pricing and scan options before their appointment. The service offered several scan packages, which were clearly detailed on the service's website and information leaflet.
- Women were given relevant information about their ultrasound scan when they booked their appointment, such as whether they needed a full bladder and when was the best gestation for their scan. This information was also included in the 'frequently asked questions' on the service's website.
- The provider was flexible. Appointments could be arranged during the evenings and weekends.
- There were no car parking facilities at the service. However, there was on street public car parking available.

Meeting people's individual needs

- **The service generally took account of individual needs.**

Good

Diagnostic imaging

- Women were able to contact the service to book an appointment during normal working hours, seven days a week.
- The service also provided a twelve hour, seven days a week social media messaging service to answer any questions and respond to women efficiently.
- Women had the opportunity to provide feedback anonymously after their visit. The service sent out an email link. This data was reviewed weekly. The feedback process did have an option to provide a name and contact information should they wish the service to contact them directly to discuss any concerns.
- The appointment schedule allowed women sufficient time to ask questions before, during and after their ultrasound scan. Women and their relatives we spoke with confirmed this.
- Women received information to read and sign prior to their ultrasound scan appointment. However, at the time of our inspection this information was only available in English.
- There was not a translation service in place that could be used during an appointment for non-English speaking women. The provider told us that non-English speaking women usually attended their appointment with a family member or friend, who could translate for them. However, the use of relatives and/or friends as interpreters is not considered best practice.
- All pregnancy ultrasound scans were undertaken in a private clinic room with lots of space for additional relatives, friends or carers to accompany the woman.

Access and flow

- **Women could access the service when they wanted it.**
- There had been no appointments cancelled due to non-clinical reasons between 1 January 2018 and 1 January 2019.
- No appointments had been delayed due to non-clinical reasons between 1 January 2018 and 1 January 2019.
- Women referred themselves for baby keepsake, gender determination and reassurance scans.
- At the time of our inspection, there was no waiting list or backlog for appointments. From January 2018 to January 2019, the service performed 2648 baby keepsake scans. Data provided by the service showed that no scans were cancelled or delayed for non-clinical reasons during this period.
- Women were offered a choice of appointment. Women could book an appointment via the service's website, phone, text message or social media web page. Services were available seven days a week.
- There was no waiting time for scan results. Women were given a CD (compact disc) and/or DVD (digital video disc) of their keepsake baby images at the end of their appointment.

Learning from complaints and concerns

- **Concerns and complaints were treated seriously, investigated and measures taken to resolve them. There was an electronic reporting system in place to record complaints received. A complaints policy was in place.**
- Women had the opportunity to provide feedback anonymously after their visit. The service sent out an email link. This data was reviewed weekly. The feedback process did have an option to provide a name and contact information should they wish the service to contact them directly to discuss any concerns.
- The service displayed information on how to complain to the management and the CQC in the waiting areas and consulting room.
- Managers told us complaints regarding the service were dealt with by the manager on duty to ensure they were resolved in a timely manner. Complaints were recorded in the 'complaints log' which was an on-line database.
- All complaints were reviewed by the registered manager weekly.

Good

Diagnostic imaging

- The service had received two complaints between 1 January 2018 and 1 January 2019. Both complaints were managed under the formal complaints procedure. They were responded to and closed in a timely manner. The complaints were not upheld.

Are diagnostic imaging services well-led?

Good

Leadership

- **The registered manager had the right skills, knowledge and experience to run the service.**
- All employee reviews were completed by the directors and registered manager to ensure all employees had access to the managers of the company.
- The managers and director operated an open-door policy in which all employees could access the managers at any time. The managers told us, the employee access to the managers of the company ensured a team that was happy and motivated and who feel their contribution is valued.
- The registered manager was also a director. The service also had a second director who was also the general manager. The service had an operational manager who was also the directors' personal assistant.

Vision and strategy

- **The service had a vision, it believed the delivery of quality care was the top priority, and the staff worked to achieve it.**
- The service did not have a formally documented strategy but provided the service under the belief 'the more you know, the more you care'. The staff member we spoke with was aware of the service belief and strategy and confirmed this.

Culture

- **The provider promoted a positive culture.**
- Managers told us they fostered a culture which put the women at the centre of everything we do. This was role modelled by the managers of the company who shared and valued women who used the service's feedback.
- The staff were welcoming, friendly and helpful. It was evident that they cared about the service they provided and tried to get the best possible images and make the experience as happy and positive as possible.
- The provider was aware of the duty of candour regulation but had not had any incidents that met the threshold for implementing the duty of candour.

Governance

- **We were assured that generally there were sufficient governance arrangements were in place to ensure high standards of care were maintained.**
- There was no infection prevention and control policy in place. However, the service had a checklist in place to assure themselves that the service was cleaned regularly and in line with infection prevention and control standards. They had a system in place to assure themselves that all equipment was fit for purpose. For example, equipment had been serviced regularly and all items in the first aid kit were in date This meant we were assured these had been checked by the registered manager.
- We were assured the provider had identified what training in key skills they needed and had a system in place to ensure they and their staff were up to date with training.
- There was a system in place to show how the service managed incidents and complaints.
- The provider had indemnity insurance in place.

Managing risks, issues and performance

- **We were assured effective systems were in place to identify, reduce and eliminate risks, and to cope with both the expected and unexpected.**
- The provider generally demonstrated an understanding of the potential risks within their service. They were able to evidence risk assessments

they had carried out and there was a risk register in place. The risk register included slips, trips and falls, manual handling, electrical, fire and stress. However, there was no risk assessment for the collapse of a woman or visitor and infection risks were not always controlled well. This meant we were assured they generally had identified risks within their service and they had acted to minimise those risks.

- The service had a management plan that identified management of risk in ultrasound in pregnancy had been assessed and was managed by the registered manager. The registered manager stated as the service did not provide medical services or advice they deemed the service to be low risk.
- To ensure the service remained low risk, the service followed four steps to ensure they remained a safe provider of ultrasound scans:
  - Scan for less than 30 minutes continuously, in line with the British medical ultrasound society (BMUS) guidelines for professional ultrasound practice.
  - All equipment was serviced at manufacturers recommended intervals.
  - All sonographers were trained to only operate in the obstetric and gynaecology setting on the ultrasound equipment.
  - If they had any concerns regarding the wellbeing of the woman, they immediately request they attend their healthcare provider.

Managing information

- **The service collected, managed and used information well to support its activities, using electronic systems with security safeguards.**
- There was a system in place to ensure women were provided with the terms and conditions of the service being provided to them, and the amount and method of payment of fees. The terms and conditions were available on the service's website and were given to women to read and sign before any scan was performed. They clearly stated that the full price of the scan must be paid before the scan was undertaken.
- Women's records and scan images were easily accessible and were kept secure. Electronic systems were password protected.
- The provider told us they deleted the scan images from the ultrasound machine as it became full. There was no facility to store images.
- Staff had completed information governance training as part of their induction.
- The provider was registered with the Information Commissioner's Office (ICO), which was in line with The Data Protection (Charges and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights.

Engagement

- **There was evidence of engagement with women and we saw evidence of change because of comments or complaints received.**
- The provider used customer surveys to gather feedback on the services they provided. They asked women for suggestions on how they could improve.
- The provider asked women to post feedback about the service on their social media web page. We viewed 20 reviews in the last month, all apart from one was positive. The negative response had been responded to in a timely manner.
- We were given many examples of improvements that had been made to the service because of comments or complaints received. For example, opening times had been increased to accommodate people who were working during standard office hours. The service was available at weekends and until 9pm on Tuesdays.

Learning, continuous improvement and innovation

- The staff at the service did not undertake any continuous improvement or innovation apart from changes made following service feedback. Staff did however, undertake continuing professional development activities and had booked courses to update their skills in ultrasound.
- The service had responded to feedback from the women who used the service's requests for more flexible opening hours. The service was available weekends and evenings to cater for women who used the service who wished to access services out of traditional working hours.

Good

Diagnostic imaging

- The service had purchased a large high definition projector screen to ensure a better experience for the whole family attending the scan.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The service should improve management of infection control risks, by ensuring the cover for the examination couch is changed between each woman and the shared a cotton towel in use in the toilet is replaced with disposable (one use) towels.
- The service should ensure all DBS check were carried out, every three years to be in line with good practice.
- The service should ensure information provided to women prior to their ultrasound scan appointment, was available in a variety of languages (in addition to English).
- The service should ensure women who used the service had access to a translation service that could be used during an appointment for non-English speaking women.