H17 Ltd

Cherished Moments

Inspection report

81 Hobs Moat Road
Solihull
B92 8JL
Tel: 07506686580

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

Ratings

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

Summary of findings

Overall summary

This was our first inspection of this service. We rated it as requires improvement because:

- The service did not always control infection risk well. The risk of cross-contamination was not always mitigated. We did not see evidence of hand hygiene audits during our inspection.
- Staff did not carry out quality assurance checks on the ultrasound equipment. The service did not have any arrangements for peer review of scans and reports. Performance was not monitored, and the service did not check the results provided to women were reliable.
- The service did not have a referral pathway for women potentially identified as experiencing mental health crises or acute anxiety. The service did not have a clear process for reporting, investigating and learning from safety incidents.
- The service did not have any vision or values. The service did not have a robust governance framework to support the delivery of good quality care. Risks were not always identified, reviewed or mitigated. The registered manager did not have full oversight of the performance and safety of the service.

However:

- Staff received training in key skills, understood how to protect women from abuse and kept detailed records of women's care and treatment.
- Staff worked together as a team to benefit women and those who accompanied them and supported women to make informed decisions about their care and treatment.
- Staff treated women with compassion, kindness and respected their privacy and dignity. They provided emotional support to women and those who accompanied them and took time to explain the procedure before and during the scan.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement 	We rated this service as requires improvement. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Cherished Moments

Cherished Moments is operated by H17 Limited. It provides 2D, 3D, 4D, HD live and gender keep sake baby scans to self-paying women and their families. The service is a fixed location private clinic providing trans abdominal ultrasound scan services for women aged over 18 years across Birmingham.

The service has had a registered manager in post since it first registered with the CQC in May 2021. This was the first inspection since registering with the CQC.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced visit to the service on 3 November 2021.

Cherished Moments is registered with the CQC to carry out the following regulated activities:

- Diagnostic and screening procedures

How we carried out this inspection

During the inspection visit, the inspection team:

- Spoke with the registered manager and the ultrasound technician.
- Observed and spoke with five women attending for scans.
- Reviewed twelve records.
- Spoke with four relatives of women attending for scans.
- Looked at a range of policies, procedures and other documents relating to the running of the service.

We carried out a comprehensive inspection of the service under our regulatory duties. The inspection team comprised of a lead CQC inspector, specialist advisor who was a sonographer and an off-site CQC inspection manager.

We undertook this inspection because we received information giving us concerns about the safety and quality of the services.

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 to improve:

- The service must ensure offensive waste is disposed of in line with national guidance. (Regulation 12(1)(h)).
- The service must ensure that approved wipes are used for cleaning of the ultrasound equipment as per manufacturer's recommendation. (Regulation 12(1)(h))
- The service must ensure hand hygiene and environmental cleaning audits are carried out. (Regulation 12(1)(h)).
- The service must ensure peer reviews and imaging reports are audited for quality purposes. (Regulation 17(1)(2)(b)).
- The service must ensure that quality assurance is carried out on the ultrasound equipment. (Regulation 17(1)(2)(b))

Summary of this inspection

- The service must ensure a referral pathway for women potentially identified as experiencing mental health crises or acute anxiety is in place. (Regulation 17(1)(2)(b)).
- The service must ensure there is a governance system in place to ensure referrals made to NHS services are followed up. (Regulation 17(1)(e)).
- The service must ensure equipment faults and other safety incidents are reported as incidents. (Regulation 17(1)(2)(a)).
- The service must ensure assurance process are in place to check ongoing competencies of the ultrasound technician. (Regulation 18(2)(a)).
- The service must ensure all staff are appropriately trained for their role. (Regulation 18(2)(a)).
- The service must ensure enhanced Disclosure and Barring checks are carried out. (Regulation 19(1) (a)(2)).

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 ensure single used pre-filled bottles are used in line with recent guidance. (Regulation 12(1)(h)).
- The service should ensure information on how to complain is readily available and accessible to women who use the service and learning from complaints is shared with staff. (Regulation 17(1)(2)(a)(b)).
- The service should ensure they have a risk register to monitor and mitigate the risks for the service. (Regulation 17(1)(2)(a)(b)).

Our findings

Overview of ratings

Our ratings for this location are:

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

Requires Improvement

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Requires Improvement

This was our first inspection of this service. We rated safe as requires improvement.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up-to-date with their mandatory training. Staff confirmed they had completed their mandatory training. Staff files showed mandatory training compliance was 100%.

The mandatory training was comprehensive and met the needs of women and staff. It included safeguarding, infection prevention and control, fire safety awareness and workplace first aid.

Staff received an induction when first employed by the service. Induction checklists were in staff files which included all required subject areas.

Managers monitored mandatory training and alerted staff when they needed to update their training. Mandatory training information and completion data were held as paper copies in staff files. All staff could access their own records and the managers could access all records.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. The training was suitable and in line with the safeguarding children and young people roles and competences for health care staff intercollegiate document 2014. The registered manager was the identified safeguarding lead and had completed level three safeguarding training for both children and adults. The ultrasound technician had completed level two children and adults safeguarding training.

Requires Improvement

Diagnostic and screening services

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. The service had a system to ensure women were not under the age of 18 years. Women completed a form which required them to provide their date of birth including their age at the time of attendance.

The service had an up-to-date safeguarding children and adult policy which was issued in March 2021. This detailed all aspects of identifying and dealing with abuse including information on female genital mutilation.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had a safeguarding book to record any safeguarding concerns. Staff knew how to contact the local authority to escalate their concerns. The service reported no safeguarding referrals had been made since they opened in May 2021.

The registered manager followed safe recruitment procedures to ensure staff were safe and suitable to work with women who received care from the service. The provider's records and discussions with staff showed required employment checks were made before staff provided care. For example, checks of staff previous employment, work history and checks with the disclosure and barring service.

Cleanliness, infection control and hygiene

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

Staff cleaned equipment after contact with women. Staff used antibacterial spray to clean the ultrasound equipment. This was not in line with the manufacturer's guidance on cleaning and maintenance of the ultrasound equipment which recommended the use of approved wipes for cleaning. We could not be assured that the risk of cross-contamination was mitigated.

Staff used refillable ultrasound gel bottles from large gel pack and not single used pre-filled bottles which posed a risk of cross contamination. This was not in line with recent guidance.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff used cleaning schedules to demonstrate areas had been cleaned, we found schedules were completed since the service was established in May 2021. We did not see evidence of infection prevention and control or hand hygiene audits during our inspection. Following our inspection, the service provided a general infection control audit checklist carried out on the 5 November 2021. This showed 100% staff compliance with hand hygiene and environmental cleaning audits.

Staff followed infection control principles including the use of Personal Protective Equipment (PPE). The ultrasound technician wore personal protective equipment (PPE) such as gloves and aprons and changed these between each scan.

The service had an up-to-date infection prevention and control policy issued in March 2021 which reflected relevant legislation and published professional guidance. Staff had reported no healthcare acquired infections since the service was opened in May 2021.

Clinical areas were clean and had suitable furnishings which were clean. All surfaces, flooring and equipment such as chairs were wipeable. The premises were visibly clean and well maintained.

Requires Improvement

Diagnostic and screening services

Staff had their arms bare below the elbow and used hand gel between each woman.

The service had a robust COVID-19 testing regime in place. Staff carried out COVID-19 lateral flow tests twice per week and maintained a record of these. There was a COVID-19 policy to provide guidance for staff to help reduce the spread of infection. Women who attended the service completed a form which asked if they had symptoms or had been in contact with someone who had COVID-19. Staff could clearly articulate how to mitigate risk of spreading COVID-19 and had reduced the number of people allowed into the scanning room to reduce the risk of spreading the infection.

Environment and equipment

The maintenance and use of facilities and equipment did not always keep people safe. Staff did not always manage offensive waste well.

Staff did not carry out daily safety checks of specialist equipment. There was no safety checklist for the scanning machine. Staff did not carry out quality assurance on the ultrasound equipment as recommended by the British Medical Ultrasound Society. The Health and Social Care Act and the provision and Use of Work Equipment regulations require equipment to be suitable for purpose and regularly inspected. The service did not have a clear process for staff to check the scan equipment was working correctly to ensure the results provided to women was reliable.

Staff did not always dispose of offensive waste safely. Offensive waste is non-clinical waste that's non-infectious and does not contain pharmaceutical or chemical substances but may be unpleasant to someone who comes into contact with it. Gloves, aprons and sanitary towels were disposed of as normal waste and this was not in line with Department of Health and Social Care Health Technical Memorandum 07-01 – safe management of healthcare waste.

The design of the environment followed national guidance. The service was located on the ground floor. It had widened doorways and ramps to ensure it was accessible to wheelchair users, those with limited mobility and pushchairs. It had a waiting room which included a reception area, a scanning room, storage area and toilet facilities.

The service had suitable facilities to meet the needs of women's families. There was a large wall mounted monitor at the end of the couch so women and those attending with them could view the scan from all areas of the room.

The service had enough suitable equipment to help them to safely care for women. The service had a first aid kit containing stock which was all in date.

Staff stored substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations in a locked cupboard.

The service's ultrasound machine was leased. There was a maintenance agreement in place to ensure the equipment was maintained annually. We reviewed the service records for the equipment, which detailed the maintenance history and service due dates of equipment.

Assessing and responding to risk

Staff did not always complete and update risk assessments for each woman and removed or minimised risks. However, staff identified and quickly acted upon women at risk of deterioration.

Requires Improvement

Diagnostic and screening services

Staff did not have access to mental health liaison and specialist mental health support if staff were concerned about a woman's mental health. There was no referral pathway (for example, referral to a single point of contact) for women potentially identified as experiencing mental health crises or acute anxiety. Staff were unable to articulate a referral system to enable them to refer women for mental health support to keep women safe.

Staff responded promptly to any sudden deterioration in a woman's health. Due to the nature of the service, there was no emergency resuscitation trolley on site. However, a defibrillator was shared amongst the community services and staff knew how to access the community defibrillator. Staff could access a first aid box and the registered manager and ultrasound technician had up-to-date first aid training. In the event of a woman becoming acutely unwell, the service would call 999.

Staff completed risk assessments for each woman on admission. Women were made aware within the consent form that the service did not provide any clinical diagnostics. We observed staff advising women to continue with their NHS scans as part of the maternity pathway.

Staff discussed the potential risks of frequent scanning with women, they also advised women to read the information in the client waiver form.

The ultrasound technician reviewed the woman's details before carrying out the scan, they checked consent and confirmed the woman was aware the scan was for keep sake purposes and not to provide diagnostic screening.

Staff knew about and dealt with any specific risk issues. Staff followed the referral procedure which involved them informing the woman that they had seen something on their scan which should be checked at the hospital for a clinical diagnosis. They called the most appropriate hospital on the woman's behalf. Staff had access to the numbers of three different early pregnancy units (EPU) which staff could contact to refer women. Staff had referred 12 women to the EPU. We saw completed forms which detailed the findings and reasons for referral.

Any reason for a referral was documented on the woman's record form and clearly explained to them. Records of women who had been referred were stored in a separate folder in a locked filing cabinet. This meant that managers could monitor the number of women that had been referred to other services.

Staffing

The service had enough staff with the right training to keep women safe from avoidable harm and to provide the right care and treatment.

The service had enough staff to keep women who used the service safe. The staff comprised of one ultrasound technician and a registered manager who was the owner and carried out the role of the receptionist and administrative staff.

Managers made sure staff had a full induction and understood the service. The ultrasound technician had received a formal induction. There was a recruitment policy in the event of more staff being recruited.

Staff would not work alone; both members of staff where always at the building when there were scans booked. One member of staff would stay at the reception and the other would perform the ultrasound scan.

Records

Requires Improvement

Diagnostic and screening services

Staff kept detailed records of women's care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Notes were comprehensive, and all staff could access them easily. Staff kept detailed records of women's appointments, referrals to NHS providers and completed scan documents. Records were clear, included appropriate information, were up-to-date and only available to those who needed them.

Records were stored securely. Paper records were used and were stored securely in a locked filing cabinet behind the reception desk. Of the 12 sets of notes checked during our inspection, all had relevant details on as well as information about the woman's pregnancy or any pre-existing medical conditions.

Unborn babies' heartbeat could be recorded on a small electronic device during the scan which could be inserted into a heartbeat teddy bear for the women to take home. If the women decided not to buy the heartbeat bear, the recording was deleted.

Incidents

The service did not always manage safety incidents well. Staff did not always recognise and report incidents. The registered manager investigated incidents but did not share lessons learned.

Staff did not report incidents relating to equipment breakdown in line with the provider's policy. For example, staff told us of an incident where a baby's heartbeat had not been detected due to a fault in the ultrasound device. We reviewed the incident reporting system and no equipment breakdown had been reported as an incident.

The service did not report any serious incidents from May 2021 to the time of our inspection.

Staff had reported 12 anomalies as incidents which included when a babies' heartbeat had not been found. Incidents were not investigated or followed up; therefore, no lessons were learned.

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

The service had no never events. In the reporting period from May 2021 to this inspection, there were no never events at the location. A never event is a serious incident that is wholly preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers. The event has the potential to cause serious patient harm or death, has occurred in the past and is easily recognisable and clearly defined.

Staff understood the duty of candour. They were open and transparent and gave women and families a full explanation if and when things went wrong. 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 duty of candour regulation only applies to incidents where severe or moderate harm to a woman has occurred. The service had one incident where duty of candour needed to be used. Staff sent a verbal and written apology to the woman involved.

Requires Improvement

Diagnostic and screening services

Are Diagnostic and screening services effective?

Inspected but not rated

We do not currently rate effective.

Evidence-based care and treatment

The service provided care and treatment based on national guidance but did not always provide care and procedures based on evidence-based practice.

The service did not regularly review the effectiveness of the service through local audits. For example, the service did not have a formal system to identify women who attended frequently for scans.

The service did not have a clear process to audit imaging reports for quality purposes.

Staff did not always follow up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Local policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations such as, the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS). Staff were aware of how to access this information but did not always follow them.

The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief and sexual orientation when making care and treatment decisions.

Staff followed the National Institute for Clinical Excellence guidelines for frequency (soundwaves) and length of scan guidelines and ensured the safety of all involved as their highest priority. This was written on the waiver which women signed before scans. Staff performed scans as a bonding experience for families and their unborn child.

Nutrition and hydration

Food and fluid were not offered to women due to the nature of the service.

Women who were having a gender scan were encouraged to attend their appointment with a full bladder depending on their length of gestation/ type of scan. This information was given to women when they contacted the clinic to book their appointment. It was also included in the 'frequently asked questions' on the service's website.

Pain relief

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

Pain relief was not administered by the service.

Patient outcomes

Requires Improvement

Diagnostic and screening services

The service did not monitor all aspects of effectiveness of care and treatment.

Managers and staff did not carry out a comprehensive programme of repeated audits to check improvement over time. For example, staff did not carry out audits into the quality of ultrasound scanning undertaken and the reports generated. The service did not have any arrangements for peer review of scans and reports. Peer review is the evaluation of work by one or more people with similar skills and competence as the producer of the work.

Staff implemented local changes to improve care. They monitored feedback through a variety of social media platforms and email and adapted the service where necessary.

Women on average used the services approximately three times throughout their pregnancy, their early scan, gender confirmation and 4D scans. To ensure the level of safety was kept to the highest standard, staff asked women to wait a minimum of seven days between scans.

Where a multiple pregnancy was detected during an early scan, staff would let the mother know they had detected two heartbeats and advised them to speak to their midwife for confirmation at their 12-week scan. If detected after a 12-week scan and it was not picked up by the NHS, women would be referred to the NHS provider.

Competent staff

The staff were competent for their roles; however, the service did not have an assurance process in place to check their ongoing competencies.

Staff training needs were not identified through regular observations, or supervision. The staff members annual appraisals and one to one discussion was the only time staff had their competencies checked. Staff said their competencies were checked on a regular basis by an external company. We saw no evidence this had been done.

The provider offered inhouse training for staff and staff accessed external training courses through the franchise. The ultrasound technician said they attended training for six months prior to commencing work with this service. Evidence reviewed during our inspection revealed all competencies were signed on the same day. There was no evidence of staff training start and end dates. We therefore could not be assured staff had undergone the required training to enable them to competently carry out scans.

Staff did not have the right skills to meet the needs of women. At the time of our inspection, the service employed one ultrasound technician. We reviewed their staff file and they had received training to enable them to safely operate the ultrasound equipment. However, we observed ultrasound scans and found they had limited understanding of controls on the ultrasound machine and only knew how to manipulate controls to get the images required. Understanding around gain control was limited.

Staff had the opportunity to discuss training needs with their line manager. Staff told us they received one-to-one meetings with the registered manager every month. However, this was not documented in the staff files we reviewed.

The manager gave all new staff a full induction tailored to their role before they started work. When first employed, staff undertook induction training which comprised both face-to-face and online learning. Staff completed annual mandatory training, which included ongoing training as required, and third-party training courses in key areas.

Multidisciplinary working

Requires Improvement

Diagnostic and screening services

Staff worked together as a team to benefit women and those who accompanied them. They supported each other to provide good care.

Staff could contact the services by telephone and make appointments on behalf of the women who needed them. This was recorded in notes we reviewed.

We saw positive working relationships between the manager and the ultrasound technician during our inspection.

The service had positive communication with health care professionals when communicating with NHS services to make a referral. The NHS services included three local hospitals.

Seven-day services

Services were available four days a week.

The service provided a four-day service and was closed from Sunday until Tuesday. They operated varying hours to meet patient demand, between 10am and 6pm, depending on the day. Saturday clinics were provided twice a month from 9am to 2.30pm. This allowed all women to access the service at a time that suited them.

Health promotion

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

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain women's consent.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Staff asked woman to complete a waiver form which included information about consent. The limitations and risks associated with the scan were discussed before the practitioner proceeded. This was so that all women could make an informed decision before having the scan.

Staff made sure women consented to treatment based on all the information available. Women completed and signed a declaration to state they understood the type of procedure they were attending for.

Staff clearly recorded consent in the women's records. Staff were aware of the importance of gaining consent from women before conducting an ultrasound scan.

Women attending for a scan filled in a consent form which included sections for demographic information, medical history, explained what each scan was, ultrasound safety information and what to expect. The consent form was clear that the scans undertaken did not take the place of the routine NHS scans and that all women should also attend for these.

Requires Improvement

Diagnostic and screening services

Staff did not receive training on the Mental Capacity Act as part of their induction and annual mandatory training. However, they could articulate how and when to assess whether a woman had capacity to make decisions about their care.

Are Diagnostic and screening services caring?

Good

This was the first inspection of this service. We rated it as good.

Compassionate care

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

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. During our inspection, staff immediately built a rapport with women and those who accompanied them including children, encouraging a calm and reassuring environment. All staff treated women with dignity and respect and provided compassion throughout their scan journey.

Women said staff treated them well and with kindness. We spoke with five woman and four people who accompanied them. They all spoke positively of the service and described their experiences as good.

Staff followed policy to keep women care and treatment confidential. The scan room was closed at all times during the appointment to ensure women's dignity was maintained.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs. Reception staff were often the first to speak with the attending woman and we saw evidence of staff being courteous.

Emotional support

Staff provided emotional support to women and those who accompanied them to minimise their distress.

Staff gave women and those close to them help, emotional support and advice when they needed it. They gave women time to understand what the service were being offered to them and how much the price would be for each appointment.

Staff had not undertaken training on breaking bad news but told us they demonstrated empathy when having difficult conversations. They gave an example of an emotional conversation they held with a woman who had a scan anomaly and could clearly articulate how the referral was made to an NHS service.

Staff supported women who became distressed in an open environment and helped them maintain their privacy and dignity. Staff told us they gave women as much time as they required if they became distressed. They supported and gave women time to ask questions.

Requires Improvement

Diagnostic and screening services

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. Staff demonstrated a caring approach, listened to women and those who accompanied them, assessing their needs and aiming to achieve a good outcome.

Understanding and involvement of women and those close to them

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

Staff made sure women and those close to them understood their care and treatment. The ultrasound technician took time to explain the procedure before and during the scan and checked the scan package chosen by women and those accompanying them. The ultrasound technician explained what was happening throughout the scan.

Staff talked with women and their relatives in a way they could understand. The ultrasound technician asked women if they had any questions throughout and at the end of the scan. Women and those attending with them felt involved in the scan, and any questions they had were answered in a way they understood.

Women gave positive feedback about the service. Staff received feedback through emails and the manager was in the process of introducing feedback cards. A woman who used the service said, 'although my experience is one I would like to forget due to the outcome, I just wanted to say a heartfelt thank you for the care I received on the day'.

All women we spoke with said they felt informed about the procedure and understood staff were not performing a diagnostic scan.

Are Diagnostic and screening services responsive?

Good

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

Service delivery to meet the needs of local people

The service was planned and designed to meet the needs of the women requiring the service.

Facilities and premises were appropriate for the services being delivered. The service had enough comfortable seating for women and those accompanying them. The scan room could accommodate up to eight people, but staff restricted numbers due to COVID-19. The waiting room had two large sofas for women to wait for their scans.

The clinic was based in Solihull and was reachable by public transport. There was street parking available outside the clinic as well as free parking outside the building.

The clinics ran in line with the demand of the women, enabling them to make bookings at a time to suit them.

Requires Improvement

Diagnostic and screening services

The service offered a range of scan packages, all of which included a wellbeing scan. Costs and details of deposit and full payment was clearly explained on the website, in information at the clinic, and by staff when women attended their appointment.

Managers monitored and took action to minimise missed appointments. Bookings into the service could be made by telephone, by social media platforms or the providers website. Due to the nature of the service, non-attendance was not regularly monitored.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences.

Staff provided a service to pregnant women and tailored them completely to suit women's needs. The receptionist greeted women when they arrived for their appointment, explained their scan package and asked them to complete their consent form.

Staff carried out trans abdominal ultrasound scans from week seven to week 32.

The building and the clinic were accessible for those with a disability. The clinic was based on the ground floor. There was lots of space within the reception area and the scanning room for a wheelchair.

Women with multiple pregnancies were advised to have double appointments for the extra images required of each unborn baby in the womb.

Staff offered a free rescan if they could not get the desired images of the baby or if they were unable to determine the gender due to the position of the baby, placenta, body mass index of the mother or multiple babies.

Staff recorded unborn babies' heartbeat and saved them in the ultrasound data system for 12 months, this gave the option for mothers who lost their pregnancy to have their babies' heartbeat transferred onto a recording tape device that went into a stuffed toy to help with their loss.

Access and flow

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

The service did not have a waiting list for appointments, and at the time of our inspection there was no back log for appointments. Staff explained the booking system was flexible, and they operated clinics around times to suit women.

Appointment slots were 15 minutes long which allowed staff enough time to perform the scan and gave the woman and their families enough time ask any questions they may have. They left gaps throughout the day to allow for any eventualities.

Women were seen on time during our inspection. Staff kept women informed in the waiting room and advised them of any delays.

Learning from complaints and concerns

Requires Improvement

Diagnostic and screening services

Women were able to give feedback and raise concerns about the service received. However, information and guidance about how to complain was not available and accessible.

The service did not display information about how to raise a concern. We saw information about how to complain was not available on their website and was not accessible to women.

The service had not appointed an independent complaints adjudication service to refer any dissatisfied complainant. They told us dissatisfied complainants would be referred to the CQC.

Records we reviewed showed there had been a recent complaint relating to a scan outcome. The complaint was responded to, investigated and closed in a timely manner.

All complaints went to the registered manager, who dealt with them in line with their own complaints policy.

Staff understood the policy on complaints and knew how to handle them. The service had a complaints and compliments policy which was issued in March 2021. Members of staff received training in dealing with concerns and complaints.

Staff knew how to acknowledge complaints and women received feedback from managers after the investigation into their complaint. Staff gathered information to try to resolve matters, offered apologies and followed up as required.

Are Diagnostic and screening services well-led?

Requires Improvement

This was the first inspection of this service. We rated it as requires improvement.

Leadership

The manager did not have the right skills and abilities to run a service providing high-quality sustainable care. They were visible and approachable in the service for women and staff.

The registered manager led the service. We were concerned that they did not currently have the skills, knowledge or experience to lead a service providing high-quality sustainable care. This was because they demonstrated a lack of understanding of their responsibilities in terms of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3). Following the inspection, the registered manager had been responsive to our concerns raised and had started to make improvements such as hand hygiene and environmental audits to comply with regulations.

The service was small and the registered manager oversaw the day-to-day running of the service.

The manager was approachable, and staff felt well supported. They knew what the management arrangements were.

Staff had positive relationships with each other and had good inclusive working relationships.

Vision and Strategy

Requires Improvement

Diagnostic and screening services

The service did not have a vision or strategy for what it wanted to achieve and workable plans to turn it into action.

The service did not have a clear plan to support how the service was going to meet the service priorities to deliver good quality sustainable care for women.

Staff told us their vision was to build the service and provide the best services.

Culture

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

The manager promoted a positive culture that supported and valued staff.

Staff were proud of working for the service and spoke positively about the culture of the service. Staff worked well together as a team and there was an open and honest culture.

Staff told us they could raise concerns with the manager without fear of retribution.

The service promoted equality and diversity. Staff were mindful of their service being accessible to all.

Governance

The leader did not always operate effective governance processes throughout the service and with partner organisations. Staff were clear about their roles and accountabilities and had regular opportunities to meet.

The clinic manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to complaints. There was no robust governance framework in place to support the delivery of good quality care.

The provider did not have an agreed, shared and comprehensive definition of which incidents to report. As a result, they did not have fully developed systems to record, analyse or learn from the complete range of incidents, or a process for reporting them. Therefore, staff did not fully understand what incidents to report, some incidents may not be fully investigated and learning from incidents gained and shared.

The provider did not ensure that all staff underwent appropriate checks as required by schedule 3 of the HSCA 2008 (regulated activities) regulation 2014. Not all staff had an enhanced Disclosure and Barring (DBS) checks in place. For example, the ultrasound technician had a standard DBS in place. The DBS (A Guide to Adult Workforce Roles for Registered Bodies and Employers) states that enhanced level DBS is required by individuals who carry out activities with adults. Obligations are brought under the Safeguarding Vulnerable Groups Act 2006 a regulated activity provider. We raised this as an issue with the provider during our inspection. Following our inspection, the registered manager submitted an application for an enhanced DBS.

Referrals made to the NHS by the service were retained and stored securely. However, they were not audited to ensure the referrals were of a high quality.

Staff had regular ad hoc meetings but did not record minutes of the meetings. The registered manager and ultrasound technician attended the meetings. We could not be assured that necessary actions taken during the meetings were followed up.

Management of risk, issues and performance

The service had limited systems to manage risks. There was limited recognition and escalation of relevant risks and identified actions to reduce their impact.

The provider did not have robust systems to monitor, analyse or take action on safety, quality, performance or risk. There were no robust arrangements for identifying, recording and managing risks and mitigating actions. Risks we identified during our inspection such as lack of quality assurance for the ultrasound equipment, lack of audits had not been identified by the provider and therefore could not be mitigated.

The registered manager was unable to provide evidence of any audits and did not have full oversight of the performance and activity in the clinic. There was no programme of clinical and internal audit to monitor quality and systems to identify where action should be taken and to identify areas for improvement. Following our inspection, they sent us hand hygiene and environmental audits carried out on the 5 November 2021. The results showed 100% compliance.

There was little understanding of management of risks and a lack of performance management and audit systems to identify and address concerns. For example, the service did not carry out peer reviews to review the quality of the ultrasound technician's work. Therefore, there was no process to make improvements or identify any areas for development. Additionally, there was no assurance that scans were appropriately conducted, and the right scan information was given to women.

Staff did not contact women to check on their wellbeing and what they were told by the service they were referred to. The service did not have a system in place to ensure such referrals were followed up. For example, of the 12 incidents recorded which entailed no foetal heartbeat or viable pregnancy detected, no follow up contact was made to seven women. Four women had contacted the service to confirm a miscarriage and one had raised a complaint about the scan.

The service did not have a risk register. The registered manager was unable to identify any risks to the service. We could not be assured that the registered manager had oversight of risks and took timely action to make improvements of the service

The ultrasound technician did not provide medical advice to women as scans performed were non-diagnostic. Should the ultrasound technician be concerned with any significant findings, they adhered to the referral process and ensured an NHS appointment was made for them before leaving to maintain safety. All findings and processes were recorded on scan check forms.

Information Management

The service collected, managed and used information well to support all its activities, using secure electronic systems with security safeguards.

Requires Improvement

Diagnostic and screening services

The service held nominal data on women who used the service. All held data was a combination of paper records and electronically with password entry. Any paper records were kept in a locked cupboard inside the clinic. All staff had access to the electronic and paper records

The scanning machine had built in memory and every scan was kept on record unless deleted by the ultrasound technician. This allowed staff to keep women's records on file and access any previous reports to see if there was any specific information they may need to know for the current scan to be carried out.

Appointments were booked using an electronic booking system. The computer staff used was password secured and to maintain confidentiality was positioned in the reception area in a way that wasn't seen by others.

The booking system could only be accessed by authorised individuals, this prevented unauthorised staff accessing personal data.

Engagement

Leaders and staff actively and openly engaged with women, equality groups, the public and local organisations to plan and manage services.

The service mostly relied on social media and email for feedback. Any advertising or promotional events was in accordance with legislation. Staff carried out promotion through social media and it went through an approval system for that platform.

The service had effective relationships with the local safeguarding team and hospitals. They also had a good relationship with a similar baby scanning service in the local area that they could go to for advice.

Learning, continuous improvement and innovation

The provider did not improve their service by learning from when things went well or wrong as they did not have governance processes in place to support this.

The service did not have any effective systems and processes to learn, and to continuously improve the service.

Leaders did not encourage innovation. Staff did not have a good understanding of quality improvement methods and how to put them into practice to improve the service.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service must ensure offensive waste is disposed of in line with national guidance. (Regulation 12(1)(h)). • The service must ensure that approved wipes are used for cleaning of the ultrasound equipment as per manufacturer's recommendation. (Regulation 12(1)(h)) • The service must ensure hand hygiene and environmental cleaning audits are carried out. (Regulation 12(1)(h)).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service must ensure peer reviews and imaging reports are audited for quality purposes. (Regulation 17(1)(2)(b)). • The service must ensure that quality assurance is carried out on the ultrasound equipment. (Regulation 17(1)(2)(b)) • The service must ensure a referral pathway for women potentially identified as experiencing mental health crises or acute anxiety is in place. (Regulation 17(1)(2)(b)). • The service must ensure there is a governance system in place to ensure referrals made to NHS services are followed up. (Regulation 17(1)(e)). • The service must ensure equipment faults and other safety incidents are reported as incidents. (Regulation 17(1)(2)(a)).

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The service must ensure assurance process are in place to check ongoing competencies of the ultrasound technician. (Regulation 18(2)(a)). • The service must ensure all staff are appropriately trained for their role. (Regulation 18(2)(a)).
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed • The service must ensure enhanced Disclosure and Barring checks are carried out. (Regulation 19(1) (a)(2)).