BabyBump Limited

Baby Bump Limited

Inspection report

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

Ratings

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

Summary of findings

Overall summary

We have not previously rated this location. We rated it as inadequate because:

- The registered manager had not completed mandatory training that was appropriate for their role.
- Systems and processes regarding safeguarding were not always appropriate to keep people safe. We did not see evidence of staff having completed safeguarding children training.
- The service did not always control infection risk well.
- The service did not have appropriate arrangements, prior to the scan, in place to assess individual risks to women and their foetus. The service sometimes accepted inappropriate referrals that were not in keeping with the service being non-diagnostic.
- The service did not have enough staff to provide the right care.
- Staff were not always confident in identifying what constitutes an incident. The services incident policy was not tailored for the service.
- Staff could not demonstrate that they monitored the effectiveness of care and treatment.
- The registered manager did not always make sure staff were competent for their roles.
- The service did not always consider service users individual needs and preferences.
- The service did not have information regarding how to complain, for service users in the service or on the website.
- The service did not have a clear vision or strategy for what it wanted to achieve.
- The registered manager did not always operate effective governance processes.
- The registered manager did not always identify the risks specific to the service.

However:

- The service had a suitable environment. Staff were trained to use equipment, which was suitably maintained.
- Records for women attending the service were stored securely and were completed accurately.
- The service mainly provided care and treatment based on national guidance and evidence-based practice.
- Staff worked well together; they supported each other to provide good care.
- The service provided women with health promotional information to help them lead healthier lives.
- Staff supported women to make informed decisions about their scan. They followed national guidance to gain service users' consent.
- Staff treated service users with compassion, kindness, and respect.
- Staff provided emotional support to service users to minimise distress.
- Staff supported service users to understand the scans offered and make informed decisions about them.
- The service planned care in a way that met the needs of the local community.
- Service users could access the service when they needed it.
- Staff and service users felt respected, supported, and valued. There was a good, open culture.
- Information systems were integrated and secure.

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Summary of this inspection

Background to Baby Bump Limited

Baby Bump Limited is privately operated by Baby Bump Limited. They offer non diagnostic scans from 7 weeks to term. They provide early reassurance scans from 7 weeks, 2D wellbeing scans from 12 weeks and 4D scans from 12 weeks. From March 2022 to March 2023 the service completed 537 scans.

The service registered with the Care Quality Commission (CQC) in 2021 and has had the same registered manager in place since then.

The service is registered to provide diagnostic and screening procedures.

How we carried out this inspection

We carried out a short-announced, comprehensive inspection of the location on the 3 March 2023 and completed off site interviews on the 6 and 7 March 2023. The inspection team was made up of two CQC inspectors and an inspection manager offsite. Overall oversight of the inspection was provided by the head of hospital inspection.

We inspected this service as it had not been inspected previously and it was part of our routine schedule.

We reviewed specific documentation, completed observations, spoke with 4 service users, and interviewed the registered manager and sonographer.

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

Areas for improvement

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

Action the service MUST take to improve:

- The service must provide care and treatment in a safe way and must appropriately assess the risks to the health and safety of service users receiving the scans. Regulation 12.
- The service must ensure that all persons providing care to service users have the appropriate competence, skills, and experience to do so. Regulation 12.
- The service must do all that is reasonably practicable to mitigate risks. They must ensure that chaperones are routinely offered before every intimate examination. The option of a chaperone must be clearly advertised on the services website and on information leaflets within the service. Regulation 12.
- The service must assess and reduce the risk of infections. The service must ensure that there are suitable furnishings that are wipeable to reduce the risk of infection. Regulation 12.

Summary of this inspection

- The service must have adequate systems and processes to prevent the abuse of service users. Staff must receive safeguarding training that is relevant, and suitable for their role, as outlined in the intercollegic guidance. Regulation 13.
- The service must have effective governance systems or processes to ensure the safe and effective delivery of care. Systems and processes must be regularly audited. Regulation 17.
- The service must assess, monitor, and mitigate the risks to the health, safety, and welfare of service users. The service must have a comprehensive audit schedule in place to review performance or enable improvement. The service must ensure that they follow best practice guidance for the cleaning of ultrasound probes used in intimate examinations. Regulation 17.
- The service must ensure that it has an effective system in place to ensure that people working at the service have the relevant employment checks and competency checks in place, including staff appraisals, to keep service users safe. Regulation 17.
- Persons employed by the service must have appropriate training that is necessary to fulfil their role. Regulation 18.

Action the service SHOULD take to improve:

- The service should have a bodily fluid spills kit.
- The service should consider having handwashing facilities in the scanning room.
- The service should consider having a privacy screen in the scanning room to ensure the privacy and dignity of women using the service.
- The registered manager should consider having minuted meetings with the other director for the service.

Following this inspection, we served the provider two Warning Notices under Section 29 of the Health and Social Care Act 2008. The warning notices told the provider they were in breach of Regulation 12 and 17 and gave the provider a timescale to make improvements to achieve compliance. The principles we use when rating providers requires CQC to reflect enforcement action in our ratings. The warning notice identified concerns in the safe and well led domain. This means that warning notices that we served have limited the rating for safe and well led to inadequate.

The service has moved into special measures. Services placed in special measures will be inspected again within 6 months. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question or core service, we will take action in line with our enforcement procedures to begin the process of preventing the provider from operating the service. This will lead to cancelling their registration or to varying the terms of their registration within 6 months if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted within a further 6 months, and if there is not enough improvement, we will move to close the service by adopting our proposal to vary the provider's registration to remove this location or cancel the provider's registration.

Our findings

Overview of ratings

Our ratings for this location are:

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

Inadequate

Diagnostic and screening services

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

Is the service safe?

Inadequate

We rated it as inadequate.

Mandatory training

The registered manager had not completed mandatory training that was necessary to fulfil their role. The sonographer was mainly compliant with mandatory training that they received from the NHS which was applicable to their role.

The registered manager's mandatory training completion was limited. We did not see evidence of health and safety training, data security training or fire training, despite them being the lead for fire safety. The registered manager did not have infection prevention control training or chaperone training at the time of inspection but since then these courses have been completed.

The registered manager and sonographer told us that the sonographer completed their mandatory training with the NHS. We requested evidence of this training and received a screenshot of modules and dates when completed. From the data we had access to, it appeared that the sonographer kept up to date with their mandatory training, but we did not see evidence of safeguarding training.

Safeguarding

Systems and processes regarding safeguarding were not always appropriate to keep people safe. However, staff understood how to protect service users from abuse and knew how to apply their knowledge.

The service had a safeguarding policy which said that staff needed to have level 1 and level 2 safeguarding training for adults and children. When we inspected, the registered manager did not have training, specific for their role on how to recognise and report abuse in relation to adults or children. Following the inspection, the registered manager completed level one, two and three safeguarding adults training but we did not receive any evidence that safeguarding children training had been completed. We requested evidence of safeguarding training for the sonographer but did not receive this.

The service had a separate policy for Female Genital Mutilation (FGM), despite it being outlined in the safeguarding policy. The FGM policy provided the NHS websites definition of what FGM is but did not provide procedural advice.

The registered manager told us that she acted as a chaperone if women requested one. On the day that we inspected the registered manager told us that she did not have training to be a chaperone and that women were not routinely offered a chaperone, but it was available on request. The Medical Defence Union state that chaperones should routinely be offered before intimate examinations and that the option of a chaperone should be clearly advertised through service users' information leaflets, on notice boards or on the website. We did not see evidence of the chaperone procedure being advertised to women.

The registered manager told us that staff had not completed any safeguarding referrals and that no women had requested a chaperone.

When we spoke with staff, they knew how to identify adults and children at risk of, or suffering, significant harm and how to make a safeguarding referral and who to inform if they had concerns.

Staff could give examples of how to protect service users from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff had knowledge of FGM and knew how to escalate any concerns to the appropriate services. We observed a laminated information leaflet for the sonographer regarding FGM by the Department of Health situated in the scanning room.

Cleanliness, infection control and hygiene

The service had some unsuitable furnishings. The service kept equipment and premises clean.

The service did not always have suitable furnishings. In the reception area and in the scanning room the settees and chairs were not covered in a wipeable material which posed an infection risk.

The service did not have handwashing facilities in the scanning room which meant that the sonographer had to wash their hands in the bathroom sink before and after a scan. The World Healthcare Organisation's (WHO) '5 Moments for Hand Hygiene' (guidelines are for all staff working in healthcare environments and define the key moments when staff should perform hand hygiene to reduce the risk of cross contamination between service users) was not above the sink in the lavatory and sinks did not have elbow closing taps.

The service was visibly clean and tidy. We saw evidence of completed cleaning schedules for each area of the service. Tasks included disinfecting door handles, wiping the sinks and vacuuming.

Staff followed infection control principles including the use of personal protective equipment (PPE), which there were appropriate levels of. We observed a scan in which the sonographer wore a mask, was bare below the elbow and had clinical gloves on. The sonographer used a paper towel to cover the examination couch during the scanning procedure. We observed the sonographer changing the towel at the end of the woman's appointment. The sonographer was witnessed washing their hands before and after scans. However, hand hygiene audits were not undertaken to measure staff compliance with the WHO's '5 Moments for Hand Hygiene'.

The registered manager told us that there had been no healthcare acquired infections identified since they registered with the Care Quality Commission (CQC) in 2021.

Staff cleaned equipment after service user contact. Sonographers completed a clean of the scanning bed, the probes and washed their hands between every scan. We saw evidence of completed cleaning schedules. The service had the appropriate cleaning materials for the decontamination of transvaginal probes, a poster on the scanning room wall for transducer decontamination which outlined best practice and the sonographer had a good knowledge of how to clean the transducers. The sonographer had trained in the NHS on how to clean transducers.

The service had reduced their COVID-19 measures, in line with NHS guidance. The service had hand sanitising gel at the reception desk and in wall dispensers throughout the service. The registered manager said they were aware of the risk of COVID-19 and if cases were to increase, they would implement procedures to keep service users safe. COVID-19 was included on the services risk register.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use equipment. Staff managed clinical waste well.

Staff conducted safety checks of specialist equipment. The sonographer completed probe and ultrasound machine calibration checks monthly.

The registered manager provided evidence of up-to-date servicing records in place for the ultrasound machine.

The service had suitable facilities to meet the needs of women and their families. The service was located on the ground floor and was accessible for people in wheelchairs or babies in prams. There was a large reception and waiting area where women and their families were greeted and the toilet with baby changing facilities was close by. The scanning suite was spacious, homely, and well arranged. The sonographer turned down the lights when undertaking a scan to darken the room, which meant scans could be observed clearly. The couch in the scanning room was adjustable so could be lowered and raised.

The service had a fire evacuation plan in place. Fire extinguishers were accessible, stored appropriately, and had all been serviced within the date indicated.

The service kept a first aid box. The sonographer was trained in basic life support and the registered manager had first aid training.

The service kept adequate stocks of PPE such as masks, gloves, and aprons.

The service did not have a privacy screen in the scanning suite. The registered manager told us that the sonographer ensured the privacy and dignity of the service user by leaving the room when the person was changing.

The registered manager provided us with an electrical safety assessment report following the inspection. The assessment had been completed on 13 March 2023 following our inspection and showed that the last safety electrical assessment should have been completed in 2022. The assessment showed that all was in a good state of repair, well maintained and was safe for use.

The service had a clinical waste bin situated in the scanning room. The bin was difficult to open and contained some items that were not clinical waste. The service had a contract with an external company for clinical waste disposal.

The service did not have a bodily fluid spills kit which should have been available for women bleeding or if a woman's waters were to break.

Assessing and responding to risk

The service sometimes accepted inappropriate referrals which were not suitable given that the service is non-diagnostic. Staff identified and quickly acted upon women at risk of deterioration.

The services website, consent forms and registered manager confirmed that the service was for non-diagnostic, keepsake purposes only. However, we saw evidence of a scan being completed, despite the woman reporting heavy bleeding prior to their attendance. The exclusion criteria did not adequately explain who was suitable for a scan within the service and did not reference heavy bleeding as a reason for exclusion.

The service had clear processes in place to guide staff on what actions to take if any suspicious findings were found on the ultrasound scan. If they had concerns, the sonographer followed the service's referral pathway and referred the woman to the most appropriate healthcare professional, with their consent. As in, the medical emergency policy, the sonographer told us that they would speak to the registered manager who would make a referral to the local hospital.

Staff had access to a first aid box and the registered manager had first aid training. There was also clear guidance for staff to follow if a woman suddenly became unwell whilst attending the service. If staff had concerns about a woman's condition during their ultrasound scan, they stopped the scan and telephoned 999 for emergency support. The registered manager provided us with an example in which a woman's health had deteriorated suddenly and how the staff responded effectively. Staff contacted 999 if they suspected an ectopic pregnancy.

The service used the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers (SOR), which was displayed in the scanning room and helped to remind staff to complete the appropriate checks. We observed the sonographer completing the checks during appointments, which included: confirming the woman's identity and consent; providing clear information and instructions, including the potential limitations of the ultrasound scan; following the BMUS safety guidelines; and informing the woman about the scan findings.

The service had latex free covers for the transvaginal probes which minimised the risk of an allergic reaction for women with a latex allergy.

Staffing

The service did not have enough staff to provide the right care.

The service did not have enough staff to provide the right care. On the day of inspection, the registered manager needed to complete personal errands and therefore left the service. As there were no other staff available, a relative of the registered manager covered the reception desk during that period.

The registered manager told us that she was a chaperone for the sonographer. Whilst we were on inspection the service was busy and the registered manager could not complete their interview with us as she was attending to the reception desk. If a woman requested a chaperone, we were not assured that the registered manager would have the capacity to undertake that role in such busy circumstances.

The service had a registered manager and a sonographer who had both been in post since the service had registered with the CQC in 2021. There were 2 directors one of whom was the registered manager.

Inadequate

Diagnostic and screening services

The service did not have an induction policy in place, but the sonographer told us that staff were required to read the policies and procedures and undertake relevant training before starting their role.

The service did not have any vacancies.

The service had low rates of sickness. The sonographer had been off from work on one occasion due to sickness in the last 12 months.

The service did not use bank or agency staff. If the sonographer or registered manager were unwell the appointments would be rearranged, and they would close the service.

Records

Staff kept records of women's care and treatment. Records were stored securely and available to staff who required them.

We reviewed 10 service user records that had been completed by the sonographer between June 2022 and March 2023. The records were accurate, complete, and legible. They had the time, date, signature, and name of the sonographer who had completed the scan. The sonographer had clearly outlined the findings of the scans. Consent was documented on all the records that were completed.

We reviewed 10 consent forms from 2021 to 2023. The consent forms were completed accurately with service users' signatures to confirm they had read and understood the information.

Records were stored securely on the scanning machine which was password protected. The registered manager and the sonographer were the only people with access to the scanning machine.

Incidents

The services incident policy was not tailored for the service. Staff were not always confident in identifying incidents but were clear of the systems regarding how to record and report safety concerns.

The service had an incidents policy. The policy was generic in terms of its content, some of the information did not apply to the regulated activity being completed. The policy stated that 'very minor injuries' such as 'small cuts' and 'non extensive' bruises should not be reported. We felt that this advice was inappropriate and could potentially impact upon staff's understanding to manage safety incidents well.

Staff were not always confident in defining what an incident was in the context of the service which may have impacted on the identification and recording of potential incidents in the past.

Staff had a good knowledge of the processes of recording and escalating an incident.

Staff had reported one incident since the service opened in 2020. Staff had correctly identified an incident which they had logged and completed an incident report for.

Is the service effective?

Inadequate

Diagnostic and screening services

Inspected but not rated

We do not rate effective in diagnostic imaging services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Staff were aware of the policies and how to access them. The policies had not been reviewed and were often not tailored for the service.

The service provided information for women who were booking their scans online, in line with BMUS guidelines. This included that sonographers aimed to minimise ultrasound exposure, that they respected confidentially, that they worked in an ethical and non-discriminatory way and were accredited.

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

The registered manager told us that they kept up to date with best practice and changes to guidance by reading updates sent by the CQC and by speaking with the sonographer regularly.

Staff protected the rights of service users subject to the Mental Health Act and followed the Code of Practice.

Women's outcomes

Staff could not demonstrate that they monitored the effectiveness of care and treatment. They could not demonstrate that they used the findings to make improvements and achieved good outcomes for women.

Outcomes for service users were obtained by reviewing social media comments and through informal feedback. We did not see any evidence of outcomes from service users being recorded or being used to improve the service.

Competent staff

The registered manager did not always make sure staff were competent for their roles. We saw limited evidence of the manager appraising staff's work and performance.

The registered manager told us that staff do not lone work. On the day of the inspection the registered manager left the location for approximately half an hour and a relative was left in charge of the reception. We have not had any evidence that the relative was employed by the service or that they were a volunteer. We did not see any evidence of the persons disclosure and barring service certificate (DBS) or other credentials that would make them suitable to be in that role. We were concerned that the relative would not be covered by the services indemnity insurance and that they would not have the appropriate knowledge of the systems and policies which may have led to safety concerns.

The registered manager told us that they completed annual appraisals with the sonographer. We requested completed appraisals with staff. We did not receive a completed appraisal from 2022 but an appraisal with a prospective date on it for 16 March 2023. We reviewed the appraisal and found it to be limited. The appraisal form had not been provided to the sonographer prior to the meeting and there was no discussion around achievements, performance, or objectives/ goals for the future.

The registered manager told us that they completed quarterly "scan checks" which monitored whether the sonographer was maintaining professional practice and standards. They sent us records of these checks from December 2021, March 2022, and September 2022. These 'scan checks' were not signed by the registered manager or sonographer and so we were not fully assured.

The sonographer completed peer reviews of their scan images with another sonographer who they worked with for the NHS. Three scans were reviewed every two months by the external reviewer. The external sonographer provided high scores for the sonographers reports and image quality. The review was sent to the registered manager.

The registered manager and the sonographer told us that an induction was completed when the sonographer started. This involved the sonographer becoming familiar with the policies and procedures and having a tour of the premises.

Multidisciplinary working

Staff worked well together. They supported each other to provide good care. The service had good working relationships with the local hospitals and a charity for bereaved parents.

We observed staff worked well together. Women and families were greeted as they arrived at the service and supported to fill in the paperwork if it was required.

The sonographer explained that they had good working relationships with other sonographers in the area and sought their support if required.

The registered manager explained that they had regular contact with the early pregnancy unit at the local hospitals and felt they had a good working relationship.

The registered manager had a good relationship with a local charity that supported women who were bereaved. The registered manager and sonographer provided details of this charity to women who needed it.

Seven-day services

Services were available 2 days per week.

The registered manager told us that the service opened 2 days per week, one of which was a weekend day, dependent on service user demand and availability of staff.

Services were cancelled if there was staff sickness.

Health promotion

The service provided women with advice leaflets to lead healthier lives.

Inadequate

Diagnostic and screening services

The service had health promotion information by the Royal College of Obstetricians and Gynaecologists and by the Chief Medical Officer for the UK in the waiting area. Information on smoking, physical activity and alcohol consumption in pregnancy was available. Further information on group B streptococcus (GBS) (a severe infection that can affect foetuses and new-borns) was also accessible.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their scan. They followed national guidance to gain women's consent. However, the registered manager did not provide evidence that they had been trained in the mental capacity act.

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. The service had a Mental Capacity Act policy in place which staff knew how to access. However, the registered manager did not provide us with evidence that they had received training in the Mental Capacity Act.

The registered manager told us that they had not had any instances in which women have been unable to give consent. They were clear that if women lacked in mental capacity that the scan would not be completed.

Women consented to procedures on the website when booking their appointment. Within the terms and conditions there was a section for consent which provided information about the scans performed and the woman's right to cease the scan at any point. In addition to this, women were also asked to sign a paper form and the sonographer got verbal consent prior to the ultrasound scan. This enabled women to make an informed decision on whether to proceed with the scan. We saw evidence of 10 completed consent forms between 2021 and 2023.

Is the service caring?

Good

We rated it as good.

Compassionate care

Staff treated service users with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

Staff treated women and their families with compassion. We reviewed 10 online reviews and observed interactions between the staff and service users which confirmed that staff treated service users with kindness.

We observed staff being discreet with women and their families when they arrived at the service. Staff took time to interact with service users and those close to them in a respectful and considerate way.

During our inspection we observed staff introducing themselves, explaining their roles, providing details of the scan, and welcoming any questions.

Staff followed policy to keep women's care and treatment confidential.

We spoke with 3 service users and 1 family member of a service user who confirmed that staff treated them well and with kindness.

Inadequate

Diagnostic and screening services

Emotional support

Staff provided emotional support to women, families, and carers to minimise their distress.

Staff understood the emotional and social impact that a person's care, treatment, or condition had on their wellbeing and on those close to them. We spoke with a woman who had attended the service and a concern had been detected. She told us that the staff provided her with time, emotional support and signposted her to the early pregnancy unit and to a bereavement charity. She felt that staff cared.

The registered manager told us that they followed up women who they have referred to the hospital to check on their emotional wellbeing.

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

The service did not offer training for breaking bad news, but the sonographer was experienced in their role and provided examples of how she had demonstrated empathy when having difficult conversations in the past.

Understanding and involvement of women and those close to them

Staff supported women, families, and carers to understand the scans offered and make decisions about them.

Staff made sure women and those close to them understood their care and treatment. We observed the sonographer explaining scans with the women and their families who had attended.

The services website had useful information regarding scans and the terms and conditions. However, some of the scans advertised were no longer being offered and some of the wording in the terms and conditions was confusing.

Is the service responsive?

Requires Improvement

We rated it as requires improvement.

Service delivery to meet the needs of local people

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

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

The registered manager planned services based on the availability of the sonographer employed. The service opening times were Friday and Saturday which meant that people who were working throughout the week could make an appointment. The website stated that the service was also open on Sundays, but this was incorrect, this was mentioned to the registered manager, and she said she would update the information.

Inadequate

Diagnostic and screening services

Facilities and premises were appropriate for the services being delivered. The service was on the ground floor, it had disabled access, with a large waiting room and scanning suite.

The premises were in Hoylake on a high street. Parking was difficult due to the side streets nearby being for permit holders only. The service was located close to a local train station. It was convenient for women to travel by public transport from the surrounding areas in Cheshire and Merseyside.

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

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

Meeting people's individual needs

The service did not always consider service users' individual needs and preferences. The provider was not always compliant with the Accessible Information Standards. Staff were trained in equality and diversity training.

The staff were not able to make adaptations for women with protected characteristics prior to the scan as this information was not requested on referral. For example, there was no question of mental health requirements when booking an appointment. The registered manager said that there was a comments section on the booking form and that the service would try to accommodate women's individual needs when they attended for their scan.

The services documentation and the information on the website was not available in different languages. The service did not have access to an independent translation service but said that they would use a popular internet translation service if they needed to.

The service did not have a hearing loop for women with hearing impairments or access to braille or documents with larger text for people with sight problems.

The service did not provide separate sessions for early pregnancy scans and scans later in a woman's pregnancy, this meant that women who may have experienced miscarriage or had anxiety about their early pregnancy scan could share the waiting area with women who were much more advanced in their pregnancy.

The service had an equality and discrimination policy and the sonographer had training in equality and diversity training from the NHS.

Women could buy a range of baby keepsakes after their scan, including heartbeat bears, key rings, and confetti balloon.

Access and flow

Service users could access the service when they needed it and received their scan images promptly.

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

The service did not have a waiting list for appointments. Women were able to access prompt appointments, usually on the same week.

Inadequate

Diagnostic and screening services

The service completed 537 appointments from March 2022 to March 2023.

The service had 9 cancellations between March 2022 and March 2023. Women who cancelled their appointments were given an alternative date and time to attend.

The service offered 3 scans per hour meaning that each woman was allocated 20 minutes for an appointment. Staff we observed did not rush the woman and took their time discussing information.

Payment for scans was taken prior to the appointment, meaning that service users that did not attend (DNA) was low.

Staff supported women if they required transfer to local early pregnancy units.

Learning from complaints and concerns

The service did not clearly outline how women could complain about the service being offered. The service had not received any complaints since they registered with the CQC.

The service had a complaints policy. We requested this policy and found that it was a procedure.

The service did not make it clear to service users how they could complain. The service did not display information about how to raise a concern in service user areas. The website provided contact details for the service but did not have a dedicated section regarding how to make a complaint

The service had not received any complaints since they were registered in 2021.

The registered manager told us that the service was registered with the independent sector complaints adjudication service (ISCAS).

Is the service well-led?

Inadequate

We rated it as inadequate.

Leadership

The registered manager did not always have awareness of the main risks for the service. They were visible and approachable in the service for women and staff.

We interviewed the registered manager offsite. They were not always aware of the main risks that the service faced.

The service had the same registered manager in place since it first registered with the CQC in 2021. The registered manager was fully involved in the day to day running and handling of the service

Staff told us that the registered manager was supportive, visible, and approachable. Throughout the inspection, we saw the registered manager interacting with and supporting staff and women who used the service.

Inadequate

Diagnostic and screening services

Vision and Strategy

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

There was not a clear vision and set of values for the service.

The registered manager told us about aspirations they had to offer more treatment options and potentially more scan clinics in the future, but nothing had been shared with the team and no concrete plans had been made.

Following the inspection, the registered manager sent us a vision and mission statement for the service.

Culture

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

Staff felt respected, supported, and valued in their roles. The sonographer said that the registered manager recognised her clinical expertise and was open to listening to their ideas for the service.

Staff felt proud to work for the service. The sonographer and registered manager had been in post since the service registered with the CQC.

The sonographer felt that they would be able to raise concerns with the registered manager.

Staff's wellbeing was acknowledged on the services risk register. The registered manager identified stress as a potential risk and told us that informal discussions around wellbeing occurred.

The service had an antibullying policy and a blame free culture policy in place that staff could access.

Governance

The registered manager did not always operate effective governance processes. Staff were clear about their roles and accountabilities.

The service did not have a process for monitoring and reviewing policies to ensure that they were up to date and relevant for the regulated activity being completed. We did not see evidence of a process which informed the registered manager whether staff had read the policies or when policies should be reviewed. From 12 policies that we reviewed, 11 did not have a version control, review date or author. The policies did not provide adequate explanations of the processes and were mainly limited in their content. Some of the policies contained information that was not relevant to the service, some of which contradicted service processes.

The registered manager told us that they held monthly staff meetings which were minuted. They told us that the meetings provided an opportunity to discuss service feedback and to review updates regarding regulations. We requested the last 6 months of meeting minutes and received data from April, June, September, November 2022, and January 2023 which suggested that meetings were not taking place monthly. On review, no information regarding updates to regulations or service feedback was mentioned and the meetings did not contain information regarding performance, incidents, or risks. The meeting minutes were not signed by those present and appeared to have been created following the inspection. The registered manager did not have meetings with the other director for the service.

Inadequate

Diagnostic and screening services

The service did not have an effective system which ensured that people working at the service had the relevant employment checks in place to keep service users safe. The service did not adhere to their recruitment policy which clearly outlined what employment checks were to be completed when a person was considered for a role. We found that one person was working for the service without any employment checks, that the sonographers file did not provide proof of professional references, proof of identification or a DBS and that the directors files did not contain DBS checks.

The service did not have an effective system which ensured that staff working for the service had the appropriate competency checks in place to keep service users safe. The sonographer told us that they had not received an appraisal since they had been employed by the service. The registered manager told us that they had. When we requested the sonographers' appraisals, we did not receive them from 2022 but instead we were sent an appraisal that was scheduled following our inspection. The registered manager told us that they completed quarterly 'scan checks' in which they would assess whether the sonographer was completing tasks such as explaining what they would do during the scan and whether they introduced themselves. We requested evidence of these checks which they provided for December 2021, March 2022, and September 2022. The documents appeared to have been created following the date of our inspection.

The registered manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to service user complaints. We were not assured that the registered manager had a good understanding of what constitutes an incident and there had been no complaints to review.

The registered manager did not have an effective system which ensured oversight of the sonographers NHS mandatory training. When we spoke to the registered manager, she was unsure whether the sonographer had completed some of the training required and when we requested data some modules were not included.

The provider had taken out the appropriate insurance for the service which was in date.

Management of risk, issues, and performance

The registered manager did not always identify the risks specific to the service, despite having a risk register. They did not have a documented policy to cope with unexpected events.

We were not assured that the service always followed best practice. BMUS and SOR recommended that a standard operating procedure was required and should be regularly reviewed and updated for the cleaning of ultrasound probes used in intimate examinations. We requested this information from the registered manager, but this was not provided.

The services processes and systems regarding the exclusion criteria were limited. The exclusion criteria did not clearly outline who was inappropriate for a scan. The exclusion criteria did not exclude women who were bleeding heavily or in excessive pain, despite the service being non diagnostic. There was confusion regarding the age at which women could access scans within the service. Some of the other policies confused this further, the consent policy provided information regarding how to obtain consent for children.

The service did have a risk register in place which identified some generic risks such as stress, fire, and a resurgence of COVID-19 cases. The risk register clearly identified the risks, who could potentially be harmed, control measures, the responsible owner and when actions would be completed by. However, the registered manager was unsure what the services main risks were when she was asked. One risk that was mentioned as a priority by the registered manager was not identified on the risk register.

The registered manager said that one of the main risks was the scan machine failing. Despite this, the service did not have a business continuity policy in place on the day that we inspected. It was not listed on the index of policies. We did receive a copy of a business continuity policy as part of our data request which appeared to have been created after the date of inspection.

The registered manager did not always review their performance or collate data to enable to understand how they could make improvements. The service did not have a comprehensive audit schedule in place to review performance or collate data to improve the service. We did not see evidence of audits for hand hygiene, gender inaccuracy, rescans, waiting times or cancellations.

The service did not gather adequate service user information prior to the scan, which meant that there was a potential oversight of potential risks. The service could not be adapted to meet the individual needs of women as this information was not captured.

The registered manager was aware of the requirements for reporting incidents to the CQC using the statutory notification route, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009 but did not have access to the secure portal.

Information Management

Staff could find the data they needed. The information systems were integrated and secure.

Staff could access systems and processes on the scan machine and computers.

There were robust arrangements for the confidentiality of service users' identifiable information. USB's (Universal Serial Bus) were used to transfer data from the scanning machine to the computer to allow transfer of the images. The registered manager told us that once images were uploaded, the USB's content was deleted. The registered manager ensured that when scan images were emailed to women and their loved ones that it was completed as a secure transfer. The computer on the reception desk and the scanning machine which contained confidential information were both password protected.

The sonographer had level 1 training for data security awareness. We did not see evidence of the sonographer or registered manager having training in information governance.

The service had policies on information management including the records retention policy and confidentiality policy.

Engagement

The registered manager actively and openly engaged with staff and women who used the service.

Staff communicated with each other between scans being completed and in staff meetings.

The service received feedback from women and families via social media platforms or in person. There was no option to leave written feedback at the location or on the website.

Women told us that the information they received during their scan was clear and they were able to ask the sonographer questions.

Inadequate

Diagnostic and screening services

The service maintained regular contact with local NHS providers to ensure referral pathways were in place for women who needed them.

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 did not do all that is reasonably practicable to mitigate risks including not routinely offering chaperones before every intimate examination. The service did not always assess the risk of preventing, detecting and controlling the spread of infections. The service did not have wipeable furnishings in some clinical areas.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment The service did not always have systems and processes to effectively prevent abuse of service users. Staff must receive safeguarding training that is relevant, and at a suitable level for their role.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing The staff did not always receive appropriate training to enable them to carry out the duties they are employed to perform.

This section is primarily information for the provider

Enforcement actions

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 did not ensure that care and treatment was provided in a safe way, did not appropriately assess the risks to the health and safety of service users receiving scans and did not ensure that all persons providing care to service users had the appropriate competence, skills and experience to do so.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service did not have effective governance systems or processes to ensure the safe and effective delivery of care. The service did not always assess, monitor, and mitigate the risks to the health, safety, and welfare of service users. The service did not have an effective system in place to ensure that people working at the service had the relevant employment checks in place.