Hey Baby 4D South Yorkshire Limited

Hey Baby 4D Barnsley

Inspection report

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

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	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

We rated this location requires improvement because:

- The service did not have clear training records and managers did not use effective processes to check and record mandatory training compliance.
- Staff did not consistently complete environmental and equipment cleaning records and there were no action plans to demonstrate that managers addressed non compliance found through audit.
- Staff did not complete and update risk assessments for each woman.
- The service did not always operate effective governance processes. We found staff recruitment processes were not always followed, and managers did not check to make sure staff were aware of and understood guidance and key policies.
- Leaders and teams did not always identify relevant risks and issues and identify actions to reduce their impact.

However:

- The service had enough staff to care for women and keep them safe. Staff understood how to protect women from abuse.
- Staff worked well together for the benefit of women, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity and made it easy for people to give feedback.

We rated this service as requires improvement overall. This was because we rated safe and well-led as requires improvement and caring and responsive as good. We do not rate the effective domain in diagnostic and screening services.

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 it as requires improvement. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Hey Baby 4D Barnsley

Hey Baby 4D Barnsley is an independent, non-diagnostic baby scanning studio located near Barnsley town centre and registered with the Care Quality Commission (CQC), since December 2021. It is registered to provide diagnostic and screening regulated activities to adults age 18 to 65.

The service has 2 managers registered with CQC, who also manage 2 other Hey Baby franchise locations.

The service provided 2D, 3D, 4D and trans-vaginal scans, from 6 to 38 weeks gestation. These included early reassurance scans, wellbeing and gender scans, and late reassurance scans. In addition, the service offered non-invasive prenatal testing (NIPT) from 6 weeks gestation. This is a method of determining the baby's sex and risk that the fetus will be born with certain genetic abnormalities, using a sample of the woman's blood.

All scans were completed by fully qualified sonographers.

The service had an ultrasound scan room, a waiting / reception area and a separate quiet room. There was a rest area and a store room.

This was a short notice announced inspection. This meant the provider had limited notice that we were inspecting.

This was the first time we had inspected this service.

How we carried out this inspection

During the inspection visit, the inspection team

- inspected all five key questions and rated four; (''effective'' key question is not rated for diagnostic imaging services)
- looked at the quality of the environment
- spoke with the registered managers
- spoke with 2 receptionists
- spoke with a sonographer
- spoke with services users and their guests
- reviewed 7 service user records
- looked at a range of policies, procedures and other documents relating to the running of the service.

After our inspection visit, we reviewed performance information about the service and information provided to us by the service.

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

Summary of this 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 implement effective systems and processes to ensure all staff are compliant with mandatory training. (Regulation 12(1) (2c)) and Regulation17(1)(2)(a)(b)).
- The provider must ensure all equipment, including and not limited to the transvaginal scan probe, is cleaned and maintained in line with manufacturer's guidance and that this is recorded appropriately. (Regulation 15(1)).
- The service must implement effective systems and processes to mitigate the risk of women under the age of 18 receiving regulated activities. (Regulation 17(1)(2b)).
- The service must ensure care and treatment is provided in a safe way for women, including assessing the risks to the health and safety of service users of receiving the care or treatment and doing all that is reasonably practicable to mitigate any such risks. (Regulation 12 (1)(a)(b)).
- The service must complete risk assessments to safely supply nutritional supplements, including but not limited to baby nutritional supplements, and have an effective process to track, manage the storage and check expiry dates. (Regulation 17(2)(b)).
- The service must assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities. (Regulation 17(2)(a)).

Action the service SHOULD take to improve:

- The service should consider further ways of signposting service users to safeguarding help and advocacy.
- The service should update COVID-19 information on their website, so that it accurately reflects current practices at the location.
- The service should ensure fire evacuation drills resume and are recorded in accordance with policy.
- The service should date and label clinical sharps waste bins in accordance with NHS England guidance.
- The service should keep interview records for all staff in accordance with the provider's policy.
- The service should consider further ways to provide assurance that all staff are compliant with reading the provider's policies and national guidance.
- The service should consider ways to provide assurance that bank sonographer's scan quality is of a constantly high standard.
- The service should consider including GDPR training as a mandatory module for sonographers, in accordance with best practice guidance.

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

Is the service safe?

Requires Improvement

Mandatory training

The service provided mandatory training in key skills to staff. However, they did not make sure everyone completed it.

The provider had a recruitment policy, which identified mandatory training modules for all staff groups. The policy stated registered managers, employed sonographer and the reception staff completed online training endorsed by the Hey Baby franchise. All sonographers employed on a sessional basis (bank) with substantive NHS roles, were required to submit evidence of completed NHS mandatory training.

Sonography and reception staff we spoke with told us they had protected time to complete e-learning and were up to date with all mandatory training. The registered managers recorded staff training compliance on individual staff's electronic training matrices, which were provided after our inspection. However, these did not always state the individual staff member's role. For example, one bank sonographer was shown as 'manager', and 2 documents were headed with the name of another Hey Baby location, although managers we spoke with told us sonographers did not work across different sites.

We also found discrepancies between the modules listed on the individual staff training matrices and those listed by staff role in the provider's recruitment policy. For example, supervision and risk assessment training mandated for registered managers was not shown in the registered managers' training matrices.

The provider's recruitment policy stated General Data Protection Regulation (GDPR) and information governance training was mandated for reception staff and registered managers but not for sonographers. This was not in accordance with best practice, which states anyone that processes personal data within an organisation should receive GDPR training.

Training matrices we reviewed showed both registered managers, 2 reception staff and 2 sonographers had received GDPR or information governance training. However, one reception staff was 'pending' training and 1 sonographer had no training recorded. This meant we were concerned staff may not understand their obligations regarding GDPR.

The policy stated the audit schedule served as a reminder when training was due. However, the matrices showed variable training compliance. For example, no sonographers had completed mandatory mental health crisis training, and 1 sonographer had not completed 7 of 13 mandatory modules, including basic life support, health and safety awareness and equality and diversity training.

This meant there was no clear oversight of mandatory training completion for all staff and limited assurance that all staff received training in accordance with the provider's policy.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had completed training to a level appropriate to their role.

There was an adult and children safeguarding policy and a separate female genital mutilation (FGM) policy. In addition we saw local authority safeguarding teams contact details and the Department of Health FGM safeguarding pathway displayed in the staff rest area. Staff we spoke with knew the procedure to follow if FGM was discovered or disclosed.

We asked staff specific questions about how they would recognise, for example, physical and domestic abuse. They clearly described the warning signs and told us if they considered a child or adult may be in immediate danger they would report to police without delay. Staff we spoke with also gave an example of how they had reported concerns to the local authority safeguarding team. The provider's safeguarding policy stated all safeguarding referrals were recorded in the service's electronic safeguarding log, which we saw on the computer.

The registered managers were the safeguarding leads for the service and had received level 3 training. All staff had completed safeguarding training appropriate to their role in accordance with the provider's recruitment and safeguarding policies.

The service displayed domestic abuse help information on a poster in the unisex toilet. There was a process for people to discreetly seek immediate help, by tearing a coloured tab off the poster and handing it to staff. However, we did not see any other informational posters or leaflets displayed in public areas to signpost service users to safeguarding help.

Cleanliness, infection control and hygiene

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

There was an infection prevention and control policy, which identified the registered managers as leads for overall infection prevention and control.

All equipment and environments we looked at appeared visibly clean. Staff we spoke with told us every appointment slot incorporated time for cleaning equipment after each scan. They explained how they cleaned environmental areas and clinical equipment, for example, the transvaginal ultrasound probe.

Managers monitored cleaning compliance through monthly audits of all areas and the audit schedule we reviewed for 2022/23 indicated cleaning schedule audits were fully completed.

However, there were some apparent gaps in environmental cleaning records for the toilet, kitchen, reception and scan room, and records did not consistently state when the service was closed. For example, cleaning records were incomplete for the scan/quiet room on 8 occasions in April 2023.

This meant although the environment looked visibly clean, the service was unable to demonstrate that all environmental areas were cleaned in accordance with the provider's schedules and to a consistently high standard.

In addition, there were apparent gaps in daily cleaning records for the transvaginal and abdominal probes and records did not consistently state when the service was closed or that the probes were not used. For example, on 8 occasions in March, and 3 occasions in May 2023.

All cleaning records had a section at the bottom for managers to sign and date for monitoring purposes. However, most of the records we saw were not signed or dated by a manager, to show they reviewed completion of the schedules and we did not see action plans to address any non compliance found through audits.

This meant we were not assured all equipment was always cleaned and maintained in line with manufacturer's guidance and that this was recorded appropriately. We were not assured of the effectiveness of cleanliness audits.

The service had staff hand washing facilities and there was sanitising hand gel in the scan room.

We observed sonography staff washing their hands prior to and after scanning women. This concurred with feedback from women who said they saw staff washing or sanitising their hands. There were hand hygiene posters above sinks in the kitchen and toilet to provide a visual guide to effective handwashing. Staff had sufficient supplies of personal protective equipment (PPE). Hand hygiene was a mandatory training module for all staff. The training matrices provided showed all but 2 staff had completed this.

Information about the service's COVID-19 infection prevention and control measures was displayed on the website. This stated women were permitted to bring up to 3 guests and that mask wearing in healthcare was still mandatory. It requested women and their guests to wear a face covering or mask when in attendance at the clinic, unless exempt. However, elsewhere on the website, it stated women could bring 4 guests and staff we spoke with explained wearing a face covering was optional for service users and staff. We observed service users did not wear face coverings during scans. This meant service users may find some information on the website confusing due to inconsistencies.

Cleaning equipment such as cleaning materials and mops were stored appropriately in a lockable store.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment mostly kept people safe. Staff mostly managed waste well.

Access to the premises was via an obscured glass door. The door threshold was slightly raised and hazard tape was in place to warn visitors of this potential trip hazard. Staff at reception had a clear line of sight to the entrance door.

Environmental risk assessments were completed and accessible to all staff.

Access to the scan room, quiet room and restricted areas such as the store room was controlled with key-pad locks. There was a sign to indicate when the scan room was occupied.

The environment was bright and spacious.

Requires Improvement

Diagnostic and screening services

The service had suitable facilities to meet the needs of women's families. For example, there were baby change facilities. All seating was in good order and could be wiped clean. There was a separate quiet room where staff discussed bad news with women in private. There was a wheelchair accessible unisex toilet and the scan room was accessible for people who used a wheelchair.

The service had enough suitable equipment to help them to safely care for women. For example, the scan room was lockable to ensure privacy during scans. The examination couch was height adjustable. There was a large wall mounted monitor to ensure women and their guests could see ultrasound images. There was appropriate additional seating to accommodate up to 4 guests. The room had a comfortable ambient temperature.

All items of portable electrical equipment we checked was tested and date-labelled.

The scan machine was serviced and calibrated within the last year. However, equipment safety check records to be completed by sonographers daily, were incomplete. There were apparent gaps in checks and the records did not state if the service was closed. Checks for the abdominal probe, transvaginal probe, scanning couch and ultrasound scanner were not recorded on 4 occasions in January, 3 occasions in April and 6 occasions in May 2023. This meant we were unclear how the provider was assured clinical equipment was always safe prior to use.

All fire extinguisher appliances inspected were signposted and serviced within an appropriate timescale. Fire exits were clear of obstructions. We saw a fire safety awareness poster displayed in the staff rest area. The service had a fire risk assessment and fire alarms were serviced. We saw records of monthly fire alarm checks completed by the landlord, and emergency lighting was last tested in April 2023. No fire evacuation drills were completed during 2022, which was not in accordance with the provider's policy. However, after our short notice announcement of the inspection, we saw the provider held a team meeting, during which the fire evacuation procedure was discussed with staff that attended the meeting.

There was a kitchen used by staff to make beverages and have meal breaks.

Substances hazardous to health subject to control of substances hazardous to health (COSHH) regulations 2002, were stored in a locked store room. We saw data sheets and risk assessments for most of these substances. However, there was no risk assessment or data sheet for the transvaginal ultrasound probe cleaner. We brought this to the attention of the manager at the time and they provided a written risk assessment after our inspection.

Staff mostly disposed of clinical and domestic waste safely. However, we saw a clinical sharps waste bin that contained phlebotomy waste which was not labelled and dated when assembled. This was not in accordance with Health Technical Memorandum (HTM 07-01) on best practice for waste management.

We saw the service's environmental statement which described their commitment to promoting environmental awareness to employees.

Assessing and responding to patient risk

Staff did not complete and update risk assessments for each woman. Staff knew what to do and acted quickly when there was an emergency.

The provider's website stated the service did not provide scans for women under the age of 18 and that proof of age may be required on arrival. Staff we spoke with explained if a woman declared a satisfactory date of birth but appeared

younger than 18, they always asked for photo identification as proof of age at booking. However, although the consent form prompted women to declare date of birth, there was nowhere on the form for staff to evidence additional photo identification checks. Sonography staff clarified prior to scanning, they asked women to confirm date of birth but did not ask for documented proof of age.

This meant the service was unable to evidence how they were assured additional checks were completed and there was a risk women under the age of 18, may receive regulated activities at the service.

Staff did not always complete and record risk assessments for each woman on arrival and relied on women disclosing any health and pregnancy risks in a free text box for optional comments, on the electronic booking form. For example, although we saw booking and paper consent forms captured information about allergies, expected due date and NHS maternity provider, there were no prompts for disclosure of high risk factors such as history of miscarriages, ectopic pregnancies, multiple births, bleeding and pain.

We saw risk assessment prompts in the early pregnancy assessment rescan guidance for sonographers and if the woman answered 'yes' to any of these, they made an onward referral to an early pregnancy unit (EPU). However, we were not assured sonographers consistently asked the same questions, and staff we spoke with confirmed women's responses were not documented. The protocols for VIP 4D scan, wellbeing and gender scan, late reassurance scan, wellbeing and 4D baby scans did not include any risk assessment prompts.

In addition, we found liquid vitamin D supplements for babies, contained in free gift bags which were given to women who had later pregnancy scans. However, the service did not complete risk assessments to safely supply nutritional supplements, and did not have an effective process to track, manage the storage and check expiry dates.

This meant there was limited assurance that all risks to the health and safety of women and babies were suitably and sufficiently assessed and staff did all that was reasonably practicable to mitigate any such risks.

The service strongly recommended women attend all NHS antenatal appointments and staff shared key information to keep women safe when handing over their care to others. For example, when making an onward referral to an EPU, sonographers sent a printed report of what they saw on the scan and images to the recipient service and women also received a copy. All referrals to EPU were recorded and monitored by the registered managers.

Sonography staff we spoke with confirmed they followed 'as low as reasonably achievable' (ALARA) recommendations for length of scans and frequency of ultrasound sound waves. This was described in the service's health and safety policy and protocols we saw for all types of scan provided clearly stated scan times of under 20 minutes. The provider's website stated the scanning machine was set in accordance with ALARA recommendations.

There was a health and safety/cardiopulmonary resuscitation (CPR) policy. Staff we spoke with knew how to respond promptly to any sudden deterioration in a women's health. The registered managers were named on a health and safety poster as the service's health and safety contacts and had completed first aid training. A first aid box was kept at reception and we saw all items were within expiry dates.

Staffing

The service had enough staff with the right qualifications, skills, and experience to keep women safe from avoidable harm and to provide the right care.

Requires Improvement

Diagnostic and screening services

The service employed 1 full time substantive sonographer and 2 bank sonographers, who had substantive NHS roles. All held up to date registration with their professional body.

The managers planned staffing rotas in advance and a manager was usually on site or contactable by telephone when the clinic was open. Staff were flexible to cover any staff absences.

There was a lone working policy in place which described current arrangements to keep staff and people using the service safe.

The service had no vacant posts.

Records

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

The service had a data protection policy which described management, privacy, retention period, storage, and disposal of women's personal data in line with national guidance.

Scan images were held digitally on the scan machine and accessed via electronic password. They were archived to an electronic back up system, retained for 12 months and then erased.

Hard copy images were printed while women waited and sent electronically via an encrypted system.

Paper documents were stored securely in a lockable cabinet and archived documents were stored securely for 8 years.

Paper and electronic records were easily accessible to staff.

We saw a records audit tool for staff to audit 10% of customer records each month. However, the manager explained the audits had not started.

Incidents

The service managed safety incidents well. Staff knew how to report incidents and near misses.

There was an emergency and significant events policy in place. In addition, we saw a poster which described the provider's incident reporting process, with examples of what should be reported to the Health and Safety Executive (HSE).

Staff we spoke with knew what incidents to report and how to report them. However, they confirmed there had been no reportable incidents since the business opened and there were no entries in the accident book.

The managers demonstrated clear knowledge of reporting and investigating incidents and gave examples of incidents would report to the franchisor and to CQC.

Staff understood the duty of candour.

Requires Improvement

Diagnostic and screening services

The service subscribed to the Central Alerting System (CAS), a web-based cascading system for issuing patient safety alerts, important public health messages and other safety critical information. The registered manager told us how they reviewed alerts.

Is the service effective?

Inspected but not rated

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. Managers did not always check to make sure staff were aware of and followed guidance.

Policies were reviewed by the franchisor and update information such as changes in professional guidance was cascaded via Hey Baby success forum meeting minutes and emails.

An electronic policy review schedule was maintained for management oversight. Policies we looked at were in date and signed by the registered manager as local policy owner.

Registered managers told us they made staff aware of significant changes in policies, legislation and best practice, via email at the earliest opportunity. This was in accordance with the provider's communications policy. Managers explained staff were also required to sign a document, in their personnel files, to confirm they had read and understood all policies and national guidance. However, 4 of 10 personnel files we looked at did not contain a signed policies document.

This meant we were unclear how the provider was assured staff were always aware of significant changes in legislation and key policies.

The service subscribed to the British Medical Ultrasound Society (BMUS) as low as reasonably achievable (ALARA) protocols by using the lowest possible output power and shortest scan times possible consistent with achieving the required results.

The latest Society of Radiographers (SoR) guidance clearly defined the minimum expected competencies for diagnostic and non-diagnostic (souvenir) scans. The service sometimes offered and gained written consent for transvaginal early scans, which ordinarily, would be conducted in diagnostic services. However, when we asked about this, the registered manager and staff we spoke with explained these scans were non-diagnostic and used to enable a 'better view' of the foetus.

All reports, including transvaginal scan reports we saw carried a written disclaimer which stated it was not a diagnostic facility and the scan should not be considered a replacement of NHS scan. Sonography staff we spoke with confirmed they did not diagnose, but simply recorded what they saw and where required, made onward referral to an EPU.

We also noted sonographers sometimes used doppler, for gestational age of 16 weeks and above, to obtain an audio sound of the baby's heartbeat. Best practice SoR guidance stated ''doppler should only be used with clinical justification in line with national clinical and safety guidance, if within the practitioner's scope of practice". The same

guidance stated doppler was not recommended for non diagnostic scans at any gestational age. However, we saw evidence the franchise directors had sought clarification from the ultrasound lead at the SoR. The outcome was a change to the provider's health and safety policy, which meant pulsed wave doppler would not be used under 16 weeks gestation.

Although the service offered some scans and modalities, defined as out of scope of a keepsake scan service, we were assured this did not impact on women's safety because they were conducted for non-diagnostic purposes, by qualified sonographers who practised within the scope of their professional competency.

Patient outcomes

The manager collected audit data of performance metrics and always use these results to understand performance, make decisions and improvements.

The manager had overall responsibility for measuring the quality and safety of the service and monitoring trends in performance.

For example, numbers of rescans and referrals made to the EPUs were audited and recorded to show reason for referral. We saw how the service used this information and feedback they sought from a local NHS maternity hospital to change how early scans were managed.

The manager completed a clinical governance form monthly with collated audit results, for review with the franchise director. However, managers were unsure how their service's safety performance compared with others in the franchise.

Competent staff

The service made sure staff were competent for their roles. However, recruitment procedures were not always followed. The manager appraised staff's work performance to provide support and development.

All sonography staff were registered with a professional body, and were experienced practitioners. All were up to date with revalidation.

Job description for all roles were accessible to all staff.

However, we looked at 9 personnel files for substantive and bank staff and 1 recent leaver, and found recruitment records were not maintained in accordance with the provider's recruitment policy. For example, 2 contained contracts that were not signed and dated by the employer and employee, and 4 (including a sonographer and a reception staff member who had recently left) had no interview records. This meant we were not assured the provider's recruitment processes were always followed for all staff.

All staff personnel files we saw contained an employee on-boarding form with a check list to record their induction, which included use of IT, policies file and familiarisation with equipment.

The provider's clinical governance and communications policies stated the managers provided monthly supervision sessions to formally review all staff performance. However, we did not see records of monthly meetings in the personnel files we looked at. Managers clarified meetings were arranged ''as required''. Managers used an appraisal template to record annual performance reviews for substantive staff and bank sonographers.

Requires Improvement

Diagnostic and screening services

We requested evidence of peer reviews of sonographer's scan quality. However, those provided were all for the same sonographer. We saw evidence that staff were supported to improve practice through constructive feedback comments from the franchise clinical lead and staff were provided with opportunities to shadow other colleagues within the franchise, to enhance their learning.

Multidisciplinary working

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

Staff spoke positively of team working, effective communication and peer support.

The service had established relationships with the early pregnancy services and local NHS trusts.

Seven-day services

Services were available to support timely and flexible care.

The service was open 6 days a week including until early evening on 3 days a week.

The website was designed to take online bookings 24 hours a day.

Health promotion

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

The social media page promoted healthy lifestyles.

We observed health information displayed in the toilet area. For example, posters that promoted healthy diet during pregnancy.

In addition, we saw information about the importance of keeping hydrated and there was drinking water available upon request.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Staff gained consent from women for their care and treatment in line with legislation and guidance. They made sure women consented to ultrasound scans based on information provided to them at the time of booking.

The website booking system clearly stated the provider was only able to perform scans to persons over the age of 18.

Women completed an electronic consent form before their appointment and provided consent to share scan results for onward referrals or use scan images in Hey Baby promotional material. Women completed an additional consent form prior to a transvaginal scan.

Requires Improvement

Diagnostic and screening services

We saw information on the provider's website which signposted women to help and advocacy when they were experiencing mental ill health.

Is the service caring?

Good

Compassionate care

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

Staff we spoke with explained how they followed policy to keep patient care and scans confidential.

Women we spoke with told us staff treated them with compassion and kindness and respected their privacy and dignity. Sensitive topics of discussion took place in the scan room, which had a privacy screen and lockable door.

We observed staff were discreet and responsive when caring for women and took time to interact with them and those close to them in a respectful and considerate way.

Women we spoke with described staff as "lovely ladies at the front desk; really friendly and reassuring.'' They said they "felt very welcomed; it was a lovely experience.''

This concurred with feedback we reviewed on the website and social media, which showed consistently high levels of satisfaction.

Emotional support

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

Staff gave women and those close to them help, emotional support and advice when they needed it.

Staff we spoke were experienced in breaking bad news to women in an empathic way. There was a dedicated quiet room available for woman who received bad news and was used whilst staff made the relevant onward referrals for medical care. Staff ensured women did not leave the clinic without fully understanding where they would receive help and support.

There was a poster with contact details to help women who may be suffering with depression and anxiety. Information on the provider's website signposted women to local and national bereavement services and first steps services for depression and anxiety.

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.

Requires Improvement

Diagnostic and screening services

Staff made sure women and those close to them understood their care and procedures and provided clear information about scan options and costs on the website.

The service provided opportunities for woman to choose who they wanted in the scan room and whether they wanted to be told the gender of their baby. We observed sonographers made it a special experience when revealing a baby's gender by using pink or blue lighting in the scan room. We saw how the sonographer engaged with women's children during scans and explained some of the features seen on the monitor screen in a way they could understand.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. For example, via telephone calls, email and comments on social media platforms.

All the women and their guests we spoke with gave positive feedback about the service and told us they were very satisfied and would recommend this service to others.

Is the service responsive?

Good

Service delivery to meet the needs of local people

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

Facilities and premises were appropriate for the services being delivered. There was a service level agreement in place with a pathology provider, to process blood samples for the NIPT service. A sonographer / midwife was employed on a sessional basis, when phlebotomy services were required.

The service was located near Barnsley town centre and there was ample car parking nearby.

The opening times were as flexible as possible to meet the needs of women's working patterns and hours.

Staff ensured that women who did not attend appointments were contacted to understand why they didn't come and offered the opportunity to rebook.

Meeting people's individual needs

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

Women were able to book appointments at a time convenient for them, up to an hour in advance. They were encouraged to declare any reasonable adjustments they needed to attend the scan at the booking stage. This could also be done on the telephone or on arrival at the clinic.

The clinic reception, toilet area and scan room were accessible for wheelchair users and pushchair access.

Requires Improvement

Diagnostic and screening services

Women could request a trained chaperone at any time, to attend their appointment and a poster was displayed to raise awareness of this service.

The service had a comprehensive equality and diversity policy which promoted a supportive and inclusive culture. We saw a poster prompting service users to let staff know their preferred personal pronouns, so their experience could be personalised.

In addition, we saw a poster on the scan room door which promoted awareness of the needs of autistic people, and prompted service users to inform staff of any sensory sensitivities, during the scan procedure.

There was a button on the provider's website to enable translation of the information into several different languages. Staff we spoke with told us they used a telephone application if translation services were required on site.

The service offered women a range of baby keepsake and gender reveal merchandise.

The service signposted women to a number of specialist pregnancy and miscarriage charities and online pregnancy support groups.

Access and flow

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

Women booked scan appointments online or by phone. On arrival, women who had not completed a consent form online completed a paper form.

Staff reported they had enough time to complete referrals and it was easy to contact local EPUs. GPs or hospitals.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

The service had a complaints policy and a display poster which described the complaints process. Women could raise complaints in person, in writing, by telephone, social media and email. The service subscribed to an external arbitration service, to assist in the event that complaints could not be resolved locally.

Staff understood the complaint policy and knew how to respond, resolve, and escalate complaints.

The service audited complaints. It received 3 complaints in 2022 and 1 in 2023. We found the registered manager responded appropriately and the complainants were satisfied with the outcome.

Requires Improvement

Diagnostic and screening services

Is the service well-led?

Requires Improvement

Leadership

Leaders had the skills and abilities to run the service. However, although they understood the priorities and issues the service faced, they did not always manage them effectively. They were visible and approachable in the service for women and staff.

The provider met the Fit and Proper Persons Requirement (FPPR) (Regulation 5 of the Health and Social Care Act (Regulated Activities) Regulations 2014). This regulation ensures that directors are fit and proper to carry out this important role.

The registered managers held overall responsibility for the leadership of the service with support from the franchise directors. However, although they understood the priorities and issues the service faced, we found managers did not always ensure they followed the provider's policies. For example, by ensuring staff recruitment records were robust, ensuring action plans were in place for non compliances identified through audit and ensuring effective communication with all staff regarding clinical governance.

Managers ensured they were always contactable in the event they were at another of the locations they managed.

Staff we spoke with told us they felt confident to discuss any concerns with the manager.

Vision and Strategy

The service had a vision for what it wanted to achieve although there was no formalised strategy to turn it into action.

The service displayed the Hey Baby franchise values of being fair, family orientated, fun and friendly, on their website. We reviewed the franchise fundamental standards which outlined the different ways the service cared for woman and visitors and their related policies.

The registered managers had a formal vision for the service which was displayed in reception. For example, by 2024 their aim was to be the clinic of choice for expectant parents in the area. Managers we spoke with told us about their plans to turn their vision into reality although they had not developed a formal strategy.

Culture

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

Staff spoke positively about their roles and demonstrated pride and passion. They worked well as a team and supported each other to deliver high quality care.

The website and social media displayed a strong emphasis of care for women.

The service had a whistle blowing policy which encouraged staff to raise any concerns confidentially with the manager.

There were clear processes for investigation and learning from concerns, as well as support for staff raising them.

Staff told us they enjoyed their work, felt appreciated and valued. They described a positive working environment and supportive relationships with colleagues.

Women we spoke with told us they felt confident and comfortable to raise any concerns with staff.

Governance

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

The registered managers had overall responsibility for clinical governance. The policy stated they attended monthly service review meetings with the franchise directors to discuss audit results and performance. We did not see minutes of these meetings although we saw correspondence between the franchise director and the registered managers, concerning recent changes to policy.

Governance processes were not always effective. For example, we saw monthly staff bulletins, containing information such as feedback from service users, rescans and referrals, policy updates, health and safety updates and training reminders. Staff were required to sign and date these when they had read the bulletins. However, only 2 staff had signed and dated 2 of 10 bulletins we looked at. Records to demonstrate all staff had read and understood all policies were also incomplete or missing. This meant we were unclear how the provider was assured all staff were aware of important updates and communication to staff was effective.

In addition, there was a lack of interview records within some staff personnel files, staff training matrices were not kept up to date and there were no action plans in place to address non- compliance with completion of cleaning records.

We did not see evidence of regular scan quality reviews for bank sonographers in the 6 month's data provided, up to the date of our inspection. However, an appraisal completed for a bank sonographer in December 2022 indicated 'excellent' scanning proficiency. This meant we were unclear how the provider was assured all sonographer's scans were of a consistently high quality.

Management of risk, issues and performance

Leaders and teams did not always identify relevant risks and issues and identify actions to reduce their impact. They had plans to cope with unexpected events.

The service had valid insurance covering both public and employer liability.

The service had a business continuity policy which outlined procedures for staff to follow in the event of equipment failure, building closure or short notice staff absence. Staff had access to a list of emergency numbers for the building, equipment, and franchise directors.

We saw evidence of environmental risk assessments and risk assessment for use of products subject to COSHH (2002) regulations.

However, we identified further risks from the inspection such as the distribution of the nutritional supplements without any risk assessments, potential risk of women under the age of 18 receiving regulated activities and risks associated with incomplete mandatory training records. The service did not use a risk register to track and monitor known risks and record associated actions taken to mitigate them.

The registered manager explained that should the scan machine fail, there was an agreement in place to receive a call out within 48 hours. The equipment was purchased when the service opened, was still under warranty and serviced annually.

Information Management

Staff could find the data they needed, in easily accessible formats. The information systems were secure. Data or notifications were consistently submitted to external organisations as required.

The service had a data protection policy, which referred to requirements under GDPR 2018 legislation.

We observed closed circuit television (CCTV) was operational continuously in public areas and there was a poster informing of the use of recording equipment.

Staff effectively managed and shared women's personal data in a safe and secure way during onward referrals to the early pregnancy units (EPUs). The provider was registered with the information commissioner's office (ICO).

Information about how the provider stored and used women's personal data was available on the website. This explained data would be shared with local authorities and NHS if any medical referrals or safeguarding concerns were identified.

Information technology systems had security measures in place such as password protection, to ensure confidentiality and compliance with information governance requirements.

Staff were able to effectively retrieve previous scan information for women returning for additional scans.

Digital images from the scan machine were downloaded to allow printing of images. Images held on the scanner were downloaded to a secure back up system where they were stored for 12 months before being erased. Paper records were stored in a locked cabinet prior to archive and secure storage for 8 years.

Information on the website was clear about the services provided and about costs. In addition, there was information on display at the service regarding costs of scan packages and gift items.

The registered managers were clear about how to submit statutory notifications to CQC and what was reportable.

Staff reported sufficient numbers of computers, printers, and a reliable ultrasound machine in the service

Engagement

The registered manager actively and openly engaged with staff and service users to plan and manage services. They collaborated with partner organisations to help improve services for women.

The service engaged well with women, staff, NHS and charitable organisations to plan and manage services. For example, to assist those suffering from loss during and after pregnancy.

Requires Improvement

Diagnostic and screening services

The service's website provided a wide range of information about the services offered and booking process.

The registered managers were visible, which provided women and visitors with opportunity to express their views and opinions face to face.

Staff we spoke with told us their managers engaged with them, were very supportive and visible. They said they were encouraged to voice their opinions and speak up if they had any concerns and felt appreciated by their colleagues.

The registered managers encouraged staff from this and the other locations they managed to share service improvement ideas. For example, managers implemented a poster explaining that coloured lighting used for gender reveal may cause sensory overwhelm to anyone with a sensory processing disorder or autism.

The provider engaged with service users through the service's web site and social media accounts, to promote its services. The provider monitored feedback from women and their families via feedback forms and social media comments.

The service worked to develop partnerships with local businesses and sponsored a local women's football team in order to support their local community and promote their own services for local women.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Staff we spoke with explained they were keen to improve services where required and were receptive to opportunities to do this.

The provider described plans to work with local businesses to develop the service as an information hub for mothers and babies.

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 15 HSCA (RA) Regulations 2014 Premises and equipment The provider did not ensure all equipment, including and not limited to the transvaginal scan probe, is cleaned and maintained in line with manufacturer's guidance and that this is recorded appropriately.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service did not implement effective systems and processes to mitigate the risk of women under the age of 18 receiving regulated activities. The service did not complete risk assessments to safely supply nutritional supplements, including but not limited to baby nutritional supplements, and have an effective process to track, manage the storage and check expiry dates. The service did not assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service did not ensure they implemented effective systems and processes to ensure all staff are compliant with mandatory training.

This section is primarily information for the provider

Requirement notices

The service did not ensure care and treatment is provided in a safe way for women, including assessing the risks to the health and safety of service users of receiving the care or treatment and doing all that is reasonably practicable to mitigate any such risks.