Hey Baby 4D Yorkshire West Ltd

Hey Baby 4D Halifax

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.
- The service did not demonstrate all staff had completed safeguarding training to a level appropriate to their role and in accordance with intercollegiate guidance.
- Substances hazardous to health subject to control of substances hazardous to health (COSHH) regulations 2002 were not always stored in accordance with the provider's infection prevention and control policy.
- Staff did not complete and update risk assessments for each woman.
- Although the manager collected audit data of performance metrics, the service did not always record findings and action plans and use these results to understand performance, make decisions and make improvements.
- The service did not always make sure staff were competent for their roles. For example, there were no completed induction and appraisal records.
- The service did not operate effective governance processes. For example, staff recruitment processes were not always followed, audit activities were not always documented and managers did not check to make sure staff followed guidance.

However:

- The service had enough staff to care for women and keep them safe.
- The service controlled infection risk well.
- 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.

Summary of findings

Our judgements about each of the main services

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

Summary of findings

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Summary of this inspection

Background to Hey Baby 4D Halifax

Hey Baby 4D Halifax is an independent, non-diagnostic baby scanning studio located just outside Halifax town centre and registered with CQC in 2021. It is registered to provide diagnostic and screening regulated activities to adults age 18 to 65.

The service has a manager registered with CQC.

The service provided 2D, 3D and 4D and transvaginal scans, from 6 to 38 weeks gestation. These included early viability scans, dating scans, reassurance scans, growth, wellbeing and presentation scans. All scans were completed by fully qualified and registered sonographers.

The service had one ultrasound scan room, a waiting / reception area and a separate quiet room which was also used as a staff rest area.

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

The service had no service users on the day of inspection. 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 manager

• spoke with one receptionist / scan assistant

• reviewed 31 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 spoke with a sonographer and 3 women who used the service. We also reviewed performance information about the service and information provided to us by the service

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

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, including but not limited to, safeguarding vulnerable adults and children, to a level appropriate for their role. (Regulation 12(1) (2c)) and Regulation17(1)(2)(a)(b)).
- The service must implement systems and processes, including but not limited to appraisals and supervision to ensure staff are suitably qualified, competent, skilled and experienced. (Regulation 12(1) (2c) and Regulation 17(1)(2)(d)).
- 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 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 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 ensure it provides up to date versions of information, including, but not limited to, local authority safeguarding policies.
- The service should record all safeguarding referrals in the safeguarding log, in accordance with local policy.
- The service should consider further ways of signposting service users to safeguarding help and advocacy.
- The service should ensure fire alarm checks resume and are recorded in accordance with policy.
- The service should complete a health and safety risk assessment for safe storage of all cleaning equipment, including but not limited to substances hazardous to health, and mops and buckets.
- The service should consider further ways to ensure all staff are aware of recent national guidance and evidence-based practice, to ensure staff always operate within the scope of the regulated activities provided by the service.

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 the registered manager and the reception staff completed online training endorsed by the Hey Baby franchise and all sonographers with substantive NHS roles, were required to submit evidence of completed NHS mandatory training.

The audit schedule showed staff training records were last audited in September 2022. However, we found discrepancies between the modules listed on the audit schedule and those listed by staff role in the provider's recruitment policy. For example, the audit schedule identified fire safety, hand hygiene, clinical cleanliness, safeguarding and mental capacity, but not equality and diversity, health and safety, basic life support, information governance and mental health crisis management training.

After our inspection, we received an updated electronic training matrix which listed all staff and all mandatory training modules, as shown in the policy. However, there were some apparent gaps in staff completion.

For example, one staff member was overdue all but one module. Of seven named sonography staff, one had no mandatory training recorded, six had no first aid training recorded, and none had general data protection regulation (GDPR) training, basic life support, and mental health crisis management training recorded.

This meant there was no clear oversight of mandatory training completion for all staff and no 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. However, not all staff had completed training to a level appropriate to their role.

Requires Improvement

Diagnostic and screening services

There was an adult and children safeguarding policy which included the contact details of local authority safeguarding teams. In addition, there was a copy of a local authority joint multiagency safeguarding adults policy and procedures summary, which described local arrangements. However, this was dated April 2018 and a revised version was published in June 2021. This meant staff may not always refer to the most up to date local authority safeguarding information.

There was a separate female genital mutilation (FGM) policy. 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 child abuse. They clearly described the warning signs and told us if they considered a child 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 out of hours. The provider's safeguarding policy stated all safeguarding referrals were recorded in the service's safeguarding log. However, staff confirmed there were no entries in the log.

Mandatory safeguarding training requirements for staff groups were described in the provider's recruitment policy. It stated, the registered manager in their capacity as safeguarding lead, and all sonographers must receive level 3 training. However, the registered manager was trained to level 2 and of the seven sonographers, one had no safeguarding training recorded and one had completed level 2 training only. This meant we were not assured all staff received safeguarding vulnerable adults and children training, to a level appropriate for their role and in accordance with Intercollegiate guidance.

The service displayed safeguarding 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. We saw the poster was dated May 2021 and a tab was removed. However, staff we spoke with did not know who had removed the tab and when. We did not see any other informational posters or leaflets displayed in public areas to signpost service users to safeguarding help and advocacy.

Cleanliness, infection control and hygiene

Staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.

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

All equipment and environments we inspected were visibly clean. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly.

The 2022 monthly audit schedule we reviewed was colour coded green or ticked to confirm staff had checked compliance with cleaning of the transvaginal probe and cleanliness of the scan room, reception, kitchen and toilet. However, there were no audit records for 2023 and we did not see any previously completed audit tools or action plans. This meant we could not be assured how effective cleanliness audits were. When we asked about this, the registered manager explained they conducted visual checks and actioned any non-compliance immediately. They confirmed the audit schedule was under review and audit activities would resume soon.

Staff we spoke with told us every appointment slot incorporated time for cleaning equipment after each scan. Staff we spoke told us how they used correct cleaning agents to specific pieces of equipment, for example, the transvaginal ultrasound probe.

The service had hand washing facilities and sanitising hand gel in the scan room for sonographers to decontaminate their hands. There were hand hygiene posters above every sink to provide a visual guide to effective handwashing. Staff had sufficient supplies of personal protective equipment (PPE).

Information about the service's COVID-19 infection prevention and control measures was clearly displayed on the website and wearing of a face covering was optional for service users and staff.

Environment and equipment

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

Access to the premises was via a buzzer entry system and staff at reception had a clear line of sight to the entrance door. Access to the scan room, quiet room and restricted areas such as staff kitchen, was controlled with key-pad locks. The environment was bright and spacious.

The service had suitable facilities to meet the needs of women's families. For example, there were child friendly posters in the waiting area and 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. The scan room was not accessible for people who used a wheelchair, although this was stated on the provider's website and in the provider's statement of purpose.

The service had enough suitable equipment to help them to safely care for women. For example, the scan room was lockable and had a movable fabric screen 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 five guests. The room had a comfortable ambient temperature.

Staff carried out daily safety checks of specialist equipment. For example, we saw completed daily checks of the scanner. We saw the machine had been serviced and calibrated within the last year.

All fire extinguisher appliances were signposted and serviced within an appropriate timescale. An appliance mounting bracket next to the kitchen door was coming loose from the wall and we brought this to the attention of the manager, as we were concerned about potential risk of injury. Fire exits were clear of obstructions. The service had a fire risk assessment and fire alarms were serviced. We saw fire alarm checks, and power outage tests recorded diligently for 2022 but there were no records for 2023. The last annual fire evacuation drill was completed in July 2022.

There was a kitchen used by staff to make beverages. However, the kitchen was also used to store several colour coded cleaning mops and buckets. In addition, substances hazardous to health subject to control of substances hazardous to health (COSHH) regulations 2002 were found in an unlocked kitchen cupboard. This was not in accordance with the provider's infection prevention and control policy which stated cleaning equipment such as cleaning materials and mops should be stored in a lockable cupboard or other enclosure.

We saw data sheets and risk assessments for most of the cleaning substances. However, there was no risk assessment or data sheet for the transvaginal probe cleaner. We brought this to the attention of the manager at the time and were told they would ensure the data sheet and risk assessment were added.

Staff disposed of clinical and domestic waste safely.

Requires Improvement

Diagnostic and screening services

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 told us they asked women to provide photo identification as proof of age at booking. However, although the consent form prompted women to enter their date of birth and declaration of age at time of scan, there was no record of photo identification checks, and some women had recorded the baby's estimated gestational age instead of their own age or date of birth. This meant some records did not indicate whether the woman was 18 or above. Sonography staff clarified they did not ask for proof of age as this was the remit of reception staff.

This meant 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 (marked 'comments optional') 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 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.

This meant there was limited assurance that all risks to the health and safety of women 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 typed 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 manager.

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. Laminated protocols for all types of scan provided clearly stated scan times of under 20 minutes and 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 manager 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. However, recruitment and inductions procedures were not always followed.

Requires Improvement

Diagnostic and screening services

The service did not use the staff recruitment matrix, referenced in the provider's recruitment policy. The manager explained they maintained oversight through review of the internal audit schedule. However, this showed the last staff records audit was completed in March 2022.

All seven sonographers had substantive NHS roles and held up to date registration with their professional body. However, we looked at four personnel files and found recruitment records were not maintained in accordance with the provider's recruitment policy. For example, none contained application and interview records, two did not contain sufficient references and none contained induction records.

A recently appointed non-clinical staff member had worked three shifts. However, they had no references and no interview notes on file. We saw evidence of a new disclosure and barring service (DBS) application and a previous employer's certificate on file. However, the provider's policy stated DBS was portable only if the candidate had signed up to the DBS update service. This new employee had not done so.

This meant we were not assured the provider's recruitment and induction processes had been followed for all staff.

Following the inspection, the registered manager sent us a blank template implemented by the franchise, to audit staff induction which showed a checklist for employee records, policies, procedures and training.

The manager planned staffing rotas two months in advance and staff were flexible to cover any staff absences.

There was a lone working policy in place which described current arrangements in place 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 behind reception and archived documents were stored in a locked basement room.

Paper and electronic records were easily accessible to staff.

Incidents

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

Requires Improvement

Diagnostic and screening services

There was an emergency and significant events policy in place which described the provider's incident reporting process.

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 manager demonstrated a 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.

Is the service effective?

Inspected but not rated

Evidence-based care and treatment

The service provided care and procedures mostly 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 was cascaded via Hey Baby success forum meeting minutes. All policies we looked at were in date and signed by the registered manager as local policy owner.

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.

According to the provider's communications policy, the registered manager made staff aware of significant changes in policies, legislation and best practice, via email at the earliest opportunity. Staff were also required to sign a document, kept in their files to confirm they had read and understood all policies and national guidance. However, we saw these were not always kept up to date and staff we spoke with were unaware of the latest Society of Radiographers (SoR) guidance 'competencies for ultrasound practice in private baby scan clinics' published in October 2022.

This meant we had concerns staff may not always be aware of significant changes in legislation, guidance and evidence based practice.

The latest SoR competencies guidance clearly stated CQC's definition of a souvenir scan (non-diagnostic) as *''use of ultrasound to record sound, pictures or videos of your baby to keep as a memento. Souvenir scans are not for diagnosing problems with you or your baby.''* It defined diagnostic scans as *''use of ultrasound to check the health of you and your baby …so you know your pregnancy is progressing as planned.''*

The provider was registered with CQC as a non-diagnostic service. However, the service offered 'wellbeing' packages and sometimes offered and gained written consent for transvaginal early scans, which ordinarily, would be conducted in diagnostic services. When we asked about this, the registered manager explained these scans were for non-diagnostic purposes; used to enable a 'better view' of the baby and to 'assess women's wellbeing'. 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.

Requires Improvement

Diagnostic and screening services

We looked at six wellbeing reports completed by sonographers and found they contained information such as the baby's growth against an expected fetal growth chart, position of placenta, depth of fluid surrounding the baby and whether any obvious abnormalities were detected. One report indicated presence of a fibroid. However, the report did not indicate whether this was acted upon and referred back to the woman's GP. All reports, including transvaginal scan reports we looked at carried a written disclaimer which stated it was not a diagnostic ultrasound facility and the examination should not be considered as a replacement of the NHS fetal anomaly (20 week) scan, dating scan or and NHS growth scan.

The latest SoR guidance also clearly defined the minimum expected competencies for diagnostic and non-diagnostic (souvenir) scans. We noted sonographers sometimes used doppler, (a diagnostic competency) and staff we spoke with explained the purpose was to 'enhance imaging'. We noted the SoR 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 proposed change to the provider's policy; pulsed wave doppler would not be used under 12 weeks gestation and it was agreed the health and safety policy would be updated and shared with the group in due course. This was communicated to franchise managers via the Hey Baby success forum minutes in February 2023.

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

Patient outcomes

The manager collected audit data of performance metrics but did not 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 referrals made to the EPUs were recorded to show reason for referral. Staff sometimes made follow up calls to women to assess the accuracy of the referrals. However, they explained calls were not always answered and calls were not made if the staff thought it may cause distress or the woman had not provided consent, so outcomes were not always known.

The manager completed a clinical governance form with collated audit results, for review with the franchise directors at least monthly. However, we did not see evidence of audits completed after December 2022 and the registered manager was unsure how safety performance compared with others in the franchise. Although we saw audits shown as complete by use of a green box or a tick on the 2022 schedule, we did not see any completed audit tools to evidence outcomes, or action plans.

This meant we could not be assured how effective the audits were and remained unclear how the service used audit results to understand performance, make decisions and improvements.

Competent staff

The service did not make sure staff were competent for their roles. The manager did not appraise staff's work performance or hold formal supervision meetings with them to provide support and development.

Requires Improvement

Diagnostic and screening services

All sonography staff were registered with a professional body, held substantive posts in the NHS, and were experienced practitioners. All were up to date with revalidation.

The provider's clinical governance and communications policies stated the manager provided monthly supervision sessions to formally review staff performance. However, staff we spoke with told us they did not receive supervision, there were no records of one to one meetings and no evidence of continuous professional development meetings or documented performance appraisals.

The registered manager and staff we spoke with told us scan procedures, scan image and documentation quality were audited to check staff followed policy and guidance. However, they confirmed these checks were not documented. This meant we could not be assured how effective the audits were for monitoring image quality and staff compliance and against policy.

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 although they did not engage with colleagues who worked at other franchise locations.

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 six days a week and until early evening on Monday, Thursday and Friday.

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 waiting area. For example, posters that promoted immunisation, hand hygiene awareness and leaflets about taking vitamins during pregnancy.

In addition, we saw information about keeping hydrated and there was complimentary bottled water available.

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.

Requires Improvement

Diagnostic and screening services

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.

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 private scan room, which had a lockable door and a screen to protect women's modesty.

Women told us that staff were discreet and responsive when caring for them and took time to interact with them and those close to them in a respectful and considerate way. For example, they told us 'staff kept me, and my partners mind occupied whilst we were waiting to have our scan procedure, this was important to us as we were both feeling anxious having previously received bad news'.

Women we spoke with told us they had a 'welcoming, positive experience and would use the service again.' 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.

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

Staff we spoke with told us they had received training from their substantive employer and 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 information on the provider's website which signposted women to local and national bereavement services and first steps services for depression and anxiety.

Requires Improvement

Diagnostic and screening services

Understanding and involvement of women and those close to them

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

Staff made sure women and those close to them understood their care and procedures and provided clear information about scan options and costs on the website. Women we spoke with told us they were able to make amendments to their bookings when it became apparent the scan option they had chosen was not be suitable to meet their needs.

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 heard sonographers made it a special experience when revealing a baby's gender by using pink or blue lighting in the scan room.

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 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 mostly met the needs of local people and the communities served.

Facilities and premises were appropriate for the services being delivered. However, there were steps into the scan room which meant people who used wheelchairs or those with mobility issues could not use the service.

The service was located just outside Halifax town centre on a bus route and there was a public carpark 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 declare any reasonable adjustments they needed to attend the scan at the booking stage. This could also be discussed on the telephone or on arrival at the clinic.

Requires Improvement

Diagnostic and screening services

The reception and unisex toilet were accessible for wheelchair users and pushchair access. However, the scan room was not wheelchair accessible which meant the service was unable to provide scans for women permanently in a wheelchair. This was made clear on the provider's website.

Women could request a chaperone at any time, to attend their appointment and this was displayed on signage and on the website.

The service had a comprehensive equality and diversity policy which promoted a supportive and inclusive culture.

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. The service offered a waiting list if their chosen date was full. 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 and investigated them.

The service had a complaints policy and a signposting poster was displayed. Women could raise complaints in person, in writing, by telephone, social media and email.

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

The service had received one complaint. We found the registered manager responded appropriately and the complainant was satisfied with the outcome.

Is the service well-led?

Requires Improvement

Leadership

Leaders had the skills and abilities to run the service, however, they did not fully understand and manage the priorities and issues the service faced. They were visible and approachable in the service for staff.

Requires Improvement

Diagnostic and screening services

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 manager held overall responsibility for the leadership of the service with support from the franchise directors. However, they had not identified, prioritised and managed all the risks associated with the lack of effective governance processes throughout the service.

The registered manager was usually on site and contactable by telephone when off site, when the clinic was open. Staff we spoke with told us they felt confident to discuss any concerns with their 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 registered manager did not provide a formal vision or strategy for the service. However, they told us about aspirations to grow the business and maintain excellence. For example, they intended to provide non-invasive prenatal tests (NIPT) in the future.

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

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.

Requires Improvement

Diagnostic and screening services

The registered manager 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. However, we did not see minutes of these meetings and the registered manager confirmed they rarely had contact with the franchise directors.

We reviewed most of the provider's policies and found some did not always reflect local practices. For example, the service did not hold monthly supervision sessions as stated in the clinical governance policy and the manager did not hold fortnightly meetings with staff as stated in the communications policy.

In addition, the recruitment policy stated a recruitment matrix was used for each staff member. However, this was not provided; monthly checks on staff personnel and training files were incomplete and there was a lack of recruitment documentation in all staff files.

Records to demonstrate all staff had read and understood all policies were incomplete or missing.

The audit schedule was out of date; there was no evidence of completed audit tools or action plans and no audits documented as completed for 2023.

Peer review of scan quality and observational audits of sonographer's practise were not recorded.

Management of risk, issues and performance

Leaders and teams identified and escalated most relevant risks and issues and identified 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 most of the products subject to COSHH (2002) regulations. However, these did not include the cleaning agent for the transvaginal probe.

The registered manager confirmed there was no risk register in place. This meant unmitigated risks, for example, those associated with storage of the cleaning equipment and hazardous cleaning agents in the kitchen, were not recorded.

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 General Data Protection Regulation (GDPR) 2018. However, according to the training matrix, only the registered manager was up to date with information governance training. This meant we were concerned staff may not understand their obligations regarding GDPR.

Requires Improvement

Diagnostic and screening services

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. Staff effectively managed and shared women's personal data in a safe and secure way during onward referrals to the early pregnancy units (EPUs).

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

Information technology systems had appropriate security measures in place 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 a data stick to allow printing of images. The data stick was then erased. 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 at reception 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 manager was clear about how to submit statutory notifications to CQC and what was reportable.

Engagement

The registered manager actively and openly engaged with staff and service users to plan and manage services.

The service engaged well with women and staff, to plan and manage services.

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

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

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

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

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.

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 implement effective systems and processes to ensure all staff are compliant with mandatory training, including but not limited to, safeguarding vulnerable adults and children, to a level appropriate for their role. (Regulation 12(1) (2c)) and Regulation17(1)(2)(a)(b)). • The service did not implement systems and processes, including but not limited to appraisals and supervision to ensure staff are suitably qualified, competent, skilled and experienced. (Regulation 12(1) (2c) and Regulation 17(1)(2)(d)). • 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. (Regulation 12 (1)(a)(b)).

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. (Regulation 17(1)(2b)). • The service did not assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activities. (Regulation 17(2)(a)).