Hey Baby 4D Hull Ltd

Hey Baby 4D Hull

Inspection report

Unit 4-5 Home Farm
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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 as requires improvement because:

- The service did not have clear training records which included all staff. It did not ensure all staff had completed safeguarding training, which included female genital mutilation (FGM) awareness training. There were significant safety concerns found in the kitchen and staff were not trained to check the safety of a helium gas cylinder. The service did not complete risk assessments for supplying women with nutritional supplements.
- Although the manager collected audit data of performance metrics, the service did not always use these results to understand performance, make decisions and improvements or achieve good outcomes for women. They did not always make sure staff were competent for their roles.
- The service did not always operate effective governance processes. We found discrepancies within staff records. For example, the list of employed staff did not match with the personnel and training records. We found differences between the training audits and training requirements listed for each staff.
- The manager did not always identify risks or recognise associated actions to reduce their impact. The service did not have a process to safely supply, track, or store nutritional supplements. It did not have a vision for what it wanted to achieve or a strategy to turn it into action. Policies were not always version controlled and did not always reflect current operational procedures.

However:

- The service provided mandatory training to cover all key skills to staff. It had enough staff to care for women and keep them safe, kept good care records and staff understood how to protect women from abuse. The service controlled infection risk well, managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment and worked well together for the benefit of women. They advised women on how to lead healthier lives, supported them to make decisions about their care, and had access to good information.
- Staff treated women with compassion and kindness, provided emotional support and respected their privacy and dignity. They helped women understand their scan results.
- The service planned care to meet the needs of local people who could access the service when they needed it and provided same day scan results. Staff took account of women's individual needs and women were encouraged to leave feedback.
- The manager supported staff to develop their skills. Staff felt respected and valued. They were focused on the needs of women receiving care and were committed to improving services continually. They were clear about their roles and accountabilities. The service engaged well with women to plan and manage 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 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. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Hey Baby 4D Hull

The Hey Baby 4D service at Hull is operated by Hey Baby Hull 4D Limited. The clinic opened in 2018 and provides private non-diagnostic ultrasound services to self-funding women who are over the age of 18 and more than six weeks pregnant. Ultrasound scans are separate from NHS standard care pathways.

The service offers early pregnancy reassurance scans from six weeks of pregnancy, dating, growth, gender, later reassurance scans and 3D and 4D scans up to 31 weeks of pregnancy. They also provide Non-Invasive Prenatal Tests (NIPT) which is a blood test to determine gender and identify chromosomal conditions, such as Down's Syndrome.

The service has a registered manager in post.

The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures.

We have not inspected this service before.

How we carried out this inspection

The inspection team comprised of two CQC inspectors and an offsite CQC inspection manager. We gave the service 24 hours' notice of the inspection because we needed to be sure it would be in operation at the time we planned to visit.

We spoke with six members of staff including the registered manager, sonographers, senior scan assistant and scan assistants. We spoke with eight women who had used the service and reviewed feedback on website browser platforms and social media. We reviewed a range of policies, procedures and other documents relating to the running of the service including consent, scan reports and referral letters. We reviewed the appointment system.

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.

Outstanding practice

We found the following outstanding practice:

- The service had an outstanding safeguarding process for women or visitors to discreetly seek immediate help from staff.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations.

Action the service MUST take to improve:

Summary of this inspection

The service must have effective governance processes to check and record mandatory training completion for all staff and ensure staff records include all current and relevant information. Regulation 17(2)(a)(b)(f).

The service must have a female genital mutilation (FGM) policy. They must ensure all staff have completed safeguarding and FGM awareness training to recognise the potential risks and protect vulnerable children from abuse. They must make sure policies reflect the legal requirements for regulated health and social professionals to report female genital mutilation (FGM) directly to police. Regulation 12(1)(c) and Regulation 17(2)(a)(b)(f).

The service must complete risk assessments to safely supply pregnancy and baby nutritional supplements, and have an effective process to track, manage the storage and check expiry dates. Regulation 17(2)(b).

The service must complete a health and safety risk assessment for the kitchen area and equipment. The manager must ensure the gas cylinder is stored safely and securely and staff are appropriately trained to use it. The manager must ensure all equipment is stored safely and does not block access. Regulation 15(1)(c)(e)(f).

The service must ensure all policies are accurate, version controlled and there is an effective process to check staff have read latest policies. Regulation 17(2)(d)(ii)(f).

The service must have effective recruitment process for all staff employed which meet the CQC regulation requirements in employing fit and proper persons to carry out the regulated activities. Regulation 19(1)(a)(b)(2).

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

Action the service SHOULD take to improve:

The service should ensure the mandatory training policy reflects the specific training requirements for each staff role and training records.

The service should continue to develop the clinical governance and quality assurance audit sheet and use the results to support service performance in terms of quality, safety, and outcomes.

The service should develop a vision and a strategy to turn the vision into action.

Our findings

Overview of ratings

Our ratings for this location are:

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

Requires Improvement

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Requires Improvement

We rated Safe as requires improvement.

Mandatory training

The service provided mandatory training to cover all key skills to staff. However, the systems used to monitor the training were not effective and did not include all staff.

We reviewed two different mandatory training audits; one showed the training completed by the manager, receptionists, and sonographers and a more recent version which showed the training completed by receptionists.

We found discrepancies between the training modules shown on the training audits and the mandatory training requirements listed for each staff role as referenced in recruitment policy. For example we saw modern slavery, personal appearance, social distancing, and duty of candour training listed on the training records, but not as training requirements. We also saw mental health crisis management and LGBTQ+ training added to the training requirements, but they weren't added to the training audits.

We found discrepancies between the training modules completed by staff in similar roles. We also found differences in the names of training modules such as information security and information governance. These discrepancies meant the mandatory training completion, guidance and training records were unclear for all staff.

We reviewed the November 2021 and December 2021 monthly staff bulletin which asked all sonographers to submit evidence of their NHS training. However, we did not see completed mandatory training records for all sonography staff. This meant there was no clear oversight of the training completed at the NHS by sonography staff.

The registered manager provided a list of employed staff. We checked these names against the training audits and what staff had told us and there were three members of staff who did not have training records. This meant there was limited oversight of mandatory training completion for all staff.

Staff we spoke with told us the manager alerted them when they needed to complete or renew their training. They had protected time to complete it and training included reviewing related policies. For example, the infection control policy was read alongside the hand hygiene training module.

Requires Improvement

Diagnostic and screening services

Following our inspection, the manager added new training modules of awareness of mental health and learning disabilities and some staff had already completed it.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff we spoke with knew how to recognise and report abuse and knew how to apply it. However, the service did not ensure all staff had completed safeguarding training, which included female genital mutilation (FGM) awareness training.

The manager did not ensure all sonographers had completed safeguarding training in the NHS. This meant there was limited oversight that sonographers were trained to identify and recognise safeguarding risks during transvaginal scans.

The service did not have a specific FGM policy, although FGM was referenced in safeguarding policies. This meant there was limited guidance for staff to identify or report it. In addition, not all sonography staff knew their legal requirement, as regulated healthcare professionals, to report FGM directly to police rather than transferring this responsibility to the manager. Following the inspection, the manager created a new comprehensive FGM policy.

Following the inspection, the manager enrolled some staff, including reception staff, to complete FGM training, provided locally, and training records showed most staff had completed it.

The service had up-to-date safeguarding adults and children's policies for staff to follow which included the contact details of local authority safeguarding teams.

Staff received safeguarding training on how to recognise and report abuse. The manager shared safeguarding scenarios as part of staff training. Most staff we spoke to were able to confirm their safeguarding training levels however, the training records did not always state the level of safeguarding training completed.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act.

Staff knew how to report and escalate any safeguarding concerns to the safeguarding lead, who was trained to level 3 in children and adult safeguarding.

The service reflected good practice by displaying information regarding safeguarding from abuse in the toilets and there was a process for women to discreetly seek immediate help.

Cleanliness, infection control and hygiene

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

All clinical areas were visibly clean and had suitable furnishing which were clean and well maintained.

Cleaning records were up to date to maintain safety and hygiene standards and demonstrated that all areas were cleaned regularly to address the risks presented by COVID-19.

Requires Improvement

Diagnostic and screening services

The service had a clinic cleanliness policy which outlined the cleaning schedules for daily cleans and weekly deep cleans. The appointment booking system was designed to allow time for staff to complete, record, and clean areas and equipment in-between scans.

The manager and senior receptionist carried out regular quality checks of cleaning standards.

The service followed national guidance relating to the COVID-19 pandemic. For example, appointment slot times were increased to allow for cleaning between scans and only one woman and her visitors were allowed in the clinic at any time to adhere to social distancing. Staff encouraged visitors to use the hand gel at the clinic entrance and wear masks. There was appropriate signage reminding visitors of COVID-19 risks.

Staff followed infection control principles including the use of personal protective equipment (PPE), hand washing and sanitisation, and social distancing. However, we saw one member of staff wearing nail varnish, but they followed infection control guidance and wore gloves during cleaning. Following the inspection, the manager added personal appearance as a new training module.

The service had hand washing facilities and sanitising hand gel in the scan room for sonography staff to decontaminate their hands and equipment following scans. There were hand hygiene posters above every sink to provide a visual guide to handwashing.

Women were provided with appropriate information about COVID-19 restrictions at the time of booking. They completed a declaration which covered symptoms or known exposure and staff could record COVID-19 positive status. Staff continued to perform lateral flow tests in line with national guidance.

Environment and equipment

There were significant safety concerns in the kitchen which did not keep people safe. Staff were not trained to use the helium gas cylinder. However, staff managed clinical and non-clinical waste in a way that kept people safe.

We reviewed the service's statement of purpose which stated that women and visitors can access the kitchen to use the toilet facilities.

We saw a freestanding 100kg compressed helium gas cylinder in the kitchen which was used for blowing up balloons as part of gender reveal merchandise. This meant there was a risk of the cylinder falling over onto someone and causing injury. There were additional concerns because the gas nozzle was at eye level height which could cause an eye injury. We raised this with the manager who took immediate action to secure the cylinder as per the manufacturing instructions and service's own risk register.

We also found the gas valve to be in an open position which meant a risk of helium gas leakage. Staff were not trained to ensure the gas valve was closed when not in use as per BOC's manufacturing guidance. Following the inspection, the manager completed an appropriate risk assessment on this equipment. They had made sure staff had completed training and had introduced daily checks.

We found limited access into the kitchen as it was also being used to store large boxes containing merchandise. We saw the rubber skirting board near the entrance was ripped. These meant there was a safety risk of slips, trips, or falls.

Requires Improvement

Diagnostic and screening services

We found a carbon dioxide fire extinguisher in the kitchen was not stored appropriately within its wall bracket and it did not have a safety testing sticker. Following the inspection, the manager explained the fire extinguisher was replaced annually and therefore did not require a safety testing sticker. In addition, a new extinguisher had been delivered the week of the inspection however the existing wall mount was not suitable. The manager submitted new evidence of the extinguisher appropriately secured in place.

Following the inspection, the manager said they would complete a health and safety risk assessment for the kitchen.

We found an additional safety issue in the sonography room with the sharps bin being stored inappropriately on a high shelf which was above head height. This did not adhere to best practice guidelines and meant there was a potential risk of needles falling out and causing injury. We raised this with the manager who took immediate action to rectify this.

Following the inspection, the manager sent photographic evidence to demonstrate that improvements in these areas had been made. For example, the gas cylinder was secured against the wall, the skirting board had been fixed, the kitchen looked well maintained with clear aisles and the sharps box had been relocated to a locked cupboard.

The service had enough suitable equipment to help them to safely care for patients. Staff followed a clear process to report faults or low equipment stock. All electrical equipment had been safety tested within the last 12 months to ensure it was safe.

The manager ensured the maintenance, service and timely repair of the ultrasound scanning machine. The sonography staff carried out daily safety checks on the ultrasound machine and checked it was set to the lowest possible output power to comply with the “as low as reasonably achievable” (ALARA) protocols. The service ensured that the numbers of scans completed by sonographers each day was monitored and limited to avoid work related musculoskeletal disorders.

Assessing and responding to patient risk

Staff knew what to do and acted quickly when there was an emergency however, the service did not complete risk assessments for supplying women with nutritional supplements.

The service did not have a process to safely supply pregnancy and baby nutritional supplements which were given to women as post scan goody bags. Staff were not trained to complete risk assessments for women receiving these nutritional supplements. They did not track, manage the storage, or check expiry dates. This meant a significant safety risk as they could be medically inappropriate or not compatible with other medication or supplements.

Not all sonographers we spoke to have an awareness of the pause and check list issued by The Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (BMUS) BMUS and it was not displayed in the scan room. However, we observed sonographers complying with the principles of the check list during scans.

Staff responded promptly to any immediate risks to women’s health and followed clear policy guidance for emergency support. Most staff were first aid trained and all had access to a first aid box.

Staff completed fire, health, and safety mandatory training. The service carried out regular fire alarm tests and drills which involved staff walking through the fire evacuation process and resetting the alarm.

Requires Improvement

Diagnostic and screening services

Staff completed risk assessments for women's scans, such as allergies and health conditions, using booking form and COVID-19 declarations. Woman were asked to share their babies gestational age, date of last period and /or estimated due date and there was a free text box to write any relevant past medical history or current concerns. Sonographers asked further health questions before commencing the scan and check the reason for the scan.

The service provided clear guidance for sonographers to follow if they identified unexpected results. We observed three examples of staff referring woman with a suspected high-risk condition, such as an ectopic pregnancy, to their local early pregnancy assessment unit (EPAU). Staff had access to the telephone numbers for all the local EPAU's and NHS clinical teams.

We reviewed these referrals which showed key information was shared. We also heard staff advising woman to attend A&E if they had any pain or bleeding prior to their scheduled hospital appointment.

The website clearly stated the service was only available to woman over the age of 18 and said that proof of age may be required on arrival.

The service used non-latex transvaginal probes if a transvaginal scan was required.

The service strongly recommended women attend all NHS antenatal appointments and were advised to bring their NHS pregnancy records. This meant sonographers had access to women's obstetric and medical history. The service monitored the frequency of scans provided for women and audits the number of rescans completed.

Staffing

The service had enough staff with the right qualifications, skills, training, and experience to keep women safe from avoidable harm and to provide the right care. The manager regularly reviewed staffing levels and skill mix and gave new staff a full induction.

The manager and senior scan assistant planned staffing rotas at least four weeks in advance and most staff had set working days. The manager was always on call the clinic was open.

Staff were flexible to cover any staff absences.

The manager made sure all new staff had a full induction tailored to their role and offered a high level of support. New staff had three months to complete their mandatory training.

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

Records

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

Patient notes were comprehensive and relevant staff could access them easily. The service kept electronic booking forms, scan records, consent forms and scanned referrals.

We observed staff maintaining the confidentiality of women. They ensured printed confidential information was not left unattended and ensured conversations were discreet.

Requires Improvement

Diagnostic and screening services

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

Incidents

The service managed safety incidents well. Staff recognised and reported incidents. The manager investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave women honest information and suitable support. The manager ensured that actions from safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. The service had a comprehensive emergency and significant events policy. We reviewed three accidents documented in the accident book. The manager demonstrated a clear knowledge of reporting and investigating incidents and would submit incident reports to the franchisor.

The manager shared feedback and lessons learned from safety incidents or audit results via monthly bulletins, secure messaging, and verbal communication. For example, staff were encouraged to complete a deep clean for one area of the clinic because a number of key areas were identified as being routinely missed from cleaning audits.

The service had a policy which covered duty of candour which meant that staff were guided to know when and how to apply duty of candour. Not all sonographers we spoke with understood the term duty of candour, but they understood the principles of being open and honest.

The manager demonstrated an appropriate change in process following the recent National Patient Safety Alert on 'The safe use of ultrasound gel to reduce infection risk'.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not rate the effective domain in diagnostic and screening services.

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. However, the manager did not always check to make sure staff had read updated guidance.

The manager was responsible for updating the local policies. They shared policy updates in the monthly bulletin and asked staff to sign the policy signature sheet. However, we did not see signatures for all staff for the last three policies updated in August 2021. This meant there was a risk staff were not compliant with reading recent national guidance and evidence-based practice.

The Hey Baby franchise had a dedicated team to monitor policies for compliance with national and best practice guidance. The clinical leads provided input into clinical policieswhen new guidance is released. Policy and guidance updates were cascaded across all clinic locations simultaneously to ensure all staff delivered care in line with requirements.

Staff were able to understand policies and procedures and could access them online or within the policies folder.

Sonography staff we spoke with regularly reviewed guidance and alerts directly from the National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR). This meant care was in line with the latest understanding of best practice.

The service subscribed to the 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. Staff told us that if a rescan was required it would be rescheduled for a different day.

The service complied with good infection prevention practice when using non-sterile ultrasound gel following the recent update from UK Health Security Agency (UKHSA) to reduce risk of infection.

Staff followed the improving news delivery in ultrasound (INDIRA) framework which sets out information on delivering bad news.

The service had a process for staff to communicate any psychological and emotional needs of women and their visitors at handovers between reception and the scan room.

Nutrition & hydration

The service gave women appropriate information about drinking extra fluids and attend with a full bladder before trans-abdominal ultrasound scans to ensure the sonographer could gain effective ultrasound scan images.

Staff provided additional water during the appointment if necessary.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain or discomfort during scans. They stopped scans if the woman reported unusual pain.

Patient outcomes

The manager collected audit data of performance metrics but did not always use these results to understand performance, make decisions and improvements or achieve good outcomes for women.

The manager had overall responsibility for measuring the quality and safety of the service and monitoring trends in performance. They completed a clinical governance form with collated audit results, and this was reviewed with the franchisor directors at least monthly.

The service had a comprehensive programme of audits which were recorded on a clinical governance and quality assurance audit sheet. Staff involved in audit collection explained the service had recently created a new audit sheet to avoid duplication of data collection.

The service audited 5% of all scans to measure the quality of communication and customer care in order to indicate any additional training requirements. We read in the monthly bulletin that data would be analysed and shared however, we did not see any outcome evidence of this. We were not assured the service was able to measure performance based on recorded numbers alone.

Requires Improvement

Diagnostic and screening services

We reviewed the audit results for the number of free rescans offered to women whose first scan wasn't successful. We read that the most common reasons for rescanning was that women were being scanned too early or the baby wasn't in the best position for scanning.

We reviewed the audit for the number of referrals made to the early pregnancy assessment units (EPAU) and numbers of follow up calls made to assess the accuracy of the referrals. We read that follow up calls were not completed for women's referrals in October or November 2021 however the manager had taken action to remind all staff.

We did find some audits which were used to understand performance, make decisions and improvements. For example, the service had recently started using the British Medical Ultrasound Society (BMUS) audit tool to complete peer reviews for sonographer's scans to ensure the accuracy and quality of scan images and videos. Sonographers benefited from peer reviews especially when suggested comments or areas for improvements were given. We reviewed a sample of peer reviews and found them to be detailed, constructive and supported best practice. This ensured consistency when measuring sonographer's performance and was in line with British Medical Ultrasound Society (BMUS) guidance.

The service completed a cleanliness audit in January 2022 which showed the cleaning of kitchen window was repeatedly being missed and a difference between the cleaning completed by staff roles. The registered manager made immediate improvements by requesting staff to distribute the cleaning duties equally between them.

Following the inspection, the registered manager informed us they had been externally audited by the Hey Baby franchise and had scored 93% in November 2021. The service was unable to benchmark against other services as not all Hey Baby services had been audited.

Competent staff

The service did not always make sure staff were competent for their roles. However, managers appraised staff's work performance and provided support and development.

On inspection we were unable to review staff recruitment files and we requested evidence of the staff recruitment matrix as referenced to in the recruitment policy. The registered manager was unable to submit a matrix because they only had "a small team and it isn't necessary". They confirmed they had oversight from reviewing the internal audit schedule monthly.

We reviewed further evidence of pre-employment checks for eight staff. These staff were experienced, qualified, and had the right skills and knowledge to meet the needs of patients. However, we did not see pre-employment checks (including DBS checks) for at least two staff members; one who worked at the service but was not listed by the registered manager and another for the phlebotomist who completed the blood test for the Non-Invasive Prenatal Tests (NIPT). This meant we did not have assurance that pre-employment checks had been completed for all staff. The service did not meet the CQC regulatory requirements in for employing fit and proper persons to carry out the regulated activities.

Staff felt supported to develop their skills and knowledge. The clinical governance policy stated the manager provided monthly supervision sessions to review staff performance. However, staff we spoke with did not receive supervision and instead had an appraisal after the first six months and then every three months or annually.

The service had a disciplinary policy to manage poor staff performance.

Requires Improvement

Diagnostic and screening services

The manager gave all new staff a full induction tailored to their role which included shadowing opportunities observations. Sonographers were offered 4D scan training by the clinical leads.

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. We observed constructive examples of staff working well together.

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

The communications policy stated that the registered manager held fortnightly meetings with staff. Staff also met daily to discuss any immediate updates or issues, with information summarised in a bulletin displayed in the staff area.

Seven-day services

Services were available to support timely patient care and was open two days during the week and at weekends.

It did not provide emergency care and treatment.

The appointment times were flexible to accommodate women and the service was open until 7.30 pm on two weekday evenings and all day on the weekends 9am to 5.30pm.

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.

The service displayed relevant health information and support in the waiting area.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care and knew who to contact for advice. The service had a mental capacity reasoning form. This enabled sonographers to clearly detail their rationale in either declining a scan due to the absence of mental capacity, or to proceed with the service following adequate assessment of the woman.

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.

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.

Requires Improvement

Diagnostic and screening services

The service could provide consent information in different formats such as in larger font and could be translated into most languages using a translation service on a tablet.

We reviewed consent forms and found these were completed fully.

Following our inspection, the manager added new staff training modules of awareness of mental health and learning disabilities and some staff had already completed the training.

Are Diagnostic and screening services caring?

Good

We rated Caring as good.

Compassionate care

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

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed sonographers delivering compassionate care to woman and their visitors.

Women said staff treated them well and with kindness. Women we spoke with all gave positive feedback such as “very pleased” and “would recommend”. Feedback from social media confirmed that staff were “very friendly” and “reassuring, calm and caring”, “brilliant and went over and above to help get the end result”.

Sonography staff took time to welcome or introduce themselves to women and their visitors.

Staff followed policy to keep patient care and scans confidential.

The service used a privacy screen to provide women privacy from sonographers when undressing for transvaginal scans. The service was able to maintain the privacy and dignity of women during scans by closing the scan room door, providing appropriate coverings, offering to leave the room while they undressed. Women we spoke to with confirmed staff respected privacy and dignity whilst in the waiting room and scan room.

Staff understood and respected the personal, cultural, social, and religious needs of women and how they may relate to care needs. Staff gave examples of providing compassionate care to surrogate women and new parents. Following our inspection, the manager added LGBTQ+ awareness onto the staff training requirement list.

Emotional support

Staff provided emotional support to women and their visitors to minimise their distress.

We observed positive examples of staff delivering emotional care when woman required onward referrals. They demonstrated empathy when having difficult conversations.

Requires Improvement

Diagnostic and screening services

Staff were conscious of the emotional needs for women attending scans and always offered a trained chaperone. It purposely allowed only one family in the clinic at any time. This ensured there was no cross over of women attending the scans for different reasons. For example, some women may be anxious about their scan because of previous pregnancy losses and other women may be celebrating gender reveals and buying merchandise.

Staff supported women who became distressed in the clinic and helped them maintain their privacy and dignity by offering them a discrete alternative exit from the sonography room.

Staff understood the emotional and social impact that a person's care, treatment, or condition had on their wellbeing and on those close to them. Staff provided further support to women following unexpected news with a follow up telephone call however, this had not been completed for November or December 2021 referrals.

Staff we spoke with, undertook scenario training on breaking bad news. Sonographers used the Improving News Delivery in Ultrasound guidance issued from the British Medical Ultrasound Society (BMUS) to help them discuss their findings in the most sensitive and dignified manner.

The service subscribed to the Antenatal Results and Choices (ARC) service who provide genetic counselling for woman who have received a positive non-invasive prenatal test (NIPT).

Staff were trained to signpost women to specialist and emotional support services.

Understanding and involvement of women and those close to them

Staff supported women and visitors to understand their condition.

The service made sure women understood their treatment by providing clear information about scan options and costs on the website. They were supported to make informed decisions about their care and were guided to choose the right scan depending on the stage of their pregnancy.

Staff took time to explain the scan procedure scans to women and gave them time to understand the information and ask any questions. We heard that surrogate families were always given longer appointment times which meant staff were able to offer the appropriate level of emotional support.

The service benefited from two large wall mounted monitors so that women and visitors could view the ultrasound images at the same time.

The service provided opportunities for woman to choose who they wanted in the scan room during gender reveals. For example, one woman we spoke with said they did not want to know the gender of the baby and left the room for the sonographer to reveal the gender to the father. We heard sonographers made it a special experience when revealing a baby's gender by using pink or blue lighting in the scan room.

Staff supported onward referrals to referrals to early pregnancy assessment units (EPAU) or NHS hospitals when scan results indicated abnormalities or other unexpected results. This ensured women did not leave the clinic without fully understanding where they would receive help and support going forward.

The service's website contained useful direct website links to many specialists supports services and charities.

Women could give feedback on the service and were supported to do this.

Requires Improvement

Diagnostic and screening services

Are Diagnostic and screening services responsive?

Good

We rated responsive as 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.

The service had allocated car parking spaces and would reimburse the Humber bridge toll for women travelling from Grimsby, Cleethorpes, or Scunthorpe.

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

Managers monitored and took action to minimise missed appointments and the booking system sent out automatic reminders 24 hours ahead of appointments.

Managers ensured that women who did not attend their scan were contacted via an email for early reassurance scans or a telephone call for all other scans giving them an opportunity to rebook up until 32 weeks gestation.

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 done on the telephone or on arrival at the clinic. This information was transferred onto the printed clinic list which meant staff could prepare any adjustments before the women's arrival.

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

The clinic was designed so that it was accessible for wheelchair users and pushchair access. For example, all doors were wide enough for access and the couch could be height adjusted.

Staff understood and knew how to support women with a sensory loss and language translation. Women were able to read information about scans, terms and conditions, and consent in most languages using a translation service on a tablet available at reception.

Staff gave positive examples of how they responded to and made reasonable adjustments for women with individualised needs. For example, staff helped women who had limited mobilities and wore clear face visors instead of masks to allow women with sensory impairments to lip read scan information.

Requires Improvement

Diagnostic and screening services

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

The service could signpost women to a number of specialist pregnancy and miscarriage charities, online pregnancy support groups as well as a genetic counselling team.

Access and flow

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

Women were able to book scan appointments online or by phone. The service offered a waiting list if their chosen date was full.

The service provided reassurance scans for women who could not get an early appointment in the NHS especially during the COVID-19 pandemic.

We reviewed the clinic sheet for the day of the inspection, and it showed back-to-back appointments from 11am to 2pm and from 3pm to 7pm.

Staff would communicate any delays to woman waiting for future appointments using the booking system's messaging service.

The manager did not monitor waiting times but did report the number of cancelled clinics in the monthly staff bulletin. When women had their appointments cancelled at the last minute, staff made sure they were rearranged as soon as possible.

Staff reported they had enough time to complete referrals and it was "an easy process" to contact local EPAU's or hospitals.

Women who received unexpected news had the option to leave the clinic via the sonography room and staff would contact them with their EPAU appointment date and time.

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 included women in the investigation of their complaint.

The service encouraged women to raise complaints or provide feedback via the website, social media, telephone, in person or by email.

Staff understood the relevant policies on complaints and feedback and knew how to respond, resolve, and escalate complaints.

The manager had overall responsibility for logging and investigating all reviews, complaints, and feedback. They responded to complaints appropriately, issued apologies and offered free rescans or partial refunds if necessary. They shared lessons learned in the monthly staff bulletin.

We heard many positive examples of how immediate actions had been taken as a result of complaints or feedback:

Requires Improvement

Diagnostic and screening services

- there was an immediate ban on staff using personal mobile phones in the clinic
- there was an additional IT security for women accessing their scan images
- staff rotas were printed after every amendment
- the website information was improved to make it clear that the service was only available to women over the age of 18.

Are Diagnostic and screening services well-led?

Requires Improvement

We rated well-led as requires improvement.

Leadership

The manager had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and staff. They supported staff to develop their skills and take on more senior roles.

The service had a leadership team structure which included roles, but not individual names for staff, and the senior receptionist's role was not included.

The manager held overall responsibility for the leadership of the clinic with support from the franchise directors and clinical leads. They managed the service effectively during the COVID-19 pandemic and ensured the safety of women attending for ultrasound scans. They understood the operational challenges such as cancelling clinics at short notice if sonographers were required to self isolate and no cover was available. They also introduced additional cleaning processes to address infection risks.

Staff felt confident to discuss any concerns with the manager.

The manager encouraged staff development and supported succession planning which was evidenced by the senior receptionist's role.

The manager responded positively and took immediate actions as a result of the concerns we found on inspection and showed willingness to learn and improve.

Vision and Strategy

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

The registered manager did not provide a formal vision or strategy for the service or for the Hey Baby franchise.

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.

Following the inspection, the manager shared ideas for the service's vision which was focused on achieving a higher standard of quality and safety and striving for excellence.

Requires Improvement

Diagnostic and screening services

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 and provided opportunities for career development. 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, and were rewarded. Staff told us that work had promoted their positive wellbeing and the manager was "good at praising staff", "supportive" and "a great mentor". The manager created a positive working environment by ensuring there was always drinks, fruit and snacks for staff.

The service encouraged women and staff to raise any issues. We saw examples of where concerns had been investigated with a view to ensuring improvements.

Governance

The manager did not always operate effective governance processes. However, staff at all levels were clear about their roles and accountabilities and had regular opportunities to discuss and learn from the performance of the service.

We reviewed all the policies some of which were not version controlled and did not always reflect current operational procedures. For example, the service did not hold monthly supervision sessions as stated in the clinical governance policy and the service 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, when we requested this information the manager said it "wasn't necessary" as there was only a small team of staff and said they completed monthly checks on staff personnel and training files.

We reviewed the staff personnel and training records and found discrepancies in the names of the staff employed at the service. There were inconsistencies between the names of current staff, pre-employment checks, training records and signatures on staff bulletins and policies.

We understood one member of staff was employed as a phlebotomist and completed blood tests for the non-invasive prenatal tests (NIPT) however, we did not see any pre-employment checks or completed mandatory training.

The manager had overall responsibility for clinical governance. They attended monthly service review meetings with the franchise directors to discuss audit results and performance.

The service had a formalised governance framework and a new audit process to support the safe and effective delivery of care. The manager had a schedule of reminders to check compliance of audits.

The manager conducted a range of clinical governance and quality assurance audits including peer reviews, clinical and service reviews as well as rescans and referrals.

Requires Improvement

Diagnostic and screening services

Management of risk, issues, and performance

The manager did not always identify risks and issues or recognise actions to reduce their impact. However, they collected audit data to manage performance. They had plans to cope with unexpected events.

The manager had limited knowledge of the risks we identified during the inspection. For example, the safe and secure storage of the gas cylinder and sharps box. In addition, the service did not provide training or guidance on the awareness of female genital mutilation (FGM).

Following the inspection, the manager took immediate actions. They had completed a risk assessment for the gas cylinder, relocated the sharps box, enrolled staff onto FGM training and created an FGM policy.

We identified further risks from the inspection such as the distribution of the nutritional supplements without any risk assessments and incomplete mandatory training records.

The service had a comprehensive programme of audits which were recorded on a clinical governance and quality assurance audit sheet. Staff involved in audit collection explained the service had recently created a new audit sheet to avoid duplication of data collection.

The service had completed appropriate risk assessments on the rest of the service to maintain safety for women and staff. They used a risk register to track and monitor known risks and had associated actions taken to mitigate risks.

Staff knew how to identify and report incidents appropriately and the registered manager effectively managed and investigated incidents.

The manager shared quality, safety, and performance issues in monthly staff bulletins such as staff training reminders, feedback on operational issues, updates to policies and health and safety and performance numbers from the previous month.

The service had valid insurance covering both public and employer liability, including professional indemnity insurance for registered professional staff.

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 managers.

Information Management

The service collected reliable data. Staff could find the data they needed, in easily accessible formats. The information systems were integrated and secure.

The information used in reporting, performance management and delivering quality care was accurate, valid, reliable, timely and relevant.

Staff reported sufficient numbers of computers, printers, and ultrasound machines in the service.

The service had policies and procedures in place to promote the confidential and secure processing of information held about women. Staff effectively managed and shared women's personal data in a safe and secure way during onward referrals to the early pregnancy assessment units (EPAU).

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.

Engagement

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

There were consistently high levels of constructive engagement with staff.

We heard positive examples from staff describing how the manager proactively engaged with them in person, by phone, messaging applications and emails. Staff were kept updated with best practice developments from a monthly staff bulletin. They were encouraged to participate in active discussions to help improve the day to day running of the service. They said the manager "does listen" and was "very responsive".

The service encouraged women to provide feedback post-scan, offering a variety of formats and platforms to provide this through to suit individual needs. The manager monitored and responded appropriately to all reviews, complaints, and feedback.

The service shared examples of how feedback was used to improve the quality of care and service delivery. For example, a sonographer suggested the introduction of transvaginal scans to obtain a clearer image of pelvic organs which meant a better quality image for early reassurance scans. Staff implemented a three-stage check of consent forms because an audit showed they weren't fully completed. They could use the new booking system to send text messages to notify women of any clinic delays.

Staff we spoke with had a good working relationship with the local early pregnancy assessment units (EPAU) and NHS hospital services.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services and the manager encouraged innovation.

For example, staff were offered phlebotomy training required for the Non-Invasive Prenatal Tests (NIPT).

We heard of positive examples of service improvements shared from this service. For example, sonographers had started peer reviews and receptionists periodically reviewed the patient centeredness and quality of sonographers' communication techniques.

Staff felt positively rewarded by the manager and felt confident to suggest improvements to the service.

The service was the first clinic within the franchise to.

- remove 4D scanning prior operate a 'closed clinic' approach (meaning only one couple permitted to enter at a time) during the pandemic.
- pilot the new booking system which also included online consent forms and COVID questionnaires and send text reminders to customers.

Requires Improvement

Diagnostic and screening services

The manager provided positive examples of improvements made to the service. These had subsequently been implemented across the Hey Baby franchise such as;

- improving the consent form to include the promotion of the chaperone service.
- updating the customer booking confirmation email.
- implementing the audit framework to ensure consistency across all the clinics.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service must have a female genital mutilation (FGM) policy. They must sure all staff have completed FGM awareness training to recognise the potential risks and protect vulnerable children from abuse. They must make sure policies reflect the legal requirements for regulated health and social professionals to report female genital mutilation (FGM) directly to police. Regulation 12(1)(c)

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The service must have effective governance processes to check and record mandatory training completion for all staff and ensure staff records include all current and relevant information. Regulation 17(2)(a)(b)(f). The service must have a female genital mutilation (FGM) policy. They must sure all staff have completed FGM awareness training to recognise the potential risks and protect vulnerable children from abuse. They must make sure policies reflect the legal requirements for regulated health and social professionals to report female genital mutilation (FGM) directly to police. Regulation 17(2)(a)(b)(f). The service must complete risk assessments to safely supply pregnancy and baby nutritional supplements, and have an effective process to track, manage the storage and check expiry dates. Regulation 17(2)(b).

This section is primarily information for the provider

Requirement notices

The service must ensure all policies are accurate, version controlled and there is an effective process to check staff have read latest policies. Regulation 17(2)(d)(ii)(f).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment The service must complete a health and safety risk assessment for the kitchen area and equipment. The manager must ensure the gas cylinder is stored safely and securely and staff are appropriately trained to use it. The manager must ensure all equipment is stored safely and does not block access. Regulation 15(1)(c)(e)(f).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The service must have effective recruitment process for all staff employed which meet the CQC regulation requirements in employing fit and proper persons to carry out the regulated activities. Regulation 19(1)(a)(b)(2).