Hey Baby 4D Birmingham South Ltd

Hey Baby 4D Solihull

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 service as requires improvement because:

- The service did not meet legal requirements ensuring staff employed had the necessary checks in place, ensuring records required by risk assessments were kept, ensuring clinical waste was securely stored and using audits to ensure the quality of the service. Not all staff had training in key skills.
- Staff did not monitor the effectiveness of care by auditing their service. They were therefore unaware of how well the service was performing or if improvements were needed.
- The service had minimal systems in place to identify risk, plan to eliminate or reduce them.
- Four requirement notices were served to address the above rating for safe and well led therefore the ratings were limited to requires improvement

However,

- The service had enough staff to care for women and keep them safe. Staff understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records.
- Staff provided good care and treatment. Staff worked well together for the benefit of women, advised them 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, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of local people and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for their results.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires Improvement 	

Summary of findings

Contents

Summary of this inspection

Background to Hey Baby 4D Solihull

Hey Baby 4D Solihull is operated by Hey Baby 4D Solihull South Ltd. The service opened on 2 June 2020. It is a franchise of Hey Baby 4D and is located in Solihull, Birmingham, serving those in the local community.

Hey Baby 4D Solihull provides pregnancy ultrasound services to self-funding women, from eight to 40 weeks of pregnancy.

The service is available to women aged 18 years and above. All ultrasound scans performed at Hey Baby 4D Solihull are in addition to those provided through the NHS as part of a pregnancy care pathway.

The service has had a registered manager in post since 2 June 2020. The service has not been inspected previously.

Hey Baby 4D Solihull is registered with the CQC to carry out the following regulated activities:

Diagnostic and screening procedures.

How we carried out this inspection

We carried out a comprehensive inspection of the service under our regulatory duties. The inspection team comprised of a lead CQC inspector and an offsite CQC inspection manager. We gave the service short notice of the inspection because we needed to be sure it would be in operation at the time we planned to visit.

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

Areas for improvement

Action the service MUST take to improve:

The provider must ensure there are systems and processes in place to maintain effective oversight of risk and role competencies. (Regulation 17)

The provider must ensure that clinical waste is stored securely. (Regulation 15)

The provider must ensure records are kept of testing required by Legionella risk assessments. (Regulation 12)

The provider must ensure recruitment procedures are operated effectively (Regulation 19)

Action the service SHOULD take to improve:

The provider should ensure all staff complete mandatory training in a timely way. (Regulation 18)

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	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 imaging

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

Are Diagnostic imaging safe?

Requires Improvement

Mandatory training

The service provided mandatory training in key skills to all staff but compliance to training was not monitored.

The registered manager had not monitored compliance with mandatory training and had not alerted staff when they needed to update their training. The registered manager had not ensured all staff completed a range of mandatory training identified in the provider's policy as necessary. At the time of our inspection, one member of staff had seven mandatory training courses outstanding, one of which was safeguarding children. This member of staff completed the training after our inspection. The registered manager and sonographer had completed training.

After the inspection, the registered manager provided the outstanding training certificates.

Staff had access to mandatory training, which was specific for their role, for example staff completing forms which contained confidential personal information with clients were required to complete Recording Information and General Data Protection Regulations. Staff undertaking phlebotomy completed competency training every two years. The last phlebotomy competency training was done in 2020 and will be due later this year.

The registered manager ensured staff were registered with a training provider, who provided online training appropriate for the service. Staff told us they were able to request additional training, and this would be provided for them. Staff confirmed they were given time to do training.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Not all staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. The service had clear safeguarding processes and procedures in place. Staff had access to an up to date safeguarding policy. The registered manager and sonographer had both completed safeguarding level three training. The registered manager was the safeguarding lead.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff we spoke with were able to clearly articulate signs of different types of abuse, and the types of concerns they would report or escalate to the registered manager.

One member of staff had completed safeguarding adults training level two the day before our inspection but had not completed safeguarding children training.

After the inspection, the member of staff completed outstanding training and sent us the certificates.

A separate female genital mutilation (FGM) policy provided staff with clear guidance on how to identify and report FGM. FGM training was provided separately.

The registered manager had a system which meant women at risk of abuse could alert staff, by saying they had found a piece of paper on the floor. Women could tear a strip of paper off a sign, which explained to them what to do.

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.

Clinical areas were visibly clean and had suitable furnishings which were visibly clean and well-maintained. The clinic rooms, toilets, reception and waiting areas were all visibly clean. The service followed the policy originally supplied by the franchise and included additional cleaning they required as a result of COVID-19 changes. Cleaning schedules were displayed in the clinic in line with this policy. Staff cleaned equipment and waiting areas after customer contact. For example, the couch in the treatment room used by clients was covered with a disposable cloth which was changed between clients.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. The registered manager employed a cleaner two days a week. The cleaner completed a cleaning log. Staff undertook cleanliness visibility checks of toilet and other areas throughout their shifts. The registered manager had introduced more detailed cleaning logs in response to COVID-19 which prompted staff to clean every surface in the room they were cleaning.

Staff followed infection control principles including the use of personal protective equipment (PPE). There were appropriate hand washing facilities and sanitising hand gel was available. Staff had their arms bare below their elbows and washed their hands before and after each scan. PPE, such as latex-free gloves and antiseptic wipes were readily available for staff to use at the service.

In the 12 months before the inspection, there had been no incidences of healthcare acquired infections at the location.

The registered manager had updated the COVID-19 policy to provide guidance for staff to help reduce the spread of infection. Staff were following this policy.

The sonographer followed the manufacturer's and infection prevention and control (IPC) guidance for routine disinfection of equipment. The sonographer wore gloves when carrying out scans in line with IPC compliance.

Requires Improvement

Diagnostic imaging

There was a set non-invasive prenatal test (NIPT) procedure in place outlining the steps to take when obtaining blood samples. The guidance cross referred to the service's IPC policy, outlining hand hygiene steps and the safe disposal of sharps and clinical waste to prevent and control the spread of infection.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. However, staff did not manage clinical waste well.

Staff did not ensure clinical waste was disposed of safely. Clinical waste was stored at the back of the premises. One bin was faulty and not locking properly. The registered manager told us that it had been raised with the company but at the time of our inspection it had not been rectified.

This was a breach of Regulation 15 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The service had 13 clinical waste collections per year; the bins were emptied every four weeks. Staff carried out waste streaming in line with Department of Health and Social Care Health Technical Memorandum 07-01, which reflected national best practice. Staff wore correct PPE while dealing with clinical waste and followed a safe process.

The registered manager had employed a specialist company for Legionella testing. Legionella is a bacterium that causes illnesses, such as Legionnaires' disease or a fly-like illness. The risk assessment scored the service as high risk. The risk assessment required the registered manager to record water temperatures, when taps/toilets were flushed and de-scaling. The registered manager had not completed any of these requirements.

This was a breach of Regulation 12 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The service had suitable facilities and had enough suitable equipment to meet the needs of women. The clinic's environment was fit for the purpose of service provided. Staff completed regular checks of stock, first aid kit and equipment.

The service did not require a resuscitation trolley. There was a first aid box which was within expiration date. Staff were up to date with adult and children first aid training. Staff told us in case of an emergency they would call 999.

Staff carried out safety checks of specialist equipment. The scan equipment was serviced annually and maintained by the company who installed it. The equipment was new when the service opened and was covered by a five-year warranty. The electrical equipment was due for electrical testing in June 2022. This was in line with the provider's safety policy.

Disposable equipment was ordered in small quantities at a time, so expiry dates were never reached.

The layout of the building meant the member of staff in reception had direct view of clients, as well as being able to observe the door into the scanning room. The waiting area was light and comfortable, with a display area where products could be displayed.

Requires Improvement

Diagnostic imaging

The premises were a modern single storey building and had access suitable for people using wheelchairs. The building had access through the front entrance, into to the reception area. There was one, separate scan room. The scan room had a modern couch which could be adjusted for comfort. One large screen was on the wall and a couch for people accompanying the woman. The scan room also had a hand-washing sink and storage cupboards for disposable items.

One straight corridor linked the reception area, the scan room, the toilet and kitchen area. The toilet had some adaptations for people with limited mobility and an emergency pull cord. There was a baby nappy changing area next to the toilet.

Staff had access to a small kitchenette for staff use only, a back door from the kitchenette gave access to the area where the yellow clinical waste bins were kept.

The service offered NIPT services and had a contract with an accredited clinic in place. The clinic used was accredited with the American Association of Blood Banks (AABB) and Human Tissue Authority (HTA), as well as others.

NIPT is a method of determining the risk that the fetus will be born with certain genetic abnormalities by testing small fragments of DNA that are circulating in a pregnant woman's blood.

An abnormal number of these chromosomes could indicate the presence of certain inherited conditions, such as Down's Syndrome and Turner Syndrome. The tests can be done as early as 10 weeks into the pregnancy. The service had appropriate facilities and equipment for taking blood samples. The sharps bins for needles used for taking bloods were stored safely and emptied quarterly.

The NIPT procedure provided clear instructions on the labelling, packaging and method of postage. In addition, the package was sent via recorded delivery to enable tracking. NIPT kits came in individual packs, one per woman. The kit contained individual needles, a tourniquet (used to obtain blood samples through applying pressure on the arm) and vials for blood samples. One member of staff was a trained phlebotomist.

Fire risk assessments had been undertaken but had not been written down. As the service employed fewer than five people, they were not required to have a written fire risk assessment. The service had two fire extinguishers which were easily accessible from all areas of the building. The service used an electric air pump for balloons.

The scan room door had a sliding sign which allowed staff to select 'in use' or 'vacant' and the door was also lockable.

Sonographers could adjust the scanning machine and their chair for their comfort, as well as adjusting the scan couch. The registered manager also factored breaks into the schedule, so staff could avoid work related musculoskeletal disorders.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.

The registered manager had completed risk assessments for identified risks, such as COVID-19, fire and health and safety.

Diagnostic imaging

Staff knew about and dealt with any specific risk issues. The service had a clear pathway staff could follow which was explained in the provider's policy. Should any anomalies be found, the client was informed in a caring, honest and professional manner. The client was given a detailed medical report dealing with the findings. Staff followed the referral pathway agreed with the local NHS, Foetal Medicine Unit (FMU) or Early Pregnancy Unit.

Staff shared key information to keep patients safe when handing over their care to others. Staff responded promptly to any immediate risks to women's health. Staff told us they would phone 999 if they suspected anything which required urgent action. This meant that staff knew what to do and acted quickly when there was an emergency. The sonographer explained their findings to the client then asked staff at reception for additional support where necessary.

The service provided clear guidance for the sonographer to follow when they identified unexpected results during a scan. Staff gave examples of redirecting women who were experiencing pain or bleeding to their local NHS clinical team. The sonographer made rapid referrals when they found concerns about a woman's health and documented their phone calls with NHS services to maintain an audit trail of referrals.

The registered manager told us they had referred 35 women to NHS in the past year because of potential concerns found. Dedicated referral forms were available to document any referrals made. These included a description of the scan findings, the reason for referral, who the receiving healthcare professional was and what action they were going to take.

The registered manager told us they did not make referrals to GP's, but instead made referrals to the woman's maternity provider.

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. Managers regularly reviewed and adjusted staffing levels and skill mix and gave bank and locum staff a full induction. However, the provider did not operate robust recruiting procedures, including undertaking all relevant checks.

The registered manager completed a risk assessment for the location, which was last updated in February 2022. This stated all staff had to have a Disclosure and Barring Service (DBS) check before starting their employment at the location. All staff had an up to date DBS check. We reviewed all three personnel files and all staff had proof of identification, employment onboarding forms, evidence of induction training and qualification certificates. However, one member of staff had one verbal reference instead of the two documented required, no history of employment and no declaration of health, all items which were required. We highlighted this to the registered manager.

This was a breach of Regulation 19 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

A copy of professional memberships were kept on file. The sonographer was registered with the British Medical Ultrasound Society for working in a non-diagnostic setting and had professional indemnity insurance.

The service had enough staff to keep women safe. The service employed one sonographer and one receptionist/ customer care. Appointments were, therefore, dependent on the sonographers' availability, however, people told us

they had not had to wait. All members of staff could support the sonographer as chaperones but had not done formal chaperone training. Clients booked their appointments online and the registered manager and receptionist shared responsibility for managing enquiries, appointment bookings, supporting the sonographer during ultrasound scan procedures and printing scan images.

The registered manager was registered with locum agencies but not using them currently. They confirmed that all staff, locum too, would need to undertake a full induction.

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.

The service had an up to date information governance policy, and a data retention policy. The registered manager was the information governance lead for the service. The service was registered with the Information Commissioner's Office.

Clients' notes were comprehensive, and only staff who needed to see them had access. Pre-scan questions were asked during the booking-in process and consent forms at the service ensured enough information was obtained from women prior to their scans; for example, in relation to number of weeks they were pregnant. Women were also required to declare medical conditions that might affect their scan. Images stored on the scanning machine were backed up every three months or when data meant storage was almost full. Scan images were kept for one year, then appropriately destroyed.

Staff ensured women's confidential personal information was maintained and not accessible to others. For example, women's registration forms were kept at reception in a covered file prior to the woman being called in to the scanning room.

Records were stored securely. Some records were kept electronically, and computers were password protected. When a woman was referred to hospital, a copy was sent to the FMU by email. A copy was also printed out for the woman to take to hospital with them. Reports were put into a sealed envelope for the woman to take so no paperwork was visible.

After initial consultations, the service held contact details for women requiring test results from NIPT to enable feedback of blood test results. The sonographer telephoned the woman to inform them of the result. A copy of the results were sent to the woman after the telephone call. If the woman consented, the information was shared with the woman's maternity provider.

Incident reporting, learning and improvement

Staff recognised and reported incidents and near misses. When things went wrong, staff had guidance from a protocol to follow, which included apologising and giving women honest information and suitable support. Managers ensured that actions from safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. The service had an up-to-date incident reporting policy, which detailed all staff responsibilities to report, manage and monitor incidents. The service used an electronic system, and an incident log was available in the clinic. The service had had three incidents in the past year, all related to the

property, such as two incidents of water ingress caused by the premises above. On both occasions the landlord had been quickly contacted, customers had also been quickly contacted and their appointments rescheduled. The registered manager was responsible for conducting investigations into all incidents at the location and understood the processes they would follow.

Staff were able to learn from any incidents that occurred in other Hey Baby 4D services because the information was shared between services.

Staff understood the duty of candour. In the past year, there were no duty of candour notifications. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The registered manager could explain the process they would undertake if they needed to implement the duty of candour because of an incident, which was in line with the requirements.

Are Diagnostic imaging effective?

Inspected but not rated

We inspected this area but do not rate.

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Staff were aware of how to access policies, which were stored electronically as well as in paper format. Local policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence and the British Medical Ultrasound Society (BMUS). The policies were written originally by the franchise. However, policies were adapted to provide effective guidelines for each clinic location.

Staff were made aware of updates to policies as they were made. All policies and protocols we looked at had a next renewal date, which ensured they were reviewed by the service in a timely manner. Staff signed a policy update sheet when they were provided with updates. For example, the scan procedure policy had changed recently to reflect the use of disposable gel bottles, rather than refilling them. All staff had been made aware of this update.

The service followed the 'As Low As Reasonably Achievable' principles. This was in line with national guidance (Society and College of Radiographers and BMUS, Guidelines for Professional Ultrasound Practice (December 2018)). This meant sonographers used minimum frequency levels for a minimum amount of time to achieve the best result. Machines were pre-set to the lowest frequency and this was checked during services, as well as the sonographer checking.

The service was inclusive to all pregnant women and supported all women regardless of their age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation to make their own care and treatment decisions.

Nutrition and hydration

Requires Improvement

Diagnostic imaging

Staff took into account women's individual needs where fluids were necessary for the procedure.

Due to the nature of the service, food and drink was not routinely offered to women. However, bottles of drinking water were available. To improve the quality of the ultrasound image, women were asked to drink extra fluids on the lead up to their appointment. Women who were having a gender scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. It was also included in the 'frequently asked questions' on the service's website.

Pain relief

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

Staff checked women were comfortable during their scan and halted scans if women experienced any discomfort.

Patient outcomes

Staff did not monitor the effectiveness of care.

The registered manager did not have an audit programme that provided assurance about much of the quality and safety of the service. The registered manager carried out some audits where they monitored women's experience, cleanliness, health and safety, equipment, policies and procedures.

The registered manager collected some data for their own use on an on-going basis. This included information about the number of ultrasound scans completed and the number of referrals made to other healthcare services. Collecting such data meant the registered manager identified that early reassurance scans were the most popular, followed by gender identification. However, the registered manager had not identified audits of peer reviews and staff files were needed to give valid data and identify trends.

Sonographers were not part of a peer review process to ensure the accuracy and quality of ultrasound scan images, videos, and reports.

In the year from February 2021 to February 2022 the service had referred 35 women to antenatal (NHS) care providers due to the detection of potential concerns.

The registered manager ensured there were clear criteria for doing scans and repeat scans. Rescans were done in the most appropriate timescales. This was to ensure women were not persuaded to have multiple scans, which would not have given them any more information than they already had.

Competent staff

There was a lack of systems and processes in place to ensure that staff were competent in their role.

The service did not have effective systems and processes in place to ensure that staff were competent for their roles as the registered manager did not maintain oversight of training compliance and competencies for sonographers who worked at the service.

Requires Improvement

Diagnostic imaging

The registered manager did not conduct an initial competency assessment of the sonographer when they had first joined the service. The registered manager had checked the sonographer's registration and indemnity insurance.

The registered manager did not ensure annual sonographer competency assessments (and monthly reviews) were completed or ultrasound scan reports were peer reviewed. Peer reviewing ultrasound scan reports means an assessment of the accuracy of a report issued by another radiologist, such as being scored on the report quality and image quality, or if a referral was needed had it been made to the appropriate people.

Staff accessed their training through the service's electronic training portal. Training records confirmed some staff had completed role-specific training.

The registered manager gave all new staff a full induction tailored to their role and experience before they started work. All staff underwent an induction programme which included providing information about staff roles and responsibilities, and mandatory and role-specific training. New staff also completed a three-month probation period.

Managers made sure staff received any specialist training for their role. For example, the member of staff who took bloods for NIPT's was a trained phlebotomist.

The registered manager did not have the evidence from audits to manage any performance issues of the sonographer.

Managers had an appraisal process in place to support staff to develop through annual, constructive appraisals of their work. Not all staff benefitted from the appraisal process, though the sonographer had annual appraisal records in place.

Staff were provided with NIPT procedure guidance. This ensured that women were told the associated benefits and limitations of this screening method. This service (blood testing) was provided by a third party.

Multidisciplinary working

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

The team worked well together and communicated effectively for the benefit of the women and their families.

Staff worked across health care disciplines and with other agencies when required to care for women. The service had links with the local NHS trusts to ensure they had effective referral pathways for women when needed. The service had established pathways in place to refer women local NHS trust if any abnormalities or concerns were identified.

We observed positive staff working relationships promoted a relaxed environment and helped put women and their families at ease.

The registered manager maintained oversight of the NIPT service and processes were in place to track samples, through to receipt in the lab and subsequent results sent through an encrypted email.

Seven-day services

Requires Improvement

Diagnostic imaging

Hey Baby 4D Solihull was not an acute service and did not offer emergency tests or treatment, although they reminded women to call emergency services if necessary and gave women contact details of other NHS services available to them. This meant services did not need to be delivered seven days a week to be effective.

Services were supplied around the availability of the sonographer, according to client demand. This meant the location was not open all day, seven days a week. Services at the location were typically provided on six days of the week, being closed on Thursdays. The times of opening varied each day. Women we spoke with said they had no problems booking an appointment that suited them.

Booking for appointments was available seven days a week, 24 hours a day using the provider's online booking system available to their website. Booking forms allowed clients to select their preferred language. The registered manager and owner of the service spoke several languages in common with people in the local community. Staff used a well-known website for translations. Telephone lines were open during the day and calls were diverted to the owner's mobile phone.

Health promotion

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

The service had relevant information promoting healthy lifestyles, for example, hypnobirthing. The service's website contained health and wellbeing in pregnancy advice, such as keeping healthy during pregnancy, foods to avoid, things to ask your midwife and when to seek medical advice. Women were advised to contact their maternity unit immediately if they thought their baby's movements had changed and/or reduced. This was in line with national recommendations (NHS England, Saving Babies' Lives: A care bundle for reducing stillbirth (February 2016)). Leaflets were available in multiple languages.

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

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff completed training in relation to consent and the Mental Capacity Act (2005) (MCA), as part of their induction and mandatory training programme. There was an MCA policy for staff to follow, which clearly outlined the service's expectations and processes. Staff understood the relevant consent and decision-making requirements of legislation and guidance. The service followed the franchise policy relating to individuals who suffered from any condition covered under the MCA. This detailed how staff should support women and ensure they acted in their best interests.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Before their scan all women received written information to read and sign. This included information about ultrasound scanning and safety information, a declaration form which included the franchise terms and conditions, such as scan limitations, referral consent, and use of data.

Staff made sure patients consented to treatment based on all the information available.

Requires Improvement

Diagnostic imaging

Staff clearly recorded consent in women's records. The sonographer was responsible for obtaining the informed consent of women and completing ultrasound (paper) reports during the woman's appointment. A copy was provided to the woman to take away. Informed consent documentation placed emphasis on the fact that 4D scans were elective and non-diagnostic. Wellbeing checks during the scan processes included the gestational age of the baby and various biometric measurements. Documentation clearly stated that any measurements taking during scanning did not supersede those made at NHS appointments. This information was also given to women verbally, prior to scanning taking place to ensure that women continued to attend regular care within the NHS which was provided for diagnostic purposes.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, MCA and the Children Acts 1989 and 2004 and they knew who to contact for advice. Staff received and kept up to date with mandatory training on the MCA and Deprivation of Liberty Safeguards. Staff were aware of the providers polices for Mental Health. They understood how and when to assess whether a woman had the capacity to make decisions about their care.

Are Diagnostic imaging caring?

Good

We have not previously inspected this service. We rated it as good.

Compassionate care

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

Women told us staff were discreet and responsive when caring for them. Staff were very passionate about their roles and were committed to providing personalised care.

Staff followed policy to keep women's care and treatment confidential. Staff ensured scans were conducted in a way that protected women's privacy and dignity. Staff kept the door to the scanning room shut during the scan to ensure women's privacy was maintained and women were covered throughout.

Women consistently and emphatically said staff treated them well and with kindness. Staff were very warm, kind and welcoming whey they interacted with women and their companions. Staff took time to interact with women and those close to them in a respectful and considerate way. For example, staff asked the woman's name upon arrival and would support them throughout their appointment. The receptionist and registered manager were available to act as chaperones during ultrasound scans to ensure women felt comfortable and received enough emotional support.

Feedback from women included, "The sonographer was so reassuring, they were 100% kind, considerate and thoughtful," "I've been to other places, explained our situation but we were just a number. This place was great. The sonographer explained everything, it was really informative" and, "We booked on the website, they've given us lots of info, we can't fault them."

Women and their companions were also able to leave feedback on open social media platforms, which the registered manager frequently monitored. We reviewed a selection of reviews (from the hundreds available) and found the service

was very highly rated (five stars), and feedback was overwhelmingly positive. For example, responses included statements such as, “Wonderful welcome. Gorgeous setting. Sonographer was phenomenal and made me feel so special. Such a lovely lady!” and, “I had an amazing experience with Hey Baby, they didn’t rush the scan, the lady who scanned me went through everything thoroughly with me so I understood everything.”

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs.

Emotional support

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

Staff gave women and those close to them help, emotional support and advice when they needed it. The service held staggered appointment times; women booked at a time to suit them. Women could provide information at the time of booking an appointment, so staff knew if there was a concern. Women could wait in the scan room till they felt able to leave and leave by the back door if they preferred. Staff were mindful early scans held a higher risk of complications being identified. The sonographer gave the woman the option of starting the scan without the other screen in the room being turned on, especially if there is a child present. This meant if any anomalies were identified the sonographer could make their diagnosis and share the information in an informed, compassionate manner. Staff were calm and reassuring throughout the scan. The sonographer provided reassurance about the scan images and clearly explained what they observed. Women were told they could stop the scan at any time, a poster on the wall reminded them of this.

Women told us staff demonstrated empathy when having difficult conversations. Staff supported women who received upsetting news. The sonographer delivered initial feedback to women and gave women more time and emotional support, for example, in the event of a scan revealing an anomaly or the lack of a heartbeat. Staff gave women aftercare and offered them a drink. Staff could offer women an early scan leaflet with information referring to their next medical steps or signpost women to the miscarriage trust.

Staff understood the emotional and social impact that a woman’s care, treatment or condition had on their wellbeing and on those close to them. Bereavement counselling was available to women by the Kicks Count service. The service had access to written patient information to give to women who had received difficult news. Staff would arrange appropriate follow-up care where appropriate by contacting the relevant midwife with her consent.

After initial consultations, the service held contact details for women requiring test results from non-invasive prenatal testing (NIPT) to enable feedback of blood test results though arrangement of a face to face consultation. Women were signposted to other services which could offer support and counselling where necessary.

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. Staff communicated with women and those accompanying them in a way they could understand. Staff adapted the language and terminology they used when performing the scan. They took the time to explain the procedure to ensure women understood. Family

and friends were welcome in the scan room and there was one screen positioned in the scan room to ensure everyone could see the scan images. The registered manager told us during the COVID-19 pandemic they had restricted women to one visitor accompanying each woman, although these restrictions had been lifted and at the time of our inspection, four people could accompany the woman. Children were welcomed in the waiting area and the scan room.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. Women and their partners felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. Staff took time explaining procedures to women before and during ultrasound scans and left adequate time for women and their companions to ask questions.

Staff supported patients to make informed decisions about their care. Staff made sure women were told about the different scans available and the costs associated with them. Staff provided women with various leaflets signposting them to other care providers and reminded women they should attend their NHS appointments.

Women having NIPT's had the type of tests being undertaken explained to them, including what the results would mean. Women who received bad news were signposted to other services for support and counselling.

Are Diagnostic imaging responsive?

Good

We have not previously inspected this service. We rated it as good.

Service delivery to meet the needs of local people

Women's individual needs and preferences were central to the delivery of tailored services and were delivered in a way to ensure flexibility and choice. The service also worked with others in the wider system and local organisations to plan care.

Staff planned and organised services, so they met the changing needs of people who used the service. Although appointments were available around the availability of the sonographer, people told us they could access services and appointments in a way and at a time that suited them. The service had varied their opening hours depending on the availability of the sonographer and operated clinics six days a week including weekends. The service was not open on Thursdays. The service was flexible because they did not have a fixed closing time, the last appointment depended on the number of bookings.

Managers planned and organised services, so they met the changing needs of the local population. The registered manager explained they had changed the scans that were available during the COVID-19 pandemic and had stopped doing express gender scans and 4D scans. The registered manager increased the time slots between bookings, so each scan was booked for 20 minutes instead of 15 minutes. This gave staff more time to do the additional cleaning and meant the reception area was not full. The VIP 4D scan time was also reduced from 30 to 20 minutes but clients were given a heartbeat bear. At the time of our inspection, all scans were available.

The registered manager provided clear guidance to clients to explain exactly what was involved and what the service could check for. Staff made sure women understood the scans they had did not replace those provided by the NHS.

Requires Improvement

Diagnostic imaging

There was a proactive approach to understanding the needs and preferences of different groups of people and to delivering care in a way that meets these needs, which was accessible and promoted equality. This included people with protected characteristics under the Equality Act, and people who were in vulnerable circumstances or who have complex needs. The registered manager explained the local area was a multi-cultural area.

Information about services offered at the location were accessible online. The service offered a range of ultrasound scans and non-invasive pre-natal testing for pregnant women; such as wellbeing, viability, growth, presentation, and gender and 4D scans. Staff gave women relevant information about their ultrasound scan when they booked their appointment. This included whether they needed a full bladder and when was the best gestation for their scan. Ultrasound scan prices and non-invasive prenatal test (NIPT) prices were detailed on the service's website, and we observed staff clearly explaining costs and payment options to women during their appointments.

Facilities and premises were appropriate for the services being delivered. The environment was appropriate for the service being delivered and was customer centred. The scan room was large with ample seating and additional standing room for several guests, and children of all ages were welcome to attend. The scanning room had one large wall-mounted screen which projected the scan images from the ultrasound machine. This screen enabled women and their families to view their baby scan more easily and from anywhere in the room. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service (December 2014).

The service did not formally monitor rates of patient non-attendance. However, the registered manager said there was a very low rate of non-attendance because the service requested a non-refundable deposit payment on appointment booking. If a woman suffered a miscarriage before their appointment, staff would refund the deposit payment immediately. Women were able to postpone their appointments if they phoned in advance of the appointment.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. They directed women to other services where necessary.

Managers and staff worked to make sure women did not stay longer than they needed to. Staff were able to print photos out for people to take with them.

All scans bar the express gender scan started with a wellbeing check. The sonographer looked at the baby's movements, heartbeat, position, and placental position. The sonographer also looked at the presentation of the baby, head and abdominal circumference measurements. Other measurements, such as femur length measurements and estimated foetal weight were done on growth and presentation scans. The service had systems to help care for women in need of additional support or specialist intervention.

The service also specialised in providing antenatal scans for women from 16 to 40 weeks of pregnancy. Gender confirmation and growth scans were also available. Women who mostly wanted a scan for souvenir purposes had a well-being scan as well and could view their baby in 4D. NHS pregnancy scans show a two-dimensional image. A 4D scan enables women to see their baby moving as a 3D image. Women with a history of ectopic or failed pregnancy had a range of scans they could access. The service only provided private pregnancy ultrasound scans. They did not undertake any ultrasound imaging on behalf of the NHS or other private providers.

Requires Improvement

Diagnostic imaging

Women who wanted to find out the gender of their baby outside of their appointment, such as at a gender reveal party with their family and friends, were given a scratch card telling them whether they were expecting a boy or a girl. If people didn't want to know the gender of their baby, the sonographer asked them to close their eyes while looking for the baby's gender.

The service offered women a range of baby keepsake and souvenir options which could be purchased. The registered manager told us they had not offered the full range of products during the COVID-19 pandemic so they would not encourage families to have large gatherings.

The service had access to a web-based spoken interpreting service for non-English speaking women when needed.

The service used technology and equipment to enhance the delivery of effective care and treatment to women. The service utilised up-to-date scanning equipment to provide high-quality ultrasound images. They also had one large wall-mounted screen situated in the scan room which enabled women and their families to view their baby more easily.

Women were able to access their scan photos and download them onto their phone/laptop, via a link which was sent to them. The link was accessible for up to six months because sometimes women wanted to have a secret gender reveal party and did not want to see the scan immediately.

Access and flow

People could access the service when they needed it. Due to the nature of service provided, there were no national recommended waiting times. They received the right care and their results promptly.

All women self-referred to the service. Women could book their scan appointments in person, by phone, by email or through the service's website. People could purchase a voucher so women could book a scan when they liked. During our inspection, clinics ran on time. Women were given a written report if they were referred to their midwife or hospital. Women who did not need to be referred were sent an email which contained a link giving access to the Hey Baby 4D Solihull application at the end of their appointment.

The service followed the franchise foetal abnormality policy which detailed the process to follow if these were identified.

Women were offered a variety of appointment times, providing flexibility to those who required an appointment outside of normal working hours and at weekends. Bookings were taken either through the website or over the telephone. The registered manager monitored how women had accessed the service, for example, through word of mouth, advertising, the internet or social media.

Women who wanted NIPT were mostly able to have same day appointments. However, some tests were screened abroad and these tests were therefore, taken on Sundays, to ensure the samples arrived at the laboratory within five days.

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. The service included women in the investigation of their complaint.

Requires Improvement

Diagnostic imaging

Women, relatives and carers knew how to complain or raise concerns. The service had an up-to- date complaints policy, which outlined procedures for accepting, investigating, recording and responding to local, informal, and formal complaints about the service. The policy confirmed that all complaints should be acknowledged within 24 hours and resolved within three working days.

Staff understood the policy on complaints and knew how to handle them. The registered manager investigated any complaint received through the service's website or social media, or directly via email. The registered manager told us they attempted to deal with concerns at the time to resolve women's concerns. Staff asked women if they were happy with the service they received at the end of their appointments this helped identify any potential dissatisfaction whilst still on-site.

The registered manager investigated complaints and identified themes. In the past year, there had been six complaints. A complaint theme was regarding the poor quality of scan pictures due to the baby moving or their positioning. Where appropriate, the provider had provided re-scans. All complaints were investigated and closed in a timely manner in line with the complaints policy.

The service actively encouraged feedback, both in person, by email and though open platform social media sites. The registered manager told us feedback was important but had not identified any changes were needed as a result.

Are Diagnostic imaging well-led?

Requires Improvement

We have not previously inspected this service. We rated it as requires improvement.

Leadership

Leaders 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.

The business was a family run business led by the registered manager. They were also a 50% owner of the business. The owners both demonstrated an awareness of the limitations and the challenges the service faced. They were also aware of the actions needed to address those challenges. COVID-19 was their biggest challenge and the constantly changing government guidelines.

Regular communication took place between the registered manager and staff. Due to the small number of staff in post, staff saw each other on a regular basis to discuss pertinent topics and issues affecting the service. In the event of the registered manager being off-site, staff could contact the registered manager by telephone.

Staff informed us that the registered manager and co-owner were very friendly, approachable, and effective in their roles. Staff felt confident to discuss any concerns they had with them; and were able to approach the registered manager directly, should the need arise.

Hey Baby 4D Solihull is a franchise of Hey Baby 4D. The franchisor provided operational support such as templates for documents, though the service was responsible for their own marketing.

Requires Improvement

Diagnostic imaging

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action The vision and strategy were focused on sustainability of services.

Hey Baby 4D services were founded on four key principles; fun, family, fair and friendly. The service had a clear vision and values which were focused on providing a first-rate service consistent with the Hey Baby 4D Solihull vision and values. Staff told us the values were to provide a "friendly environment" service. The registered manager told us the ethos for the service was to provide the highest possible standards of service and care every time.

The registered manager was passionate about treating clients with empathy and understanding and led staff to make everyone's experience the best it could be. Feedback from clients overwhelmingly praised staff for the friendly and supportive environment that surrounded them. People we spoke with confirmed this and said they would highly recommend the service.

The registered manager had a strategy in place to increase the range of scans available and introduce transvaginal scans for early pregnancy (from six weeks gestation) and more opening hours in future. However, at the time of our inspection, no implementation dates had been set.

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 staff could raise concerns without fear.

Staff described the culture within the service as open and told us the registered manager was supportive to staff. Staff told us they felt respected and valued. They enjoyed coming to work and were proud to work for the service. Staff told us their colleagues were like family. Staff were aware of the whistleblowing policy and could raise any concerns. The service had a whistleblowing policy in place. We reviewed the policy and noted that it had been reviewed in July 2020.

Staff completed equality and diversity training. Staff were encouraged to raise concerns openly and without fear of recrimination.

Governance

Leaders did not always operate effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The registered manager did not have oversight of risks to the service and did not act on actions identified in an external risk assessment.

The service had a document named 'governance policy' in place. This document outlined the key responsibilities for various staff roles from a governance perspective including, but not limited to; the director, registered manager, sonographer/ ultrasound technician and receptionist.

Requires Improvement

Diagnostic imaging

We found a clear line of governance to communicate information throughout the service, and to also escalate and cascade information up and down lines of management and staff. Staff were clear about their roles and understood what they were accountable for and to whom. Staff could describe the governance processes for incidents and complaints and how they were investigated. Staff reported any governance matters such as incidents or complaints to the registered manager.

Staff were able to access the provider's policies both electronically and in paper format. The franchisor provided policy templates for the service, which the registered manager was able to adapt to meet the needs of the service.

The registered manager had an information governance policy, which staff were aware of. The registered manager provided feedback to staff through appraisals and daily meetings. For example, staff had been given information about mandatory vaccinations during one to one meetings with the registered manager.

The registered manager provided feedback to staff about any complaints, incidents, women's feedback, performance, compliance with policies and procedures and any clinic issues. Clinic opening times were agreed between them based on the availability of the sonographer. Staff understood the requirements of duty of candour and were aware of the policy in place.

Management of risk, issues and performance

The service had minimal systems in place to identify risk, plan to eliminate or reduce them. They had plans to cope with the expected and unexpected.

The registered manager had not identified the need to ensure staff working at the service had completed the required mandatory training and competencies to carry out their role. In addition, there were no systems or processes in place to ensure that all staff working within the service had received references and work histories.

The registered manager did not have an effective audit programme to provide assurance of the quality and safety of the service. Local audits, such as clinical and compliance audits were not undertaken regularly; data was not collected by the registered manager to monitor performance. Additional assurance was provided by the franchisor conducting compliance visits. The franchisor had completed one compliance visit in February 2022 and had identified several areas where the service needed to improve. The franchisor had identified similar findings to ours; that audits and risk assessments were not up to date and peer reviews needed to be done regularly. The franchise audit had identified the actions needed but had not set any timeframes for these to be achieved.

Risk within the service was monitored and overseen through use of a document named 'risk assessment'. We reviewed this document and saw it identified potential hazards, including but not limited to; infection, fire and ultrasound. The risk assessments clearly outlined the owner for each risk with action dates and area to indicate when actions were complete. However, we could not gain assurances this document was effectively monitored or overseen due to the identified issues with lack of documentary evidence for references and work history, lack of Legionella monitoring and the lack of audits in use. Sonographer peer review audits were not undertaken in accordance with recommendations made by the British Medical Ultrasound Society, and the franchisor had not completed annual sonographer competency assessments.

This was a breach of Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

Requires Improvement

Diagnostic imaging

The service had a clinic contingency plan in place to identify actions to be taken in the event of an incident that would impact the service. For example, extended power loss, short notice staff sickness and equipment failure. The contingency plan included contact details of relevant individuals or services for staff to contact.

Information Management

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

The service was up to date with information governance and had data retention policies. These stipulated the requirements of managing patients' personal information in line with current data protection laws. The service was registered with the Information Commissioner's Office (ICO), which is in line with 'The Data Protection (Charges and Information) Regulations' (2018). The ICO is the UK's independent authority set up to uphold information rights.

Scan reports were retained for a period of eight years and scan images were retained for one year, so that any issues following the scan could be identified and rectified. This information was clearly detailed in the terms and conditions of the service.

The service's public website provided a range of information around various scanning packages and NIPT services that were offered. Information explained that NIPT is not available through the NHS and outlined the process of testing and how the test identifies various chromosomal abnormalities, as well as the gender of the baby.

NIPT results were sent to the registered manager (from a third-party service) using encryption codes to ensure confidentiality.

The service had secure processes in place to share information to women and other relevant healthcare professionals where required. The service had a public website in place to provide information for women on various scan packages and examinations offered.

Engagement

Leaders and staff actively and openly engaged with women, staff, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

Women were asked to provide feedback when they visited. The service used social media and google reviews to obtain feedback from women and their families. Feedback included, "Had my first experience at Hey Baby today. It was a great experience. Staff are really friendly and they really put my mind at ease" and, "Amazing experience. We went for a reassurance scan as my anxiety has been driving me crazy and loved every second".

The registered manager and sonographers had developed working relationships with local NHS hospitals, which meant staff were able to refer women to the appropriate service if any anomalies were detected.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Requires Improvement

Diagnostic imaging

The service actively sought feedback and made changes as a result of feedback. For example, the NIPT laboratory provider had been amended following feedback regarding results' time frames.

Hey Baby 4D Solihull sent women a link to access their scans. The franchisor was developing a new website which was being rolled out to franchisees, this would provide access for women to provide feedback directly to the website.

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 19 HSCA (RA) Regulations 2014 Fit and proper persons employed The provider must ensure recruitment procedures are operated effectively.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider must ensure there are systems and processes in place to maintain effective oversight of risk and role competencies.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment The provider must ensure that clinical waste is stored securely.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The provider must ensure records are kept of testing required by Legionella risk assessments.