Hey Baby 4D Birmingham Ltd

Hey Baby 4D Birmingham

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	Good
Are services safe?	Good
Are services effective?	Inspected but not rated
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Good

Summary of findings

Overall summary

This was our first inspection of this service.

We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills, 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. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.
- Staff provided good care and treatment. Managers made sure staff were competent. 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, took account of women's individual needs, and made it easy for people to give feedback. Although clinics were arranged depending on the availability of the sonographer, people told us they 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.

However,

- The provider did not always use a translation service to support them to provide accurate and complete information to women whose first language was not English.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good	This was our first inspection of this service. We rated it as good because: • The service had enough staff to care for women and keep them safe. Staff had training in key skills, 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. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service. • Staff provided good care and treatment. Managers made sure staff were competent. 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, took account of women's individual needs, and made it easy for people to give feedback. Although clinics were arranged depending on the availability of the sonographer, people told us they 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. However,

Summary of findings

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Summary of findings

Contents

Summary of this inspection

Background to Hey Baby 4D Birmingham

Hey Baby 4D Birmingham is operated by Hey Baby 4D Birmingham Ltd. The service opened on 28 March 2020. It is a franchise of Hey Baby 4D and is in Acocks Green, Birmingham, serving those in the local community.

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

The service is available to women aged 18 years and above. All ultrasound scans performed at Hey Baby 4D Birmingham 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 25 February 2020. The service was registered by CQC in January 2020. The service has not been inspected previously.

Hey Baby 4D Birmingham 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

- The provider should ensure they use a translation service to support them to provide accurate and complete information to women whose first language was not English. (Regulation 9)

Our findings

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Good

This was the first inspection for this service. We rated safe as good.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up-to-date with their mandatory training. The mandatory training was comprehensive and met the needs of women and staff. The registered manager ensured all staff completed a range of mandatory training which included fire safety, infection control, safeguarding, health and safety, Mental Capacity Act, equality and diversity and information governance.

Staff also completed role specific mandatory training. For example, staff completing forms with women which required confidential personal information were required to complete Recording Information and General Data Protection Regulations (GDPR). At the time of our inspection, all staff had completed their mandatory training.

The registered manager monitored compliance with mandatory training and alerted staff when they needed to update their training. Staff confirmed they were given enough time to do training.

The registered manager ensured staff could access online training appropriate for the service. Staff told us they were able to request additional training and this would be provided for them.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Good

Diagnostic and screening services

Staff received training specific for their role on how to recognise and report abuse. The service had clear safeguarding processes and procedures. All staff were trained to at least safeguarding level two for both vulnerable adults and children; for example, healthcare assistants completed safeguarding level two training and the sonographer completed safeguarding level three training. The registered manager was the safeguarding lead and had completed safeguarding level three training.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff had access to an up-to-date safeguarding policy. 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. Staff told us how they had identified a safeguarding concern in the past and had made a referral to the local authority.

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

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.

Everyone arriving at the clinic had their temperature taken and were asked about their current health status. All visitors were asked to sanitise their hands and wear masks.

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 scan room safety and hygiene policy originally supplied by the franchise. The registered manager had added COVID-19 changes to this policy.

Cleaning schedules were displayed in the clinic in line with this policy. Staff cleaned equipment and waiting areas after every customer contact. For example, the couch in the treatment room used by women was covered with a disposable cloth which was changed between patients.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff completed a daily cleaning log and undertook cleanliness visibility checks of toilet areas throughout their shifts. Staff documented and rectified any areas of concern as necessary. 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). The service had appropriate handwashing facilities and sanitising hand gel was available. Staff had their arms bare below their elbows and washed their hands before and after each scan. Personal and protective equipment such as latex-free gloves and antiseptic wipes were readily available for staff to use at the service.

In the twelve 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.

Good

Diagnostic and screening services

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 infection prevention and control (IPC) compliance.

The service offered non-invasive pre-natal testing (NIPTS) 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).

NIPTS means the baby's DNA circulating in the mother's blood can be checked for certain chromosomes. An abnormal number of these chromosomes could indicate the presence of certain inherited conditions, such as Down's Syndrome and Turner Syndrome. Down's Syndrome is a condition where a person has an extra chromosome. Turner Syndrome only affects women and results when one of the X chromosomes is missing or partially missing. The tests can be done as early as ten weeks into the pregnancy.

The service had an NIPT procedure 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. Staff managed clinical waste well.

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. The premises were a modern single storey building and had access suitable for people in wheelchairs. The building comprised a graduated ramp with handrails and flat access through the front entrance into to the reception area. There was one separate scan room with a modern couch which could be adjusted for comfort. Two large screens were on the walls and a couch for people accompanying the woman. The scan room also had a hand-washing sink and storage cupboards for disposable items.

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 daily 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 had been safety tested within the last 12 months. This was in line with the provider's safety policy.

Staff disposed of clinical waste safely. 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. Clinical waste was safely stored in a secure, locked area at the back of the premises, with locked bins. The area could only be accessed with a key.

Disposable equipment was labelled with dates when it was opened and disposed of when the expiry date was reached.

Good

Diagnostic and screening services

The service had appropriate facilities and equipment for taking blood samples. The non-invasive prenatal test (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. Non-invasive prenatal testing (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. The sharps bins for needles used for taking bloods were stored safely and emptied quarterly.

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.

Staff knew about and dealt with any specific risk issues. The service provided clear guidance for sonographers to follow when they identified unexpected results during a scan. This was referenced in the provider's policy, which stated every woman would have a diagnostic well-being check. Should any anomalies be found, staff told us they informed the woman in a caring, honest and professional manner. The woman was given a detailed medical report clearly explaining the scan findings. Staff followed the referral pathway agreed with the local National Health Service (NHS), Foetal Medicine Unit (FMU) or Early Pregnancy Unit EPU/EPAU.

Staff gave examples of redirecting women who were experiencing pain or bleeding to their local NHS clinical team. Sonographers 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 114 women to NHS services 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.

Staff told us they would either phone a woman's GP if a hospital appointment wasn't needed, with the woman's consent or recommend the women called them themselves.

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 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 service had two locum sonographers, both of whom worked for the NHS. Sonographers were able to alert other staff to any problems by sending an instant message to reception, so they didn't need to leave the room. Sonographers were also able to access support from other sonographers. For example, they would contact another sonographer in the network of similar services the registered manager was part of to ask another sonographer to look at scans for a second opinion. A group of registered managers had developed a support network so sonographers could access support and managers could share good practice. The sonographer we spoke with confirmed they were able to access support in a timely way.

Staffing

Good

Diagnostic and screening services

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.

The service had enough staff to keep women safe. The registered manager planned staffing levels to meet demand on the service, measured by the number of bookings made in advance. The service employed two locum sonographers and one healthcare assistant (HCA). All members of staff were trained as chaperones. Women booked their appointments online and the registered manager, owner and HCA shared responsibility for managing enquiries, appointment bookings, supporting the sonographers during ultrasound scan procedures and printing scan images.

The registered manager completed a risk assessment for the location, which was last updated in April 2021. 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 five personnel files and all staff had proof of identification, residence, and an up-to-date curriculum vitae on file. The service had obtained two references for all staff in line with their policy. We also saw employment offer letters, evidence of induction training, qualifications, and professional memberships were kept on file.

The sonographers were registered with the Health and Care Professionals Council (HCPC) and had professional indemnity insurance.

The service had low vacancy, turnover, and sickness rates and staff described the team as consistent and stable. The service did not use bank or agency staff. The registered manager had an arrangement with a locum sonographer to cover any absenteeism.

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 (ICO).

Women's notes were comprehensive, and all staff could access them easily. Pre-scan questionnaires and consent forms at the service ensured enough information was obtained from women before their scans; for example, in relation to number of weeks pregnant, and number of previous pregnancies. Women were also required to declare medical conditions that might affect their scan.

Staff ensured women's confidential personal information (CPI) was maintained and not accessible to others. For example, women's registration forms were kept at reception in a covered clip board before they were called in to the scanning room.

Records were stored securely. All records were kept electronically, and computers were password protected. When a woman was referred to hospital, they were given a printed copy of the referral form to take with them. A copy of the report was emailed to the woman or hospital on request. 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.

Good

Diagnostic and screening services

Incident reporting, learning and improvement

The service managed safety incidents well. Staff recognised and knew how to report incidents and near misses. Managers 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. 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 to report incidents and an incident log was available in the clinic. The service had never had an incident. If an incident was to occur, the registered manager was responsible for conducting investigations into all incidents at the location.

As there had been no clinical incidents at the time of our inspection, we were unable to see documentary evidence that patient safety incidents had been recorded, however, the quality assurance feedback monitoring form had specific areas to document actions taken, by who and mitigating steps taken to avoid reoccurrence of potential incidents.

The service had no never events. Since the service opened in February 2020 to this inspection, there were no 'never events', or serious incidents at the location.

Staff understood the duty of candour. In the past year, there were no incidents requiring 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 regulatory requirements.

Informal staff meetings took place on a regular basis where discussions included topics such as infection prevention and training. 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.

The sonographer informed the woman of the result of NIPT's. A copy of the results was given to the woman to share with her maternity provider if she chose to. If any anomalies had been identified, the woman was asked for her consent and the service also shared the information with the woman's maternity provider.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not currently rate effective.

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women subject to the Mental Health Act 1983.

Good

Diagnostic and screening services

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. The franchisor provided policy templates for the service, which the registered manager was able to adapt to meet the needs of the service.

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 (NICE) 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 during monthly team meetings. All 11 policies and protocols we reviewed 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 signed this update.

The service followed the 'As Low As Reasonably Achievable' (ALARA) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society (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 scans.

The service had an effective audit programme that provided assurance about the quality and safety of the service. The registered manager carried out audits where they monitored women's experience, cleanliness, health and safety, ultrasound scan reports, equipment, policies and procedures. The registered manager also completed annual sonographer competency assessments and monthly reviews.

Sonographers audited each other's scans and scan documentation. They scored on the report and image quality and checked when a referral was needed that it had been made to the appropriate service. The registered manager had oversight of this.

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 two large wall-mounted screens 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 a couple of months because sometimes women wanted to have a secret gender reveal party and didn't want to see the scan immediately.

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

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

Good

Diagnostic and screening services

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 monitored the effectiveness of care. They used the findings to make improvements and achieved good outcomes for women.

The registered manager collected 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. This enabled the registered manager to understand what audits were needed to give valid data and identify trends and areas for improvement. The franchisor had not completed any audits, so it was not possible for the service to benchmark themselves against similar services.

Sonographers were part of a peer review process to ensure the accuracy and quality of ultrasound scan images, videos, and reports. The franchise did not have oversight of this and had not set any targets.

In the past year, the service had referred 114 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

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. Staff accessed their training through the service's electronic training portal. Training records confirmed staff had completed role-specific training.

The registered manager conducted an initial competency assessment of sonographers when they had first joined the service. The registered manager also completed a competency assessment which included checking their registration, indemnity insurance and revalidation status.

Good

Diagnostic and screening services

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. For example, sonographers who had trained outside the UK undertook qualification conversion training during their induction. 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 non-invasive pre-natal testing (NIPT's) was a trained phlebotomist. Phlebotomists collect blood samples from patients and send them off for analysis and testing. Phlebotomists were trained to be able to explain and discuss the benefits and limitations of NIPT screening with women.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff had the opportunity to discuss training needs with the registered manager and were supported to develop their skills and knowledge. The registered manager would manage any performance issues of sonographers. The IT system meant other sonographers could securely support sonographers on or off site and identify specific types of scans during which to target support.

Managers had an appraisal process in place to support staff to develop through six monthly, constructive appraisals of their work. Staff had their first appraisal after six months with the service and then six-monthly after that. All staff who had worked at the service for a year or more had received two or more appraisal meetings.

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

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 healthcare 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.

The registered manager was able to track NIPT samples from when they were received in the laboratory, when they were analysed and when the results were sent out. Women were asked about their maternity provider when they booked a NIPT and with their consent, a copy of the results was sent to their provider.

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

Seven-day services

Hey Baby 4D Birmingham 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.

Good

Diagnostic and screening services

Services were supplied according to women's demand and the opening times varied each day to meet this demand. his meant the location was not open all day, seven days a week. Services at the location were typically provided six days a week, being closed on Tuesdays.

This offered flexible service provision for women and their companions to attend around work and family commitments.

Booking for appointments was available seven days a week, 24 hours a day using the provider's online booking system available to their website.

Health promotion

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

The service had relevant information in patient areas promoting healthy lifestyles, for example, pregnancy yoga and general health and support. 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. This was in line with national recommendations (NHS England, Saving Babies' Lives: A care bundle for reducing stillbirth (February 2016)).

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), as part of their induction and mandatory training programme. There was a Mental Capacity Act (2005) 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 mental capacity act (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 pre-scan questionnaire and declaration form which included the franchise terms and conditions, such as scan limitations, referral consent, and use of data.

Staff clearly recorded consent in women's records. Sonographers were responsible for obtaining the informed consent of women and completing ultrasound (paper) reports during the woman's appointment, with the support of the scan assistant. A copy was provided to the woman to take away.

Good

Diagnostic and screening services

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 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 Mental Capacity Act and Deprivation of Liberty Safeguards. Staff were aware of the providers policies for Mental Health. They understood how and when to assess whether a woman had the capacity to make decisions about their care.

The phlebotomist ensured women understood the procedure for NIPT's and what the results could mean before they asked for the woman's consent. Consent was obtained in line with current legislation and guidance. Where anomalies were found, the results were documented, and the phlebotomist sought the woman's consent to share the information with their maternity provider.

Are Diagnostic and screening services caring?

Good

This was the first inspection for this service.

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. 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 health care assistant and registered manager were available to act as chaperones during ultrasound scans to ensure women felt comfortable and received enough emotional support. A chaperone was always present during transvaginal scans.

Feedback from women included, "We are glad that we picked them as we have received an excellent service from them", "Having previously attended a different company for a very early reassurance scan I have to say that Hey Baby 4D is just brilliant. The girls on the reception are so lovely and chatty and put you at ease, and they are genuinely excited for each expectant couple there. The sonographer has been lovely both times and takes time to explain everything" and "The sonographer is so professional and made beautiful pictures for us. The receptionist and manager are so caring. They looked after us as if we are special."

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, "what a lovely couple could not recommend this place enough, very friendly and reassuring and the scan was done in such detail and they knew my worries so they helped in all areas to make me feel comfortable and relaxed."

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs. For example, the registered manager explained that if women wanted a female sonographer, they were referred to a different clinic where a female sonographer would be available.

Staff had a privacy screen to ensure the privacy and dignity of women. The scan room door had a sliding sign which allowed staff to select 'in use' or 'vacant' and the door was also lockable. Telephone lines were open during the day and calls were diverted to the owner's mobile phone. This meant the owner could move away from the reception area if necessary, to afford discretion and privacy to the caller.

Women we spoke with were delighted with the service they received. Women told us they felt the service they received was 'excellent' and praised the staff highly. They told us staff were very friendly and kind and this made them feel very comfortable.

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 until they felt able to leave and there was an option to leave by the back door if they preferred. Staff were mindful early scans held a higher risk of complications being identified. The sonographer gave women the option of starting the scan without the other screens in the room being turned on, especially if there was 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.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff supported women who received upsetting news. The sonographer delivered initial feedback to women. Sonographers were able to send an instant message to staff on reception so they could give 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 them to their next medical steps or signpost women to the miscarriage trust.

Good

Diagnostic and screening services

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. The service signposted women to an external bereavement counselling charity if they required additional bereavement support. The service had access to written patient information to give to women who had received difficult news. Where women gave their consent, staff would also arrange appropriate follow-up care by contacting their midwife.

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 were two screens 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 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 NIPTs 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 and screening services responsive?

Good

This was the first inspection for this service. We rated responsive 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.

Good

Diagnostic and screening services

Staff planned and organised services, so they met the changing needs of people who used the service. People 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 sonographers and operated clinics six days a week including weekends. Women told us they had not had to wait to book an appointment. The service was flexible with the last appointment dependant 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 scans, gender scans and 4D scans. The VIP 4D scan time was also reduced from 30 to 15 minutes. This was to reduce the time women and their partners spent in the clinic to reduce the risks of spreading COVID-19. At the time of our inspection, all scans were available.

Information about services offered at the location were accessible online. The service offered a range of ultrasound scans 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 were detailed on the service's website, and we observed staff clearly explaining costs and payment options to women during their appointments.

The registered manager identified there was a demand for non-invasive pre-natal testing (NIPT) and had increased the services available to include these. The registered manager provided clear guidance to women s to explain exactly what was involved and what the service could check for. The registered manager had also made late reassurance scans available. Staff made sure women understood the scans they had did not replace those provided by the NHS.

Booking forms allowed women to select their preferred language. The registered manager and owner of the service spoke several languages in common with people in the local community.

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 they had provided services for many same sex couples and the local area was a multi-cultural area. Staff made women aware the sonographers were male and signposted them to another clinic where female sonographers were available if they preferred.

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 enough seating and additional standing room for several guests and children of all ages were welcome to attend. The scanning room had two large wall-mounted screens which projected the scan images from the ultrasound machine. These screens 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 was aware 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.

Good

Diagnostic and screening services

The service offered non-invasive pre-natal testing (NIPTS) services and had a contract with an accredited clinic in place.

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.

All staff ensured women did not stay longer than they needed to. Staff were able to print photos out for people to take with them.

All scans 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 as well as 2D. 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.

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 sealed envelope with a printed picture telling them whether they were expecting a boy or a girl. The sonographer could turn the screens off while looking for the baby's gender. Women who provided feedback on social media sites were very enthusiastic about the service's gender reveal lighting, where the lights in the room could be changed to pink or blue.

The service offered women a range of baby keepsake and souvenir options which could be purchased. This included heartbeat bears which were offered after 16 weeks, a selection of photo frames, and gender reveal products such as scratch cards footballs and shooting cannons. Heartbeat bears contained a recording of the unborn baby's heartbeat. 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.

Staff used a well-known website for translations however, they sometimes used families to translate for women whose first language was not English. This is not good practice because a lack of a formal translation service could pose a risk to expectant mothers if anomaly findings were not communicated and understood correctly.

The service also used an online 'read aloud' function. The registered manager told us the franchise could provide easy to read and large print information leaflets for women with sight impairment.

Access and flow

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

Good

Diagnostic and screening services

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. All women were given a printed report. Women who needed to be referred could request their report be sent to their midwife, hospital or GP via email. Women could be emailed a link where they could access their pictures and videos electronically, depending on the package they purchased.

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

NIPT results usually took two weeks to be received from the laboratory.

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.

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 three working days and resolved within 21 working days.

The service clearly displayed information about how to raise a concern in patient areas. Staff understood the policy on complaints and knew how to handle them. The registered manager investigated any complaint received through the service's comments cards, website or social media. The registered manager 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 two complaints. All complaints were investigated and closed in a timely manner in line with the complaints policy. Action was taken in response to complaints received to help improve women's experience and service provision. For example, when the sonographer needed the room to be quiet to listen to a baby's heartbeat, they explained they would not be talking while doing this.

Staff could give examples of how they used patient feedback to improve daily practice. The service actively encouraged feedback, both in person, via email and open platform social media sites. The service had acted on feedback. For example, the service had introduced late reassurance scans and non-invasive pre-natal testing (NIPTs) to meet patient demand. The registered manager had also increased the range of gender reveal items available following a request for these.

Hey Baby 4D Birmingham's induction programme included a course on customer care and dealing with complaints which all staff had completed. All staff knew who to contact if they received a complaint.

Good

Diagnostic and screening services

Are Diagnostic and screening services well-led?

Good

This was the first inspection for this service.

We rated well-led as good.

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. They supported staff to develop their skills and take on more senior roles.

The registered manager led the service and was also a director of the business. The owners both demonstrated an awareness of the service's performance, limitations and the challenges it faced. They were also aware of the actions needed to address those challenges.

Staff informed us that the registered manager and director 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 Birmingham is a franchise of Hey Baby 4D. The franchisor provided marketing and operational support such as templates for documents, and digital marketing services. The franchisor had not provided any clinic visits, national provider meetings or training events at the time of our inspection.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services. Leaders and staff understood and knew how to apply them and monitor progress.

The service had a clear vision and values which were focused on providing a first-rate service consistent with the Hey Baby 4D Birmingham vision and values. Staff told us the values were to provide a "fair, family oriented, fun and friendly' service." These were displayed in the clinic.

The registered manager told us the ethos for the service was to provide the highest possible standards of service and care every time. They were passionate about treating women with empathy and understanding and led staff to make everyone's experience the best it could be. Feedback from women overwhelmingly praised staff for the friendly and supportive environment that surrounded them. Everyone we spoke with confirmed this and said they would highly recommend the service.

The registered manager had plans to expand the service by offering more appointments.

Culture

Good

Diagnostic and screening services

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 we met were friendly, welcoming and confident. Staff told us they felt supported, respected, and valued by their managers. They enjoyed coming to work and were proud to work for the service. Every member of staff told us their colleagues were like family. We observed staff working well as a team. Staff were aware of the whistleblowing policy and could raise any concerns.

Staff completed equality and diversity training. Staff were encouraged to raise concerns openly and without fear of recrimination. We saw examples of this in the implementation of the accident, incident, safeguarding and complaints procedures. In addition, staff had shared concerns about the flooring in the clinic which had been changed to ensure it was non-slip, as a result of staff sharing the feedback.

Governance

Leaders operated 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.

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.

The registered manager had an information governance policy, which staff were aware of. The registered manager provided feedback to staff through appraisals and monthly staff meetings. Staff also benefitted from 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, any clinic issues, audit results, staffing and rotas in the monthly team meetings.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The registered manager had an effective audit programme to provide assurance of the quality and safety of the service. Local audits, such as clinical and compliance audits were undertaken regularly; data was collected by the registered manager to monitor performance. Where issues were identified, we saw these were and addressed quickly and openly. Additional assurance would be provided by external audits undertaken by the franchisor if requested. The franchisor had not set any key quality indicators, so the registered manager had not been able to benchmark the service against other clinics in the Hey Baby group.

Good

Diagnostic and screening services

Sonographer peer review audits were undertaken in accordance with recommendations made by the British Medical Ultrasound Society, and the franchisor completed annual sonographer competency assessments.

The registered manager had completed risk assessments for identified risks such as COVID-19, fire, health and safety and Legionella. Legionella is a bacterium that causes illnesses such as Legionnaires' disease or a fly-like illness. A standard template was used to ensure consistent information was captured. The risk assessments identified who or what was at risk, the hazards and their potential effects, existing control measures in place, the risk rating, whether the risk was adequately controlled, and additional control measures needed. Most of the risks were graded low and had adequate controls in place to minimise each risk. Staff were aware of the risk assessments because they had been circulated to all employees and the management team. All risk assessments were reviewed annually or sooner if indicated.

The service had a clinic contingency plan with identified actions to be taken in the event of an incident that would impact the service. For example, extended power loss, severe weather events, 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 reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The service was up-to-date with information governance and had data retention policies. These stipulated the requirements for 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. Scan reports could be reviewed remotely by another sonographer to enable timely advice and interpretation of results when needed, to inform patient care.

We saw that appropriate and accurate information was effectively processed, challenged and acted upon. Key performance, audit, and patient feedback data was frequently collated and reviewed to improve service delivery.

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 and their families were asked to provide feedback when they visited. The service also used social media and internet reviews to obtain feedback from women and their families. Feedback included, "This is the best place to have a scan in Birmingham" and, "They go above and beyond to make your time there special, nothing is too much."

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

Good

Diagnostic and screening services

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation.

The service demonstrated a strong commitment to professional development. This included on-line and site based continuous professional development training for personal and professional growth. One member of staff told us how they were being supported to train as a sonographer.

The service had implemented a lighting system to enhance the gender reveal scan experience. The colour of pink, or blue, was revealed once the gender of the baby had been identified by the sonographer. This service was a choice given to women and not compulsory.

Depending on the package purchased, women could view their scans on their mobile phones and share them with their families. Women could also share their reports with their maternity providers from their phones.