

Hey Baby 4D Kent West Ltd

Hey Baby 4D Tunbridge Wells

Inspection report

88
London Road, Southborough
Tunbridge Wells
TN4 0PP
Tel:

Date of inspection visit: 12 May 2022
Date of publication: 22/07/2022

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 the 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 and acted on them.
- Staff provided good care and treatment. They worked well together for the benefit of women and supported them to make decisions about their care and had access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity, and 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. People could access the service when they needed it and did not have to wait for their results.
- The service considered the impact a potential failed pregnancy or anomaly finding could have on women and their family.
- 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 families to plan and manage services and all staff were committed to improving services continually.

However:

- The sharps bin was not located within the clinical room and we saw staff transporting sharps to the sharps bin.
- The clinical waste bin situated outside of the clinic was not locked.
- Boxes were stored on the floor of the storeroom. This meant that there was no free access to the floors and shelves for cleaning.
- The service did not have access to interpreters or signers.
- Paper records were stored securely but records were not in order and relevant information was not kept together.
- There were policies and procedures which had not been reviewed or updated.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	We rated it as Good. See the summary above for details.

Summary of findings

Contents

Summary of this inspection	Page
Background to Hey Baby 4D Tunbridge Wells	5
Information about Hey Baby 4D Tunbridge Wells	5
<hr/>	
Our findings from this inspection	
Overview of ratings	7
Our findings by main service	8
<hr/>	

Summary of this inspection

Background to Hey Baby 4D Tunbridge Wells

Hey Baby 4D Tunbridge Wells is operated by Hey Baby 4D Kent West Limited. The service opened in 2020 and had not been inspected before.

The service provides private pregnancy scanning for the community of Tunbridge Wells and the surrounding areas.

The service provides ultrasound scans for reassurance or gender determination from six to 42 weeks of pregnancy which are:

- Early reassurance scanning offering transvaginal scans to women from under 10 weeks and abdominal scan from 10 weeks and above.
- Gender scan (from 16 weeks)
- Growth and wellbeing scan (from 24 to 28 weeks)
- Four-dimensional (4D) scan package (from 24 to 34 weeks)

Appointments include scan findings and images for keepsake purposes. In the event of possible anomaly detection, women and families are referred to the local NHS early pregnancy assessment unit or maternity service depending on the stage/gestation of pregnancy.

The service also provides non-invasive prenatal testing (NIPT). NIPT is a screening test used to determine the risk of a child being born with certain chromosomal abnormalities such as Down's Syndrome, Edwards and Patau's syndrome and the gender of the baby.

The clinic was open from 12pm to 8pm on Monday and Wednesdays, from 10am to 6pm on Thursdays and from 9am to 5pm at weekends.

The service registered with CQC in July 2020. The service has had the same registered manager in post since registration.

How we carried out this inspection

We carried out this unannounced inspection using our comprehensive inspection methodology on 12 May 2022.

During the inspection visit, the inspection team:

- Spoke with the registered manager, a sonographer and reception staff.
- Spoke with two women.
- Looked at a range of policies, procedures, audit reports and other documents relating to the running of the service.

Summary of this inspection

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 **SHOULD** take to improve:

- The service **SHOULD** ensure that all clinical waste storage outside of the building is secure.
- The service **SHOULD** ensure sharps bins are accessible within the clinical room.

Action the service **MUST** take to improve:

- The service **MUST** ensure all paper records are kept in order, with all relevant information within records kept together. (Regulation 17) (2)
- The service **MUST** ensure all policies and procedures are reviewed within their review date and updated as required. (Regulation 17) (2)






Our findings

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Are Diagnostic imaging safe?

Good 

We rated it 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. All staff we spoke with had completed their mandatory training and training was specific to their roles. For example, the administrative staff had completed chaperoning training. Staff confirmed they were given enough time to do training.

The mandatory training was comprehensive and met the needs of women and staff. The training was provided through e-learning and relevant updates and information was provided during team meetings.

Managers monitored mandatory training and alerted staff when they needed to update their training. The training met the requirements of the service and the manager kept up to date records of employees training. Mandatory training included a range of subjects such as infection prevention and control, equality, diversity and inclusion, manual handling, basic life support, fire safety awareness and Mental Capacity Act (MCA).

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.

Staff received training specific for their role on how to recognise and report abuse.

Safeguarding training was part of the mandatory training programme with staff having completed level one and level two adult safeguarding training, and level one and two children's safeguarding training. The sonographers safeguarding training included awareness of female genital mutilation (FGM). FGM is the partial or total removal of the female external genitalia for non-medical reasons.

The registered manager had completed level three safeguarding training and was the service's safeguarding lead.

Diagnostic imaging

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. The service did not see women under the age of 18 years and would ask for identification if they had reason to believe they did not meet this criterion. Women using the service could bring children with them to appointments.

Staff described the escalation process to use if there were any safeguarding concerns.

Staff knew how to make a safeguarding referral and who to inform if they had concerns.

The service had an adult safeguarding policy in place which had been reviewed in February 2022. The policy outlined various types of abuse. For example, FGM, domestic violence and neglect. The policy provided clear guidance to staff on how to report and escalate any identified adult safeguarding concerns.

Staff knew of the safeguarding policy and where to find it. The policy also referenced the local authority safeguarding adults and children's guidelines. The information described the process of making a referral and contact information.

Safeguarding referrals were completed by the registered manager. There had been one safeguarding referral made to the local authority within the last 12 months. The safeguarding incident was reported in line with the service's policy.

The service had a chaperone policy in place. A chaperone poster was displayed in the waiting room offering this service to women upon request.

We reviewed the employee files and all staff had received a disclosure and barring service (DBS) check prior to commencement in post.

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 clean and had suitable furnishings which were clean and well-maintained.

There were cleaning checklists situated within the reception area, client and staff toilets and the scanning room. Cleaning checks were completed throughout the day. The clinic manager or reception staff would be responsible to check the cleanliness of the areas and for documenting their checks on the checklist.

Staff cleaned equipment after client contact and labelled equipment to show when it was last cleaned.

The sonographer cleaned the equipment and the scanning couch at the start of each clinic and after each scan. This included the thorough cleaning of scanning probes between each client using antibacterial wipes.

Staff mostly followed infection control principles including the use of personal protective equipment (PPE).

The service had an infection prevention and control (IPC) policy in place. We reviewed the infection control protocols and assurance frameworks introduced as part of the service's response to COVID-19. Staff kept equipment and premises visibly clean. Most infection risks were minimised and within the last 12 months there had been no incidences of healthcare acquired infections.

Diagnostic imaging

Hand-washing and sanitising facilities were available for staff and visitors, with hand sanitising gel and face masks available at the entrance to the service.

We saw staff regularly use hand sanitiser and wash their hands before and after client contact.

However, during our inspection we saw boxes stored on the floor of the storeroom. This meant that there was no free access to the floors and shelves for cleaning. Following the inspection, the manager told us that plastic movable pallets had been purchased to enable the cleaning of the floor.

Environment and equipment

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

The design of the environment followed national guidance. There was a large waiting area which was visibly clean and tidy. Chairs were spaced around the waiting area to enable social distancing for clients to wait for their appointment, including space for anyone they brought along with them.

Staff did not always dispose of clinical waste safely. The service kept two lockable clinical waste bins in the outside area at the back of the clinic. We found one of the bins was unlocked. However, the clinical waste bins situated within the scanning room were stored correctly in colour coded bags.

The service offered non-invasive prenatal testing (NIPT). NIPT 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.

Staff had access to PPE when carrying out ultrasound examinations or taking blood samples for NIPT.

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

However, during the inspection the sharps bin used was stored in a lockable cupboard which was kept within the storeroom. This is a sharps safety risk. We saw the sonographer walk into the storeroom with a used needle, obtain the key and unlock the cupboard in order to dispose of the needle. We raised this as a concern to the registered manager due to the increased risk of a needle stick injury.

The registered manager told us following the inspection that the sharps box was now stored in the scanning room and following a clinic would be stored in a lockable cabinet within the scanning room.

Staff carried out daily safety checks of specialist equipment. The sonographer told us they carried out quality assurance checks on the equipment at the start of each clinic. The checks were to evaluate the safety and performance of the ultrasound equipment ensuring that the information obtained in a clinical ultrasound procedure was accurate, and clinical practices were safe. The sonographer told us they would record any unusual findings in a logbook. However, we did not see evidence to show that the findings were recorded routinely.

Diagnostic imaging

A service level agreement was in place with an external company for the day to day maintenance of equipment. Failures in equipment were reported to the technical support team. Staff told us the technical support team were responsive when contacted and repairs were completed with minimal disruption to the service.

Fire extinguishers were accessible and suitably stored and their maintenance schedule was up to date.

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 completed risks assessment for each woman on arrival. Women were advised at the point of booking and on attendance that scans were non-diagnostic, and they still needed to attend NHS scans and appointments.

Sonographers outlined the limitations of the scans to each woman including anomaly diagnosis, maternal health and gender of the foetus.

The sonographer used the British Medical Ultrasound Society (BMUS) and Society and College of Radiographers (SCoR) pause and check list to reduce the risk of error. Checks were carried out to correctly identify woman. The sonographer checked the women's full name, date of birth and first line of address, as well as any previous imaging the woman had received.

The service only used latex-free covers for the transvaginal ultrasound probe, which minimised the risk of an allergic reaction for women with a latex allergy.

Staff knew about and dealt with any specific risk issues. The service provided clear guidance for sonographers to follow when they found unexpected results during a scan. Staff told us they were sensitive and caring when giving bad news to women and a detailed medical report clearly explaining the scan findings was given to them. Staff followed a referral pathway with the local NHS trust.

Due to the nature of the service, there was no emergency resuscitation equipment on site. However, staff had access to a first aid box. There were clear guidelines for staff to follow if a woman suddenly became unwell whilst attending the clinic and staff could describe to us the action they would take.

The sonographer had access and support from a sonographer within a different location attached to the service. They would peer review scans and offer advice if required. The service also had access to two independent sonographers who worked with the franchisor if further support or guidance was required.

Staffing

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

The service had enough staff to keep women safe. There were no national guidelines for staffing of an ultrasound scan centre. The service was staffed by the registered manager who oversaw the day to day running of the clinic. The clinic employed one sonographer and one reception staff member who also had the role of chaperone.

Diagnostic imaging

The registered manager assessed the number of bookings in advance to make sure the clinic was suitably staffed. If the clinic was to need extra cover then the reception role would be covered by the registered manager and a sonographer employed by a location attached to the clinic would support. However, we were told that this was rare and unlikely due to organising staffing and the clinic around appointments.

The reception staff member was a trained chaperone. When chaperoning women or supporting the sonographers during ultrasound procedures the reception would be covered by the registered manager.

Women booked their appointments online and the registered manager managed enquiries and appointment bookings.

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 used both paper and electronic records but were in the process of moving toward using electronic records only. Women completed a pre-scan questionnaire and signed a consent form prior to their ultrasound scan. Information on the pre-scan questionnaire included the number of weeks pregnant and the number of previous pregnancies.

Records were stored securely. Paper records before February 2022 were kept in a secure locked cupboard. The paper records were not in order and we found women's pre-scan questionnaires and further information weren't necessarily stored together. This made it difficult to follow the women's journey to see whether there were any concerns raised during the ultrasound regarding the pregnancy and to see whether the correct process of referral was made and the woman had been supported.

However, records were in the process of being uploaded electronically and we saw records from February 2022 were stored electronically and the information was recorded in a clear and accurate way. These records included estimated due date, type of ultrasound, findings and conclusion.

We reviewed four sets of women's electronic records. These included the procedure findings, the name of the sonographer who undertook the scan and the date of the scan. Reports were completed immediately ensuring they were accurately recorded.

We reviewed five referral letters to NHS services following concerns during the women's keepsake scan. The referral letter contained the women's details and the details of the concerns identified during the baby scan.

The service kept baby images securely on the scanning machine for six months. These could be retrieved if the mother lost or mislaid the images. The images were deleted after this time period.

Medicines

The service did not stock or administer medicines or contrast media for any scanning procedures. These were not required for the type of service offered.

Incidents

The service had appropriate processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents.

Diagnostic imaging

The service had an incident reporting policy. This policy covered the reporting and investigation of incidents, together with processes for analysis and improvement.

Staff knew what incidents to report and how to report them. Staff knew how to raise concerns and how to report incidents and near misses in line with provider's policy.

The service had no reported clinical incidences at the time of our inspection. Due to this we were unable to see documented evidence that client safety incidents had been recorded. However, if an incident was reported the quality assurance feedback monitoring form had specific areas to document what actions taken were taken, what improvements were made to avoid recurrence and what lessons were learnt.

The sonographer checked and recorded any issues with the scanning equipment in a book kept with the machine. Staff knew how to record these as formal incidents if a disruption to service occurred as a result of these issues, or a risk was identified to the service user or staff.

Staff understood the duty of candour. The registered manager could explain the process they would undertake if they needed to implement the duty of candour.

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. This is provided for by *regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014*.

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 any topics and issues affecting the service.

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

Are Diagnostic imaging effective?

Inspected but not rated 

We do not currently rate Effective in diagnostic imaging

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.

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.

Diagnostic imaging

The service adhered to guidelines from National Institute for Health and Care Excellence (NICE), British Medical Ultrasound Society (BMUS) and Society and College of Radiographers (SCoR). Scanning forms were developed and updated in line with BMUS policies.

The registered manager was responsible for clinical policy updates. Policies were due to be reviewed annually or when national guidance advised a change in practice. Policies were version controlled which included the date of the last review and the next review date. However, during the inspection we found there were two policies that were due to be reviewed in February 2022. We told the manager and following the inspection these policies were reviewed and updated.

Sonographers followed NICE *Ectopic Pregnancy and Miscarriage: diagnosis and initial management (2012)* guidance, and protocols were in place for the referral of women to the local NHS trust when necessary.

Written consent was obtained from all service users following completion of a pre-scan questionnaire and discussion with the sonographer.

The service used technology and equipment to enhance the delivery of effective care and treatment to women. The service had a large wall-mounted screen situated in the scanning 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 or laptop, via a link which was sent to them.

Patient outcomes

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

The registered manager monitored the rate of detection of anomalies. Due to the nature of the service provided, the service did not routinely monitor or learn of client outcomes.

The service did not participate in national audits due to the size of the service. However, the service sought feedback through a variety of methods including social media platforms and feedback through the service's website.

The registered manager had recently started to complete audits which monitored women's experience, cleanliness, health and safety, ultrasound scan reports, equipment, policies and procedures. Scan reports were audited. The information on the report and image quality was checked as well as if a referral had been made to the appropriate service following a detection of foetal anomaly or miscarriage. The registered manager had oversight of peer reviews and could request further support or guidance from the franchisor.

Staff did not always monitor the effectiveness of care. The registered manager had only recently collected data about the number of ultrasound scans completed and the number of referrals made to other healthcare services. However, the registered manager was keen to use the data found to identify trends and areas for improvement.

The registered manager ensured there were clear criteria for doing scans and repeat scans. There was a record of how many times a woman booked into the service to make sure they were not attending for multiple scans.

Diagnostic imaging

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.

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

Managers supported staff to develop through yearly, appraisals of their work. All staff told us they had completed an appraisal which included reflection about their role and provided an opportunity for positive and constructive feedback.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge.

Staff were provided with non-invasive prenatal testing (NIPT) procedure guidance. This ensured that women were told the associated benefits and limitations of this screening method. Blood testing for NIPT 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 to women and their families.

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.

During the inspection we observed that positive working relationships promoted a relaxed environment and helped put women and their families at ease.

Seven-day services

Services were available to support timely patient care.

The service operated Monday and Wednesday 12pm to 8pm, Thursday 10am to 6pm and 9am to 5pm at weekends.

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 on their website.

Health promotion

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

Diagnostic imaging

The service had relevant information promoting healthy lifestyles and support in waiting and clinical areas. 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.

Staff gained consent from women for their care and treatment in line with legislation and guidance.

All women were given a written consent form prior to examination. The consent form provided information. For example, details on 4D scanning, information around wellbeing checks and what to expect during and after the scan.

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

We saw staff obtaining verbal and written consent from women before continuing with the procedure.

Staff gave a detailed explanation of the procedure, discussing any potential risks to the unborn child. Staff made sure women were well informed before making decisions on whether to proceed with the scan or not. Staff gave women the choice of withdrawing their consent and stopping the ultrasound scan at any time.

Are Diagnostic imaging caring?

Good 

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.

Staff were discreet and responsive when caring for women.

Women said staff treated them well and with kindness. The service was organised and professional. Staff took time to interact with women and those close to them in a respectful and considerate way.

Staff followed policy to keep care and treatment confidential. Staff were discreet and compassionate when making referrals.

Diagnostic imaging

The service was able to maintain the privacy and dignity of women during scans by closing the scan room door, providing appropriate coverings, offering the choice of a privacy screen, and leaving the room while they undressed. Conversations in the scanning room could not be overheard.

Appointment length was adequate to ensure when required, sonographers could discuss foetal health concerns and the need to refer to maternity services. Staff were discreet and compassionate when making referrals and these women waited in the scanning room until the report was completed. If a scan was not possible because of positioning of the foetus, staff offered women refreshments, or they could go for a walk and attend for a scan at a later time at no extra cost.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs. Women could request a female chaperone and information on requesting a chaperone could be found within the pre-scan questionnaire, on the website and on posters at the front desk.

The service sought feedback via social media. We saw positive feedback. Staff told us that service user satisfaction was extremely important and described offering further free scans if a service user was disappointed with the image quality.

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 and women booked at a time to suit them.

Staff gave examples of how they would reassure women who were nervous and answer any questions. Women told us staff helped them to feel calm and relaxed.

Sonographers told us they would explain the referral process and the need for further diagnostic tests.

Staff supported women who became distressed in an open environment and helped them maintain their privacy and dignity. If a scan identified anything of concern, the sonographer would discreetly alert the reception staff.

Women told us they felt listened to, the communication with staff was good and staff were very accommodating. Staff understood the need to be compassionate, sensitive and show empathy when scans indicated miscarriage or foetal anomaly.

Staff could offer women an early scan leaflet with information referring them to their next medical steps or signpost women to the charity 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. The service signposted women to an external bereavement counselling charity if they required additional bereavement support.

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.

Diagnostic imaging

Staff made sure women and those close to them understood their care and procedures. Staff took the time to explain the procedure to ensure women understood. Women and their partners felt fully involved in their care and were given the opportunity to ask questions throughout their appointment. Staff supported women to make informed decisions about their care.

Staff supported women to make informed decisions about their care. Staff provided women with various leaflets signposting them to other care providers and reminded women they should attend their NHS appointments. Women having non-invasive prenatal testing (NIPT) had the tests being undertaken explained to them, including what the results would mean.

The sonographer asked service users whether they wanted to know the sex of the baby and avoided revealing it if they did not.

Are Diagnostic imaging responsive?

Good 

We rated it as good.

Service delivery to meet the needs of local people

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

Managers planned and organised services, so they met the changing needs of the local population. People could access services and appointments in a way and at a time that suited them. The service had varied their opening hours depending and operated clinics six days a week including weekends. Women told us they had not had to wait to book an appointment.

The service offered a range of ultrasound scanning packages and non-invasive prenatal testing to women from six weeks of pregnancy. 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, 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 provided clear guidance to women who were interested in non-invasive prenatal testing (NIPT) to explain 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.

Facilities and premises were appropriate for the services being delivered. The environment was appropriate for the service being delivered and was customer centred.

The service did not formally monitor rates of 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. Women were able to postpone their appointments if they phoned in advance of the appointment.

Diagnostic imaging

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.

The premises were accessible for service users with a disability. The service did not have access to interpreters or signers, staff had access to an online translation service. Staff had undertaken equality, diversity and inclusion training.

The service provided private ultrasound scans and non-invasive prenatal testing (NIPT) blood test to self-referring women only. The service did not complete imaging on behalf of the NHS.

Information about the scan packages available was displayed on the website and provided during telephone enquiries.

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.

Access and flow

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

Access to the service was on a self-referral basis only. Appointments for early reassurance, gender, growth and wellbeing and 4D scanning packages were offered in a timely manner and booked via phone, email or through the service website.

The registered manager monitored how women accessed the service, for example, through advertising, the internet or social media.

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.

The service scheduled appointments so only one woman was in the clinic at any one time ensuring the woman's privacy and dignity, particularly in the event of a poor outcome. Appointment times were 45 minutes long and during our inspection we saw appointments ran on time.

Women were given a printed scan report and were provided with a link where they could access their scan pictures and video electronically.

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

Diagnostic imaging

The service monitored waiting times for blood results. The service level agreement with the blood laboratory confirmed that women should receive their results within seven working days of their test. Staff monitored the waiting times for receiving blood test results. Any concerns or delays were discussed with 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 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.

Staff knew how to acknowledge complaints and women received feedback from managers after the investigation into their complaint. Staff understood the complaints policy and knew how to avoid minor issues escalating into a formal complaint. Managers shared feedback from complaints through emails and meetings, and learning was used to improve women's' experience.

Are Diagnostic imaging well-led?

Good 

We rated it 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.

The registered manager was also the director of the business. They were responsible for updating policies, procedures and guidance as well as staff management. Staff told us the registered manager was always available to provide clinical advice and guidance. Staff said they were supportive and encouraged their development.

Staff informed us that the registered manager was approachable and effective in their role. Staff felt confident to discuss any concerns they had with them and were able to approach the registered manager. Hey Baby 4D Tunbridge Wells was a franchise of Hey Baby 4D. The franchisor provided marketing and operational support such as templates for documents, and digital marketing services.

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, however, this did not happen often and the registered manager was always available in the instance of a woman attending for an transvaginal early reassurance scan.

Vision and Strategy

The service had a vision for what it wanted to achieve.

Diagnostic imaging

Staff told us the values were to provide a “fair, family oriented, fun and friendly’ service.” These were displayed in the entrance of the clinic and on the website.

The registered manager told us the service aim was to provide parents with reassurance, as well as amazing bonding experiences with their unborn baby throughout their pregnancy.

Culture

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

Staff were proud of the service and spoke highly of the culture. Staff told us they felt supported, respected, and valued by their manager. They enjoyed coming to work and were proud to work for the service.

We observed staff working well as a team. There was a whistleblowing policy in place, and staff were aware of the policy and could raise any concerns. Staff had completed equality and diversity training.

Staff told us they were encouraged to raise concerns openly and they felt they were able to do this.

Throughout our inspection, the registered manager responded positively to feedback and keen to learn and improve the service.

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.

Staff were clear about their roles and understood what they were accountable for. Staff could describe the governance processes for complaints and how they were investigated, as well as what to do if an incident did occur.

The registered manager had an information governance policy which all staff were aware of. The service had a review date for each policy and procedure. However, we found not all the policies and procedures had been reviewed or updated within the last 12 months which was not in line with the service’s own review frequency. Following our inspection, the registered manager told us reviewed and updated the out of date policies.

Staff told us policies and updates were shared by email and discussed within staff meetings. Staff meeting minutes we saw showed this was shared with staff.

The registered manager provided feedback to staff through appraisals and monthly staff meetings. Staff received feedback from the registered manager about any complaints, women’s feedback, performance, compliance with policies and procedures, any clinic issues, audit results, staffing and rota’s 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.

Diagnostic imaging

The service had effective systems, such as audits and risk assessments to monitor the quality and safety of the service.

Risk assessments such as fire and health and safety had been completed and the action plans implemented. There was a fire risk evacuation procedure however, we found this policy was due for a review. All staff had completed mandatory fire safety training

Local audits, such as clinical and compliance audits were undertaken regularly. However, data was not collected by the registered manager to monitor performance. 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 locations.

Women attending for their scan were required to complete a Covid-19 risk assessment alongside their pre-scan questionnaire.

Information Management

The information systems were integrated and secure.

Scan reports and scan images were retained for six months, 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 care. We saw that appropriate and accurate information was effectively processed, challenged and acted upon.

The service had a data protection policy and all staff completed training in information governance.

Key performance, audit, and feedback from women and their families data was frequently collated and reviewed to improve service delivery.

Engagement

Leaders and staff actively and openly engaged with women.

The service encouraged women to provide feedback through online reviews, social media reviews or email and staff engaged well with women and their partners. The service had a website which provided information to women about the service provided. The service actively sought feedback from women by means of a formal feedback form.

We saw positive feedback about the clinic. Most compliments showed the service provided a relaxed and calm environment.

Service users we spoke with told us they would recommend the service to others.

Learning, continuous improvement and innovation

All staff were committed to learning and improving services.

All staff were committed to continually learning and improving services. There were systems and processes in place for learning. Staff were encouraged to attend further training for their development for example, the reception staff had completed her non-invasive prenatal testing (NIPT) training.

Diagnostic imaging

The service sought out feedback from women and people accompanying them to see if there was any more they could do to improve their experience.

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	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>The service did not organise or store records correctly. Paper records were not in chronological order and not all pre- scan questionnaires and health records were store securely together.</p> <p>Policies and procedures were not all reviewed within their review date or updated as required.</p>