

Hey Baby 4D - The Revive Healthy Living Centre

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Good



Are services safe?

Good



Are services effective?

Not sufficient evidence to rate



Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Good



Summary of findings

Letter from the Chief Inspector of Hospitals

Hey Baby 4D - The Revive Healthy Living Centre is operated by Hey Baby 4D Limited.

The service provides a baby scanning service which includes reassurance scans, gender determination scans and non-invasive pregnancy testing. We inspected diagnostic imaging.

We inspected this service using our comprehensive inspection methodology. We carried out the short notice announced part of the inspection on 16th January 2019. To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

Services we rate

We have not previously inspected this service. At this inspection, we rated the service as **good** overall.

We found areas of good practice:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well. The service had suitable premises and equipment and looked after them well.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.
- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.
- 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 monitor the effectiveness of the service.
- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- The service took account of patients' individual needs.
- People could access the service when they needed it.
- The service treated concerns seriously, investigated them and learned lessons from the results, and shared these with all staff.
- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

Amanda Stanford

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Summary of each main service

Good



We rated the service as good overall because Staff had mandatory training in key skills. Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Infection risks were controlled well and there were suitable premises and equipment.

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

Care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.

Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness. The service had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

Summary of findings

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Good



Hey Baby 4D - The Revive Healthy Living Centre

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Hey Baby 4D - The Revive Healthy Living Centre

Hey Baby 4D - The Revive Healthy Living Centre is operated by Hey Baby 4D Limited. Hey Baby Derby, was founded in 2015, originally situated in the Derby City Centre. In September 2017, they relocated to the Revive Healthy Living Centre which is an NHS building. It is a private clinic and primarily serves the communities of the Derbyshire region, however, it also accepts women from outside this area.

The service provides ultrasound scans for reassurance or gender determination and provides non-invasive pregnancy tests (NIPT) which predominantly screens for downs syndrome, Edwards syndrome and Patau's syndrome. The NIPT test also offers optional gender determination from 10 weeks gestation.

The clinic has had a registered manager in post since 2015. This is the service's first inspection since their registration with CQC.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and an Assistant Inspector. The inspection team was overseen by Simon Brown, Inspection Manager.

Information about Hey Baby 4D - The Revive Healthy Living Centre

The service is registered to provide the following regulated activities:

- Diagnostic Imaging

During the inspection, we visited the reception and clinic areas. We spoke with four staff including a sonographer, reception staff and senior managers. We spoke with two women and four relatives. We also reviewed 13 'client experience' feedback records and five sets of women's records during our inspection.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with CQC, which found the service was meeting all standards of quality and safety it was inspected against.

Activity (November 2017 to December 2018)

During this period the service carried out 2740 scans, there were 200 'no shows' and 134 rescans (when a scan had been unsuccessful and had to be done again). The

scans included early reassurance scans, gender scans and late reassurance scans. Early reassurance scans that were not successful using a transabdominal method were sometimes undertaken using a transvaginal scan.

One senior sonographer and two reception and administrative staff, the registered manager and the director worked at the clinic. There were no medicines kept or administered at the service.

Track record on safety (November 2017 to December 2018)

- No never events
- No clinical incidents of no harm, low harm, moderate harm, severe harm or death
- No serious injuries
- No complaints

Services provided at the hospital under service level agreement:

- Clinical and or non-clinical waste removal

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Our rating of safe was **Good** because:

- The service provided mandatory training in key skills to all staff and made sure everyone completed it.
- Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.
- The service controlled infection risk well.
- The service had suitable premises and equipment and looked after them well.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.

Good



Are services effective?

We did not rate the effectiveness of the service, however;

- The service provided care and treatment based on national guidance and evidence of its effectiveness. Managers checked to make sure staff followed guidance.
- 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 monitor the effectiveness of the service.
- Staff of different kinds worked together as a team to benefit patients.
- Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Not sufficient evidence to rate



Are services caring?

Our rating of caring was Good because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.
- Staff involved patients and those close to them in decisions about their care and treatment.

Good



Are services responsive?

Our rating of responsive was **Good** because:

Good



Summary of this inspection

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- People could access the service when they needed it.
- The service treated concerns seriously, investigated them and learned lessons from the results, and shared these with all staff. There had been no formal complaints made about the service.

Are services well-led?

Our rating of well-led was **Good** because:

- The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff, patients, and local community groups.
- Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.
- The service had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.
- The service engaged well with patients.
- The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.

Good








Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Not rated	Good	Good	Good	Good
Overall	Good	Not rated	Good	Good	Good	Good

Diagnostic imaging

Safe	Good 
Effective	Not sufficient evidence to rate 
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We have not previously rated 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.

- All staff completed mandatory training annually which was provided by the local authority. Staff were responsible for booking themselves onto the training, however the registered manager had oversight and ensured compliance by maintaining individual training records for each member of staff. Their training included fire safety, first aid and in 2019 it would also include moving and handling. Records we reviewed confirmed staff were up to date with their mandatory training.
- We were told staff had annual infection control updates which were provided to the sonographer and then disseminated to all staff. Staff had effective training in safety systems, processes and practices.
- Staff said they had not received any formal awareness training regarding the needs of people with mental health conditions or learning disabilities.

Safeguarding

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

- The service had a safeguarding policy in place which had been regularly reviewed and updated. All staff were aware of the safeguarding policy.
- The service safeguarding lead was a sonographer and trained in level 2 safeguarding with access within the local authority to someone trained to level 3. We found administrative staff were not trained in safeguarding, however they were booked onto the course at the time of our inspection and they were fully aware of their own safeguarding policy.
- All staff had Disclosure and Barring (DBS) checks in place.
- Staff knew their responsibilities, how to recognise a potential safeguarding issue and the actions they should take. They had very close links with the local safeguarding team in the local authority whenever they required advice or to raise a concern.
- Child Sexual Exploitation (CSE) and Female Genital Mutilation (FGM) was included in the safeguarding training and was part of the sonographer training. Staff appeared knowledgeable in this area and said they were confident to identify and raise such a concern if required, however they had not experienced a concern of this nature at the clinic.
- The service had their own chaperone policy, which was up to date and all appropriate staff were chaperone trained. Staff we spoke with knew their responsibilities as a chaperone and were confident to

Diagnostic imaging

report any issues without hesitation. We saw signs offering chaperones throughout the clinic, for example attached to the front desk in the reception and waiting area, in addition it was offered on their website and it was documented whether the woman accepted or declined the offer of a chaperone.

- The clinic clearly displayed they had a zero tolerance of abuse.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection.

- The entire clinic was cleaned daily by staff, however the scanning equipment was cleaned by the sonographer following each appointment. Cleaning schedules were displayed and completed for each room, which included daily tasks such as bins emptied, scanning couch cleaned and any debris removed. Weekly tasks included floors, surfaces, toys, skirting boards cleaned and a thorough cleaning of the scanning couch.
- We saw staff using hand sanitiser and hand washing facilities often and after every contact. The service had their own health and safety policy which included minimising the risk of infection, however they did not carry out hand hygiene audits.
- Infection prevention and control was included within the sonographer training and disseminated to all staff. Following the sonographers being updated on their guidance, they had introduced Tristel (the nationally recommended decontamination process for probes), improving their infection control.
- Non-Invasive Pregnancy Testing (NIPT) kits were used at the clinic. They were all inclusive of the equipment required to perform the test. Personal protective equipment (PPE) was available and always used. The kits had a security seal and labelled 'Category B – Biological Substances' for transit to ensure the kit would not be reopened and was tamper evident.

- Sharps bins were taken to the local health centre monthly for disposal. All other clinical waste was managed through a service level agreement. The waste was placed in a locked compound and removed each week for disposal.
- Cleaning equipment was stored in a locked cupboard away from the public.

Environment and equipment

The service had suitable premises and equipment and looked after them well.

- The environment was appropriate for the services being carried out and they had effective equipment. Clinical staff were trained by the equipment manufacturer in the use of it and they provided the maintenance and servicing of the equipment. There were two scanning machines and two computers as back up in case of failure.
- In the event of an IT failure there was alternative equipment for use and any information required from an electronic system which relied upon internet connectivity could be found in the booking forms which were held on the computer desktops.
- Resuscitation equipment was not available in the clinic itself, however as the clinic was located within a larger building there was an automated external defibrillator in the main reception which they had access to in an emergency. There was also an NHS clinic within the same building where they could summon help while awaiting emergency services. Staff were aware they should dial 999 in the event of an emergency. There was a first aid box available in reception which was checked and stocked by reception staff. All items were in date at the time of our inspection. All staff had completed training in first aid and knew what to do if a visitor to their clinic became unwell.
- The clinic had a large store cupboard which was locked with ample stock for the service.
- Blood samples taken for the purposes of NIPT were done in an appropriate environment, sharps were immediately placed in a sharps bin and disposed of monthly. Samples were labelled and sealed inside the kit and transported to a laboratory situated in Italy with a robust tracking system through a courier.

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Assessing and responding to patient risk

Staff completed and updated risk assessments. They kept clear records and asked for support when necessary.

- Staff had processes in place to ensure women were not attending for scans prior to six weeks into their pregnancy. They had a calculation tool on their website, they also had a number of questions they asked before allowing a woman to book a scan. The women were asked to complete a consent form while waiting in the reception areas and the sonographer checked they were scanning the correct woman by checking three points of ID.
- Staff said they followed the referral procedure set out in their 'Referral Policy'. This involved them informing the woman if they had seen something on their scan which should be checked at the hospital for a clinical diagnosis. They called the most appropriate hospital on the woman's behalf and made sure an appointment was booked, explaining why they felt a referral was required. They then gave the woman any information and images that may have assisted the hospital. We were told women would never leave the clinic without a clear plan of what to do next. We reviewed the service's referral policy, however we did not see evidence in records as it was not a common occurrence and the randomly chosen records we reviewed did not contain any referrals. They told us they rarely passed on information to GPs, however they often shared information with women's midwives and associated hospital team with their consent.
- Women were made aware within the consent form that the service did not include any diagnoses, therefore women were advised to continue with their NHS scans as part of the maternity pathway. The sonographer verbally reiterated this to women in addition as part of their appointment.
- Scans were carried out following 'As Low As Reasonably Achievable' (ALARA) guidance and women were given the information which allowed them to make informed decisions about the risk of scanning. Prior to carrying out any scans, the sonographer asked if they had been feeling unwell or experienced any

pain or bleeding. If the woman disclosed she had experienced any symptoms, then they were referred to their midwife or hospital for further investigation and the scan would not go ahead.

- We were told if a multiple pregnancy was detected by the sonographer, they would refer the woman to maternity services straight away due to the increased risks associated with multiple pregnancies.
- Risk assessments were carried out for the premises and any potential risks to women were identified, logged in their register, actioned and documented. We reviewed the risk assessments during our inspection, which were all actioned and recorded appropriately. For example, we saw a risk to children visiting the service where low-level plug sockets were accessible. We saw the control measure was to purchase socket covers and we saw they were being used.

Staffing

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

- The service was provided by one sonographer and two reception/administration staff who were overseen by the registered manager. The director was jointly responsible for governance with the registered manager, however they did not participate in any daily provision of the service.
- Staff told us there was no formal induction policy, however they were well supported and were given the opportunity to shadow other staff for as long as they felt they required to feel competent in their role.
- Unlike radiographers or midwives, sonographers are not subject to professional registration under section 60(2) of the Health Act 1999 (9) (Regulation of health professions, social workers, other care workers) and are not registered with the Health and Care Professional Council (HCPC). However, the sonographer for the service had completed qualifications through Birmingham City University to level 7 in Obstetric Ultrasound, which included training in measurements, use of Doppler, transvaginal scans and gynaecology.

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- At the time of our inspection, the service had one sonographer. The sonographer worked three days per week which were Monday, Wednesday and Saturday and scans were available during their shifts of 12.00pm to 8.00pm Monday and Wednesday, and 9.00am to 5.00pm on Saturdays. There was always a receptionist in the clinic during opening hours, regardless of sonographer attendance, to answer the telephone and take bookings.

Records

Staff kept records of women's care. Records were clear, up-to-date and easily available to all staff providing care.

- There were records kept and were a mixture of paper and electronic at the time of our inspection. However, we were told the service were in the process of scanning any paper records into the electronic system.
- The service collected only the details from the woman to enable staff to identify the correct woman and carry out their scan. Paper records were consent forms, which were kept in a locked cabinet inside a locked cupboard in the clinic.
- We reviewed five consent forms during the inspection, all were legible, complete and contained the relevant information. Any record held could be made available to the woman for her to pass on to the hospital, midwife or GP.
- NIPT results were returned from the laboratory electronically and they were password protected. The sonographer had direct access to them and informed the woman accordingly. If the result was negative, it was emailed to the woman with password protection. If the result was positive, it would be emailed directly to the woman's maternity services for them to inform the woman in an appropriate environment with the support she may require. The process was explained to women prior to undertaking the test and a consent form completed to share the information with another provider of care and treatment to the woman.

Incidents

The service had a process in place to manage patient safety incidents but they had not reported any incidents in the past year.

- The service had their own 'Emergency and Significant Events Policy' which was in date and all staff were aware of. We reviewed the policy prior to the inspection and found it contained the process to follow for all staff, in order to identify and report an incident. It also set out the process leaders followed to investigate the incident and carry out their obligations under duty of candour.
- Staff we spoke with knew how to recognise an incident and how to report it and senior staff and leaders knew their responsibilities under the duty of candour regulation, however no never events or incidents were reported between 1st November 2017 and 1st November 2018. Staff also confirmed there had been no further reports between then and the date of the inspection.
- Staff told us that if there was an incident relating to NIPT for example, they would provide a verbal apology to the woman, followed up in writing. An investigation would be carried out and the woman kept informed of any outcomes.

Are diagnostic imaging services effective?

Not sufficient evidence to rate 

We do not rate effective.

Evidence-based care and treatment

The service provided care based on national guidance and managers checked to make sure staff followed guidance.

- 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). Staff were aware of how to access policies.
- Staff demonstrated a good understanding of national legislation that affected their practice. For example, sonographers followed the 'Ectopic pregnancy and

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miscarriage: diagnosis and initial management' guidance (NICE, 2012) when they identified a foetus did not have a visible heartbeat and measured less than 7.0mm.

- Women were always told when they needed to seek further help and supported to access it before leaving the clinic. They were always referred to their midwife or hospital for any medical advice.
- The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.
- There was an audit programme in place to provide assurance of the quality and safety of the service. Peer review audits were undertaken in accordance with recommendations made by the British Medical Ultrasound Society. Other audits, such as clinic and local compliance audits were undertaken regularly. They monitored patient experience, cleanliness, health and safety, ultrasound scan reports, equipment, and policies and procedures. The service followed the ALARA (as low as reasonably achievable) principles, outlined in the 'Guidelines for professional ultrasound practice, 2017' by the Society and College of Radiographers (SCoR) and BMUS. Where possible, sonographers completed all ultrasound scans within 10 minutes to help reduce ultrasound patient dose.

Nutrition and hydration

Staff gave women enough to drink to meet their needs.

- At the time of our inspection we saw there were drinks available for women and were requested from staff as they were kept in the staff kitchen area. There were sugar free drinks available if required. Processes were explained to women at the time of booking, however there was a café close by if women wanted to purchase alternative food or drinks.

Patient outcomes

Managers monitored the effectiveness of care and treatment and used the findings to improve them.

- Meetings were held at the clinic to discuss audits and practice, although these were on an ad hoc basis due to the small number of staff. We reviewed minutes from six most recent staff meetings and saw clinical audits were discussed. At the most recent meeting it was identified that the database used by the service could audit rescans and missed appointments for example, however there was no easy way to produce a report showing referrals.
- Any referral that had to be made to another service, such as the woman's midwife were noted on the woman's report. These were not filed separately so it was difficult to retrieve all documentation of those scans which had required a referral to other services. We were told that this documentation would now be stored in a separate folder, so they could be easily retrieved and counted for any audit purposes in future. The registered manager had escalated the matter to the franchise headquarters to ensure a way of auditing referrals could be added into their new database.
- Service activity, audit results and patient feedback were regularly discussed during the monthly team meetings.
- We were told verbal suggestions were made between the staff on an ongoing basis, for example a suggestion to remove 'patient experience forms' and replace them with 'client experience forms'.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staffs' work performance and held supervision meetings with them to provide support and monitor the effectiveness of the service.

- All staff we spoke with said they were always encouraged to seek out training and further their development. They were comfortable to approach leaders to discuss their development at any time, however they had opportunity to discuss formally in one to one meetings and bi-annual appraisals, which were held regularly where any training needs were also identified. Staff said they felt they had the right skills and knowledge to fulfil their roles. The sonographer was trained through BMUS and attended annual updates.

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- Training records, including equipment training were available in each staff member's personal file, which was kept in a locked cupboard in the clinic. The sonographer was trained in phlebotomy and the registered manager was also trained in case they were unavailable. Staff received updates and the registered manager carried out the practice periodically to maintain their competency.
- The service had not had to deal with poor performance at the clinic since their registration, however leaders said they had a process in place to manage it should they need to.
- Staff told us when they were trainees they had as much opportunity to shadow and undertake additional training as they felt they needed. They said they never felt under pressure to undertake a role unless they felt entirely competent, even after all training had been completed.

Multidisciplinary working

Staff worked together as a team. All staff supported each other to provide a better service.

- The service had relationships with local hospitals and maternity services as well as local safeguarding specialist should they need to refer someone to them. They were able to contact by telephone, any of the services and make appointments on behalf of women who needed them.
- They had effective working arrangements with the laboratory that provided the NIPTs to achieve timely results for women with robust processes in place for tracking of the samples, analysis and return by password protected email.

Seven-day services

- The service did not provide appointments seven days a week, however they did open until 8.00pm two days a week and opened 9.00am to 5.00pm on Saturdays, which gave opportunity for most women to attend at a time to suit them.

Health promotion

- There were various leaflets displayed around the clinic and reception area, for example NIPT, Future Health, NHS 'How do you handle life's ups and downs?', Live

Well, Stop Smoking, Get Fitter and Look after your health. There were posters illustrating pregnancy displayed in reception and in the clinic in both English and German.

Consent and Mental Capacity Act

Some staff understood how and when to assess whether a woman had the capacity to make decisions about their care. They followed the service policy and procedures when a woman could not give consent.

- Staff were aware of the Mental Capacity Act and requirement for consent, however some staff had more experience than others. All staff knew the consent process and ensured women were informed of procedures and the requirement for consent prior to carrying out a scan.
- All information about the scans were included in their consent forms which were tailored for each type of scan. The forms set out what they would and would not do and any potential risks associated. Staff were happy to give more information verbally to women before signing the consent forms if they required it.
- Consent was always sought to share information with their midwife or hospital in the event of a suspected anomaly or a positive NIPT result. Any reason for referral was documented on the sonographer report section of the form and clearly explained to women.

Are diagnostic imaging services caring?

Good 

We have not previously rated this service. We rated caring as **good**.

Compassionate care

Staff treated women with compassion. Feedback from women confirmed staff treated them well and with kindness.

- Staff always treated women with dignity, compassion and respect, before, during and after their scan. Women we spoke with confirmed they were treated well and with a kind and caring manner. We observed

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two scans and saw staff spoke with women in a respectful and considerate manner and remained professional in their processes and information provided to them.

- We saw checks were made to ensure the right woman was receiving the right scan at the right time. Staff told us they explained any scanning risks to give women informed choices at the time of booking at when gaining consent. There was a large room in between reception and the clinic which meant conversations could not be overheard in either of the rooms, protecting women's privacy.
- When scans were not successful, women were offered a follow up scan in some circumstances. If a transabdominal scan for early reassurance was not successful, women were offered a transvaginal scan where appropriate. Staff told us they gave women as much time as they required if they became distressed and would be supported in a private room where they had space and time to ask questions and arrange follow up appointments with their midwife or hospital if needed, where they could access further support such as counselling.
- Posters were displayed throughout the clinic about their zero tolerance to disrespectful, discriminatory or abusive attitudes or behaviours. Staff told us they were confident to report anything of those behaviours.

Emotional support

Staff provided emotional support to women to minimise their distress.

- Women were provided with emotional support when they required it and given information in accordance with the Health Protection Agency (HPA) advice on potential risks associated with baby scanning regularly, however there were no leaflets available containing this information.
- Staff said if there was an anomaly identified in a scan, the woman would be referred to her midwife or hospital and they made the arrangements for them before leaving the clinic. They told us they always ensured the woman knew what to do next and what

support was available for them. Women were encouraged to continue their NHS maternity pathway, which was reiterated in the consent form signed by every woman before scanning.

- For NIPTs, staff provided women with appropriate information including a specific consent form and a booklet for them to take away, which was included as part of the kit. The procedure was explained clearly along with the process following either a negative or positive result. In some circumstances, women were asked for consent to forward their contact details to a genetic counselling service which is provided by the laboratory, who would call them on the same day. In the event of a positive result, they were referred straight to their midwife and additional support could be sought through the NHS.

Understanding and involvement of patients and those close to them

Staff involved women and those close to them in decisions about their care and treatment.

- Staff communicated appropriately with women to ensure they understood their care and were aware of what they received. Women were able to express their views and were actively involved in decision making.
- Women and their partners or relatives were welcomed by staff and there was enough room to accommodate up to six people in the clinic, however staff said the number was discretionary and could accommodate more if required.
- The service displayed all of their scans and packages with pricing on their website and confirmed at the time of booking. They took payment in the reception areas while women waited for their appointments and completed their consent forms. This meant the sonographer would come through to reception to call the women through to the clinic and they could leave through an alternate exit after the scan rather than walking back through reception.
- NIPTs were discussed at length with each woman considering the test, including what the process entailed, what they were testing for, how long they should expect to wait for results, what the results would show and how the results would be feedback to them. Staff always explained to women where there were

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limits to confidentiality and discussed sharing of information if it was required. All women were referred to their midwife or hospital if there were concerns of any kind.

Are diagnostic imaging services responsive?

Good 

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

Service delivery to meet the needs of local people

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

- The service ensured a patient centred environment for women and people accompanying them. This included comfortable seating in the reception area, clinic and quiet room. Accessible toilets and a play desk for small children with reading and colouring books and pencil crayons provided in the reception area and the clinic room.
- Information was available in accessible formats including posters illustrating pregnancy and birth, located on the walls in the reception area and in the clinic room. Leaflets were readily available in the reception area.
- There was free car parking provided for the shared premises which had ample spaces and was lit after dark. The clinic did not have toilet facilities within, however it was a short walk to the main reception area and it was well signposted to and from the toilets. There was a garden area with a path which women had to use to get to the main reception. This was a covered path and was gritted by the building facilities team in cold weather.
- The service offered flexible appointments to suit most women's requirements.

Meeting people's individual needs

The service took account of women's individual needs.

- Appointment times were allocated and allowed enough time for any question's women wanted to ask. Staff said appointments usually lasted up to 25 minutes and they followed the British Medical Ultrasound Society (BMUS) 'Guidelines for the safe use of diagnostic ultrasound equipment'. In line with BMUS, they observed the ALARA principle (as low as reasonably achievable) which refers to output levels from the equipment and associated time frames.
- The service had access to a telephone-based interpretation service and staff told us they would work with them to arrange any assistance if it was required for any communication needs or sensory loss.
- The service provided reasonable adjustments for people with a disability, including ramps to access the building, disabled toilets, and the reception, clinic and quiet room all had enough space for a wheel chair.
- Some information was available in another language including posters being written in English and German.
- Staff told us they had little experience of working with people who required additional support. However, they described how they would adapt their process of working to support them. They said they would allow them to visit and familiarise themselves with the clinic and the woman's journey, they would allow extra time for their appointment and include their partner or relatives to gain a better understanding and help them to feel more comfortable.

Access and flow

People could access the service when they needed it. Waiting times were in line with good practice.

- The service received bookings through an online booking system or over the telephone, where women were asked which type of scan they would like and were offered a choice of appointments at a time to suit their needs. Staff said If there was no availability on a particular day, staff offered the next available appointment. Staff signposted to local private clinics in Nottingham or Leicester if required.
- During our inspection, we saw the service was flexible in seeing patients at the time of their arrival, even when arriving much earlier than their appointment

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time if it would not impact on any other appointments. Staff told us they mostly kept appointments on time, however if an appointment overran or a woman required further support following her scan then the sonographer always kept other women in the waiting area informed of any delays and how long they may have to wait. Cancellations were very rare but were explained to women, and rebooked either the next day, or the next available appointment date.

- Waiting times for NIPTs results were up to seven working days and these wait times were explained to women during their appointment. Staff told us women were made aware if the results were negative they would receive a password protected email, however if the results came back positive, staff would pass this information onto their midwife, and the midwife would contact them directly.
- Staff told us they left enough time in between appointments to avoid the reception area being crowded, to give a more personal touch and time to discuss any issues or make referrals if required. During our inspection, women were seen on time or early for some appointments, which women remarked they were pleased about. Staff said they very rarely had any women waiting for their appointment, however they were fully informed of any delay and women didn't appear to mind as long as they were updated.

Learning from complaints and concerns

The service treated concerns seriously, investigated them and learned lessons from the results, and shared these with all staff.

- Information was displayed showing how to make a complaint. All complaints went to the registered manager, who dealt with them in line with their own complaints policy, which we reviewed prior to our inspection. All complaints were investigated jointly by the registered manager and the director and feedback to them in due course.
- Changes and improvements were made following feedback received. For example, one woman told staff the ultrasound gel was too cold, the service purchased

a bottle warmer and ensured the gel was warmed before appointments. One woman requested accessible water in the reception area. The service ordered a water machine following the request.

- The service was provided by a small number of staff who shared learning during adhoc meetings. One staff member described an informal complaint when they were unable to provide a picture during their 4D scan. They offered a rescan and the woman was happy with their response. The service had a robust system in place for collating feedback in a 'client experience' form which was stored digitally and reviewed for trends and themes.
- The service had received no formal complaints in the last 12 months.

Are diagnostic imaging services well-led?

Good 

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

Leadership

Managers at all levels in the service had the right skills and abilities to run a service providing high-quality sustainable care.

- Leaders of the service were subject to checks through the Disclosure and Barring Service prior to employment as were the rest of the staff. In addition, they required references from previous employers and employment history as well as proof of any qualifications held relevant to their employment in line with schedule 3 of the HSCA 2008 (regulated activities) regulation 2014 to ensure they have the skills, knowledge, experience and integrity they need.
- Leaders understood their service's challenges to quality and sustainability and all staff told us they were visible and approachable. Staff told us leaders were caring, inclusive and effective.

Vision and strategy

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The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff, women and local community groups.

- The service had a clear vision and values, which all staff were aware of and enthusiastic to demonstrate throughout their work. We were told the vision and values were developed by the registered manager when the franchise was in its infancy and they were now company wide values. Current staff were not involved in developing the vision and values as they were already in place, however they told us they were shared values of all staff.
- Their strategy was a robust and realistic one which was developed by the director and registered manager and used to measure their progress.

Culture

Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.

- All staff described the culture as a positive one, focused on common goals of providing the best service they could achieve in an environment that was calm and welcoming while remaining professional and protecting the public and each other from avoidable harm. Leaders were supportive and made them feel valued and respected.
- Staff we spoke with said they were very proud to work for the organisation and keen to develop the service. They were always included in decision making as they worked together as a team.
- Senior staff were aware of their responsibilities under the duty of candour and gave an example of how they would meet their duties. However, the service had not had to exercise it so far since their registration. Leaders were aware and included it in their Emergency and Significant Events Policy.
- Staff who fulfilled a chaperone role told us they felt confident to raise concerns without hesitation and without fear of retribution, despite working in a very

small team. They said they had not had any cause to raise a concern so far since their registration but were assured appropriate action would be taken by leaders and learning disseminated through the team.

- The service promoted equality and diversity, they were mindful of their service being accessible to all and extended to employees. They said they looked after each other by providing breaks in appointments throughout the day where they could see the sonographer would be too busy, offering drinks for each other and took time out if they felt under pressure on busy days. Staff were happy to support each other where they required it.

Governance

The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.

- The director of the service was responsible for the governance of the service; however, we were unable to speak with them during our inspection. We spoke with the registered manager who told us there were governance processes in place which were driven by the director who managed the service. We were told governance meetings were held regularly, however not within a specified period. Policies were reviewed bi annually. We did not see any evidence of the governance meetings.
- The service had a service level agreement for collection of clinical waste, which was kept in a locked compound. The contract was set up by a senior administrator and they managed the agreement. There had been no issues at the time of our inspection.
- All staff were provided with appraisals at least bi annually, however if staff felt they required more, they were comfortable to ask managers and they would arrange. They were very clear about the boundaries of their individual roles; however, staff were happy to help where their competencies allowed and regularly had formal and informal discussions about career development. They were assured they could access any development they required relating to the service.

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- The service carried out some internal audits which were on a rolling programme and used the results to inform practice.

Managing risks, issues and performance

The service had good systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.

- The service held a live risk register which we reviewed during the inspection. It showed the risk, who was at risk, existing control measures, any further action necessary, when it was completed and by who. They kept data relating to their performance month to month and year on year which showed their progression as a service.
- The registered manager was responsible for the management of policies and procedures and their compliance. We reviewed some policies prior to the inspection and found they were all reviewed and in date. The director had oversight and reviewed policies periodically. All staff knew where to find policies and information on procedures and were knowledgeable and enthusiastic when discussing them.
- Staff told us they anticipated a risk of falling in bad weather when walking between the main reception of the building and the clinic reception. They raised this with the registered manager, who discussed the risk with the building facilitators and they agreed to ensure this area was gritted ahead of anyone arriving. The service reviewed the arrangement when the bad weather arrived and were assured the risk was mitigated appropriately.

Managing information

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

- Women had access to terms and conditions of the service through the service's website, however reception staff were happy to provide them to anyone who did not have computer access. All packages and prices were clear on the service's website; however, these were also available in the clinic and payment methods and processes were discussed at the time of booking.

- The service held very minimal data on women who used the service, however they held most data electronically with password entry and any paper records were kept in a locked cupboard inside the clinic. All staff had access to the electronic records, however the sonographer held the keys to the cupboard where the paper records were kept.
- There were arrangements in place to ensure information used to monitor and manage quality and performance was accurate, valid, reliable and relevant. Most was gathered through electronic systems and then collated by staff using franchise wide processes. If issues were identified, leaders were confident they would work together to implement a better way of gathering the information and would be supported by the franchisor to do so. Most data was kept electronically, therefore easily accessible to staff, however there had been no data breaches since their registration. At the time of our inspection they were developing a new database to capture more information and be better informed.

Engagement

The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services and collaborated with partner organisations effectively.

- Women who used the service, the public, staff and external partners were engaged and involved to support a high quality, sustainable service.
- Views and experiences were gathered often and reviewed regularly. The service offered several ways for women to express themselves, including social media, their own feedback forms and email.
- Staff told us they had ordered a water cooler for the reception area following a comment made that drinks had to be asked for and kept in the staff kitchen. They also purchased a bottle warmer to warm the gel before scans as women had commented how cold it felt.
- The service had effective relationships with the local safeguarding team, midwives and hospitals as well as links to local support networks for access to counselling.

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- The service monitored feedback through social media and their own feedback forms in the clinic and adapted their services where necessary. They input all feedback into their electronic Feedback Monitoring Form and these were discussed at team meetings to look at themes and make changes where necessary to improve the service. We saw feedback forms displayed around the clinic and staff told us they had run incentives for women to fill out the forms in the past to encourage them to share their views. We reviewed the feedback for November and December 2018, which was overwhelmingly positive. Some comments included “Amazing experience! We will be back” and “The reception is nice, having parking is great and the staff are lovely”.

Learning, continuous improvement and innovation

The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.

- There were robust systems and processes in place for learning, continuous improvement and innovation. Leaders were enthusiastic about striving for improvements by actively encouraging staff to attend further training for their development and the development of the service. They sought out feedback from women and people accompanying them to see if there was anything more they could have done to make their experience better.
- The service had recently amended their website to put frequently asked questions on the front page to ensure women were better informed. They had also reviewed and amended their consent forms to be specific to each scan, ensuring the information women received was specific to the service they were receiving.
- Data showed there were a high proportion of ‘no show’ women for some follow up appointments. After gathering further information to ascertain the reasons, it appeared women had forgotten due to the time in between scan appointments. Therefore, the service implemented a text reminder service, which had shown a decrease in the amount of ‘no show’ appointments.
- Staff worked together to share innovative ideas and implement changes to improve the service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should ensure notes of the governance meetings are kept.