The Birth Company Limited

Quality Report

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Date of inspection visit: 21 January 2019
Date of publication: 09/05/2019

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**

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

The Birth Company is operated by The Birth Company Limited. The service provides diagnostic pregnancy ultrasound services to self-funding pregnant women over the age of 18.

We inspected the diagnostic imaging facilities.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice inspection on 21 January 2019. We gave staff two working days' notice that we were coming to inspect to ensure the availability of the registered manager and clinics.

To get to the heart of women's 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 (MCA).

The main service provided was ultrasound scanning.

Services we rate

This was the first inspection of this service. We rated it as **Good** overall.

We found good practice in relation to diagnostic imaging:

- There were sufficient numbers of staff with the necessary skills, experience and qualifications to meet women's needs.
- There was a programme of mandatory training which all staff completed, and systems for checking staff competencies.
- Equipment was maintained and serviced appropriately and the environment was visibly clean.
- Records were up to date and complete and kept protected from unauthorised access.
- The service had implemented a programme of audits relating to patient outcomes
- Staff demonstrated a kind and caring approach to the women using the service and supported their emotional needs.
- Appointments were available during the evening, at weekends and at short notice if required.
- The service had supportive and competent managers. Staff understood the vision and values of the organisation.

However:

- The service had not conducted a hand hygiene audit.
- The service did not accurately collate all incidents to enable them to monitor trends. .
- Not all staff had received level two safeguarding children training, however staff understood their roles in relation to safeguarding.
- Sharps boxes did not adhere to the BS7320UN3291 standards in line with health and safety regulation 2013 (The sharps regulations).

Summary of findings

Following this inspection, we told the provider that it should make other improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Dr Nigel Acheson
Deputy Chief Inspector of Hospitals (London & South East)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	The provision of ultrasound scanning services, which is classified under the diagnostic core service, was the only core service provided at The Birth Company. We rated the service as good overall because it was safe, caring, responsive and well-led. Feedback from women and their families was positive. Women could access services and appointments in a way and at a time that suited them.

Summary of findings

Contents

Good

The Birth Company

Services we looked at
Diagnostic imaging.

Summary of this inspection

Background to The Birth Company Limited

This report relates to diagnostic imaging services provided by The Birth Company Ltd.

The Birth Company opened in 2000 operating from Harley Street in central London. The service advertises itself as providing a modern, spacious clinic, which provides a calm and relaxing environment as well as state-of-the-art scanning equipment providing the latest in ultrasound technology including 3d and 4d ultrasound scans. It is open Monday to Thursday from 8am until 8pm, Friday from 8am until 6pm, Saturday 9am until 4pm and Sunday 10am until 2pm.

It provides diagnostic pregnancy ultrasound services to self-funding women, who are pregnant and aged 18 years and above. Most ultrasound scans performed at The Birth Company are in addition to those provided through the NHS although some are private patients or from abroad.

The service has had a registered manager in post since October 2010. We inspected this service in July 2012 and was found to have met the five standards inspections, taken from the essential standards as described in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 and the Care Quality Commission (Registration) Regulations 2009.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a specialist advisor. The inspection was overseen by Terri Salt Interim Head of Hospital Inspection.

Information about The Birth Company Limited

The service provides diagnostic imaging services (ultrasound scans) to self-funding pregnant women, it was located on the third and fourth floors of 137 Harley Street, London. The service had a large reception area, two scan rooms, a quiet room, additional rooms for administration and staff. The service had toilets on both floors.

The service offers the following scans:

- Early pregnancy scan 7 – 11 weeks' gestation
- Nuchal scan (prenatal screening scan to detect cardiovascular abnormalities in a fetus) 11 - 14 weeks' gestation
- Reassurance scan 14 – 24 weeks' gestation
- Sexing scan 17 – 23 weeks' gestation
- Harmony prenatal test (is a non-invasive prenatal test (NIPT) that can be carried out after 10 weeks of pregnancy.) 10 – 40 weeks' gestation
- Safe prenatal test 10 – 40 weeks' gestation
- Anomaly scan 20 – 24 weeks' gestation
- Cervical scan 17 -21 weeks' gestation
- Wellbeing scan 24 – 40 weeks' gestation
- 4D scan (HD) 26 – 32 weeks' gestation
- Panorama prenatal screen (is a non-invasive prenatal test (NIPT) that can be carried out after 10 weeks of pregnancy.) 10 – 40 weeks' gestation

They also can provide non-invasive prenatal tests (NIPT). All women accessing the service self-refer to the clinic and are all seen as private (paying) patients.

The Birth Company was registered to provide the following regulated activities:

- Diagnostic and screening procedures

Summary of this inspection

During our inspection we spoke with five staff; the lead consultant who was the registered manager and owner, the managing director who was also the lead sonographer, sonographers and receptionists.

We gathered views from speaking to a small number of women, reviewing comment cards and feedback left via social media. During our inspection we reviewed a sample of patient records and registration forms.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

The service conducted about 800 scans per month. On each shift the service operated with two administrators, two sonographers and the clinical lead or lead sonographer.

Track record on safety

- No never events.
- No serious injuries.
- No incidences of healthcare acquired Meticillin-resistant Staphylococcus aureus (MRSA).
- No incidences of healthcare acquired Meticillin-sensitive staphylococcus aureus (MSSA).
- No incidences of healthcare acquired Clostridium difficile (c. diff).
- No incidences of healthcare acquired Escherichia coli (E-Coli).
- No deaths.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Building Maintenance and services
- Ultrasound machine maintenance

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?

Good

We rated safe as **Good** because:

- The service had systems in place to ensure staff had received mandatory training in key skills and made sure that everyone had completed it.
- Staff were knowledgeable about safeguarding processes and what constituted abuse.
- Each patient had a referral form and we saw that any risks were
- identified or documented.
- All staff demonstrated an understanding of the duty of candour and the principles behind this.
- Equipment was serviced and there were processes to ensure all items were well maintained.

However

- The service had not conducted a hand hygiene audit.
- The service did not accurately collate all incidents to enable them to monitor trends. .
- Not all staff had received level two safeguarding children training, however staff understood their roles in relation to safeguarding.
- Sharps boxes did not adhere to the BS7320UN3291 standards in line with health and safety regulation 2013 (The sharps regulations).

Are services effective?

Not sufficient evidence to rate

We do not currently rate effective for diagnostic imaging.

- Policies, procedures and guidelines were up to date and based on National Institute for Health and Care Excellence (NICE) guidelines, relevant regulations and legislation.
- Staff worked collaboratively as part of a multi-professional team to meet women's needs.
- There were systems to show whether staff were competent to undertake their jobs and to develop their skills or to manage under-performance.
- There was effective multidisciplinary team working throughout the service and with other providers.
- Information provided by the service demonstrated 100% of staff had been appraised.

Are services caring?

Good

We rated caring as **Good** because:

Summary of this inspection

- Women were treated with kindness, dignity and respect. This was reflected in feedback we received from women.
- Women received information in a way which they understood and felt involved in their care. Women were always given the opportunity to ask staff questions, and women felt comfortable doing so.
- Staff provided women and those close to them with emotional support; staff were supportive of anxious or distressed women

Are services responsive?

Good 

We rated responsive as **Good** because:

- The service offered a number scans for pregnant women such as, well-being, viability, growth and presentation, gender together with the ability for digital images.
- Patient complaints and concerns were managed according to the services policy.
- The service provided evening and weekend appointments to meet the requirements of women.

Are services well-led?

Good 

We rated well-led as **Good** because:

- Staff said managers were visible and approachable. Staff informed us they felt supported by the management team.
- There was a clear governance structure, which all members of staff were aware of.
- The service had its own risk register and the manager had clear visibility of the risks and was knowledgeable about actions to mitigate risks.
- There was a culture of openness and honesty supported by a whistle blowing policy.

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

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

At this inspection, we rated safe as **good.**

Mandatory training

- **The service had systems in place to ensure staff had received mandatory training in key skills and made sure that everyone had completed it.**
- Annual mandatory training courses were undertaken and regularly updated, training was provided either face to face or online. The service provided us with its training matrix which showed staff received mandatory training in; fire safety and evacuation, health and safety in healthcare, equality and diversity, infection prevention and control, safeguarding adults, customer care and complaints, basic life support (BLS), Mental Capacity Act 2005 and data security awareness.
- Mandatory training rates were reviewed yearly. At the time of this inspection records we viewed demonstrated 100% of staff had completed mandatory training. Staff training records were kept electronically on the services shared drive to which managers had access.

Safeguarding

- **Staff understood how to protect women from abuse. Staff had some training on how to recognise and report abuse and knew how to apply it.**
- The lead for adults and children's safeguarding was the managing director.
- Staff were trained to recognise adults and young people at risk and were supported by The Birth Company's safeguarding adults' and children's policy, staff received training in adults and children's safeguarding during induction to the service.
- The provider had developed safeguarding policies which were in place that staff were familiar with they could access them on the service's shared drive and printed copies were available.
- Safeguarding policies were up to date and reviewed regularly. They also clearly outlined staff responsibilities and how they should raise a safeguarding concern as well as immediate action to be taken where concerns related to a child or adult.
- Staff we spoke with demonstrated they understood their responsibilities and adhered to the company's safeguarding policies and procedures. The policies were clear, thorough and covered all types of abuse including female genital mutilation (FGM).
- At the time of this inspection the manager of the service was trained to level three for both safeguarding adults and safeguarding children and staff had received level two safeguarding adults training.
- However, not all staff had received level two training for children. Intercollegiate guidance: 'Safeguarding Children and Young People: Roles and competencies

for Health Care Staff', March 2014. Guidance states all non-clinical and clinical staff that have any contact with children, young people, parents or carers should be trained to level two safeguarding.

- We discussed this with the provider who confirmed later that all staff had been booked to receive level two training.
- Staff knew how to report a safeguarding concern but there were no safeguarding concerns raised from November 2017 to October 2018.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept equipment and the premises visibly clean. They used control measures to prevent the spread of infection.**
- The service had infection prevention and control (IPC) policies and procedures which provided staff with guidance on appropriate IPC practice in for example, communicable diseases and isolation.
- During this inspection we saw all areas of the service were visibly clean. Scanning rooms were cleaned daily according to the services cleaning manual and room specifications document. This was recorded on a daily check spreadsheet and was reviewed weekly.
- Staff followed manufacturers' instructions and The Birth Company's guidelines for routine disinfection. This included the cleaning of the medical devices between each patient and at the end of each day.
- Equipment and machines were cleaned following each use with alcohol wipes, this included such things as transvaginal probe covers for the probe used for internal examinations.
- Couches were covered with a disposable paper towel which was changed following each scan.
- We reviewed the machine in use during this inspection, and saw where appropriate, disinfection had taken place and evidence of a weekly check of the machine was available for review.
- We found that the service ensured the safe storage of substances hazardous to health (COSHH) and other chemicals were stored in locked cabinets.
- Between November 2017 and October 2018 there had been no incidences of health care acquired infection in the service.
- The registered manager and service lead told us they observed staff compliance towards hand hygiene, and infection prevention and control. Although we found that there was no formal audit process in place nor had a hand hygiene audit been completed for the service.
- Staff were bare below the elbow and had access to a supply of personal protective equipment (PPE), including gloves and aprons and had access to hand washing facilities.
- We saw that containers for the disposal of sharp objects (sharps bins), such as needles, were not dated, did not have signatures of staff and did not, indicate the date of construction and by whom.
- This did not adhere to the BS7320UN3291 standards in line with health and safety regulation 2013 (The sharps regulations), 5 (1) d. This requires staff to place secure containers and instructions for the safe disposal of medical sharps bins. Containers were free from protruding needles/sharp objects and were stored safely above floor level.
- Waste was handled and disposed of in a way that kept people safe. Waste was labelled appropriately and staff followed correct procedures to handle and sort different types of waste. Bins were emptied under an external agreement.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well. The environment promoted the privacy and dignity of women using the service.**
- The layout of the service was compatible with health and building notification (HBN06) guidance. Access to the service was via Harley Street.
- The service was located on the third and fourth floors and access could be gained by either a lift or stairs. For people with mobility issues a ramp could be provided. The service also had clearly marked fire exits and equipment to transfer people down stairs if required.

Good

Diagnostic imaging

- There was a large reception area with a reception desk that was staffed during opening hours. In the reception area there was a range of magazines, refreshments and toilet facilities for women and their relatives.
- The provider's maintenance and use of their facilities kept people safe. Waiting areas were visibly clean and tidy throughout. The scanning rooms were spacious and well-lit and had a sign on the door to notify people when it was in use.
- The treatment room had a additional screen so that patients, family or friends could see the scan images whilst the scan was taking place. This additional screen was used so ultrasound images could be displayed live; for patient, friends and family.
- Staff turned the lights off and pulled down the black-out blinds when undertaking a scan to darken the room, which meant scans could be observed clearly. This also promoted the privacy and dignity of women.
- The service's ultrasound machines were maintained and regularly serviced by the manufacturers. We reviewed service records for the equipment, which detailed the maintenance history and service due dates of equipment. The service record for the machine confirmed it had been serviced annually, last completed in 2018.
- The service had systems in place to ensure machines and equipment were repaired in a timely manner, when required, this ensured women would not experience prolonged delays to their care and treatment due to equipment being broken and out of use.
- Staff had sufficient space to move around the ultrasound machines for scans to be carried out safely and there were comfortable couches for women and stools for the operator.
- All equipment conformed to relevant safety standards non-medical portable appliance electrical equipment was tested. We reviewed five pieces of equipment, including computers, and the ultrasound machine, and found equipment had been serviced within the date indicated.
- The service had a first aid kit available, when we checked this, we found all the contents in date.

Assessing and responding to patient risk

- **Staff reviewed and updated risk assessments for each woman through individual referral forms.**
- Access to the service was through self-referral. Women completed a registration form, this could be completed online, in person or over the telephone.
- The registration form included their personal details, pregnancy history, including such things as the number of previous ectopic pregnancies and neonatal deaths before 37 weeks. The registration form included other questions such as the requirement for a chaperone or any allergies to such things as latex.
- Staff were trained to ask women reasons for their attendance at the service and record their answers on an electronic record. The service provided several ultrasound services for women, pregnancy scans, which included such scans as, early pregnancy scan, nuchal scan (a scan of the fluid under the skin of the baby's neck), reassurance and sexing scans. It also offered non-invasive prenatal tests (NIPT), and fertility scans.
- There were clear processes in place to guide staff on what actions to take if any suspicious findings were found on the ultrasound scan. If they had concerns, the sonographer followed the service's referral pathway, fetal abnormalities policy and referred the woman to the most appropriate healthcare professional, with her consent, for further investigations and management.
- We reviewed five referral forms. All contained a description of the scan findings, the reason for referral, who the receiving healthcare professional was and what action they were going to take.
- The sonographers could contact the lead sonographer (managing director) for advice and support during their clinics or the lead consultant who would review their findings.
- If the sonographers observed a fetal abnormality that required urgent further investigation and management, the service would refer to the women's

own NHS Trust. Examples of this were; severe fetal anaemia requiring blood transfusion, severe twin to twin transfusion requiring endoscopic laser placental separation or major fetal abnormality where the parents may request pregnancy termination.

- The service accepted women who were physically well and could transfer themselves to a couch with little support.
- The service did not offer emergency tests or treatment.
- Due to the nature of the service provided, there was no emergency resuscitation trolley on site. There was also clear guidance for staff to follow if a woman suddenly became unwell whilst attending the clinic. Staff had access to a first aid box.
- Both administration staff and sonographers had completed first aid or basic life support (BLS) training, and would put their training to use until the ambulance arrived. BLS training gives staff a basic overview of how to deal with a patient who may have stopped breathing, such as starting cardiopulmonary resuscitation.
- Staff told us if a patient required urgent treatment they would call 999. Should women arrive at the service in pain or bleeding then they would be signposted to the early pregnancy service.
- The service used the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers, which was displayed in the clinic room and helped to remind staff to carry out identification checks to ensure the correct person was being scanned.
- We observed the sonographer completing the checks during appointments, which included: confirming the woman's identity and consent; providing clear information and instructions, including the potential limitations of the ultrasound scan; following the BMUS safety guidelines; and informing the woman about the results.
- Scan reports were completed immediately after the scan had taken place, which we observed during our inspection.
- 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.

Staffing

- **The service had enough staff with the right qualifications and experience to provide the right care and treatment.**
- The service ensured there was a sonographer, the managing director or the lead consultant and two administrators present during clinic hours. On average the service had between 22 – 32 appointments booked each day and sufficient staffing to manage appointments. The service did not use agency staff.
- The ultrasound clinics were scheduled in advance and the sonographers were allocated by a manager to a list according to the needs of the patients and the service.
- We found all sonographers employed by the service were registered with the Health and Care Professionals Council (HCPC).
- There were business continuity plans in place to ensure the service operated when there were changes to normal operating circumstances. For example, sickness, absenteeism and workforce changes.
- The service had a recruitment policy and procedure in place. We reviewed five recruitment records of staff employed by the service. We found that the service was transferring from paper to electronic recruitment records, documentation could be held electronically or on paper.
- There was evidence in personnel files of identity checks, Disclosure and Barring Service (DBS) check and checks of professional qualifications and records of the Health and Care Professions Council (HCPC) registration.
- All staff we spoke with felt staffing was managed appropriately

Records

Good

Diagnostic imaging

- **Staff kept detailed records of women's appointments, referrals to NHS services and completed scan consent documents. Records were clear, up-to-date, and easily accessible to staff providing ultrasound scans.**
- The service had an up-to-date information governance policy in place for staff to refer to. The policy detailed staff responsibilities, documentation standards, and the retention of records.
- Women's personal data and information were kept secure. Only authorised staff had access to women' personal information.
- Staff training on information governance and records management was part of the mandatory training programme.
- We reviewed a sample of patient records and registration forms during this inspection and saw records were accurate, complete, legible and up to date. This included estimated due date, the type of ultrasound scan performed, the findings, conclusions, and recommendations. Paper reports of the scans were given to women directly.

Medicines

- The service did not use any controlled drugs but the service did have a quantity of Misoprostol (used in the medical management of a miscarriage). We found that the use and storage of this medicine was appropriate. Allergies were documented and checked on arrival in the service and would be documented on the notes for the sonographer.

Incidents

- **Processes were in place for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents. Lessons learnt were shared with the whole team and the wider service.**
- The service had an incident reporting policy and procedure to guide staff in the process of reporting incidents. We found that staff understood their responsibilities to raise concerns, to record safety incidents, investigate and record near misses.
- We saw if an incident occur, staff would inform the manager of the service who would record the incident on the service's incident matrix, and undertake an investigation if necessary.
- We found incidents were individually documented had been investigated appropriately, however the service's incident recording tool was not accurate as some incidents had not been collated on the services incident matrix. This meant that the service could not accurately identify trends.
- Following the inspection, the provider sent us an updated version of their incident matrix with all incidents correctly collated.
- We reviewed the service's incident log, this documented eight incidents of which three related to staffing issues, an insecure door, late non-invasive prenatal test (NIPT) results and scanning issues. We saw that following review learning had been identified. For example; a high risk NIPT test results were received seven days after submission.
- Following review, the service now highlighted all high risk NIPT tests and cross referenced these with an email that was received following the results, this ensured risks were not missed.
- We reviewed the accident and incident book and found that staff had been completing it appropriately.
- During the period November 2017 to October 2018 there had been no serious incidents requiring investigation. Serious incidents are events in health care where the potential for learning is so great, or the consequences to women, families and carers, staff or organisations are so significant, they warrant using additional resources to mount a comprehensive investigation.
- There had been no 'never events' in the previous 12 months prior to this inspection. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There had been no notifiable safety incidents that met the requirements of the duty of candour regulation in the 12 months preceding this inspection.

Good

Diagnostic imaging

- Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 is a regulation which was introduced in November 2014. This regulation requires the organisation to be open and transparent with a patient when things go wrong in relation to their care and the patient suffers harm or could suffer harm, which falls into defined thresholds. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.
- Staff understood the duty of candour and the need for being open and honest with women and their families if errors occurred. Staff could explain the process they would undertake if they needed to implement the duty of candour following an incident, which met the requirements. However, throughout the reporting period, they had not needed to do this.
- The registered manager was aware of the requirements for reporting incidents to the CQC using the statutory notification route if this met the criteria, under Regulation 18 of the Care Quality Commission (Registration) Regulations 2009.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do not currently rate effective for diagnostic imaging.

Evidence-based care and treatment

- **The service used current evidence-based guidance and good practice standards to inform the delivery of care and treatment.**
- Women's care and treatment was delivered and clinical outcomes monitored in accordance with guidance from the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS). NICE guidance was followed for diagnostic imaging pathways as part of care for uncomplicated pregnancies.
- Staff demonstrated a good understanding of national legislation that affected their practice. For example, sonographers followed the 'Ectopic pregnancy and miscarriage: diagnosis and initial management' guidance (NICE, 2012) when they identified a fetus did not have a visible heartbeat and measured less than 7.0mm.
- In addition, the service followed 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.
- 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.

Nutrition and hydration

- Due to the nature of the service, food and drink was not ordinarily offered to women. However, there was a drinking water dispenser in the waiting area, which was accessible to women and visitors.
- Women who were having an early pregnancy scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment.
- If this was not possible we observed staff providing women with extra glasses of water to improve the quality of the ultrasound image

Pain relief

- Pain assessments were not undertaken at The Birth Company although staff told us that women were made comfortable during the scanning process.

Patient outcomes

- **Staff monitored the effectiveness of care and treatment and used the findings to improve their practice.**

Good

Diagnostic imaging

- The service monitored patient outcomes through their activity, annual patient satisfaction survey and clinical audits.
  - The Birth Company undertook sonographer peer review audits. The sonographers reviewed each other's work and determined whether they agreed with their ultrasound observations and report quality and on such findings as gender or anomalies. This was in line with BMUS guidance, which recommends peer review audits are completed using the ultrasound image and written report.
  - The service reviewed and recorded how many women it had referred to the NHS early pregnancy services, the number of rescans it had conducted and the number of occasions the gender had been sought but was incorrect.
  - Further audits on the quality of images were conducted by the lead sonographer who would feed back results to individual sonographers. We reviewed these audits and found most to have been rated, acceptable.
  - We also saw that as part of routine audit the service monitored the length of time women had to wait for a scan, we saw that in most cases waiting times were less than 10 minutes.
  - The service participated in a programme of external audit, we saw that sonographers who conducted Nuchal Translucency Scans were reviewed by an external agency (the Fetal Medicine Centre) periodically who reviewed and provided individual sonographers with a licence to perform the scans.
  - The 12-week Nuchal Translucency Scan can be performed to assess the risks of Down's, Edward's and Patau's syndromes to diagnose major fetal abnormalities.
  - Other audits were conducted including, patient experience, health and safety, safeguarding, equipment and privacy and dignity. Service activity, audit results and patient feedback were regularly discussed during the monthly team meetings.

Competent staff

- **Staff had the skills, knowledge and experience to deliver effective care and treatment.**
- The service made sure staff were competent for their roles. Manager's appraised staff work performance and provided support.
- All staff had completed a structured induction programme for the service, which included the use of equipment and office systems.
- Records we checked confirmed staff received an annual appraisal and monthly supervision, which was up to date.
- Staff had the right skills and training to undertake ultrasound scans, this was closely reviewed at the service with the clinical lead having the ability to review periodically sonographer's scans and provide feedback.
- Each staff member completed a local induction, which included mandatory and role-specific training. Staff accessed their role-specific training through the service's electronic training portal. Training records confirmed that all staff had completed their appropriate role-specific training.

Multidisciplinary working

- **Staff of different disciplines worked together as a team to benefit women and their families.**
- We observed positive examples of the sonographer and administration assistants working well together. Their professional working relationship promoted a relaxed environment for women and helped to put women and their families at ease.
- Staff at the service told us that their aim was to work closely with women to support a seamless treatment pathway. If concerns were identified from a scan these were escalated to the patient's local NHS trust early pregnancy service.
- The service had established pathways in place to refer women to their GP or local NHS trust if any concerns were identified during their appointment. Staff communicated their referral to the local NHS trust or GPs by letter and telephone.

Seven-day services

Good

Diagnostic imaging

- **Although The Birth Company was not an acute service and did not offer emergency tests or treatment, it still operated in a flexible way to accommodate the needs of women.**
- The service was operational Monday to Thursday from 8am until 8pm, Friday from 8am until 6pm, Saturday 9am until 4pm and Sunday 10am until 2pm.
- Appointments were flexible to meet the needs of women, and appointments could be made available at short notice if required.

Health promotion

- Information leaflets were provided in the service for women on several topics. For example; what the scan would entail, keeping healthy, which included giving up smoking and alcohol, movements of the baby, foods to be avoided.
- The service also provided information on its website such as a 'To do list' this provided women with further information on such things as 'Free dental check-up', 'Rights at work', 'Travel during pregnancy' and 'Preparing your hospital bag' All information could be downloaded.

Consent and Mental Capacity Act

- **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. All staff were aware of the importance for gaining consent from women before conducting any ultrasound scan.**
- Women provided verbal consent which was recorded on their electronic record before they performed an ultrasound scan. For other services, such as NIPT, we saw that the service obtained written consent.
- Staff understood their responsibility to gain consent from women and respected a patient's choice if they decided not to have a scan after arriving for an appointment.
- We found that staff we spoke with had knowledge of the requirements of the Mental Capacity Act 2005 (MCA).
- There was a Mental Capacity Act (2005) policy for staff to follow, which clearly outlined the service's expectations and processes. However, staff told us that since starting the service they had not had to support women who had been assessed as lacking capacity to make decisions about the scanning procedure.

Are diagnostic imaging services caring?

Good

At this inspection, we rated responsive as **good.**

Compassionate care

- **Staff cared for women with compassion. Feedback from women and their families confirmed that staff treated them well and with kindness.**
- All staff were passionate about their roles and were dedicated to making sure women received patient-centred care.
- We observed staff treating and assisting women and their families in a compassionate manner. The scan assistants and sonographer were very reassuring and interacted with the women and their relatives in a professional, respectful, and supportive way.
- Feedback provided by women we spoke with said staff demonstrated a kind and caring attitude to them. Women told us, 'Lovely staff, very knowledgeable and detailed scan performed' 'Name (the sonographer) was excellent, she handled us with care and we are very happy. Would recommend the experience'.
- We observed staff introducing themselves to women at the start of the appointments, and the women we spoke with confirmed this.
- Staff protected women's privacy and dignity. For example, the clinic room was locked when ultrasound scans were being undertaken, and women were provided with a gown to cover themselves during intimate scans. There was also a dignity screen for women to get changed behind before scans.

Good

Diagnostic imaging

- The service obtained patient feedback through feedback forms, which allowed women to make comments about their care and provide a rating of their overall experience, however most women chose to provide feedback online.
- Paper feedback forms represented 6% of feedback received by the service. We were told that most women preferred to provide feedback using online methods. Online we saw that the service was rated as 'Five star" based on 3,095 independent reviews.

Emotional support

Staff provided emotional support to women to minimise their distress. We observed staff providing kind, thoughtful, supportive, and empathetic care.

- Staff provided reassurance throughout the scanning process, they updated the patient on the progress of the scan and how long they had before their scan was complete.
- Staff were aware that women attending the service were often feeling nervous and anxious so provided additional reassurance and support to these women. Staff were aware of their roles and responsibilities when acting as chaperones during intimate ultrasound scans ensuring women received emotional support.
- Staff felt recognising and providing emotional support to women was an important aspect of the work they did, staff had received training in discussing potentially bad news. The service had a separate room where bad news could be discussed but we were told that the service could also use the scanning room which was equipped with comfortable seating.

Understanding and involvement of women and those close to them

- **Staff involved women and those close to them in decisions about their care.**
- Staff communicated with women in a manner that would ensure they understood the reasons for attending the service. All women were welcomed into the reception area and reassured about their procedure.
- Staff took the time to explain the procedure to the woman before and during the ultrasound scan. Staff adapted the language and terminology they used when discussing the procedure with the women and their families.
- Staff recognised when women or those close to them needed additional support to help them understand and be involved in their care and treatment. Staff enabled them to access this, including access to interpreting and translation services.
- Women and those close to them could ask questions about their scan. A range of ultrasound related leaflets were available to women in the service. Women could also access information on different types of scans, and pricing information from The Birth Company website.
- All those close to the women we obtained views from said that they felt involved in the care given.

Are diagnostic imaging services responsive?

Good

At this inspection, we rated responsive as **good.**

Service delivery to meet the needs of local people

- **The facilities and premises met the needs of women who accessed the service.**
- The service recognised that women's preferred method of communication had changed, and as a result, they had developed a range of innovative products to tailor their services and meet the needs people. For example, the service provided electronic tablets for women to provide feedback whilst in the waiting room.
- 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.
- The service was located on the third and fourth floors of the building. Should a woman attend with mobility

issues the service could provide a ramp to enter the building and a lift was available for use. Clinic rooms contained adjustable couches, which staff used to support women with limited mobility.

- In cases of emergency the service could access emergency exits to the front and rear of the service using stairs
- The service provided payment details in a confirmation email prior to each patient's attendance. These included a clear price list and different options for payment. The service was registered with UK insurers for the provision of care and public liability.
- The service offered a number of scans for pregnant women such as, well-being, viability, growth and presentation, gender together with the ability for digital images.
- The service signposted women to complementary services for such things as Osteopathy, reflexology and support and psychotherapy.
- The service provided evening and weekend appointments to meet the requirements of women.
- The service was accessible by public transport being located close to bus routes and tube, the service could be accessed by car although there was limited on street parking.
- The Birth Company regularly used social media to engage with the local population and promote their service.

Meeting people's individual needs

- **The service took a proactive approach to understand women's individual needs, and delivered care in a way that met these needs, which was accessible and promoted equality.**
- Staff understood the cultural, social and religious needs of women. Women received written information to read and sign before their scan appointment, which could be made available in different languages. The service had subscribed to the 'Language line' service, this meant that people who did not have English as there first language could use an interpretation service.
- During scanning, staff made women comfortable. Women were advised that if they wanted to stop their scan, staff would assist them and discuss choices for further imaging or different techniques or coping mechanisms to complete their imaging.
- Relatives or people close to them could be present in the scanning room if requested.
- Information leaflets were given to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy; a second scan that confirmed a complete miscarriage; or an inconclusive scan. The leaflets contained a description of what the sonographer had found, advice, and the next steps they should take.
- All scans were undertaken in a private clinic room with lots of space for any additional relatives, friends, or carers to accompany the woman. If a woman was required to undress, locked doors and dignity screens were used to protect her privacy.
- The moveable couches were suitable for very overweight women; however, there was no hoist available. If a woman required the use of other bariatric (relating to the treatment of obesity) equipment, they would be referred to the NHS.

Access and flow

- **Women could access services and appointments in a way and at a time that suited them. Technology was used innovatively to ensure women had timely access to treatment.**
- Women self-referred and they could book appointments through several media platforms including, telephone and email through The Birth Company's website. Appointments were usually made by telephone at a time and date agreed by them. In the case of a requirement to conduct a scan at short notice the service told us that it would attempt to make an appointment as soon as possible.
- There were very few delays and appointment times were closely adhered to. Fetal well-being reports were produced and shared in a timely manner, on the same day.
- During our inspection, we observed that scan clinics ran on time.

Good

Diagnostic imaging

- From November 2017 to October 2018 no planned examinations were cancelled for non-clinical reasons and no planned examinations had been delayed in the same period.
- The service did not routinely record the data for women who did not attend, we were told that if a person did not attend or cancel they would be contacted to ascertain the reasons for their non-attendance and an appointment would be re-booked if necessary.

Learning from complaints and concerns

- **The service treated concerns and complaints extremely seriously. The managing director completed comprehensive investigations, which frequently involved input from other professionals, such as the lead sonographer. Lessons learned were shared with all staff.**
- The service had an up-to-date complaint handling policy, which set out the complaints process and the responsibility of staff. The managing director manager had overall responsibility for reviewing and responding to complaints. We found that the service had received three complaints in the reporting period which concerned staff communication.
- Complaints were collated into an electronic log, which was used to identify any themes and learning, and was shared with staff at their team meetings.
- Staff were encouraged to resolve complaints and concerns locally. The service had a complaints handling policy and all staff had completed a mandatory training course on customer care and complaints.
- The complaints log recorded actions the service had taken in response to the complaint. The log recorded when women had received a verbal apology from the service.
- Information on how to make a complaint was available within the clinic. Staff told us that most complaints were made through social media. Therefore, staff monitored their social media pages daily, to ensure any concerns or complaints were addressed immediately.

Are diagnostic imaging services well-led?

Good

At this inspection, we rated well-led 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.**
- The registered manager and the managing director had an awareness of the service's performance, limitations, and the challenges it faced. They were also aware of the actions needed to address those challenges.
- The sonographers reported to the managing director who was also the lead sonographer for matters of administration and for clinical matters. Administration assistants also reported to the managing director.
- Staff knew the management arrangements and told us they felt well supported. The lead sonographer or lead consultant could review any ultrasound scan within one to two hours.
- Staff also had specialist lead roles within the service. For example, the managing director was the lead for health and safety, safeguarding, and infection prevention and control (IPC).
- Staff said managers were visible and approachable. Staff informed us they felt supported by the management team. All the staff we spoke with were positive about the management of the service.

Vision and strategy

- **The Birth Company had a clear vision and strategy for what they wanted to achieve, with quality and sustainability as the top priorities.**
- The services vision and aims were to enable expectant mothers to have a positive and reassuring experience during fertility care, pregnancy and childbirth experience.

- All staff were introduced into these values during induction when first employed during the corporate induction. The appraisal process for staff were also aligned to these values of the service and individual's learning objectives.
- The service had also identified values, which underpinned their vision. Their values included: dignity, integrity, privacy, diversity, and safety.

Culture

- **Managers and staff promoted a positive culture, creating a sense of common purpose based on shared values.**
- All of the staff we spoke with were very positive and happy in their roles and stated the service was a good place to work. Staff told us that the manager was flexible in their approach to running the service.
- Staff we spoke with told us they felt supported, respected and valued, they were actively encouraged to make suggestions about changes and improvements to the services provided.
- The service operated an open and honest culture to encourage team working within the organisation.
- Staff demonstrated pride in their work and the service they delivered to women and their service partners. Staff told us they had sufficient time to support women.
- Staff told us there was a positive approach regarding incidents and they received feedback from incidents.
- Equality and diversity was promoted within the service and was part of mandatory training.
- A whistle blowing policy and a duty of candour policy were in place. Staff told us they had attended duty of candour training and described to us the principles of duty of candour.

Governance

- **Governance arrangements were clear and appropriate to the size of the service**
- The registered manager and the managing director shared overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to patient complaints. They were supported by the lead consultant.
- 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 clinical and local compliance audits were undertaken regularly. They monitored patient experience, health and safety, equipment and privacy and dignity.
- Formal minuted team meetings were held monthly. We were provided with minutes from these meetings which included; how the service was progressing in regard to the company strategy, performance, policies, and reviews of incidents and complaints and any lessons learnt.
- The registered manager also ensured that regular health and safety audits were conducted monthly. This ensured actions to improve services were recorded and monitored for completion.
- All staff were covered under the service's medical malpractice insurance, which was renewed in October 2018. Sonographers also all held their own indemnity insurance.

Managing risks, issues and performance

- **The service had effective arrangements in place for identifying and recording risks, and there was evidence that these risks and their mitigating actions were discussed with the wider team.**
- There was a risk assessment system (risk register) which included a process of escalation to escalate risks. It covered hazards and precautions in relation to a range of factors, including infection control, electrical safety, fire safety and substances hazardous to health.
- Risk assessments were completed on a standard template to ensure consistent information was used.

All templates had the risk identified, mitigating/ control measures, the individual responsible for managing the risk and the risk assessment review date.

- There was a business continuity policy which highlighted key hazards and mitigations, contact details and relevant staff and an emergency response checklist.
- The service also used patient feedback, complaints, and clinical audit results to help identify any necessary improvements and ensure they provided an effective service.

Managing information

- **The service managed and used information to support its activities, using secure electronic systems with security safeguards.**
- The provider collected, analysed, managed and used information to support all its activities, using secure electronic systems with security safeguards.
- Staff told us there were sufficient numbers of computers in the service. This enabled staff to access the computer system when they needed to.
- All staff we spoke with demonstrated they could locate and access relevant information and records easily, this enabled them to carry out their day to day roles. Patient records could be accessed easily but were kept secure to prevent unauthorised access to data.

Engagement

- **The service engaged well with women, staff and the public to plan and manage appropriate services and collaborated with partner organisations effectively.**
- The service did not routinely undertake staff satisfaction surveys, it was explained that because the service had a relatively small number of permanent employees that numbers would not produce meaningful data.
- Staff had access to the managing director, the registered manager and nominated individual all of whom operated an open-door policy. They told us that regular supervision and appraisal ensured the service provided staff with the opportunity to comment on the service.
- The service also enabled women to provide feedback by email or comment cards. We reviewed the feedback received by the service from women which was wholly positive.
- There was a website for members of the public to use. This held information regarding the services offered and the prices for each type of scan. There was also information about how women could provide feedback regarding their experience. Women were encouraged to leave feedback on the service's social media pages.

Learning, continuous improvement and innovation

- **Staff could provide examples of improvements and changes made to processes based on patient feedback, incidents, and staff suggestion.**
- The managing director took immediate and effective actions to address some of the issues we raised during the inspection.
- The service signposted women to complementary services for such things as Osteopathy, reflexology and support and psychotherapy.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The provider should consider carrying out regular hand hygiene audits to monitor and improve infection prevention and control practices.
- The provider should ensure there are effect governance arrangements in place to assure themselves that all incidents are collated within the service.
- The service should ensure that all sharps boxes adhere to the BS7320UN3291 standards in line with health and safety regulation 2013 (The sharps regulations).
- The service should ensure that all staff receive level two safeguarding training for children.