Baby Scan Studio Ashford

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	**Requires improvement**
Are services safe?	**Requires improvement**
Are services effective?	**Not sufficient evidence to rate**
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Requires improvement**

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.

Summary of findings

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

Baby Scan Studio Ashford is operated by Baby Scan Studio Limited. The service provides pregnancy keepsake scans to self-funding women, aged from 17 years, in Ashford and the surrounding areas. The scans are abdominal and include 2D, 3D and 4D keepsake and gender scans.

The service is registered to provide the regulated activity of diagnostic and screening procedures.

The clinic has a registered manager and three sonographers who carry out early reassurance scans as well as gender identification and bonding scans. The registered manager also works as the scanning assistant and receptionist.

We inspected this service using our comprehensive inspection methodology. We carried out a short-notice announced inspection on the 10 and 12 September 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

This service had not previously been rated using the current methodology. We rated it as **Requires improvement** overall because:

- The service did not provide mandatory training for staff and there was no ongoing inhouse training for fire safety, manual handling or health and safety.
- The safeguarding adult and children's policy was only reviewed five yearly and we found links to current local safeguarding services were out of date, no longer available and did not reference the most recent guidance.
- The service did not follow a clear process to ensure all staff had pre-employment checks before working with the service. The registered manager did not request references or apply for disclosure and barring service (DBS) checks prior to staff working there. However, the registered manager had applied for DBS checks for all staff that were relevant to the service and we saw evidence of certificates. Prior to our inspection, the registered manager contacted the sonographer's main place of work and requested employee references.
- A risk management policy was in place. However, we found the information minimal and did not detail how a risk should be reported by staff. Staff told us they would report any risks to the registered manager but was not aware of how to document a risk. Risk assessments did not give clear guidance on the type of risk, there was no description of the risk and no documentation to show how the service reduced risks. Risk assessments were not always reviewed, documentation was at times unreadable and written in pencil. Written records are a legal document and therefore should be written in ink so as transparent and legible.
- We found policies and protocols were written by an external company and did not have a clinical oversight of the service. This meant policies did not always relate specifically to the service. For example, the complaints policy mentioned a clinic not related to the service. We found the service did not have systems or procedures in place to ensure policies were regularly reviewed or referenced current guidelines.
- The service did not have a policy which referred to the Mental Capacity Act, 2005 and there was no service specific training on mental capacity. The register manager had not received mental capacity training. However, sonographers told us they had completed mental capacity training within their other employment.

Summary of findings

However, we found that:

- Staff cared for women who used the service with compassion. Feedback from women told us that staff treated them with kindness and patience.
- Staff spoke with women in a sensitive and calming manner. Staff provided a warm and relaxing environment for women, relaxing music and appropriate lighting for ultrasound scans. We reviewed comments from women who used the service, which indicated they felt comfortable and calm throughout their scan.
- Staff provided reassurance and support for anxious women during their first scan appointments. We saw staff speak calmly and in a reassuring manner throughout scans.
- The clinic gave women enough time during scan appointments and feedback from service users was that they did not feel rushed during their scan. We observed four women attending clinic and they were not rushed during or after their appointments.
- The service did not have a waiting list for ultrasound appointments. Women were offered appointments for the same week they asked for one. The registered manager told us they were flexible with appointments and tried to accommodate appointment requests.
- The service had comment cards for service user feedback, which women and their families were asked to complete. Women were also able to leave reviews of the service on the website and social media pages.
- We observed the registered manager engage positively with service users and staff. Staff we spoke to told us the registered manager was supportive and we observed good working relationships between manager and staff.

Following this inspection, we told the provider that it must take actions to comply with regulations and it should make improvements to help the service to improve. We issued the provider with two requirement notices. The details are at the end of the report.

Dr Nigel Acheson

Deputy Chief Inspector of Hospitals (London and South)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	We rated this service as requires improvement because it did not have effective governance systems in place, to manage risks, to ensure policies were right for the service and pre-employment checks took place.

Summary of findings

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Requires improvement

Baby Scan Studio Ashford

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Baby Scan Studio Ashford

Baby Scan Studio Ashford is a private diagnostic service based in Ashford, Kent. It is owned by Baby Scan Studio Ltd and was established in 2011.

The service provides a non-diagnostic, souvenir and keepsake pregnancy ultrasound services to self-funding women in Ashford and the surrounding area.

It provides 2D, 3D and 4D scanning and produces keepsakes for women and offers early pregnancy scans, from seven weeks, as well as gender scans and scans from 16 weeks. The service completes around 40 scans per month.

The location is open four days a week, on Thursday and Friday evenings as well as all day on a Saturday and Sunday.

The hospital has had a registered manager in post since registering with the Care Quality Commission in November 2016.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and two other CQC inspectors. The inspection team was overseen by an inspection manager and Catherine Campbell, Head of Hospital Inspection.

Information about Baby Scan Studio Ashford

The service has one ultrasound scanning room and is registered to provide the following regulated activities:

- Diagnostic and screening procedures

During the inspection we viewed all parts of the clinic including the waiting, scanning room, kitchen and toilet facilities. We spoke with two staff including the registered manager and a sonographer. We observed two ultrasound scans and reviewed ten customer feedback cards.

There were no special reviews or investigations of the service undertaken by the CQC during the 12 months before inspection. The clinic had previously been inspected under the previous methodology.

Activity from September 2018 to September 2019

- There were a total 1605 pregnancy scans completed by the clinic.

Track record on safety:

- No never events
- No clinical incidents or serious injuries.

Services provided at the hospital under service level agreement:

- Maintenance of the ultrasound equipment.

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?

Requires improvement

We rated it as **Requires improvement** because:

- We were not assured that there were effective systems and processes in place to support staff in identifying safeguarding concerns.
- The service did not respond to risks well and did not highlight risk assessments clearly.
- The service did not provide local training for staff.

However:

- The service-controlled infection risk and kept premises and equipment clean.
- The clinic had enough staff to provide the right care and treatment.
- Staff kept patient records within lockable cupboards.

Are services effective?

Not sufficient evidence to rate

We did not rate effective. However, we found:

- Policies did not reflect national guidance and were not specific to the service.
- Pre-employment checks were not in place prior to staff working with the service.
- The service did not have a written care pathway for staff to follow when referring women to maternity NHS services when finding an irregularity or health concern.
- The service did not have a Mental Capacity Act policy and the registered manager had not received specific training.

However:

- Service user's views on the service was monitored through feedback cards and social media.
- The service provided clear verbal and written information to women before and during scans, that the service was not a substitute for antenatal care provided by the NHS. Women were advised to attend all NHS antenatal appointments.

Are services caring?

Good

We rated it as **Good** because:

- Staff put women at ease, they introduced themselves, explained their role and what to expect from the ultrasound scan.

Summary of this inspection

- We saw staff provided reassurance and support for anxious women during their first scan appointments.

Are services responsive?

Good

We rated it as **Requires improvement** because:

- The service did not have a waiting list for ultrasound appointments. Women were offered appointments for the same week they booked.
- Staff provided a warm and relaxing environment for women, with relaxing music and the best lighting for ultrasound scans.

However:

- The clinic did not have access to an interpreting service for women who did not have English as their first language or who were deaf.

Are services well-led?

Requires improvement

We rated it as **Requires improvement** because:

- We found the service did not have systems or procedures in place to ensure policies were regularly reviewed or referenced the most up to date guidelines.
- There was no audit of risk assessments and we did not find evidence that staff had clear oversight to the risk assessments or governance processes of the service.

However:

- Staff we spoke with were very positive about the registered manager and their role within the service. Staff felt confident to raise any concerns and told us they were well supported.
- The service had a vision in place for what it wanted to achieve. The registered manager told us the vision was to 'focus on providing and improving a first-class family friendly service and to offer a warm and calm environment with safety being the priority'.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

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

Are diagnostic imaging services safe?

Requires improvement

We rated it as **requires improvement.**

Mandatory training

The service did not provide mandatory training in key skills to all staff.

- The service did not provide mandatory training to staff. All sonographers were employed on a zero hours contract and worked as self-employed with the service. The registered manager told us they relied on sonographers to complete all mandatory training within their NHS employment. We saw staff files which showed us all sonographers had completed their NHS mandatory training.
- A local induction was provided by the service for new staff. However, there was no ongoing in-house training for fire safety, infection control and prevention. Manual handling or health and safety.
- The registered manager had completed external mandatory training courses including first aid and health and safety.

Safeguarding

We found not all staff understood how to protect women from abuse. Staff had training on how to recognise and report abuse.

- The service did not provide safeguarding training. All sonographers had completed safeguarding level 2 and level 3 children and adult safeguarding training within their other employment. This level was appropriate to their role and in line with national guidance (Intercollegiate Document, Adult Safeguarding: Roles and Competencies for Health Care Staff (August 2018); Intercollegiate Document, Safeguarding children and young people: roles and competences for health care staff (March 2014). The registered manager had undertaken an external safeguarding level two and level three adult and children.
- The registered manager was the designated lead for both adults and children safeguarding and had completed the level 3 adult and level 3 children safeguarding training. The registered manager was available during each clinic. Staff were able to ask for safeguarding advice or support.
- The service had a safeguarding policy in place. However, the policy review date was five yearly and we found the links within the policy to current local safeguarding services. However, we found the links were no longer available.
- The policy did not reference up to date guidance, such as the safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document (March 2014).
- Sonographers had received training on female genital mutilation (FGM) and child sexual exploitation during the NHS safeguarding training completed. However, the service did not discuss FGM or CSE within their service policies.
- Staff were able to describe a safeguarding incident and how to recognise any potential safeguarding

concerns and forms of abuse. Staff told us they would speak to the registered manager if they were alerted to a safeguarding incident. However, they had difficulty describing the safeguarding referral process.

- We found no documentation during the inspection to suggest that staff had read the safeguarding policy. However, we saw staff team minutes which showed us the safeguarding policy was discussed with staff and how to complete a safeguarding referral.
- The service placed the local authorities safeguarding contact address and telephone number onto the notice board in the clinic.
- The service did not have a chaperone policy and there was no training provided for staff. Staff we spoke to know their responsibilities as a chaperone. Information given to women attending scans was that they could request a chaperone if required and there were signs for women to request a chaperone displayed on the wall.

Cleanliness, infection control and hygiene

The service-controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.

- The registered manager was the infection control lead and had completed the relevant training.
- During our inspection we did not see an infection prevention and control policy in place and we did not see evidence of annual reviews. However, following the inspection the service submitted a copy of the infection prevention and control policy.
- At the time of our inspection the clinic environment was visibly clean and tidy. The clinic was cleaned daily by staff at the end of the day and staff completed a cleaning log.
- An external cleaner completed a deep clean of the service once a month and we saw evidence of this in cleaning logs.
- Staff completed infection control training yearly as part of their mandatory training within their other employment but no local training specific to the service was provided.
- The scanning room did not have a handwash basin. The nearest handwashing facilities were on the ground floor in the toilet. However, we saw the sonographer go to the ground floor before and after clinic to wash hands. We saw the sonographer use hand gel and wore gloves between and during all service user contact. This was in accordance to NICE QS61 Statement 3: People receive healthcare from healthcare workers who decontaminate their hands immediately before and after every episode of direct contact or care.
- Equipment and machines were cleaned following each use with alcohol wipes. Couches were covered with a disposable paper towel which was changed following each scan.
- Staff kept cleaning equipment, fluids and other chemicals in locked cabinets and cupboards. This was in line with the Control of Substances Hazardous to Health Regulations 2002.
- There had been no incidences of healthcare acquired infections reported at the service.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

- The service was located on the first floor. The waiting area was large and spacious with plenty of seating of women and their families. The area was clean, bright and warm. The toilet facilities were located on the ground floor and the service provided baby changing facilities also.
- The scanning room was next to the reception. The room had appropriate lighting, was spacious and had comfortable seating for women and their families.
- The scanning was a relaxing and calm environment. The equipment used was appropriate for the ultrasound procedures provided. The service had one ultrasound machine and the manufacturer provided the maintenance and servicing. We reviewed the service level agreement. The service records showed us the scanner was maintained regularly.

Requires improvement

Diagnostic imaging

- There was sufficient storage for equipment, and we observed unused items such as wipes, and paper stored in an appropriate locked storage cupboard. Staff had access to equipment such as gloves, hand gel and ultrasound gel. All ultrasound gels were in date.
- We conducted a random check of equipment and found the equipment to be in date and checked daily. The service had a first aid kit and all items were within their expiry date.
- All cleaning liquids and bleach were kept in a locked cupboard on the ground floor.
- The premises had clearly marked fire exits, alarm points and extinguishers which were stored securely. The service had a recent fire assessment which identified staff had not had local fire safety training and fire doors were wedged open at the time of the assessment. During our inspection we found there was not an action plan in place to address the areas raised during the fire assessment. Staff told us that they had not had a service specific fire training and a regular fire drill did not take place.
- Clinical waste bags were not in use in the service and the manager told us they did not produce any clinical waste.

Assessing and responding to patient risk

Risk assessments were in place. However, risk assessments were not clear and did not provide information in how to minimise risks to service users.

- A risk management policy was in place. However, we found the information minimal and did not detail how a risk should be reported by staff. Staff told us they would report any risks to the registered manager but was not aware of how to document a risk.
- The service had a risk assessment folder in place. The risk assessments were rated in relation to type of risk. We reviewed each risk assessment and found there was not a clear description of the risk identified. The information did not detail clearly how the service would mitigate the risk or how the risk was reviewed.
- We found actions taken during the review a risk assessment was not clear, the handwriting was not always legible and information at times was written in pencil and not ink.
- Women were asked to bring their antenatal records to each scan appointment and were informed of the scanning process. The sonographer discussed further scanning options and provided a scan report.
- All women completed a pre-scan questionnaire that included pregnancy history such as any previous miscarriages or ectopic pregnancies.
- Information relating to the consent form was available to download on the services website, so women were able to read through prior to their clinic appointment. The consent form informed women that the clinic did not provide obstetric care and the ultrasound scan was for personal non-medical reasons. The form was clear that the scans did not replace any NHS scan appointments.
- The service did not offer diagnostic imaging services. Staff told us scans were not intended to be diagnostic and did not replace routine hospital scans. This was reflected on the service's website and on the consent form all women completed before the scan.
- Women were advised to attend their local midwifery services and were given a form, which detailed the findings of the scan. Women were followed then followed up with a telephone call the next day.
- Staff advised women about the importance of still attending their NHS pregnancy ultrasound scans and appointments. The sonographers ensured women understood that the ultrasound scans were in addition to those provided as part of their NHS maternity care pathway. This information was also stated in the terms and conditions for the service and on the website. Information clearly advised women to access all antenatal services made available to them by the NHS.
- The website and information on the notice boards gave advice from the British Medical Ultrasound Society in relation to safety and multiple scan use.
- The service used the 'Paused and Checked' checklist devised by the British Medical Ultrasound Society (BMUS) and Society of Radiographers. We saw a poster

clearly displayed within the scanning room. The sonographer completed the checks during scans, which included confirming the woman's identity and consent, providing clear information and instructions.

- The service had an emergency procedure policy in place which gave guidance in response to an emergency or serious concern, such as a service user became unwell or needed urgent medical attention. Staff were able to tell us what they would do in an emergency or if they had a serious concern. Staff told us that they would call 999 and request assistance.
- The service displayed information on their notice boards which advised women on 'counting kicks'. Counting kicks is a way to monitor baby's health in the third trimester.
- The registered manager told us the service did not provide scans for women under the age of 17 years. Women from 17 to 18 years had to be accompanied by a parent or responsible adult. The registered manager told us this was offer the young woman support during their scan appointment. However, the services website and booking procedure policy stated they did not scan under 16 years.

Staffing

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

- The staff comprised of three sonographers, two of which were registered as radiographers with the Health and Care Professions Council (HCPC). There were no other support staff employed. The registered manager/owner also completed the role of scanning assistant and reception.
- All three sonographers had been employed prior to the registered manager receiving references and disclosure and barring service (DBS) checks specific to the service. However, the registered manager had applied for DBS checks for all staff that were relevant to the service and we saw evidence of certificates. The registered manager had recently contacted the sonographers main place of work and requested from the NHS trust employee references.
- Staff felt the staffing levels worked well. During each clinic there was one sonographer and the registered manager working. The registered manager told us that this was enough staff for the service and they had not been in a position where they had required more.
- The service did not use agency staff. Staff rotas were completed in advance of the clinics and there was regular communication with staff to cover sickness and staff absence. In the event of any short notice sickness sonographers would cover between themselves to help prevent clinic cancellations.
- The registered manager monitored staff sickness rates. There had been no staff sickness absences from July 2019 to September 2019.
- The registered manager was responsible of the reception desk, managing enquiries, appointment bookings, supporting the sonographers during the ultrasound scans if required and helping the families print their scan images. The registered manager told us that she was easily able to manage the different roles.
- Staff told us that there was always two staff working and no staff were ever alone in clinic.

Records

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

- The service obtained health information for women prior to their scan with the pre- assessment questionnaire. For example, number of pregnancies, health conditions and reasons for scan.
- Staff kept records of women's appointments, referrals to NHS services and completed scan documents.
- Records were paper based, and not electronic. All records were handwritten, they were readily accessible to staff and up to date. Records were stored in secure lockable cabinets.
- All electronic data such as appointments was secured with a password which was changed six monthly.

Requires improvement

Diagnostic imaging

- We observed pre-scan questionnaires and signed consent forms. If a referral had been made to an NHS provider, the referral was recorded in the notes and women were given a copy of the written report to take to their local NHS midwifery service or GP.
- Sonographers completed scan reports immediately following the scan. We reviewed ten records and saw that all scan reports had been fully completed. Scan reports included the woman's estimated due date, type of ultrasound scan performed, the findings, conclusions and recommendations.
- The registered manager reviewed and audited women's records and referrals to midwifery services. Sonographers completed peer review record keeping audits on scan reports.

Medicines

- The service did not store or administer any medicines or controlled drugs.

Incidents

- There were no reported serious incidents or never events for the service between September 2018 to May 2019.
- The service had an incident reporting policy which staff could refer to for guidance. However, we found the policy was reviewed five yearly and had not been reviewed since issue in the October 2012. The policy did not consider any recent changes within the service.
- The service used a paper-based reporting system, with an accident and incident log book available for staff to access. The registered manager was responsible for investigating any incidents reported but since the service had started there had been no incidences identified.
- Staff we spoke to understood could give examples of types of incidences and how to report.
- Staff were aware of the term duty of candour and could explain to us the need to be open and honest with women when incidents occurred. Duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. The service had recently developed a duty of candour policy in September 2019. At the time of the inspection one member of staff had signed to say they had read the policy.
- The registered manager told us incidents and lessons learned would be shared with staff in the team meetings. The team meetings had been recently put in place and we saw the minutes of one meeting. The minutes showed us that staff were given an opportunity to discuss incidents and learning.
- The registered manager understood their responsibility to report any notifiable 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 the effectiveness of diagnostic services.

Evidence-based care and treatment

The service did not always provide care and treatment based on national guidance and good practice standards.

- We found policies and protocols were written by an external company and did not have a clinical oversight. This meant the policies did not always relate specifically to the service. For example, the complaints policy mentioned a clinic not related to the service.
- The registered manager told us they reviewed policies yearly. However, we found most policies had a review date of five years and the registered manager was not aware of information not relating to the service were mentioned within certain policies. Policies reviewed five yearly did not take into account changes within national guidance, clinical practice or changes within the service.

Requires improvement

Diagnostic imaging

- The policies written had no clinical oversight and were not always based on good practice standards. However, there were links to national guidance from the British Medical Ultrasound Society (BMUS) on the service's website, consent forms and leaflets.
- `Staff understood national legislation that affected their practice. The service followed national guidance from British Medical Ultrasound Society (BMUS). They did not participate in any benchmarking clinical audits.
- A management of referral policy was recently put in place. Staff complete a form when referring women to maternity NHS services when finding an anomaly or health concern.
- The service had guidance on the website and leaflets available to women in clinic which included guidance on inconclusive scans, sickness in pregnancy and a complete miscarriage.

Nutrition and hydration

- The service did not offer food or hot drinks to women or people accompanying them. They did, however, provide drinking water.
- Women were advised to eat and drink as normal before the scan. If the woman was less than 20 weeks of pregnancy, women were advised to come with a full bladder to help, ensure the best view of their baby.

Pain relief

- Pain relief was not available because abdominal pregnancy ultrasound scans were generally pain free procedures. However, we observed staff checking that women were comfortable during ultrasound scans.

Patient outcomes

Staff did not always monitor the effectiveness of care and treatment to achieve good outcomes for women.

- The registered manager told us they completed monthly audits of sonographers notes and scans. However, this was not clear when reviewing documentation during the inspection.
- The service had introduced monthly team meetings two months prior to our inspection. We saw the minutes of . We observed that staff performance and service user feedback was discussed within the team.
- The service over the last 12 months had scanned 1605 women. There were 715 early pregnancy scans and 890 scans for women over 16 weeks of pregnancy. The registered manager told us women were offered a rescan if the baby was in a difficult position and the sonographer was unable to obtain scan images. The service had rescanned 53 women over the last three months.
- The service had referred 19 women to local NHS maternity services. We observed the reasons for the referral and a clear report of the sonographers scan and advice given.
- Between July 2019 to September 2019 the service had 100% accuracy for gender scans.

Competent staff

The service did not always support staff to be competent within their roles.

- We found that employee records were not up to date and references had not been obtained prior to all three sonographers starting employment with the service. However, the registered manager had been in contact with the sonographer's employer, who had confirmed they were employees and was in the process of receiving references for all sonographers.
- We were told staff had a formal induction on starting employment with the service. However, we saw no documentation to show us staff had an induction or had local training for fire safety, manual handling or equipment.
- The staff did not have any additional training for local service updates.
- The registered manager and lead sonographer were given training on scanning equipment by the equipment engineer. We saw certificates that indicated training had occurred and the lead inspector had gone on to train all staff.

Requires improvement

Diagnostic imaging

- The registered manager and senior sonographer was provided with an update on using the updated scanner by the company engineer and this information was shared with staff.
- All sonographers were qualified and registered to practice with the Health and Care Professions Council (HCPC) as radiographers, where required to be.
- Sonographers peer reviewed each other with The British Medical Ultrasound Society competency chart. The competency chart had standardised levels of competence with six being the level to which standards should be maintained. We saw that the average competency score out of 20 peer reviews was 7.55.Performance was discussed with the sonographer and sonographer completing the peer review.
- The registered manager completed staff supervision. However, we found the discussion noted on the supervision sheets to be minimal and did not take into account the peer review competency scores when discussing performance with staff.

Multidisciplinary working

All those responsible for delivering care worked together as a team to benefit women. They supported each other to provide good care and communicated effectively with other agencies.

- We observed two staff during our inspection. We saw staff working well together and good communication during the clinic.
- There was no routine contact between the service and GP's or maternity services. However, as part of the woman's care, the sonographer would complete a referral form for women to take to NHS services following a detection of a possible irregularity and checked after that this had been done.

Seven-day services

- The service was not an acute service and did not offer an emergency service.
- The service was opened four days a week, providing a clinic on a Thursday and Friday late afternoon/evening and all day on a Saturday and Sunday. The times meant those service users who had commitments such as work, or childcare could attend an appointment.

Health promotion

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

- The service provided clear verbal and written information to women before and during scans that the service was not a substitute for antenatal care provided by the NHS. Women were advised to attend all NHS antenatal appointments.
- The website provided information and links to the British Medical Ultrasound Society. For example, articles about pregnancy and birth, healthy lifestyle and exercise in pregnancy.
- We observed leaflets and posters in clinics which included trusting your instincts, baby movements and ask your midwife. There was also a leaflet informing women to immediately call their maternity unit if they experienced swelling, severe pain, bleeding, persistent headache, high temperature, baby's movements slowing down and problems with vision. This was in line with national recommendations (NHS England, Saving Babies' Lives: A care bundle for reducing stillbirth (February 2016)).

Consent and Mental Capacity Act (Deprivation of Liberty Safeguards only apply to patients receiving care in a hospital or a care home)

- All women received written information to read and sign before their scan. This included information on what is and is not included in the scan package, information on medical records, consent and use of data. The pre-scan questionnaire and declaration form included a self-declaration, stating the woman was receiving appropriate pregnancy care and consent to share information with the NHS if required. We reviewed pre-scan questionnaires and saw they had all been fully completed with clear, signed consent.

Requires improvement

Diagnostic imaging

- The sonographer went through the pre-questionnaire with the woman, confirming names, spellings and dates of birth prior to the scan and obtained verbal consent before the ultrasound scan.
- All staff had a good awareness of gaining informed consent. However, staff told us they had never been in a position where a woman was unable to give consent.
- The service did not have a specific mental capacity act policy. However, there was a consent policy in place which gave guidance on the procedure to follow when clients lacked capacity. We found the mental capacity act was not discussed within the guidance and the policy was reviewed five yearly.
- There was no service specific training on gave information on mental capacity. The register manager had not received mental capacity training. However, sonographers told us they had completed mental capacity training within their other employment.
- Staff understood their responsibilities regarding consent including Gillick competence. The service saw teenagers from the age of 17 years. However, any teenager under the age of 18 years was informed they were to be accompanied by an appropriate adult. Staff told us if they had any concerns about a young person's capacity to consent or concerns in regard to the adult accompanying, they would not proceed with the scan and complete a safeguarding referral if it was appropriate to do so. Gillick competence is concerned with determining a child or young person's capacity to consent to medical treatment without the need for parental permission.

Are diagnostic imaging services caring?

Good

We rated it as **good.**

Compassionate care

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

- Staff cared for women who used the service with compassion. Feedback from women told us that staff treated them with kindness and patience.
- We observed a number of compliments from women who were pleased with the service that they had received. Compliments received were:

  'The manager was so lovely and made me feel so welcome when I arrived. Lovely atmosphere and the sonographer was brilliant. Such a positive experience.'

  'So calm and welcoming. Amazing sonographers who take their time and reassure you while explaining everything that you can see on the screen.'
- Staff put women at ease, they introduced themselves, explained their role and what to expect from the ultrasound scan.
- Ultrasound scans were carried out in a separate room to the waiting room and you could not overhear conversations.

Emotional support

Staff provided emotional support to women, families and carers to minimise their distress.

- Staff spoke with women in a sensitive and calming manner. The environment felt relaxed and comments observed from women using the service told us they felt comfortable and calm throughout their scan.
- Staff provided reassurance and support for anxious women during their first scan appointments. Staff behaved in a relaxed and composed manner, so as not to increase anxiety for women and their partners. We saw a sonographer calm a woman who was nervous about having their first early pregnancy scan. The sonographer reassured the woman throughout the ultrasound scan.
- If a scan identified an irregularity, staff explained the results from the scan, to women and those accompanying them, in a supportive way. The sonographer gave the woman and her family time and explained the next steps to the women. A report was provided and advised the woman to attend midwifery services.

Understanding and involvement of patients and those close to them

Requires improvement

Diagnostic imaging

Staff supported and involved women to make decisions about their care and treatment.

- Staff took time to explain the procedure before and during the scan. We observed the sonographer explain what was happening throughout the scan. The sonographer used appropriate language to clearly explain the position of the unborn baby and the images on the monitor.
- Staff communicated with women and those accompanying them in a way they could understand. We saw that staff use language and terms women could understand when performing the scan. The sonographer took the time to explain the procedure to ensure women understood.
- Women and their partners were fully involved with their care and given the opportunity to ask questions throughout the scan.
- The registered manager monitored service user feedback on their social media page and was keen to follow up on feedback which was not positive in order to gain a good understanding of the woman's experience.

Are diagnostic imaging services responsive?

Good

We rated it as **requires improvement.**

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

- The service was close to Ashford town and there were signs directing service users to the clinic. The clinic was open during early evenings and weekends which meant there was parking available for women using the service.
- The service had put thought into the clinic opening times. The service recognised that women often wanted appointments either in the evenings or at weekends and they accommodated this.
- Appointments could only be booked over the telephone, if the service received an email, the enquirer was contacted to book the appointment.
- All women were asked at the time of booking whether they were accessing NHS antenatal care. We observed staff informing women on the importance of continuing to receive their antenatal care and all women attending for later pregnancy scans were asked to bring their maternity notes with them.
- Staff provided a warm and relaxing environment for women, relaxing music and appropriate lighting for ultrasound scans.
- All scans started with a wellbeing check of baby. The service offered gender confirmation and growth scans as well as 4D images.
- The scanning room had a large wall-mounted screen which projected the scan images from the ultrasound machine. This screen enabled women and their families to view their baby scan more easily and from anywhere in the room. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service (December 2014).

Meeting people's individual needs

The service did not always take into account women with additional needs or make reasonable adjustments to help women with additional needs access the service.

- The service did not meet all women's individual needs. The clinic was on the first floor and not wheelchair accessible. The website however, did highlight that the location did not have disabled access, due to property restrictions.
- The registered manager asked during booking appointments whether clients had any disabilities or additional needs that may affect their ability to have an ultrasound scan, when booking an appointment.
- The registered manager told us that they had never had a service user who had an additional need or disability. The registered manager told us that they would refer a woman requiring additional support to a local baby scanning service who could accommodate a wheelchair.

Requires improvement

Diagnostic imaging

- The service had leaflets and information on 3D and 4D ultrasounds scans on their website. However, the information was not available in accessible formats. The consent form was only available in English. There was no information available in easy to read format or braille.
- The clinic did not have access to an interpreting service for women who did not have English as their first language or who were deaf. The registered manager told us that they had not had any women who were non – English speaking.
- We saw documentation to show us two sonographers had attended equality and diversity training within their other employment. However, there was no evidence of equality or diversity training for the registered manager or the senior sonographer. The service did not have a policy in place around making reasonable adjustments for people with learning disabilities or autism.
- The clinic gave women enough time during scan appointments and feedback we saw from the service users indicated that they did not feel rushed during their scan. We observed four women attending clinic and they were not rushed during or after their appointments.
- The service did not have a quiet area where women and family members could go following difficult or distressing news. However, staff told us they were able to stay in the scanning room for as long as they needed and were supported by the sonographer and registered manager.
- Women's outcomes and experiences were monitored through satisfaction feedback cards. The feedback cards were available for women and those accompanying them. Cards were placed in the waiting area for people to look at them and we saw service user feedback. We observed ten feedback cards dated from June 2019 to September 2019, all provided the service with positive reviews.
- The registered manager collated comments received via the website and social media comments.
- The clinic monitored complaints, to understand why service users were not happy with the service they had received.

Access and flow

People could access services in a way and at a time that suits them.

- The service did not have a waiting list for ultrasound appointments. Women were offered appointments for the same week. The registered manager told us they were flexible with appointments and tried to accommodate appointment requests. However, women could only book an appointment over the telephone.
- Women received information about their chosen scan package. Staff were flexible and allowed women to change their scan package to meet their choice.
- During the time between September 2018 to September 2019 the service had completed 1605 ultrasound scans, 715 were early scans and 890 scans were women over 16 weeks of pregnancy.
- The service have not cancelled any ultrasound appointments between September 2018 to September 2019.
- Women had specific appointment times. During our inspection, we saw women were seen on time and not left waiting to be seen for their ultrasound appointment.

Learning from complaints and concerns

There was a review of complaints and how they were managed and responded to.

- The service had a complaints policy which was written in October 2012 and was due for review in 2019. The policy detailed the process of managing complaints and staff responsibilities in this process. Complaints were acknowledged within 48 hours.
- The website gave information on how service users could provide feedback about the service and they were encouraged to complete patient feedback questionnaires.
- Information on how to make a complaint was displayed in the clinic. Feedback forms were readily available, and staff were actively encouraged to identify any potential dissatisfaction during the appointment.

Diagnostic imaging

- The registered manager investigated any complaints received through the comment's cards, website or social media. We observed a clear process of following up the complaint and actions taken. There was also evidence that the complaint had been discussed with the appropriate member of staff and actions taken.
- The registered manager gave us an example of where practice was changed as a result of a complaint. Following, the complaint we saw a change in process and documentation had been implemented in response to the complaint.
- During September 2018 to December 2019 the service received one complaint which was upheld.

Are diagnostic imaging services well-led?

Requires improvement

We rated it as **requires improvement.**

Leadership

Leaders did not always understand or manage the priorities and issues the service faced. However, they were visible and approachable in the service for clients and staff.

- The registered manager was the owner of Baby Scanning Studio. They had completed 3D and 4D training with a sonographer in 2012 prior to opening the service but had not received any formal updates since this time.
- The registered manager had not completed leadership training and had employed an outside agency to write service policies. We found that not all policies represented the service well and mentioned information which was not in line with current services staffing or procedures.
- The everyday running of the service was overseen by the registered manager as well as the supervision and appraisals of all sonographers. The registered manager had a number of roles within the service. We observed this working well during a busy clinic.
- The registered manager was subject to a pre-employment check through the Disclosure and Barring Service (DBS) and we saw this had been done.
- Staff we spoke with were very positive about the registered manager and their role within the service. Staff felt confident to raise any concerns and told us they were well supported.
- The registered manager told us they kept up to date with the British Medical Ultrasound Society (BMUS) and we saw evidence of links on the service's website.

Vision and strategy

The service needed to have a clear strategy to put the service's vision into action.

- The service had a vision in place for what it wanted to achieve. The registered manager told us the vision was to 'focus on providing and improving a first-class family friendly service and to offer a warm and calm environment with safety being the priority'.
- The service did not have a business plan in place. However, the registered manager told us they had a business model when the service was established. This was 'The service does not provide emergency services and tailors to the needs of the individual woman rather than a community service'.

Culture

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

- All staff we met were warm and welcoming and keen to talk to us about the service.
- The registered manager encouraged a positive culture, that supported and valued staff. Staff were respected and well thought of.
- The staff member we spoke with told us they enjoyed working at the clinic. They felt well supported and part of the team.
- Staff felt the was a 'no blame' culture within the service. The registered manager would speak with staff if a complaint had been made and would contact the complainant as soon as possible to discuss concerns raised.

Requires improvement

Diagnostic imaging

Governance

The service did not have effective governance processes and quality monitoring in place to ensure staff were working to service policies. There was a lack of understanding and oversight around the governance processes.

- We found the service did not have systems or procedures in place to ensure policies were regularly reviewed or referenced the most recent guidelines.
- The service did not have a governance policy. There was no evidence to show regular audits of policies and clinical reviews took place.
- Not all policies were reviewed regularly. We found information relating to other services not associated with the provider referenced within policies.
- Support staff were not employed by the service. However, we found support staff were referenced within policies.
- The service had in place both a booking procedure policy and an acceptance policy. We found there was not consistency with the age in which women could book into the service. The booking procedure policy stated women between 16 to 18 years should be accompanied by a responsible adult. However, within the acceptance policy the minimum age of service users seen was 17 years.
- The registered manager told us policies were reviewed yearly. However, there was no evidence to show this and the registered manager was not aware of the information not related to the service was within policies.
- Links to local safeguarding teams was out of date in the safeguarding policy.
- The staff files had out of date training and information within them, which made accessing the most up to date information difficult.
- Staff had not received appropriate employment or disclosure and barring services (DBS) checks prior to starting with the service. The registered manager told us that they did not see this as a concern as all three sonographers were working within the NHS trust.
- Monthly staff meetings were new to the service and at the time of our inspection the service had, only had two staff meetings. There were the minutes of one staff meeting available which was reviewed during the inspection. The meeting minutes showed staff meetings were attended by all members of the team. However, team meeting minutes were brief and there was minimal discussion around risks and service delivery.
- The service had indemnity insurance which covered the service and all staff working there.

Managing risks, issues and performance

The service did not have clear systems in place to identify and escalate relevant risks and issues and the service did not always identify actions to reduce their impact.

- The service had risk assessments in place which were risk rated high, medium and low. However, we found the risk assessments did not clearly describe what the risk was, or who was at risk.
- The risk assessments we saw did not detail what further action was in place to reduce the risks within the service and there was not a clear review date for each risk.
- The registered manager told us they reviewed risks regularly and we saw risk assessments were ticked and signed by the registered manager. However, it was not clear how the risks had been reviewed and a number of assessments had been documented in pencil rather than ink.
- There was no clear audit of risk assessments. Staff told us they would inform the registered manager if they identified a risk. However, staff were not aware of what the current risks related to the service were or where to access the information.
- Staff did not have a good understanding of current policies and protocols used within the service. There was not a clear checklist to confirm staff had read current and updated policies during the inspection. However, for the recent Duty of Candour policy it was noted that one out of the three sonographers had read the new policy.

Managing information

The service collected data and client records were secure and accessible.

- All scan reports were paper records. They were easily accessible and were kept in a locked filing cabinet. We

saw staff lock the computer terminal when not in use and electronic systems were password protected. This prevented unauthorised people from accessing personal information of women attending the service.
- Women consented for the service to store their records. This was part of their signed agreement within the form detailing the ultrasound process. This demonstrated the service's compliance with the General Data Protection Regulation (GDPR) 2018.
- The terms and conditions of the service were written on the consent form and was displayed on the Baby Scan Studio Ashford website. The consent form was also available for women to download from the website.

Engagement

The service engaged with women and staff to develop the service.

- The service had comment cards for service user feedback and women and their families were asked to complete. Women were also able to leave reviews of the service on the website and social media pages.
- We observed the registered manager engage positively with service users and staff. Staff we spoke to told us the registered manager was supportive and we observed good working relationships between the manager and staff.
- The website provided health and pregnancy information as well as information about pregnancy ultrasound scans and links to the British Medical Ultrasound Society.

Learning, continuous improvement and innovation

The service improved services by learning from when things went well or wrong.

- The clinic used customer feedback to improve the service. The registered manager reviewed complaints and we saw evidence of how change was made due to customer feedback.
- Sonographers completed training within their other employment, but we did not see evidence of continued development taking place within the service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must have in place a governance framework, to have oversight and to ensure policies are relevant to the service, reviewed regularly and reference up to date guidance.
- The provider must ensure they assess, record and review risks to service users and others regularly.
- The provider must ensure staff complete mandatory training relevant to their service, including environment, equipment and fire safety training.
- The provider must ensure they complete pre-employment checks for all staff.

Action the provider SHOULD take to improve

- The provider should consider having a policy on the Mental Capacity Act, 2005 and offer mental capacity training for staff.
- The provider should have access to an interpreter service to assist those people whose first language is not English or those who have hearing difficulties.
- The provider should consider offering equality and diversity training to staff.
- The provider should consider having an equality and diversity policy in place.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance 1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. (2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to— (a) assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services); (b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity; (d) maintain securely such other records as are necessary to be kept in relation to-- (i) persons employed in the carrying on of the regulated activity, and (ii) the management of the regulated activity

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing (2) Persons employed by the service provider in the provision of a regulated activity must--

This section is primarily information for the provider

Requirement notices

Regulated activity	Regulation
	(a) receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform.
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed (1) Persons employed for the purposes of carrying on a regulated activity must-- (a) be of good character, (b) have the qualifications, competence, skills and experience which are necessary for the work to be performed by them, and (c) be able by reason of their health, after reasonable adjustments are made, of properly performing tasks which are intrinsic to the work for which they are employed. (2) Recruitment procedures must be established and operated effectively to ensure that persons employed meet the conditions in-- (a) paragraph (1)