The Baby Skan Studio

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?	
Are services caring?	**Good**
Are services responsive?	**Good**
Are services well-led?	**Requires improvement**

Overall summary

The Baby Skan Studio is operated by Miss Kelly Ann Barritt who is also the registered provider. The service opened in 2007 and was registered for the regulated activity of diagnostic and screening procedures in September 2015. Facilities include a waiting room, scanning room, toilet and staff kitchen. The Baby Skan Studio provides obstetric ultrasound services for pregnant women from 18 years of age. Abdominal ultrasound scans are offered from seven weeks gestation to full term of pregnancy. This service is provided to self-funding women across Cornwall.

The service provided single specialty diagnostic imaging. We inspected this service using our comprehensive inspection methodology. This was our first inspection since the service opened. We carried out a short notice announced inspection on 26 and 27 September 2019 with further patient engagement on 30 September and staff engagement on 1 October 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

Summary of findings

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 was the first time we rated this service. We rated it as **Requires improvement** overall.

- The service did not operate safe recruitment practices. References for staff had not been obtained.
- There were gaps in management and support arrangements for staff, such as appraisal and supervision. Appraisals were not conducted and there was no evidence of completion of an induction or probationary period.
- A limited level of health promotion was considered or shared with patients using the service. Instead patients would receive their health promotion via the NHS maternity pathways and care.
- The safeguarding lead had not received adult and children safeguarding training to level three and the provider had not received adult and children safeguarding training to level two.
- Patients were able to give feedback and raise concerns about care received but the complaints policy was not clear about how complaints would be managed.
- The service did not control infection risk well. Premises were not always visibly clean.
- The design, maintenance and use of facilities and premises kept people safe but clinical waste and equipment were not managed well.
- Staff telephoned the NHS hospital to make referrals and gave scan pictures to women to give to the hospital, but we saw no evidence of a standardised referral form or scan report to accompany referrals.
- There was no formal incident reporting system or process for sharing learning.

However, we also found the following areas of good practice:

- A high level of care was provided within the service. Staff cared for patients and their families with compassion, kindness, dignity and respect. People were truly respected and valued as individuals.
- Staff provided emotional support to patients and those close to them to minimise their distress. Emotional and social needs were highly valued by staff and embedded in care and treatment.
- Staff involved patients and their families in decisions about their care and treatment. Their individual preferences and needs were reflected in the care delivered.
- The service was responsive to the needs of patients and their families and was tailored to pregnant women. Patients were able to access an appointment when they needed it.
- Staff worked well together to provide a caring service in a relaxed environment.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notices Details are at the end of the report.

Nigel Acheson

Deputy Chief Inspector of Hospitals (South West)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	**Requires improvement** 	This is a diagnostic imaging service run by Kelly Ann Barritt under the service name of The Baby Skan Studio. The service is based in Truro, Cornwall. We rated the service as requires improvement because well-led and safe was requires improvement, however caring and responsive were good. We do not rate effective for this type of service.

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Background to The Baby Skan Studio

The Baby Skan Studio is operated by Miss Kelly Ann Barritt who is also the registered provider and who we will refer to within the report. The service opened in 2007 and was registered with the Care Quality Commission (CQC) in September 2015. It is an independent healthcare service in Truro, Cornwall. The service primarily serves the communities of Cornwall. It also accepts patient referrals from outside this area.

It has been the same provider since the service opened and was registered with the CQC in September 2015.

The service is registered to provide the regulated activities of diagnostic and screening procedures at the location for young adults. We have not inspected this service before.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Amanda Williams, Head of Hospital Inspection in the South West.

Information about The Baby Skan Studio

The Baby Skan Studio is a small service, running clinics three or four days a week at varying times of day but mostly in the afternoons, evenings and Saturdays.

The clinic offers the following scans:

- Early pregnancy scans – trans abdominal scans from 7 weeks
- Bonding scans – from 12-25 weeks, 2D picture with a DVD
- Gender scans – from 16 weeks
- Wellbeing scans – from 14-38 weeks, 2D or 3D pictures, assessing position of baby, placenta position and estimated fetal weight
- 4D scans – from 24-30 weeks, with a DVD

The service also offers the non-invasive prenatal testing (NIPT) screening test run by a Midwife Sonographer, according to patient demand.

The service does not offer any internal scans or detailed anatomy scans.

All women accessing the service self-refer to the clinic and are private (self-funding) patients.

Facilities include a reception with a waiting area and toilet. The waiting room leads onto a scan room containing one ultrasound machine and a staff kitchen also providing some lockable storage.

In total there are two self-employed sonographers, a Midwife-Sonographer who runs the NIPT service and the service manager (the provider and owner). The Midwife-Sonographer was also able to run some scanning clinics if needed by the rota, for example in the case of sonographer sickness.

During the inspection we visited the clinic and we spoke with all four staff including the provider and sonographers. We spoke with five service users, two partners and three relatives. We also reviewed 10 sets of records, and relevant policies and documents.

We reviewed data submitted as part of the Provider Information Request, which covered the last 12 months between August 2018 and August 2019. We also reviewed additional data submitted by 4 October 2019, which dated between September 2018 and September 2019.

Summary of this inspection

There were no special reviews or investigations ongoing by the CQC at any time during the 12 months before this inspection. This was the services first inspection since registration with CQC.

Activity for 26 September 2018 to 26 September 2019:

- Total number of scans performed at the Baby Skan Studio was 1,502
- Total number of early viability scans (from 7 weeks gestation to 12 weeks) performed was 364 scans
- Total number of wellbeing, gender, family bonding and 4D scans (12 weeks - 40 weeks gestation) performed was 1,138 scans
- The total weekly clinic volume equated to an average of 29 scans
- There were 34 referrals made, which were documented and retained on file
- 12 NIPT screening tests were performed

Track record on safety between 26 September 2018 and 26 September 2019:

- No never events
- No clinical incidents
- No serious injuries
- No incidences of hospital acquired infection
- One complaint

Services provided under service level agreement:

- Cleaning by a cleaning service on a weekly basis
- Window cleaning monthly
- Maintenance of scanning equipment by a maintenance service
- Clinical waste removal as required

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 safe as **Requires improvement** because:

- Mandatory training was not provided by the service, and sonographer compliance with NHS mandatory training was not systematically reviewed by the provider.
- Staff did not always understand how to recognise, report and protect patients from abuse. The safeguarding lead and provider had not completed the relevant level of training required to demonstrate safeguarding competency.
- The service did not control infection risk well. Premises were not always visibly clean.
- The service did not have a comprehensive infection control policy and we saw poor practice which could affect patient safety.
- The design, maintenance and use of facilities and premises kept people safe but clinical waste and equipment was not managed well.
- Consumable equipment was stored correctly but had expired.
- There was a lack of systems to support maintenance of equipment. Electrical safety testing had expired in March 2019. We received evidence to demonstrate this was completed on 30 September 2019 immediately after our inspection.
- Staff responded to patient risks but did not complete formal risk assessments.
- The potential risks of frequent ultrasound scanning were not explained to all patients, although risks were minimised.
- There was an informal process for responding to medical emergencies and behaviour that challenges.
- Staff telephoned the NHS hospital to make referrals and gave scan pictures to women to give to the hospital, but we saw no evidence of a standardised referral form or scan report to accompany referrals.
- Information provided for patients on miscarriage and early pregnancy was out of date.
- The service had enough staff to keep patients safe from avoidable harm and to provide the right care and treatment.
- The service maintained minimal patient records and did not regularly communicate with other health agencies.
- There was no system of recording safeguarding concerns or identifying returning patients who presented a concern to staff.
- There was no formal incident reporting system or process of sharing learning.

Summary of this inspection

However, we also found the following areas of good practice:

- Records confirmed all sonographers were up-to-date with their NHS training, although training records were not checked on a regular basis.
- Staff reduced the risk of heat associated with ultrasound scans by recording and replaying short videos of the patient's baby to minimise the scan time.
- The service had enough staff to keep patients safe from avoidable harm and to provide the right care and treatment.

Are services effective?

We do not rate effective for this core service.

- The service had no clinical policies. Staff employed were also working within the NHS as sonographers.
- There was no recorded local induction or lone working policy or risk assessment.
- There were gaps in management and support arrangements for staff, such as appraisal and supervision.
- Appraisals were not conducted and there was no evidence of completion of an induction or probationary period.
- A limited level of health promotion was considered or shared with women using the service.

However:

- Cold water and a small selection of snacks were available which could be provided to women if they felt unwell.
- Pain was not formally monitored, as this was not required for the service provision. However, staff took steps to ensure women were comfortable during their scans.
- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.
- All those responsible for delivering care worked together as a team to benefit patients. They supported each other to provide good care but did not work collaboratively with other services.
- The services were provided at times which were more suited to the service users.
- Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Are services caring?

Good

We rated caring as **Good** because:

Summary of this inspection

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff respected and considered the individual needs of patients and their families.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal needs.
- Staff considered the emotional needs of patients and their families.
- Staff supported and involved patients, families and carers to understand their treatment and scan results. Their individual preferences and needs were reflected in the care delivered.
- There was sensitivity when performing early viability scans.
- Staff responded sensitively when concerns were detected on a scan.

Are services responsive?

Good

We rated responsive as **Good** because:

- The service was mostly planned and provided in a way that met the needs of patients' and their families who would use the service.
- The service had flexibility to meet the needs of service users.
- There was a range of adaptable packages available to patients and their relatives.
- The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.
- Patients were at the clinic for only a short time, but staff treated each patient as an individual.
- There was some support available for patients or their relatives who were vulnerable.
- People could access the service when they needed it and received the right care promptly.
- Staff demonstrated awareness of the comfort levels of their patients.
- Patients undergoing the non-invasive prenatal testing (NIPT) screening had minimal time to wait for their results.

However, we also found the following issues that the service provider needs to improve:

- People were able to give feedback and raise concerns about care received but the complaints policy was not clear about how complaints would be managed.

Summary of this inspection

Are services well-led?

Requires improvement 

We rated well-led as **Requires improvement** because:

- Leaders were not always aware of the risks, issues and challenges in the service. Leaders were not always clear about their roles and their accountability for quality, although they were visible and approachable in the service for patients and staff.
- There were a number of key policies which were not available to direct and guide staff to practice. Those available policies lacked a date, an author, review date or version control.
- There was no documented vision or strategy for the service although all staff spoke of wanting to provide a good caring service.
- There was a lack of awareness of duty of candour although staff reported they apologised to patients who were dissatisfied with their care or scan images.
- Staff development was not given enough priority. Appraisals were not completed and there was no formal review of personnel records.
- The culture did not support incidents being reported and there was no formal process of sharing learning.
- Governance systems did not ensure that recruitment and staff management practices were completely safe.
- There were limited governance processes within the service. There were no automatic reminder notifications to prevent out of date equipment or electrical testing.
- There was a lack of awareness of managing risks, issues and performance. There was no evidence of staff compliance or awareness of policies and infection control risks were not prioritised.
- There was no system to monitor, manage or mitigate risks.
- Infection control risks were not prioritised.
- There was no policy for managing health and safety risks. These risks included legionella.
- There was no business continuity plan or awareness of the need for a plan in the event of an emergency.
- Staff had access to the service's available policies and processes however the service did not have an information management policy.
- There was a limited approach to sharing information with and obtaining the views of staff.
- There was no evidence of learning from the written complaint received within the last year, or any documentation of verbal complaints and associated learning.
- There was limited interaction with external health agencies. There were no shared systems, patient alerts or processes.

Summary of this inspection

- There was no formal system for identifying learning and no evidence of the service responding to external feedback.

However

- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.
- The service recorded and analysed information to understand performance. The provider could see how many scans had been performed and how many patients had been referred to maternity services for ongoing care.
- Patients had access to a clear pricing structure on the website and it was displayed within the waiting room.
- Patients signed a copy of the terms and conditions before the scan.
- The provider encouraged innovation.
- All staff were committed to offering the best available scan images.

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	N/A	Good	Good	Requires improvement	Requires improvement
Overall	Requires improvement	N/A	Good	Good	Requires improvement	Requires improvement

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Requires improvement

We had not previously rated safe. We rated safe as **requires improvement.**

Mandatory training

Mandatory training was not provided by the service, and sonographer compliance with NHS mandatory training was not systematically reviewed by the provider.

Sonographers completed mandatory training updates with their main employer, the NHS. Training evidence was held in a folder by the provider and was reviewed at unplanned intervals. At the time of the inspection all sonographers were up-to-date with their NHS training. This included infection prevention and control and basic life support, although not all staff had undertaken adult basic life support training despite the patient group being adults. The provider who also worked as the receptionist had completed level 1 Health and Safety in the workplace training in August 2019 but had not completed first aid or basic life support training. At the time of our inspection there was no plan to complete this training. This meant that patients could be seen by staff who were not compliant in basic life support.

Training tailored for the NHS environment was not personalised for the Baby Skan Studio environment. There was no evidence of in-house induction; a standardised list of required training for each role, competency assessments or measurement of staff awareness of policies and procedures. There was a risk staff would be unaware of how to manage certain situations and would have varying levels of competency.

Safeguarding

Staff did not always understand how to recognise, protect and report patients from abuse.

Staff did not receive specific training on how to recognise and report abuse when working at the Baby Skan Studio. All sonographers had completed NHS safeguarding training for adults and children to level two with some having completed safeguarding children to level three as a requirement of their NHS role. The safeguarding lead was assigned the role of reviewing staff concerns to decide whether a referral should be made to the patient's midwife or to social workers. Staff told us they would contact the safeguarding lead even when they were not working. The lead had not completed safeguarding level three training for adults or children. There was potential for safeguarding concerns to be overlooked as the lead was not trained to safeguarding level three. At the time of the inspection no safeguarding concerns had been identified in the 12 years that the service had been operational. The provider was trained to safeguarding children level one but should be trained to adult and children safeguarding level two as they had regular interaction with patients and their families.

A safeguarding policy was stored in the staff kitchen and was reviewed during our inspection. The policy was very limited and focused on the potential for allegations of abuse against a care provider but not the potential for a patient to be experiencing abuse. Contact numbers of the local safeguarding MARU (multi agency referral unit) were available but staff said that they would usually refer their

concerns to the safeguarding lead. There was no flow chart or tool for staff to assess their concerns against to ensure a standardised approach to managing safeguarding concerns. This was highlighted with the provider during the inspection.

The safeguarding policy did not contain the telephone numbers for the community midwives. Evidence of a safeguarding flow chart was provided shortly after the inspection, but it did not contain important telephone numbers for the Midwife or local safeguarding teams. Patients attending for a scan had not always been booked by a midwife and would not have maternity notes or a named midwife. This was especially true for patients attending for an early viability scan. Patients were not required to bring their maternity notes to their scan. This meant that staff were unaware of the contact numbers for the named community midwife or the patient's GP details. There was potential for delays in safeguarding referrals or difficulty contacting healthcare professionals to share safeguarding concerns.

The service provided scans for patients over the age of 18, however there was no system to confirm a patient's age when booking or attending a scan. Staff were unaware of the potential for child sexual exploitation or domestic abuse and their role in assessing vulnerable patients. Staff explained they would discuss any concerns with the safeguarding lead who would decide if a safeguarding referral was needed.

Cleanliness, infection control and hygiene

The service did not control infection risk well. Premises were not always visibly clean.

At the time of the inspection we saw staff cleaning the couch and scan probe between each patient use. Hand gel was used between patients. We could not be assured there was good infection control awareness or practice as premises were not always visibly clean.

There was no handwashing sink in the scan room, although staff had access to a sink in the kitchen and a small sink in the toilet which required staff to walk through the waiting room. The kitchen sink only provided cold water which is unsuitable for effective hand washing. The water heater in the toilet had been turned off during the inspection so the water was also cold. Hand gel was available within the scan room and within the waiting room for patients to use. Cleaning products were safely stored under the sink in the kitchen which had a keypad lock on the door.

The service did not have a comprehensive or appropriate infection control policy and we saw poor practice which could affect patient safety.

The policy in place was very short and comprised of basic instructions but did not specify how to clean areas or items or the products to be used. The policy stated, 'end of clinic damp dust visitors' chairs, door handles, bed frame'. We saw visible dirt on and dust underneath the couch and on the bottom of the scan machine. All but two of the twelve visitors' chairs were made of fabric which was not wipe clean. Two of the chairs had ripped fabric which exposed the seat filling. The policy was not reflective of these chairs, although the provider advised there were plans for them to be recovered with a wipe clean material. There was no evidence of onsite infection control training or staff awareness of the policy.

We saw evidence of a weekly clean by an external company but no cleanliness or hand hygiene audits. Gloves were available to reduce the risk of exposure to blood borne viruses (BBV's) however there was no clinical waste. Staff disposed of clinical waste within sharps boxes which had not been set up correctly. There was no date or signature to indicate when sharps boxes were first used. There was a lack of awareness of safe sharps management and the infection control risk posed by sharps boxes remaining in use after three months. Following the inspection, we received evidence of arrangement for the collection of the sharps boxes. The provider notified the CQC of their intention to stop offering the non-invasive prenatal testing (NIPT) screening and removed it from the Baby Skan Studio website. These were blood samples which were taken by the Midwife-Sonographer to screen for a patient's likelihood of having a baby with a chromosomal abnormality. The abnormalities screened for were Edwards Syndrome, Down's Syndrome and Patau's syndrome. Sharps boxes and clinical waste were not required for the keepsake scans so would no longer be needed.

Environment and equipment

Requires improvement

Diagnostic imaging

The design, maintenance and use of facilities and premises kept people safe but clinical waste and equipment was not managed well.

The service had suitable facilities to meet the needs of patients and their families. There were seating areas for patients to wait which provided privacy as patients were able to avoid being visible to people walking by the street window. A toilet with baby changing facilities was available for patients, visitors and staff to use. The scan room provided access to an alternative exit and a kitchen. The scan room's five chairs allowed space for the patient, their belongings and up to three visitors while a large television was available for patient and visitor viewing of the scan. The scan room had a couch which was suitable for bariatric patients and the website explained that patients with a body mass index (BMI) of over 30 would have an increased likelihood of poor views. A body mass index is a calculation of a person's weight in relation to their height.

A first aid kit was available within the waiting area next to the reception desk. Water was available in the event of a patient feeling faint.

The service had a smoke detection alarm in the waiting room and fire exit doors were kept clear of obstructions. There was no smoke detector alarm in the kitchen or scan room. We saw evidence of a facilities and environment risk assessment which was due to be completed annually but hadn't been completed since January 2018. The risk assessment commented that floors were even however there was a steep slope by the front door. This did not assure us that the environment and equipment was being checked for safety regularly or thoroughly.

Staff informed us that they would all attend for scan equipment training. This had been held recently with the introduction of a new scan machine, although there was no documented evidence of this. The scan machine servicing was in date, with the next service due in November 2019.

Staff used sample packaging which adhered to the Royal Mail's P650 Packaging instruction for diagnostic specimens. This meant that non-invasive prenatal testing (NIPT) samples were sent securely to the laboratory in London. None of the 17 samples taken since 2 June 2018 had been misplaced or damaged in transport. All 17 NIPT samples had been sent for processing correctly.

Consumable equipment was stored correctly but had expired. Gloves were available for staff to use when taking blood samples and patient contact. The gloves and clinical wipes had all expired in January 2019 and February 2018 but were still in use. Aprons and eye protection were not available. There was no handwashing sink within the scan room which acted as a treatment room. The scan chair was made of fabric which was not wipeable and could pose an infection control risk. Patients are particularly susceptible to infection during pregnancy. A fabric tourniquet used to compress the arm when taking blood was stored with the NIPT equipment. Fabric tourniquets are not recommended for use in clinical areas due to the infection control risk as the fabric was not wipeable or single use and blood or bacteria could remain on the tourniquet and be transferred to other patients. Staff were unaware that sample bottles for the NIPT test had expired in January 2019. The laboratory online guidance states that samples could be rejected if the sample was sent in an expired bottle as the preservative within the bottle could become less effective and compromise the sample findings, leading to the need for a repeat sample.

There was a lack of systems to support maintenance of equipment. Electrical safety testing had expired in March 2019. We raised this at the time of our inspection. The provider was aware that the portable appliance testing (PAT) was out of date and had booked for it to be completed in immediately after the inspection. We saw evidence that it was completed on 30 September 2019.

Assessing and responding to patient risk

Staff responded to patient risks but did not complete formal risk assessments.

Staff were mostly unaware of individual patient risks when patients attended the service. Limited pregnancy or health history was discussed when scan appointments were booked. Some patients telephoned the service, but most were booked using social media messaging. Patients booking for early viability scans were advised to wait three weeks from their missed period to minimise the risk of patients attending who were under seven

weeks pregnant and therefore required referral to the NHS early pregnancy clinic for an internal scan. However, at the time of the inspection there was no documented assessment of pregnancy history or patient health risks, for example, mental health concerns or previous ectopic or recurrent miscarriages. Staff reacted to patient queries when they arrived for their appointments but did not routinely review maternity notes to manage clinical, emotional or social risks positively. One of the five patients we spoke to were advised to bring their maternity notes. If patients disclosed their pregnancy history when booking their appointment this was handed over to the sonographer prior to the scan.

A contract signed by the patient on arrival for their scan identified possible concerns and the limitations of the service. The service provided was clearly explained in the contract and patients were advised that the ultrasound being offered was not a diagnostic scan or substitute for NHS care and it would be the responsibility of the patient to 'raise any issues with their midwife'. Despite this containing information to contact their midwife immediately if pain or bleeding was experienced only one of the five patients spoken with commented that they were advised to contact the NHS if they had concerns. During the inspection staff were not heard to reinforce to patients the need to attend the NHS scans. No Public Health England pregnancy information leaflets were provided by the service.

The potential risks of frequent ultrasound scanning were not explained to all patients, although risks were reduced during each scan. Information was available on the website but was not included in the terms and conditions consent form meaning not all patients would have been aware of the potential risks. Staff reduced the risk of heat associated with ultrasound scans by recording and replaying short videos of the patient's baby to minimise the scan time, although the many patients returned for additional scans. Audible heartbeats were not recorded in the first 16 weeks of pregnancy to further reduce the risk to the fetus.

There was an informal process for responding to medical emergencies and behaviour that challenges. Sonographers rang a bell to call for support from reception when risks were identified however reception did not have a method of requesting support from the sonographer. Staff explained the call bell was a useful system to provide support to patients and their families when bad news was given.

Staff telephoned the NHS hospital to make referrals and gave scan pictures to women to give to the hospital, but we saw no evidence of a standardised referral form or scan report to accompany referrals.

Referrals were recorded in a notepad which was stored at reception and patients requiring the early pregnancy clinic or maternity assessment unit usually left the clinic with an NHS appointment arranged. However, patients requiring a fetal medicine referral were not always given an appointment immediately and there was no documented system or process to ensure that a referral to fetal medicine had been made. The fetal medicine department was open 9am-5pm Monday to Friday so most of the scans were completed when fetal medicine were closed. Staff were not able to provide a telephone handover during the Baby Skan working hours. Staff explained that patient details were remembered by the sonographer and a referral was made when the staff were next working in the NHS hospital. There was a risk that staff would incorrectly convey the details, or the referral would not be made.

Information provided for patients on miscarriage and early pregnancy was out of date. Staff were aware of the NHS support that would be provided and explained this to patients but the written miscarriage, unclear scan and early pregnancy assessment unit information available was out of date since July 2016.There was a risk that the clinical advice could have changed, and the information provided could provide patients with incorrect advice.

Staffing

The service had enough staff to keep patients safe from avoidable harm and to provide the right care and treatment. There were concerns surrounding the compliance and monitoring of training. Please see the mandatory training section above.

The service was fully staffed with no staffing vacancies. The reception was covered by the provider and two sonographers covered the clinics with a third midwife-sonographer providing sickness cover and

running the NIPT screening service. The clinic did not have a full-time sonographer, but this was not necessary as the evening clinics met the demand of the service. There was no need for bank or agency use. All sonographers were registered with the healthcare professional's council or with the nursing and midwifery council. However, we reviewed the personnel files and the provider did not have a record of all the pin numbers for the three sonographer's registrations. Only two pins were recorded.

The provider was based at the premises to take bookings and complete management tasks. When the clinic was open only one sonographer and the provider were working. There were no formal processes for the handover of information. Staff advised they communicated about clients within the clinic, and about updates and changes on social media and socially outside of work. However, there was not a formal process for seeking advice for safeguarding concerns with the safeguarding lead when they were not at work.

Records

The service maintained minimal patient records and did not regularly communicate with other health agencies. The service was focused on providing keepsake scan images for patients and their families. Scan reports were not provided following a scan although images were printed for the NHS sonographers to view the scan findings. The scan machine was password protected. Patient names were recorded on the scan machine along with the last menstrual period to calculate the expected number of weeks pregnant prior to performing the scan. Previous pregnancy history was not requested or retained by the service and was not recorded in the referral book. The referral book detailed the sonographer's name, patient name, date scanned and appointment date with the relevant NHS department but did not include the patient telephone contact details, address or date of birth. There was inconsistent recording of the reason for referral or who had documented the referral details. One of the last 10 referral entries did not detail the reason for referral and most entries were written in pencil which had potential to be amended. There was no evidence of records being audited for details including the reason for referrals, confirmation that referrals were accepted or a name of the accepting NHS staff member. There was no communication with the patient or NHS hospital following a referral. This meant that potential areas for learning and service development could be missed.

Staff were unaware of patient allergy statuses. This risk was mostly mitigated by gloves being non-latex although plasters were still available following blood tests.

Gender scan images were stored on the scan machine until they were manually removed after the patient's due date. The images were stored in case of discrepancy with the gender at a later stage in the pregnancy. This allowed a means of quality assurance if concerns or discrepancies were detected, although these were not routinely reviewed.

There was no system of recording safeguarding concerns or identifying returning patients who presented a concern to staff.

The provider advised they had not made any safeguarding referrals during the twelve years the service had been open. There was no system for recording safeguarding concerns or behaviours that challenge. This meant that staff would be unaware of previous concerns for patients who returned to the service or be able to record an alert for the patient on the booking system.

There was no communication with GP's. Patients were referred to the NHS hospital via telephone without a set proforma or expectation of the details to be communicated to the maternity services. The provider spoke of advising a client to contact their GP when they were discovered to not be pregnant but did not liaise verbally or in writing with their GP or maternity services. In this case there was a lack of awareness of the potential for phantom pregnancies. A phantom pregnancy is a mental health and potential safeguarding concern whereby someone believes they are pregnant and display the symptoms of pregnancy but no fetus is present.

Medicines

The service did not store or administer any medicines.

Incidents

There was no formal incident reporting system or process of sharing learning. The service did not maintain an incident book or risk register. There had

been no incidents reported in the twelve months prior to the inspection and the provider could not recall any incidents. There was no evidence of sharing learning from incidents, or how this learning would be recorded. There were no team meetings for the staff, although the provider advised that she had regular discussions with her staff. Sonographers commented that the provider was willing to listen to and act on suggestions and feedback.

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. No duty of candour notifications were required to be made in the last 12 months prior to our inspection date. However, the provider was unfamiliar with the application of the duty of candour. There was a risk that incidents were not recognised and under-reported as there was not a policy surrounding incident management.

Staff advised that all NIPT samples were processed correctly and there had not been incidents with the NIPT, however the out of date sample bottles could have been rejected by the laboratory and repeat screening could have been required.

Are diagnostic imaging services effective?

We do not rate effective for this core service.

Evidence-based care and treatment

The service had no clinical policies. Staff employed were also working within the NHS as sonographers. Sonographers explained how their main employment was pregnancy scanning at the NHS hospital. The sonographers were experienced in breaking bad news as this was part of their NHS employment. As such there were few formal processes for monitoring the competency of the sonographers, other than the provider checking that the patient and their family were happy with the scan images following the scan.

The sonographers were aware of as low as reasonably achievable (ALARA) principles, although these were not advertised within the clinic and staff commented that they had many returning customers. The ALARA is a principle of radioprotection to ensure the radiation received by people is as low as possible. These guidelines were not referenced in the consent paperwork signed prior to the scan although there was some brief information available on the website, but it was not guaranteed that patients would read this. There was no process for monitoring or auditing the number of returning patients, meaning some patients were exposed to a greater level of ultrasound risk which was not in line with ALARA principles. If presenting early in pregnancy the likelihood of poor image quality increased, potentially resulting in a further scan within the NHS. British Medical Ultrasound Society (BMUS) guidance advises that ultrasound scans should be avoided within the first eight weeks of pregnancy due to the thermal hazard risk. The service was offering scans from seven weeks.

The provider had piloted a cloud-based image storage system designed to store images and videos electronically. The pilot included 40 patients and feedback was positive amongst most patients, although the provider advised that it would still be possible to print the scan images. This storage system was due to be introduced formally but was not available at the time of our inspection. The provider hoped to use this system to share images when referring a patient to the NHS maternity and GP services.

Nutrition and hydration

Cold water and a small selection of snacks were available which could be provided to women if they felt unwell. However, the scanning process took a short amount of time and patients and their families did not usually need refreshments. Hot drinks were not available.

Pain relief

Pain was not formally monitored, as this was not required for the service provision. However, staff took steps to ensure women were comfortable during their scans. Patients were given a head support to rest on and staff adjusted the couch if a woman was experiencing back pain or discomfort. Staff explained to patients when they may feel some discomfort and maintained clear communication with them throughout

the procedure. Staff were keen to ensure that appointments kept to time so that patients did not experience the discomfort of a full bladder for longer than necessary.

Patient outcomes

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

The number of scans completed, and the number of referrals were recorded alongside the sonographer's name within the referral audit table. The provider explained they would monitor the number of referrals each month and discuss with the sonographer if there was a significant change in the numbers.

The provider monitored the quality of service by asking patients and their families if they were happy with their scan images. If the patient was unhappy with the clarity of images the provider would rebook a complimentary scan for a later date. However, there was no process to professionally review the quality of the ultrasound images.

If the patient was too early for an abdominal scan they were referred to the NHS early pregnancy assessment clinic. If a gender was found to differ from an original gender diagnosis the sonographer would refer to the original saved gender scans to identify learning.

All referrals to the NHS were recorded in a referral notebook, but the reason for a referral was not always recorded. There was no arrangement for communication from the NHS on the outcome of the referral, due to patient confidentiality and data protection regulations.

There had not been any concerning non-invasive prenatal testing (NIPT) screening results, but staff had visited the laboratory during their training and were confident with the online tracking system. Staff undertaking NIPTs felt able to refer to the NHS maternity services as they worked closely with the fetal medicine team within their NHS employment.

Competent staff

There was no recorded local induction or lone working policy or risk assessment. Staff recalled sonographers observing several clinics in their induction, however there was no documented evidence of a staff member's completion of induction or competency assessments.

NIPTs were completed by a staff member who worked alone at irregular times based on patient demand. The provider was unaware of the purpose of a lone working policy. Following the inspection, the provider advised that the NIPT had stopped being offered by the Baby Skan Studio. There was also a risk if one of the staff members became unwell during a clinic as the remaining staff member would be lone working and there was not a policy for this.

There were gaps in management and support arrangements for staff, such as appraisal and supervision.

We reviewed staff personnel files and saw evidence of staff NHS training, Disclosure and Barring Service (DBS) checks, photo identification and employment history. However, there was no evidence of recruitment, interview and selection processes, references from previous employment, or employment contract. We asked the provider for a copy of the job descriptions. The job vacancy advert was supplied instead of a job description. The impact is that staff were not fully aware of the expectations of their role and their full contribution to the service. There was no means to formally assess staff competency or performance against the role expectations.

The job vacancy advert stated a requirement that staff were registered with the Health and Care Professions Council (HCPC). One of the three sonographers was registered with the HCPC, the other two were registered with the Nursing and Midwifery Council (NMC). There was not always clear evidence of completion of sonographer training and the personnel files did not contain all the sonographer's registration pins. This meant there was potential for a sonographer's registration to lapse and without regular monitoring or appraisal the provider may not be aware.

Appraisals were not conducted and there was no evidence of completion of an induction or probationary period. The provider did not provide a competency assessment document for staff to complete and there was no reference to staff understanding or

awareness of policies including fire, infection control, complaints or safeguarding. We saw no evidence of staff equipment training although staff described attending the scan machine training when the machine was recently replaced. However, the provider and their staff reported having a good working relationship whereby service developments were discussed, and the provider responded to suggestions. We heard of how appointment times were reduced for some scan packages based on feedback from staff.

We saw evidence the staff member completing the NIPT screening had been accepted as a practitioner by the NIPT screening laboratory in London. A patient information leaflet was available on the website and the sonographer discussed the benefits and limitations of the screening on a telephone consultation prior to the screening. This leaflet and reference to the NIPT was removed from the Baby Skan Studio website following the inspection as the provider decided to no longer offer the service.

Multidisciplinary working

All those responsible for delivering care worked together as a team to benefit patients. They supported each other to provide good care but did not work collaboratively with other services.

During the inspection we observed the sonographer and provider working well together to deliver the service. They communicated clearly with each other and the women and their families. Sonographers, when not working, promptly responded to communication from the provider.

There were pathways to refer women as agreed with the local NHS trust but no links with local GPs. These pathways were not documented, and no scan reports were created or shared with the NHS trust when a patient was referred. There was no system for ensuring patients had attended their follow up appointments.

The NIPT laboratory had a user-friendly password accessible online portal which the provider and NIPT sonographer were able to access to track and monitor patient samples. Status updates were provided to indicate when a sample was received in the lab, being analysed and reported on. Staff explained that an email notification would advise them to access the portal and view the updated results. The online portal was accessible when the service was closed so the NIPT sonographer was able to communicate the results to the patients without delay. There was no formalised process to support staff breaking bad news to patients.

Seven-day services

The services were provided at times which were more suited to the service users.

Typically, the service was open on afternoons and evenings and on Saturdays. Appointments were flexible to meet the needs of the patient and appointments were available at short notice. Occasionally there was a short cancellation waiting list, but the provider advised that additional clinics would be run to meet demand.

Health promotion

A limited level of health promotion was considered or shared with women using the service. Health promotion was provided via the NHS maternity pathway and care. There was no on-site written information into what the scan would entail, keeping healthy in pregnancy such as stopping smoking and alcohol, movements of the baby, foods to be avoided and questions they could ask their midwife.

Consent and Mental Capacity Act

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Patients completed a consent form. The provider understood their responsibility to gain consent from patients before sonographers completed an ultrasound scan. Staff recognised and respected a patient's choice when deciding upon their scan package. Staff adapted scan packages to meet the needs of their patients. Staff explained they would verbally request consent from patients to discuss scan concerns with the NHS maternity service, although this was obtained through the consent form.

We reviewed ten sets of consent records. Six out of ten records were not completed fully as patients had not circled to indicate if they did or did not given their consent for their images to be used on the website or for promotional material. All consent forms were signed but there was no confirmation of the total price paid for the scans.

Requires improvement

Diagnostic imaging

We observed explanations of the imaging procedure and scan findings being discussed with patients and their families. As well as requiring a consent form to be completed a verbal request for consent was also made. The sonographers were employed by the local NHS hospital and had completed the NHS training on the Mental Capacity Act (2005), however there was no adapted or specific training for the service. Staff explained they did not have experience of supporting women who had been assessed as lacking capacity within this service and had not been concerned about a patient's mental capacity.

We observed patients were supported when they experienced heightened anxiety. Staff spoke of supporting a patient with mental health concerns and working with them to allay their fears of personal contact. Staff explained that complimentary repeat scans were offered to reassure the patient and obtain the desired scan images. Staff felt the service supported the patient to familiarise themselves with an ultrasound scan in a setting with fewer time constraints than the NHS pregnancy scans.

We saw an example of the NIPT consent form however all completed forms were returned to the laboratory with the blood sample. This meant we were unable to review the evidence of consent although all 17 NIPT samples had been accepted by the laboratory.

There was no information from Public Health England provided to patients or explanation of the potential risks of ultrasound within the consent form, however sonographers minimised this risk by replaying short recordings of the scan. There was a potential for patients to not be providing fully informed consent.

Are diagnostic imaging services caring?

Good

We had not previously rated caring. We rated caring as **good.**

Compassionate care

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

Staff were committed to delivering high quality compassionate care. Patients and their families were greeted in a friendly and welcoming manner. Staff took the time to interact with patients and their families in a respectful and considerate way. The provider introduced the sonographer to the family prior to their scan, making families feel relaxed and cared for.

Patients we spoke with were overwhelmingly positive about the service. Patients commented that staff treated them well and with kindness. Patients explained that staff 'put you at ease' and 'nothing was too much for them'. Many patients spoke of their desire to return to the service for future scans, whilst a significant number were already repeat customers.

Staff respected the privacy and dignity of their patients. Patients reported not feeling pressured to discuss personal information in front of other patients in the waiting room. There was adequate sound proofing between the scan room and waiting room so confidential information was not overheard. There were areas within the waiting room which were away from the street window, allowing patients to not be seen from the road, helping to maintain their privacy and confidentiality. No intimate examinations were provided at the Baby Skan Studio.

Staff respected and considered the individual needs of patients and their families. Staff spoke of how they adapted the scan packages and prices to meet the needs of their patients. We were informed of times when patients would be advised to look away from the scan when they wanted a surprise, for example, their baby's gender. We heard of patients wanting to wait until their baby was born to see their baby's facial features. Sonographers supported these requests by advising patients to look away at the appropriate time while recording the scan, so the video was available to see at a later date.

However, feedback which was left on social media was automatically transferred to the Baby Skan Studio website. This had the potential to affect patient confidentiality as profile pictures and names were transferred along with the feedback comments. This was raised with the provider during the inspection and the website was amended to remove the personal details. This was completed within three days of the inspection.

Diagnostic imaging

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal needs.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and those close to them. Staff were aware that patients could be anxious about their scans. Staff took the time to explain the scan and provide reassurance when it could be given. We observed staff speaking clearly and sensitively. Staff explained how they would offer patients who received bad news to leave the clinic via an alternative exit to avoid walking back through a busy waiting room. Patients we spoke with commented on how relaxing the service was and how they would be happy to return.

We did not see any examples of difficult information or findings being communicated to patients and their families, however staff were knowledgeable of how they would provide support. Staff explained how they would discuss how to contact the miscarriage association and explain the next steps. All patients with concerns found on a scan would be referred to the NHS hospital for a second opinion. The staff also worked at the NHS hospital and were familiar with the NHS procedures so were able to verbally explain the next steps. Patients commented that they were confident knowing the sonographers also worked at the local NHS hospital so were aware of the follow up care, if any was needed. We heard of patients being reassured by seeing the same sonographers at the Baby Skan Studio and later at the NHS hospital.

Staff sensitively asked patients how they were feeling prior to the scan. This put patients at ease whilst they were waiting for their scan. We observed reception staff walk the patient and their relatives into the scan room to introduce them to the sonographer. This provided continuity to the patient and helped patients to feel well looked after. The reception staff returned to the scan room if assistance was required and provided emotional support after the scan. We observed reception staff interacting with patients and their families after the scan, ensuring that they were pleased with their experience. Staff spoke of times when reception staff would entertain children in the waiting room to enable a more relaxed environment in the scan room.

Staff considered the emotional needs of patients and their families. We heard of times when scans would be offered outside of the main clinic hours to accommodate unwell relatives. Staff spoke of how additional complimentary scans were offered to enable very unwell relatives to meet the unborn baby. Staff also explained how scans were popular with Navy families as it allowed an opportunity for partners to attend alternative pregnancy scans if they were away with work at the time of the NHS scan.

The service provided additional non-invasive prenatal testing (NIPT). This screening included a scan and a blood test following an initial telephone consultation with a Midwife-Sonographer. The service did not complete NIPT screening regularly and no patients we spoke with had opted for the screening test. However, staff explained how appointments for the NIPT were made for times when the clinic was not open so that the patients had a convenient and private experience. The procedure was explained through individual telephone and face-to-face discussion and referral to an information leaflet. We heard how staff would ask patients how they would like to be updated on the scan results and whether they would also want to be informed that the sample had reached the laboratory ready for processing. Staff spoke of how they would sensitively refer to the NHS hospital should the screening detect a concerning result.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their treatment and scan results. Their individual preferences and needs were reflected in the care delivered.

Patients undergoing gender reveal scans were asked how and when they would like to find out their baby's gender. Patients and their relatives not wanting to find out in the scan room were advised to look away from the television and scan screen to avoid discovering their baby's gender. We saw sonographers writing the gender on a piece of paper and placing it in an envelope along with scan images showing the baby's gender. These scan images were carefully removed from the rest of the photos and placed in the envelope to further respect the patient's decision to delay finding out their baby's gender.

Requires improvement

Diagnostic imaging

We saw patients and their families being asked if they were happy with their scan images prior to leaving the service. Staff spoke of how patients would be advised to return two weeks later for a repeat scan if they were unhappy with their images. Staff explained that this would often be a complimentary scan without additional cost to the patient.

There was sensitivity when performing early viability scans. Sonographers quickly identified the baby's heartbeat and pointed to it with the cursor, so the patient and their family could find the heartbeat and reassure themselves that they had a viable pregnancy. We saw sonographers turn the scan machine's screen to face patients and their family if the television image was too far away to see the heartbeat clearly.

Staff made sure patients and those close to them understood their care and treatment. Patients and their family were made aware of the scan findings throughout their time in the scan room. We observed the sonographer interacting with the patient and their relatives in a sensitive and calming manner, while sometimes using humour to make the scan a more uplifting and enjoyable experience for families. Families we spoke with commented that the staff at the Baby Skan Studio were very caring and reassuring. Sonographers advised that the appointment times were long enough to enable this relaxed conversation with patients and their families. There was also enough time to identify the best image for patients to view.

Staff responded sensitively when concerns were detected on a scan. Staff explained how they would sensitively discuss when concerns were found on scan, for example, when there was no fetal heartbeat. Concerns detected with the development of the fetus were communicated to the fetal medicine department, although this was very infrequent. Staff were aware of the NHS support that would be provided and explained this to patients

Are diagnostic imaging services responsive?

Good

We had not previously rated responsive. We rated responsive as **good.**

Service delivery to meet the needs of local people

The service was mostly planned and provided in a way that met the needs of patients' and their families who would use the service.

The studio consisted of a waiting room with reception area and toilet with baby changing facilities. The waiting room led to a scan room which included an alternative exit and further door to a staff kitchen. Staff advised that the kitchen was only accessible between scan appointments when a patient was not in the scan room, helping to maintain patient privacy. There was a variety of toys available for children to play with in the waiting room and gentle music was played.

The waiting room was spacious with enough comfortable chairs of different styles for patients and their relatives to use while waiting for the scan. The service recommended that up to four people could accompany the patient for the scan. Within the scan room there were five chairs to accommodate four family and friends and the patient's belongings. Patients and relatives, we spoke with felt comfortable and welcome to join the scan experience and were easily able to see the television displaying the scan images during the scan.

There were two regular sonographers and one sonographer who was available for scans but typically completed the non-invasive prenatal testing (NIPT). This meant that there was often continuity for patients who were returning for repeat scans to gain a good quality image or a different scan package later in their pregnancy.

The service had flexibility to meet the needs of service users. The sonographers worked in the daytime within the local NHS hospital. This meant they were only available on evenings or weekends, when patients and their relatives would typically not be at work and therefore available. We heard how clinics were provided

on Sundays, but the demand for these scans was limited so weekend clinic availability was reduced to Saturdays only. The evening scans were usually on Tuesdays and Thursdays, but sometimes on Wednesdays as well if there was enough demand. Sonographers were flexible and worked additional shifts to cover for sickness or if there was increased demand for scans, to minimise patient waiting times. Staff recognised that greater scan demand was typically at the start of the month after patients and their relatives have been paid.

There was a range of adaptable packages available to patients and their relatives. These were displayed on the website, in the clinic and in person. Patients were required to pay for their scan package prior to their scan. This meant that patients could leave the clinic without delay if they had received bad news or needed to leave promptly.

The service accommodated different patient needs reasonably well. Staff explained how many of their clients had partners who were in the Navy. By offering early viability scans and other scan packages they were meeting the need of patient's whose partners would be unavailable for the NHS scans as they were out of the local area with work.

However, all scan packages were offered within each clinic, so patients attending for an early viability scan with a higher likelihood of bad news were sharing a waiting room with patients who were nearing the end of their pregnancy and attending for pregnancy keepsakes. Patients receiving bad news were offered to leave the service through the alternative exit, but this could have been apparent for those in the waiting room and could affect patient confidentiality if the patients were known to one another.

There was limited support for patients receiving bad news. A miscarriage leaflet was available although this had not been reviewed since 2016 and was not personalised to the service.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Patients were offered a variety of scan packages and had these explained to them when booking the appointment. Patients were sent a text message to confirm their appointment and to advise whether they needed to have a full bladder for their scan, to minimise any unnecessary discomfort or queries.

The scans were arranged with set durations of 15 or 30 minutes to allow adequate time for each scan and to minimise the number of patients sharing the waiting room. This allowed opportunities for questions to be answered. Patients commented that they had plenty of time to ask questions in the privacy of the scan room. The sonographers reported being happy with the length of appointments as they allowed for a more relaxed bonding experience for the families. If patients had poor scan views they were advised to go for a walk to encourage baby to move, rather than waiting in the waiting room. This minimised the usage of the waiting room. If it was not possible to gain a good image, a further appointment was offered to the patient two weeks later free of charge.

The scan couch was suitable for use by patients weighing up to 190 kilograms or 30 stone. There was an explanation of the limitations of a raised BMI within the website which could have deterred some patients from booking scans. This could reduce the likelihood of poor image quality and need for further repeat scans to achieve a good quality image. Staff advised that there had not been any concerns about the couch capacity in the twelve years that the service had been open. There was wheelchair access to the waiting room and scan room for visitors, although it would not have been possible for a wheelchair to gain access to the toilet or for a patient to move safely between the wheelchair and scan couch.

Patients were at the clinic for only a short time, but staff treated each patient as an individual. Staff supported patients who were anxious and gave them explanation and time to support them through the process. We saw staff showing empathy when previous miscarriages or early pregnancy concerns had been experienced.

The service redirected patients to the NHS hospital when there was clinical concern. We heard staff communicate this advice to patients on the telephone, rather than accepting a scan booking. Staff explained they had

referred patients to their midwives if during the scan they expressed concerns about their own wellbeing or that of their baby. We were given the example of patients being advised to contact their Midwife if their baby's movements had reduced or stopped. This is in line with national guidance for fetal movements, although there was no written information for patients to observe in the waiting or scan rooms.

Not all staff had received training to manage violent and aggressive patients, but staff explained that there had not been any occasions of violence or aggression. If support was needed in the scan room the sonographer could ring a bell and the reception staff would attend to provide support.

There was some support available for patients or their relatives who were vulnerable. Staff spoke of using internet interpretation services to translate written text for patients, but there was no standardised information available in an easy read format or in non-English languages. Staff explained that their patients did not usually have additional needs or were non-English speaking, but they would provide longer appointments if needed to help improve patient understanding and experience. Staff advised they often did not provide patients with leaflets on probable miscarriage or the early pregnancy clinic, instead discussing the advice and next steps verbally prior to referring for an NHS scan.

However, we saw information leaflets which were due to be revised in 2016 and belonged to the local NHS hospital. These information leaflets were not tailored to the patient experience within the service and may not be up-to-date with current practice, advice or recommendations so could mislead patients.

Access and flow

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

A range of evening appointment times were available with the clinic times typically between 4.30pm and 8.30pm. The clinic structure included a break for the sonographer to help the appointments keep to time. There was flexibility to extend the clinic as needed and staff spoke of occasions when they would accommodate additional scans to minimise patient anxiety that would increase if the patient needed to wait a few days for their scan. On the day of our inspection a patient had requested an appointment at 3pm and was given a cancellation for the same evening. Another patient was pleased with the quick access to assess the pregnancy viability prior to booking in with a Midwife and attending the NHS scan. This reduced their anxiety and need to take time out of work as the scan times were in the evening.

There was also wheelchair access through to the scan room which had been used to enable easy access for relatives. A ramp was available to enable access to either entrance and between the waiting room and scan room. The service was located on a main road through the town. There was no on-site car parking, but patients could park in a nearby multi-storey car park which was free in the evenings when most of the clinics were held. Patients commented that it was not a short walk in the rain with young children.

Cancellations of appointments would be taken but staff advised that this was infrequent as patients were normally booked appointments for within a few days of their initial contact. Upon booking patients paid a £30 deposit which deterred patients from not attending their appointment.

Patients who attended their scan but were too early to see the baby's heartbeat were referred to the Early Pregnancy clinic at the local NHS hospital for a transvaginal scan. A transvaginal scan involves the insertion of an ultrasound probe internally into the vagina and is used when a pregnancy is very small.

During our inspection the service ran to time and women were not kept waiting too long when they arrived with most patients we spoke to suggesting that it was just five minutes. All patients spoken to were pleased with the service and the minimal wait times. The ease of booking was praised by many patients. Most appointments were booked using social media and the minority over the telephone. Staff were seen to quickly respond to booking enquiries and to promptly return missed telephone calls. Patients commented that the booking process was "very professional" and with staff "knowing what to book you in for". Patients felt that staff kept their scan to "what was needed" as a keepsake scan, rather than repeating the wellbeing checks that an NHS scan would undertake. This

enabled the appointments to be calm and relaxed. Appointments were also be booked outside of the opening hours as the clinic diary and social media accounts were monitored by the owner.

Staff demonstrated awareness of the comfort levels of their patients. Staff explained that the appointment times were generous with the intention of providing an excellent service and minimising waiting times. Staff explained that they wanted to avoid patients needing to arrive with a full bladder from being uncomfortable for any time longer than necessary. A full bladder is required for early viability scans to assist the sonographer to obtain images of the fetus. Scan images were printed directly from the scan machine and given to the patient without delay, ensuring that the correct scan images were given to the correct patient.

Patients undergoing the NIPT screening had minimal time to wait for their results. The blood samples were sent via Royal Mail delivery to the laboratory within a day of the sample collection. The results were tracked by staff at the Baby Skan Studio who also received an email to notify when the results were available. Consent was requested for staff to advise of the results by telephone to reduce delay in arranging a face-to-face appointment. This meant that any concerning results could be referred to the NHS trust as soon as the patient was aware and gave consent for referral.

However, there was potential for flow to be affected during the scan clinics. This is because the likelihood of a busy waiting room was increased if staff needed to provide more time for patients to compose themselves after a scan, for example if they had received bad news and a referral was needed to the NHS hospital.

Learning from complaints and concerns

People were able to give feedback and raise concerns about care received but the complaints policy was not clear about how complaints would be managed.

The service clearly displayed information about how to raise a concern or compliment. A poster displayed this information in the waiting room and was visible when leaving the clinic as it was at eye level on the wall next to the front door. In the first instance patients were advised to discuss their concerns with the provider or to contact the Baby Skan Studio email address. One complaint had been received in the year before the inspection, and no complaints had been received between September 2017-2018. This complaint was responded to promptly and included an apology. However, the complaints process was not visible on the service's website, making it harder for patients to feedback on poor care.

There was no formal investigation process and no clear evidence of lessons identified or learning being shared. Staff we spoke with discussed sharing feedback from patients on an informal basis, but this feedback was not documented. The service did not include patients in the investigation of their complaint. The complaints policy referred patients to the Care Quality Commission (CQC) if they were unhappy with the way their complaint had been dealt with. As the CQC is not a complaints investigatory body and does not have the powers to investigate or resolve complaints this advice was incorrect. Instead feedback would help the CQC to decide what, when, and where to inspect.

A paper feedback system was available, but staff advised social media was the main source of feedback. The paper system used comment cards which had space for free text and asked, "how could we improve". The social media feedback was not structured and did not request information to help develop the service. Feedback was monitored and managed by the provider who responded promptly. Staff told us there were very few negative comments. However, the feedback from social media was public and not anonymised, meaning some patients may have avoided feeding back on poor care or areas for improvement.

Are diagnostic imaging services well-led?

Requires improvement

We had not previously rated well-led. We rated well-led as **requires improvement.**

Leadership

Leaders were not always aware of the risks, issues and challenges in the service. Leaders were not

always clear about their roles and their accountability for quality, although they were visible and approachable in the service for patients and staff.

The Baby Skan Studio was managed by the owner and registered provider and had been open since 2007. There was no awareness of the need for a lone working policy despite lone working being undertaken by the sonographer completing non-invasive prenatal testing (NIPT) screens. There was limited support for the provider as there was no deputy or senior sonographer who could assist with the creation and management of clinical policies. There was no formal system for monitoring or peer reviewing sonographer competency or providing formal performance feedback to staff as there was no appraisal or auditing process. This posed a risk that care provided could be of a variable standard, although the provider advised that they would observe scans when the clinic allowed, and they were not required on reception. The provider observed scans for clarity of images but did not have a clinical or sonographer background to comment on the scan findings.

There were a number of key policies which were not available to direct and guide staff practice. Those available policies lacked a date, an author, review date or version control. The provider was the lead for most tasks including infection control and complaints management, but a sonographer had been given the role of safeguarding lead despite not having been trained to safeguarding level three. The provider did not recognise the potential for domestic abuse or child sexual exploitation amongst other safeguarding concerns. The safeguarding policy was very limited and not maintained or updated by the safeguarding lead. However, following the inspection the provider submitted a safeguarding flow chart to detail the step-by-step process of raising concerns. There was no lone working policy, no version control on the complaints policy and no health and safety policy.

At the time of the inspection there was no system for recording or reporting on informal patient concerns. This meant we could not be assured that there was good oversight of the risks, issues or challenges in the service.

Staff told us the provider was visible and approachable and that they felt supported, especially as they regularly saw each other when working in their NHS roles. All the staff we spoke with were positive about the provider, however they did not receive any structured managerial support or oversight in the way of appraisals or competency assessments. This meant that learning and development opportunities were not routinely reviewed or considered.

Vision and strategy

There was no documented vision and strategy for the service although all staff spoke of wanting to provide a good caring service. Staff explained they valued being able to provide an opportunity for a relaxed bonding and early pregnancy experience which allowed patients to attend with up to three family members. Staff felt it was important for patients to have an opportunity to attend for a scan with family members who were unable to attend the NHS scans either due to unavailability or the restricted visitor policy. The provider was keen for the service to provide an opportunity for reassurance scans and to enhance the NHS provision but not to replace it. This viewpoint was presented by all staff.

The provider did not have a clear vision or strategy for the future. When questioned the provider suggested a potential for bladder and kidney scans to be offered but this had not been developed beyond an initial idea. The service had been running for twelve years and the provider advised that they were happy with the service being offered.

Culture

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

All staff were very positive and happy in their roles. Staff stated the service was a good place to work and sonographers were happy to be able to provide a relaxed environment for pregnancy scans. Staff told us the provider was flexible in their approach to running the service, with the provider being considered a friend.

Staff we spoke with felt supported, respected and valued. Staff felt able to make suggestions about the service and reported feeling listened to by the provider. We were given an example of the length and format of the gender

reveal scan appointments being reduced from 3D and 30 minutes to 2D and 15 minutes. This was because the sonographers found the actual scan time was shorter than the provider anticipated and 2D scans were more suitable than 3D scans for assessing fetal gender. Staff also explained that estimated fetal weights were provided rather than a full assessment of the fetal growth because this could interfere with the regular NHS growth scans which have been recommended to more patients in recent times.

Staff demonstrated pride in their work and took time to identify the best scan images for patients and their families.

There was a lack of awareness of duty of candour although staff reported they apologised to patients who were dissatisfied with their care or scan images. Duty of candour is a legal duty to be open and honest with patients or their families when something goes wrong that appears to have caused or could lead to significant harm in the future. There was no duty of candour policy and when we spoke with the provider about this there was no awareness of the principles of duty of candour, although the provider was available to discuss any dissatisfaction with scan images at the time of the scan. Staff explained how the provider offered patients with poor views a complimentary repeat scan, despite there being no guarantee of improved views. We saw evidence of a patient complaint response including an apology for the patient's experience and an apology acceptance from the patient.

Staff development was not given enough priority. Appraisals were not completed and there was no formal review of personnel records.

The culture did not support incidents being reported and there was no formal process of sharing learning. There was no risk register or incident reporting system. There were no team meetings to identify or share learning. We saw no evidence of shared learning following complaints. This meant there was a potential to miss opportunities to develop and improve the service in line with staff and patient feedback.

Governance

Governance systems did not ensure that recruitment and staff management practices were completely safe. The service did not have a recruitment policy or procedure. We reviewed personnel files and found no evidence of application forms or pre-employment references for any of the staff. We requested the job descriptions for staff but received only a job vacancy advert. This meant staff could not be fully aware of their roles or responsibilities and staff performance could not be managed in view of a contract or job description. We found no evidence of staff awareness or adherence to the policies as there was no record of training or reading of the policies. However, there was evidence of employment histories, photo ID and DBS checks.

There were limited governance processes within the service. There were no automatic reminder notifications to prevent out of date equipment or electrical testing. Policies were limited or not fit for purpose. There were no team meetings or evidence of sharing of information and learning between the provider and staff. There was no system to remind the provider of mandatory tasks including electrical safety testing, health and safety risk assessments or expiry of equipment. The annual facilities risk assessment was last completed in January 2018 but was due in January 2019. Clinical gloves, sample bottles and clinical wipes were expired at the time of inspection, with no spare equipment available on site to replace them with. There were no handwashing or infection control audits or lone working policies. Clinical sharps boxes were full, undated and contained clinical waste in addition to sharps. There were no clinical waste bags or bins despite the provider being aware of how to arrange collection of clinical waste. The fire policy stated staff should raise the alarm, however the provider explained the smoke detector would sound automatically and there was no method by which staff could raise the alarm. This meant we could not be assured that there was good oversight of the service governance.

The service held medical malpractice insurance which was renewed in August 2019. The provider also held property owner's insurance for the building which was valid at the time of inspection.

Managing risks, issues and performance

There was a lack of awareness of managing risks, issues and performance. There was no evidence of staff compliance or awareness of policies and

infection control risks were not prioritised. At the time of the inspection we asked to see evidence of staff compliance and awareness of policies. This was not provided. The provider advised that staff became aware of the policies during their induction, however there was no documented evidence of what the induction included or a manager sign-off to identify the completion of induction. Staff advised that the induction was personalised to the needs of the staff member and staff were not employed at the time. The impact is that there was not a clear process for ensuring health and safety considerations or a standardised approach to ensuring optimum care and quality staff performance.

The provider had no process for ensuring that patients were over the age of 18. Patient identification was not checked or recorded on arrival at the service. This meant that patients could have been under 18 years of age and the service would be providing the regulated activity outside the scope of their registration. The provider advised that they would consider requesting identification in future.

There was no system to monitor, manage or mitigate risks. There was no documented evidence of the risks in the service and no action plan to ensure a review date of the risks.

Infection control risks were not prioritised. Pregnant women are particularly susceptible to infection therefore the risk of infection should be minimised within healthcare settings. At the time of our inspection there was no toy cleaning policy. The provider advised that toys were cleaned with soapy water rather than disinfectant. We explained that this would not remove the bacteria from the toys. Within one week of the inspection the provider had provided a toy cleaning policy which detailed the method and frequency of cleaning with detergent. The policy assigned the cleaning to the provider although it did not include a date or author to identify ownership or date of policy review. This indicated that the provider was not aware of all the risks but was keen to minimise risks to improve performance and care.

There was no policy into managing health and safety risks. These risks included legionella. The provider was unaware of the need to perform regular water flushing to remove the potential for legionella. This was a risk as the water provided on site in the water dispenser was collected from the tap within the service.

There was no business continuity plan or awareness of the need for a plan in the event of an emergency. This was important for times when the provider was not working, however since the inspection the NIPT service has stopped being offered so the provider would always be on site when the service was open. There was no plan in the event of a situation which could stop service delivery, such as IT failure, fire or flood. In the event of a medical emergency the scan room had a bell to call the provider for assistance, but the provider was not first aid trained. The provider advised that in the event of patient deterioration or collapse 999 would be phoned for an ambulance, but there were no clear expectations of staff management of unwell patients of family members. However, the provider spoke of moving the service six years ago to its current site to remove the flood risk. The provider spoke of only closing the service for one week a year to allow for their annual leave, although additional scan clinics would be held either side of that week to ensure the service met patient demand.

Managing information

The service recorded and analysed information to understand performance. The provider could see how many scans had been performed and how many patients had been referred to maternity services for ongoing care. These figures were lifted from the referrals notebook and clinic diary and entered onto an electronic audit record. The referrals notebook and clinic diary were stored securely within the reception desk and were not visible to patients. However, there was limited detail recorded to make informed performance decisions.

Patients had access to a clear pricing structure on the website and displayed within the waiting room. The provider routinely copied and pasted the pricing structure into all electronic communication when patients were booking appointments. The scan package was communicated in text messages for patients booking in person or on the telephone.

Patients signed a copy of the terms and conditions before the scan. The consent form detailed the £30 deposit for the scan but did not include an area to

document the scan package requested and total price paid. Instead the scan package was mostly written on the consent form by the provider. The provider advised that most patients paid for their scans on arrival at the service, however there was no record to confirm that the scan paid for was the scan completed. Staff explained that scan packages were adapted based on personal need, requests and what was seen on scan. This posed a risk that there was not an accurate record of the scans performed in case of future patient concerns or feedback.

Staff had access to the service's available policies and processes however the service did not have an information management policy. There was not an information management policy. In terms of scan images, the patient consent form clearly requested permission for the service to use the patient's scan images for the website or promotional material. Of the 10 consent records reviewed only four were completed fully to reflect the giving or withdrawal of this consent. The consent forms were retained in a locked cabinet within the service, however there was no auditable evidence to ensure the images used had been used with patient permission. This meant that it was not possible for us to confirm patient consent to use the images.

Engagement

There was a limited approach to sharing information with and obtaining the views of staff.

The service did not undertake staff satisfaction surveys. We were told this was because staff always worked with the provider and were able to make suggestions or raise concerns with the provider at the time. The staff all had access to social media to communicate outside of working hours and this was evident during the inspection.

The service enabled patients to feedback in person when the provider asked if they were happy with their experience at the end of their scan; using the open-ended paper comment cards; by email and on the social media page. All staff had links to the Baby Skan Studio social media page and were able to view the feedback comments, although patient feedback was not displayed within the service. We reviewed the feedback received by the service from patients which was wholly positive.

There was no evidence of learning from the written complaint received within the last year, or any documentation of verbal complaints and learning associated. The provider advised that patient dissatisfaction was managed immediately after the scan by offering to rebook for another scan. We saw no evidence of verbal complaints being recorded or associated learning. However, staff advised that in response to the written complaint they were reminded by the provider to offer patients to leave the service through the alternative exit, if they received bad or concerning news.

There was limited interaction with external health agencies. There were no shared systems, patient alerts or processes. We saw evidence of historical communication with the local NHS maternity service, however besides recognising that the service would be making referrals to the NHS, the NHS opted not to share systems, patient alerts or processes with the Baby Skan Studio. One of the reasons given was the service not having been inspected by the Healthcare Commission, the predecessor of the CQC which was active until 2009. The provider expressed frustration that the NHS declined to work more closely with the service, although the sonographers and patients commented that there were close links because the sonographers worked within the NHS hospital. However, we saw email evidence from 3 April 2018 that the NHS fetal medicine department would provide a pathway for NIPT patients with a concerning result.

Learning, continuous improvement and innovation

There was no formal system for identifying learning and no evidence of the service responding to external feedback. During the inspection we asked for examples of learning and evidence of responding to external feedback. The provider and staff were unable to show us a record or examples of how this was undertaken. During the inspection we identified concerns. We discussed this with the provider at the end of the inspection. Following the inspection, the provider informed the lead inspector of the progress of areas identified by the CQC as concerns. The provider promptly removed patient identifiers from the feedback stream on the website as there were concerns over patient consent and patient confidentiality. On consideration of the service the provider opted to stop offering the NIPT

Diagnostic imaging

screening and updated the website to reflect this. The safeguarding policy was updated, and evidence was supplied to confirm the completion of the electrical safety testing.

The provider encouraged innovation. The provider spoke of regularly monitoring the social media reviews and responding to patient comments as necessary. Following a pilot cohort of 40 patients the provider told us they were in the process of introducing a cloud-based image storage system to meet the population trend on cloud-based technology. The provider was keen to securely save patient scan images for the foreseeable future, but still intended for traditional scan images to be printed if requested by patients.

All staff were committed to offering the best available scan images and effects. The service offered patients HD live images which allowed the images of their baby to appear with realistic skin tones. We observed patients responding positively to the effect that HD live had on their bonding experience.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure staff are trained to the correct level of safeguarding and that there is a safeguarding policy and process relevant to the service which is useable by all staff and ensures all patients are over the age of 18.
- The provider must ensure the infection control policy and processes including risk are reflective of the service and in line with the hygiene code of practice.
- The provider must develop and maintain appropriate policies and processes.
- The provider must ensure all consumable equipment is within its expiry date.
- The provider must ensure all referrals to healthcare agencies are recorded with the reason for referral and person accepting the referral.
- The provider must ensure they have a recruitment and employment process, record of staff registration or pin numbers and completion of induction and competency assessment along with regular staff appraisals and awareness of policies.
- The provider must ensure it has a system to assess patient health risks and explain the risks of ultrasound to every patient. Patients must be aware of ALARA principles to give fully informed consent and the provider must ensure all patient consent forms are reviewed and scan images are not used if permission has not been provided.

Action the provider SHOULD take to improve

- The provider should ensure the facilities and environment risk assessment is accurate and completed at regular intervals.
- The provider should ensure all consent forms record the scan package chosen and the agreed financial cost of the scan.
- The provider should consider the methods of sharing and recording communication with staff, including safeguarding concerns.
- The provider should consider the methods of sharing patient information securely with NHS trusts and ensure the receiving healthcare provider is informed of the patient history.
- The provider should consider the organisation of the clinics to promote greater sensitivity to scan findings.
- The provider should ensure health promotion is provided and all literature is current and relevant to the service.
- The provider should consider a documented vision and strategy for the service.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment 12(2)(e), 12(2)(h) and 12(2)(i) The service had not ensured processes were in place to assure itself that referrals were made safely, premises were cleaned, and staff were trained to the correct level of safeguarding.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints 16(2) The service had not ensured there was a clear and structured process of how a complaint would be handled.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance 17(2)(b) and 17(2)(c) The service had not ensured there was a complete and contemporaneous record in respect of each service user or mitigation of risks to service users.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Regulation 18 HSCA (RA) Regulations 2014 Staffing

18(1) and 18(2)(a)

The service had not ensured processes were in place to assure itself that staff were able to carry out the duties they are employed to perform.