Numi Scan Ltd

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

Numi Scan Ltd offers a non-diagnostic ultrasound baby bonding service for women aged 18 and above. It is registered to provide the regulated activity of diagnostic and screening procedures. The service allows women who wish to know the gender of their baby before their 20 week NHS scan or to enable them to bond with their baby, later in pregnancy, using 2D or 4D ultrasound. These are additional private ultrasound scans that are not part of any NHS screening programme. Early pregnancy reassurance scans are offered for worried mothers who would like to see if their foetus has a heartbeat. These types of scans are rarely available through the NHS unless the patient has experienced symptoms.

Numi Scan Ltd opened in 2017 and provides non-diagnostic pregnancy ultrasound services to self-funding women, from six to 40 weeks of pregnancy and are in addition to those provided through the NHS as part of a care pathway. The service primarily serves

Summary of findings

women living in Essex, Hertfordshire, Cambridgeshire and surrounding areas. It also accepts women from outside this area. The service also provides diagnostic vascular screening for patients over 45 years old, however the service had only undertaken five scans in the previous year.

We inspected this service using our comprehensive inspection methodology. We carried out a short notice announced inspection on 7 November 2019. We gave staff two working days' notice that we were coming to inspect, to ensure the availability of the registered manager.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

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

Services we rate

We have not previously inspected this service. At the inspection on 7 November 2019, we rated it as **Requires improvement** overall.

We found areas of practice that requires improvement:

- We were not assured that effective systems were in place to identify, reduce and eliminate risks. For example, there was no lone worker or chaperone policy in place.
- Some policies reflected out of date national guidelines and standards.
- Images were not independently peer reviewed and there was a there was limited commitment to continued professional development.

We found some areas of good practise:

- The service used well maintained equipment and premises.
- The service controlled infection risk well.
- Women could access services and appointments in a way and a time that suited them. The service used technology innovatively to ensure women had timely access to ultrasound scans.
- Staff were caring, compassionate, kind and engaged well with women and their families.
- Feedback was positive.

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 two requirement notices. Details are at the end of the report.

Heidi Smoult

Deputy Chief Inspector

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	Numi Scan Ltd offers a non-diagnostic ultrasound baby bonding service for women aged 18 and above. It is registered to provide the regulated activity of diagnostic and screening procedures. The service primarily allows women who wish to know the gender of their baby before their 20 week NHS scan or to enable them to bond with their baby, later in pregnancy, using 2D or 4D ultrasound. These are additional private ultrasound scans that are not part of any NHS screening programme. Early pregnancy reassurance scans are offered for mothers who would like to see if their foetus has a heartbeat. The service also provides diagnostic vascular screening however five patents used this service in the last year. Facilities include one ultrasound room, a waiting area, reception and a toilet and are all located on the ground floor. We rated the service as requires improvement overall. We rated the service requires improvement for safe and well-led because the processes in place to ensure that the quality and safety of the service was not effective. We rated the service as good for responsive because people could generally access the service when they needed. We rated the service as good for caring because feedback from patients was positive and we were told of positive interactions during our inspection. We do not currently rate the effectiveness of diagnostic imaging services.

Summary of findings

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Numi Scan Ltd.

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Numi Scan Ltd

Numi Scan Ltd. is a private clinic in Stansted, Essex and the service was newly registered with the Care Quality Commission and opened in May 2017. The clinic primarily serves the communities of the Essex, Cambridgeshire and Hertfordshire region. It also accepts patient referrals from outside this area.

The service offers:

- Early reassurance scanning (from seven to 15 weeks)
- Gender scan (from 16 to 22 weeks)
- Growth and wellbeing scan (from 16 weeks to 40 weeks)
- Four-dimensional (4D) scan package (from 24-34 weeks)
- Vascular screening

The clinic has had a registered manager in post since 2017 when the service opened. We have not previously inspected this service.

Our inspection team

The team that inspected the service comprised of a CQC inspection manager and an assistant inspector. The inspection team was overseen by Fiona Allinson, Head of Hospital Inspection.

Information about Numi Scan Ltd

The service provides diagnostic imaging service (ultrasound scans) to self-funding pregnant women aged 18 and above across the Stansted and surrounding area. The service is located off a main road in Stansted in a single storey clinic, there was paid parking nearby.

During the inspection, we visited the reception area, the scanning room and the storage room. We spoke with the registered manager who was the sole employee and conducted all the scans. We spoke with one woman and a partner of another woman who had used the service. During our inspection, we reviewed five scans, 20 anomaly reports and 30 consent forms.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. This was the service's first inspection since registration with the CQC in 2017.

Activity (November 2018 – November 2019)

- In the reporting period November 2018 to November 2019 the service saw 817 women for early pregnancy scans, 724 for gender reveal scans, 518 for 4D baby scans and five patients for vascular scans.

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:

- There was no written procedure to manage deteriorating patients.

However

- The service provided mandatory training including safeguarding level 3 for children and adults.
- The service controlled infection risk and kept premises and equipment clean.

Are services effective?

We did not rate effective. However, we found:

- Service user's views on the service was monitored through feedback forms and on social media.
- The service provided clear verbal and written information to women before and during scans. Women were advised to attend all NHS antenatal appointments.
- Appointments were available seven days a week.

However

- Policies did not reflect national guidance and were not specific to the service.
- The service did not have a mental capacity act policy and there was no service specific training on mental capacity.
- The registered manager, who was the sole operator, had not undergone any further sonography training or updates for two and half years.
- There was no system in place to peer review the quality of scans.

Are services caring?

Good

We rated it as **Good** because:

- Staff treated women with compassion and kindness, respected their privacy and dignity
- Staff supported and involved women, families and carers to understand their condition.

Are services responsive?

Good

We rated responsive as **Good** because:

- People could access the service when they needed it.

Summary of this inspection

- It was easy for people to give feedback and raise concerns about care received.
- The service considered the needs of local people.

However;

- There were no formal arrangements for women who did not speak English as their first language.

Are services well-led?

Requires improvement

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

- There were limited systems in place relating to the governance of the service. Not all policies had been reviewed and some were not specific to the service.
- The service did not manage risk well, there was no risk register in place.

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 have not previously inspected this service. We rated safe as requires improvement.

Mandatory training

The service provided mandatory training in key skills to staff and made sure it was completed.

The registered manager solely ran all aspects of the service and operated the equipment. On the inspection we saw that mandatory training been completed and they had attended regular courses to ensure training was in date. This included basic life support, infection prevention and control and information governance; these were completed through face to face lessons.

Safeguarding

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

The service had a 'child and vulnerable people safeguarding protection policy' however the policy did not reference up to date guidance such as the safeguarding children and young adults: roles and competencies for health care staff – Intercollegiate Document (January 2019). This would mean that the service would not be following best practise when addressing safeguarding concerns.

The registered manager had completed safeguarding adults and children level three training.

The service had not made any safeguarding referrals in the past year.

The registered manager knew how to report a safeguarding incident and how to recognise any potential safeguarding concerns and forms of abuse. The service could access advice from the local safeguarding authorities if needed.

Cleanliness, infection control and hygiene

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

The registered manager was the infection control lead and had completed the relevant training.

The service had an infection and prevention control policy dated 2017 and was due to be reviewed on 1 May 2018 but we did not see evidence that it had been reviewed.

We saw evidence that daily cleaning tasks were completed for the scanning room and the reception. Daily cleaning audits were complete from December 2018 to December 2019.

Staff kept cleaning equipment, fluids and other chemicals in a locked storage room. This was in line with the Control of Substances Hazardous to Health Regulations 2002.

Personal protective equipment, such as gloves, were available for staff to use.

The service had a blood spillage kit to ensure any blood spillages would be cleaned correctly and avoid any potential risk to patients and staff from blood borne viruses.

Diagnostic imaging

Handwashing facilities were available in the ultrasound examination room and the toilet. Hand sanitisation gel was available throughout the clinic for staff, visitors and the women to use. There were suitable handwashing facilities for the size and scope of the service. The registered manager told us they cleaned their hands with sanitising gel before and after each contact with women who used the service.

Flooring throughout the service appeared well maintained and visibly clean.

A disposable paper towel was used to cover the examination couch to avoid the risk of contamination.

There had been no incidences of healthcare acquired infections reported at the service.

Environment and equipment

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

The service was located on the ground floor and was accessible to those with additional mobility needs. The waiting area was large and spacious with some sofas, computers to view images and a small table with activities for children. The toilet facilities were clearly signposted.

The scanning room was located next to reception. The room had appropriate lighting, was spacious and had comfortable seating for the women being scanned and other invited people.

The scanning room had one wall-mounted 'slave' monitor, which projected the images from the ultrasound machine. This was in line with recommendations, as it enabled women and their families to view their baby scan more easily.

All areas we inspected were visibly clean and free from clutter.

Staff kept themselves, equipment and the premises clean.

There were effective systems in place to ensure that sonography equipment was maintained on a regular basis. We saw that equipment contracts were in place and were in date to cover equipment maintenance and failure.

The non-invasive prenatal test (NIPT) procedure provided clear instructions on the labelling, packaging and method of postage. In addition, the package was sent through recorded delivery to enable tracking.

A first aid kit was in an accessible area within the service. Supplies were in date and well organised. The registered manager was a first aider.

Assessing and responding to patient risk

There were some arrangements in place to assess and manage risk to patients.

We found no written guidance or standard operating procedure in response to an emergency or a serious concern such as if a service user became unwell or needed urgent medical attention. However, the registered manager did tell us they would call 999 in an emergency.

There was a pathway in place that staff could follow in the event of the unusual findings by the sonographer during the ultrasound scan or vascular screening. This involved them informing the patient if they had seen something on their scan which should be checked further as part of NHS care. If this happened, the patient was advised to contact their GP or midwife for further care.

Screening for Group B Streptococcus (GBS) was offered. GBS is not routinely offered in the NHS, but laboratory testing for GBS was offered by Numi Scan (through a 3rd party). The woman took the kit home, did the swabs and which Numi Scan sent to a laboratory and told the woman the results three days later.

The terms and conditions for the service clearly advised women that their ultrasound scan was not a substitute for the NHS scans offered during pregnancy and that they should still attend these. Women were made aware of this prior to their appointment and were asked to sign a contract to confirm that they had read and understood the terms and conditions before any scan was undertaken.

The service's website gave advice from the British Medical Ultrasound Society in relation to safety and multiple scan use.

Staffing

Requires improvement

Diagnostic imaging

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

The registered manager was the sole employee and operator. They ran all aspects of the service, including reception duties and operating the sonography equipment.

The registered manager was responsible for the reception desk, managing enquiries, appointment bookings and operating the scanning equipment. The registered manager told us the they were able to manage the different roles alone. We were told that if someone walked into the service the registered manager would pause the scan at a convenient moment to speak to the potential patient and then return to the scan. This could mean that people would be left unattended in reception until the scan was complete.

In the event of staff illness, the registered manager told us that the appointments would be cancelled and rescheduled. The service did not use agency staff.

There was no lone worker policy or chaperone policy in place.

Records

The service kept records of patients' care and treatment. Records were appropriate, clear, up-to-date, stored securely and easily.

The service kept completed records securely. Consent forms were locked away by the reception desk.

Any electronic records were password protected and access to the ultrasound machine was password protected.

Medicines

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

Incidents

The service had systems and processes in place to manage patient safety incidents.

There was a 'significant event monitoring and analysis template' that was designed to report incidents. Although the document described what to do with regards to notifying the Care Quality Commission, in the event of a patient death whilst being scanned, it did cite examples that may not have been appropriate to the service, for example someone detained under the mental health act.

The registered manager could describe examples of a potential incident and the subsequent action to be taken.

The service had reported no incidents since opening.

As there had been no clinical incidents at the time of our inspection, we were unable to see documentary evidence that patient safety incidents had been recorded.

The service had a duty of candour policy in place. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of 'certain notifiable safety incidents' and provide reasonable support to that person.

The registered manager described the meaning of the duty of candour and action they would take in event of the duty of candour being required. However, at the time of the inspection there had been no incidents, so duty of candour had not been applied.

Are diagnostic imaging services effective?

We do not currently rate effective in diagnostic imaging.

Evidence-based care and treatment

The service had some systems and processes in place to ensure policies and guidelines were in place however not all of these were reviewed, current and up-to-date.

The service worked in accordance with the 'as low as reasonably achievable' (ALARA) principle. The ALARA principle is used to ensure that excessive tissue heating does not occur during ultrasound examination.

The service had a health and safety policy in place and the registered manager was aware of ALARA and the highlighted the risk of tissue heating with the use of

doppler devices. A doppler device uses high-frequency sound waves to measure the amount of blood flow through arteries and veins and hence produces an audible 'heartbeat'.

Nutrition and hydration

Due to the nature of the service provided food was not required or provided in the service. Women and visitors did however, have access to water and complimentary coffee.

Pain relief

The registered manager said they checked the woman's comfort during the examination.

Due to the nature of the service provided, pain relief was not required

Patient outcomes

There were some systems and processes in place to monitor patient outcomes.

It is best practice to have the quality of images audited by a peer, or third party however this was not done by the service. The registered manager audited around 5% of their own scans.

The service sought feedback from patients on the outcomes of their scans, and we saw this feedback indicated patients were satisfied with the results due to the high level of positive responses.

Competent staff

The service did not have a formal process to make sure staff were competent for their roles.

The registered manager was a trained radiographer. However, they told us that they had not undertaken any further formal continuous professional development for two and a half years. The provider was registered with the Health and Care Professions Council (HCPC). However, since commencing the business in May 2017, they had under gone no further formal training or updates, but said they kept up to date by reviewing articles in professional magazines.

Multidisciplinary working

The service was run by a lone operator. However, they did work with other agencies as a team to benefit patients. For example, the service liaised effectively with the non-invasive prenatal tests (NIPT) equipment providers, to ensure results were communicated within three to five day expected window to patients.

If a suspected anomaly was found during a scan, the woman was advised to go to her GP or midwife, so that appropriate care could be provided.

The service offered scans for those who were concerned if they had a deep vein thrombosis (DVT) or abdominal aortic aneurism. (AAA). However, there had been less than ten of these scans carried out since the service had opened in May 2017. If a DVT was found the patient would be referred immediately to their GP so that treatment could be commenced. In the case of AAA, depending on the size of any aneurism, the patient was referred as appropriate.

Seven-day services

The service was available seven days a week to support timely patient care.

While the premises were not open all the time, the service did allow for same day bookings. Opening hours were generally Saturday 10am-6pm, Sunday noon-4pm, Monday 10am-5.30pm, Tuesday and Wednesday 10am-8pm, Thursday 10am-2pm, Friday 10am-5.30pm.

Health promotion

The services website gave information about nutrition during pregnancy and information about baby development.

Consent and Mental Capacity Act

Consent to care and treatment was sought in line with legislation and guidance. Women were asked to read and sign the terms and conditions of the service before any ultrasound scan was undertaken. The terms and conditions clearly stated that the ultrasound scan was for souvenir purposes only. They also clearly stated that they were not a substitute for the scans offered by the NHS, nor was the sonographer able to offer medical or diagnostic advice. The provider checked that women understood the terms and conditions and scan limitations, before they performed any pregnancy ultrasound souvenir scans.

All women were given a written consent form prior to their examination. The consent form provided

information including but not limited to; details on 4D scanning, information around wellbeing checks, what to expect during the scan and hydration advice to help ensure good image quality.

We reviewed 35 consent records and saw that informed consent had been sought and documented in all cases.

Information relating to the consent form was available on the website for the service, so women were able to read through it prior to their clinic appointment. The consent form informed women that the clinic did not provide obstetric care and the ultrasound scan was for personal, non-medical reasons. The form was clear that scans did not replace any NHS scan appointments.

Consent forms were stored in a secure lockable drawer.

The service did not have a mental capacity act policy and there was no service specific training on mental capacity. The registered manager had not received mental capacity training.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

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

Feedback could be given either on a paper form, copies of which were available in the waiting area, or online. Most of the feedback was given online. We reviewed online feedback and saw that all recent reviews were positive and described the staff as kind, very helpful, nice and caring.

The service carried out their own feedback survey and received consistently positive praise. A review of the feedback showed patients were positive about their experience at the service and indicated that patients had returned to the service for further scans at later stages of their pregnancy.

We spoke with one woman who described staff as informative and caring, polite and that they felt well informed about the scanning process.

A partner of a woman we spoke with described staff as 'kind' and that they had received enough information about the appointment/scanning process.

The privacy and dignity of women was respected; all scanning took place in a private room. In addition, the waiting area had music playing to ensure conversations could not be overheard. All sensitive discussions took place in the private consultation/scanning room.

Emotional support

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

The service openly welcomed additional people to accompany the woman for their scan. This enabled relatives and loved ones to share in the excitement of seeing their baby on the screen and provide support to the woman emotionally, if required.

The service provided means of contact for women who had any queries relating to their scan or general scanning processes. Details were provided at the initial point of contact or through the service's public website and social media platforms.

The service did not offer counselling services. All women who had identified anomalies with scan results were advised to speak to their local NHS trust early pregnancy unit or maternity service for further guidance and reassurance.

Understanding and involvement of patients and those close to them

Staff involved women and families to understand their condition and make decisions about their care and treatment.

Women and their partners were fully involved with their care and given the opportunity to ask questions throughout the scan.

The registered manager monitored service user feedback on their social media page and was keen to follow up on

Diagnostic imaging

feedback which was not positive to gain an understanding of the woman's experience. However, we saw no negative feedback in the recent online reviews that we saw.

The registered manager explained that a lot of women were introduced to the service by either friends, family or social media platforms.

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

Service delivery to meet the needs of local people

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

The service offered a range of ultrasound scanning packages and non-invasive prenatal testing to women from seven weeks gestation (seven weeks of pregnancy).

The premises and facilities were appropriate for the delivery of service and were open seven days a week, including evening appointments.

The service was located within a town centre and therefore offered a choice of access by public transport and car parking nearby.

If a woman and her partner wanted to share the gender of the baby with their family and friends, confetti cannons in either pink or blue were available, so that the gender of the baby could be revealed.

Meeting people's individual needs

The service mostly took account of patients' individual needs, however there was no access to translation services for women whose first language was not English.

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

The service clearly advertised scanning packages and non-invasive prenatal testing costs on its public website. In addition, the registered manager was available to discuss various packages and costs during telephone bookings.

The service offered flexibility in appointments, providing both weekend and evening appointments. Where possible, short notice appointments were available. The service recognised that if a woman was worried about their pregnancy, they could gain reassurance quickly.

The service did have access to a British sign language translator but no other translation services. On inspection the registered manager said they would translate through a family member on behalf of a relative whose first language was not English. This is not considered best practise.

There was no chaperone policy or chaperone available, as the registered manager ran the service on their own. However, the manager told us that women were usually accompanied by their partner, a family member of a friend.

The premises were all located on ground floor level. There was appropriate access and disabled toilet facilities available.

Access and flow

People could access the service when they needed it. Due to the nature of service provided, there were no national recommended waiting times.

Women were offered a variety of appointment times, providing flexibility to those who required an appointment outside of normal working hours and at weekends. Bookings were taken either through the website or over the telephone.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously and investigated them.

The service had a complaints policy in place which had been reviewed in July 2017 (prior to service opening). This provided guidance to staff on processes to be followed in the event of a woman wishing to make a complaint.

Requires improvement

Diagnostic imaging

The service had received two complaints from since opening. We reviewed complaints and saw that the service had responded to complaints in a timely manner and made changes to practice as a result of complaints.

Are diagnostic imaging services well-led?

Requires improvement

We have not previously inspected this service. We rated well-led as **requires improvement.**

Leadership

Leaders had some skills and abilities to run the service. They had some understanding and managed the priorities and issues the service faced. They were visible and approachable in the service for patients.

The registered manager was also the company director. The registered manager had been in post since service opening in 2017 and took responsibility for all aspects of the service, including governance, health and safety and quality.

The registered manager was the sole member of staff and was welcoming, friendly and helpful. They cared about the service they provided and tried to get the best possible images and make the experience as happy and positive as possible for the women and their families.

The registered manager understood financial challenges to the service did not identify lone working as a potential risk and therefore was unable to mitigate against this.

Vision and strategy

The service had a vision for what it wanted to achieve based on core values. The vision focused on sustainability of services providing excellent and responsive customer care however there was no formal strategy to achieve this.

The registered manager was passionate about providing a positive and happy scanning experience at the service.

The registered manager indicated that there was no plan to employ more staff as they enjoyed ownership of the workload.

Culture

Staff were focussed on the needs of patients. The service had an open culture where patients, their families could raise concerns without fear.

The registered manager promoted a positive culture and most of the feedback indicated that the service supported women and their families.

The registered manager understood duty of candour. The service had not had any incidents where this had needed to be applied.

Governance

There were some systems and processes in place to maintain the overall governance of the service.

The service had a quality policy in place which was last updated in May 2018, that stated there were systems and procedures in place to support their aim of total customer satisfaction and continuous improvement. The following was described in the policy as ways of supporting quality within the business:

- Regular gathering and monitoring of customer feedback
- A customer complaints procedure
- Selection and performance monitoring of suppliers against set criteria
- Training and development for our employees
- Regular audit of our internal processes however this was not always completed as some policies had not been reviewed.
- Measurable quality objectives which reflect our business aims
- Management reviews of audit results, customer feedback and complaints
- Our internal procedures are reviewed regularly and are held in a quality manual which is made available to all employees. However not all procedures had been reviewed and updated at the time of our inspection. For example, the safeguarding policy had not been updated to reflect the up to date guidance.
- Though the managing director has ultimate responsibility for quality all employees have a responsibility within their own areas of work so helping to ensure that quality is embedded within the whole of the company.

While mandatory training had been completed, we were not assured the provider had identified areas for continued professional development.

Requires improvement

Diagnostic imaging

There were pathways in place for staff to follow in the event of unusual findings, and staff were aware of when to advise women to seek further clinical review. However, there were no formal referral protocols in place for women with suspected concerns to NHS services, and for the booking of appointments.

Following the inspection, the provider informed us that steps would be taken to address the concerns raised during the inspection.

Managing risks, issues and performance

The service had minimal systems in place to identify risk, plan to eliminate or reduce them, and cope with the unexpected.

There was a lack of oversight and governance in relation to the identification and management of risks the service may face. There was no risk register in place.

The registered manager always worked alone but did not have a lone worker or chaperone policy, which would have been a key guideline to manage the associated risk. The service also had a grievance procedure and staff sickness procedure which were not adapted to suit the registered manager being the sole employee.

The service had no formal translation service in place where English was not a first language. This could have posed a risk to expectant mothers if anomaly findings were not communicated and understood properly.

Managing information

The service collected reliable data and analysed it. Data was available in easily accessible formats, to understand performance, make decisions. The information systems were integrated and secure.

The provider told us they transferred all scan images onto a CD monthly to release storage space on the scanner. They then deleted the scan images from the ultrasound machine. The archived CD's were stored securely.

Written consent forms were stored securely in locked drawers.

Non-invasive prenatal testing results were sent to the registered manager (from a third-party service) using encryption codes to ensure confidentiality.

The service had a public website in place to provide information for women on various scan packages and examinations offered.

Engagement

The service openly engaged with patients, and the public to manage services.

The service welcomed women's and visitor feedback through a variety of methods. There were feedback forms in reception and through social media enabled women to leave reviews of their experiences at the service.

The service sought feedback through a variety of methods including social media platforms and feedback through the service's website.

Learning, continuous improvement and innovation

The service had some commitment to learning and improving services.

The service used customer feedback to improve the service. The registered manager reviewed complaints and we saw evidence of how change was made due to customer feedback

We did not see evidence of continued staff development taking place within the service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure systems and processes to maintain effective oversight of risk and monitor quality of the service are fully implemented, embedded and effective.
- The provider must ensure they have regular, professional updates to ensure that they retain their competency.

Action the provider SHOULD take to improve

- The provider should arrange for a proportion of scans are peer reviewed to assure the quality of image.
- The service should ensure that there are formal referral protocols and processes in place to refer women to the local NHS trust or their GP if the scanning procedure indicates unexpected findings.
- The provider should consider having systems and processes in place to provide support and translation services to women whose first language is not English.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing