Brayford Studio Limited

Brayford Studio Limited

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	**Inadequate**
Are services effective?	**Inspected but not rated**
Are services caring?	**Insufficient evidence to rate**
Are services responsive to people's needs?	**Requires Improvement**
Are services well-led?	**Inadequate**

Summary of findings

Overall summary

We rated the service as inadequate because:

- Safe care was not provided at all times. The service did not consistently assess risks to patients and information to support care and treatment was not always available or recorded. The service did not have accurate and complete care records and patients' paper records were not stored securely. There was no policy for the destruction of records and the manager was unable to describe how this would be done within legal guidelines. There was no effective comprehensive programme of equipment and premises maintenance and checks to ensure safety. Not all training modules including safeguarding were up to date. The service did not control infection risk well, equipment cleaning was not recorded, and cleaning products were not fit for purpose. Some single use items of equipment had expired.
- The effectiveness of the service was not monitored. There was no clear inclusion criterion for scans and the process for referring patients to other services was not always followed. Consent forms were not always properly completed with the requested information and there was a lack of evidence available to show the manager had followed this up. Not all consent forms had been signed.
- The manager did not demonstrate clearly they ran the service safely and with good governance. The manager described a vision for the service but not a clear strategy. The service did not operate effective governance processes. There was insufficient evidence of assessment of the quality and safety and effective monitoring of the service. The service lacked processes to identify and manage risk. The service did not seek feedback from patients and there was limited continuous improvement and learning activities.

Summary of findings

Our judgements about each of the main services

Service	Rating		Summary of each main service
Diagnostic and screening services	Inadequate		• We rated this service as inadequate. See main summary above.

Summary of findings

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Summary of this inspection

Background to Brayford Studio Limited

Brayford Studio Limited is an independent ultrasound service based in Lincoln. The service offers a range of obstetric and gynaecology ultrasound scans providing both medical and diagnostic scans, 4D bonding and pregnancy reassurance scans. People generally self-refer to this service. Brayford Studio Limited has a registered manager who is also the owner and the only sonographer, they are also a GMC registered gynaecologist. At the time of our inspection there were no other staff employed at the service.

The service has been registered with CQC to carry out the regulated activity of Diagnostic and Screening procedures since 6 April 2022.

How we carried out this inspection

We carried out an inspection of Brayford Studios Limited on 27 July 2023 using our comprehensive methodology. The service had not previously been inspected.

Our inspection was announced with short notice. We gave the registered manager notice of the inspection date to ensure their availability on the day.

During the inspection we interviewed the registered manager/sonographer (who was the only employee of the service), reviewed scan and consent records, policies and procedures, and training records. We spoke with 2 patients by telephone in the week following the inspection. We reviewed 14 scan and consent records. We did not observe scanning procedures as there were no scans booked in at the time of our inspection.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure service user records are stored securely.(Regulation 17, good governance).
- The service must ensure records are complete, legible, dated, signed and must include clearly identifiable information of the service user such as full name and date of birth. (Regulation 17, good governance).
- The service must ensure, where patients are required to provide relevant information on consent forms about medical information, in order to identify risks to the individual patient, that this is complete. (Regulation 12, safe care and treatment).
- The service must ensure there is a clear policy for the retention and destruction of records. (Regulation 17, good governance).

- The service must ensure maintenance of equipment is carried out in line with the manufacturer's recommendations, ensuring that scanning machines are fit for purpose. (Regulation 15, premises and equipment).
- The service must ensure environmental safety and fire safety maintenance are carried out in accordance with the recommendations of risk assessments and that risk assessments are carried out annually. (Regulation 15, premises and equipment).
- The service must ensure disposable equipment is in date and fit for use. (Regulation 12, safe care and treatment).
- The service must ensure that control of substances hazardous to health (COSHH) data sheets and risk assessments are held on the premises. (Regulation 15, premises and equipment).
- The service must ensure that environmental cleaning records and audits are completed and that surfaces are free from dust. (Regulation 12, safe care and treatment).
- The service must ensure there is a clear protocol and record of decontamination of the ultrasound transducer and equipment used for decontamination is fit for purpose. Transducer sheaths must be in line with manufacturer recommendations and within the expiry date to minimise the risk of infection. (Regulation 12, safe care and treatment).
- The service must ensure sharps bins for the storage of used needles and sharp instruments are disposed of in line with National Institute for Health and Care Excellence best practice guidelines (2012) Healthcare-associated infections: prevention and control in primary and community care. (Regulation 12, safe care and treatment).
- The provider must ensure there is information on how to complain shared with people who use the service and visible within the service. (Regulation 16, receiving and acting on complaints).
- The registered person must ensure the service has full medical indemnity insurance. (Regulation 17, good governance).
- The service must ensure training updates are completed. (Regulation 17, good governance).
- The service must ensure there are regular quality assurance and improvement audits and reviews of the quality of treatment and care provided by the service in line with the service's clinical governance policy. (Regulation 18, staffing).
- The service must ensure it actively seeks service user feedback to evaluate and improve the quality of the service provided. (Regulation 17, good governance).
- The provider must ensure any staff employed by the service have full checks and reviews in line with employment law and statutory requirements, and a record of their employment is maintained. (Regulation 19, fit and proper persons employed).

Action the service SHOULD take to improve:

- The service should ensure clear and up-to date information on the types of scans provided is available on the service website (Regulation 17).

We are placing this service in special measures. Services placed in special measures will be followed up to review improvements with the provider. If insufficient improvements have been made such that there remains a rating of inadequate overall or for any key question, we will take action in line with our enforcement procedures to begin the process of preventing the provider of operating the service. This will lead to cancelling their registration or to varying the terms of their registration if they do not improve. The service will be kept under review and, if needed, could be escalated to urgent enforcement action. Where necessary another inspection will be conducted, and if there is not enough improvement, we will move to close the service.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inadequate	Inspected but not rated	Insufficient evidence to rate	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Insufficient evidence to rate	Requires Improvement	Inadequate	Inadequate

Inadequate

Diagnostic and screening services

Safe	Inadequate
Effective	Inspected but not rated
Caring	Insufficient evidence to rate
Responsive	Requires Improvement
Well-led	Inadequate

Is the service safe?

Inadequate

We rated safe as inadequate.

Mandatory training

The service had access to mandatory training in key skills but not all training was up to date.

The registered manager was the only sonographer working at the service. They had a record of mandatory training, however, some of their mandatory training had expired at the time of our inspection. For example, we saw evidence of up to date basic life support, fire safety and moving and handling. However, other training modules had expired. For example, safeguarding children and vulnerable adults, infection prevention and control, information governance and health and safety.

Safeguarding

The manager understood how to protect patients from abuse. They had training on how to recognise and report abuse but not all training updates had been completed.

The manager received training specific for their role on how to recognise and report abuse. The sonographer had completed level 3 child and adult safeguarding, however, the training had expired in 2022 and an update had yet to be completed.

The manager knew how to identify adults and children at risk of, or suffering, significant harm. They had a basic understanding of child sexual exploitation, however, did not have clear processes and protocols in place for checking the age and identity of patients attending for a scan. The manager told us they would ask for evidence of age if they felt the patient may not be 18 or older.

The manager knew how to make a safeguarding referral and who to inform if they had concerns. There was a safeguarding policy with contact details of local safeguarding teams.

The service had a chaperone policy that stated a chaperone would be available for intimate examinations or where a patient requested one. The manager told us they did not have a current chaperone and that because of this they encouraged patients to bring someone with them for their scan. However, this did not provide the 'impartial observer' as detailed in the policy.

Cleanliness, infection control and hygiene

The service did not control infection risk well. The manager did not use equipment and control measures to protect patients, themselves and others from infection.

Clinical areas were mostly clean and had suitable furnishings which were clean and well-maintained. However, we saw items on a lower shelf such as a sharps bin and a box of gloves that had visible dust.

Cleaning records were not up-to-date and did not demonstrate that all areas were cleaned regularly. There was a cleaning log on the wall in the clinic for environmental cleaning. This had been signed twice in the preceding week before our visit. The manager did not have historic cleaning logs available for us to view. Therefore, they could not evidence that regular cleaning was carried out.

The manager followed some infection control principles, including the use of personal protective equipment (PPE). We saw that gloves and aprons were available on the premises. However, a box of gloves available for use had expired in December 2022.

The manager told us they cleaned equipment after patient contact, which involved decontamination of the ultrasound transducer with alcohol wipes. However, the alcohol wipes that were available on the premises were dried out and not fit for purpose. We were shown transducer sheaths that were used for transvaginal ultrasound; however, these had expired in 2020 and 2022. There were no records of transducer decontamination maintained.

The service did not have up to date safety data sheets or risk assessments for the use and storage of cleaning materials in line with Control of Substances Hazardous to Health (COSHH) regulations.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. The service did not manage clinical waste in line with guidance.

The design and maintenance of the environment did not follow national guidance or the service's policy. Actions relating to a fire risk assessment had not been carried out with the appropriate regularity. For example, mitigating action against fire included a 5 yearly fixed wiring check that should be carried out, with a certificate of safety provided. There was no certificate relating to the fixed wiring and the manager was unable to provide evidence that this had been carried out. The fire safety risk assessment also stated that annual portable appliance testing was to be carried out, however, records showed that this had not be done since 2020.

The manager told us they carried out weekly tests of the fire alarm system, however, they were unable to provide records to demonstrate this. We saw evidence of the 2023 servicing of the fire alarm panel, lighting and extinguishers. However, there were gaps in historical servicing records and the manager told us that 6 to 12 monthly servicing in line with the service policy and risk assessment had not always been carried out due to the limited activity within the service since its registration. However, we saw records of scanning activity that demonstrated the service was operational during a time when fire safety equipment had not been maintained.

Inadequate

Diagnostic and screening services

The manager carried out daily safety checks of specialist equipment. However, annual calibration and maintenance was not always carried out. We saw evidence that the ultrasound machine in use had been calibrated in June 2023, however, there was no annual record of maintenance prior to this. The manager referred to the machine as 'new', however, records showed that it had been leased by the service since 2018. We saw that the service had been using the machine to carry out scans prior to when it was serviced in June 2023. A second ultrasound machine was stored in the waiting area. The maintenance sticker showed this was last maintained in 2019, however, the manager told us this was a spare machine and had not been used since they had leased the newer machine.

The service disposed of clinical waste safely. There was a locked clinical waste bin secured outside at the front of the building. However, a sharps bin for the use of disposing of needles used to carry out non-invasive prenatal testing (NIPT) had been assembled in 2020 and had not been discarded after 3 months, in line with national infection prevention and control guidance.

Assessing and responding to patient risk

The service did not complete risk assessments for each woman in order to remove or minimise risks and information that may inform a risk assessment process was not always recorded. The service's referral policy was not consistently followed.

The manager did not complete risk assessments for each patient on arrival. A consent form was completed by the patient on arrival and included questions about any issues with their pregnancy such as vaginal bleeding or pain. However, this part of the form was not always completed and there was no record the service followed this up. In addition, while there was a space on the consent form for information such as the date of the last menstrual period, we saw examples where this was not completed.

There was a referral policy that stated if there were any potential abnormalities identified on the scan then the woman would be referred to their local hospital for a second opinion. If there was a concern for the health of the baby or the woman, they would be advised to seek emergency care at their local hospital. However, we saw evidence where the manager did not follow the policy when they identified a possible abnormality. Instead, they invited the woman for a repeat scan in 2 – 3 weeks. The manager was unable to give us examples of when they had referred a patient to their local hospital.

The manager had completed basic life support training and told us they would call an emergency ambulance in the event of a medical emergency.

Staffing

The service was provided by the registered manager. No other staff were employed by the service at the time of the inspection.

The registered manager was the sole sonographer for the service. We were told they had previously employed a nurse who acted as the chaperone and undertook non-invasive prenatal testing (NIPT) blood tests. The manager told us they no longer provided a chaperone service, however, they had provided one NIPT service during the last year. They told us the previously employed nurse had carried that out, however, they were not employed at the time and the manager did not have a staff file for them.

The lack of a chaperone meant the manager was unable to provide an 'impartial observer' in the event of the provision of an intimate examination or when a woman requested one, as stated in their chaperone policy.

Inadequate

Diagnostic and screening services

The manager told us they had only undertaken one NIPT blood test in the current year and that this was carried out by the previously employed chaperone / nurse. However, there were no records of this and no service level agreement or contract in place for the provision of this part of the service.

Records

The service did not keep detailed records of patients' care and diagnostic procedures. Records were unclear and not stored securely.

Patient notes were not comprehensive and were not stored securely. The only record kept by the service, in addition to the image of the scan stored within the ultrasound machine, was of the consent form. This was completed on arrival at the clinic by the woman receiving the scan. There were no dedicated notes kept by the service and the margins of the consent form were sometimes used to record findings during the scan. We found the notes added to the margins of consent forms were inconsistent, often illegible and did not provide a comprehensive record of care provided or advice given.

The consent forms were completed by the patient on arrival at the clinic and we saw that these were not always completed comprehensively. There no records provided by the sonographer to indicate if they had gone through the form with the patient. For example, we saw missing information such as the date of the last menstrual period and information about complications such as vaginal bleeding or pain and other issues such as changes in the baby's movements and history of pregnancy complications.

Records were not stored securely. Records were stored loosely in the top drawer of a filing cabinet. These were not held in a folder or stored in chronological order or alphabetised. The records were disorganised, and we were unable to match a consent form to every entry in the diary. The filing cabinet had a key attached to the side of the drawer using a cable tie and the manager had to cut the cable tie to lock the cabinet, indicating that the key was not regularly used and there was a risk that records could be accessed by someone without authority.

The manager told us they kept additional records on a computer at home, for example, when they wrote letters for patients patient to pass onto their GP or NHS clinician. They also told us they backed up electronic records using memory sticks; however, they did not have these on site at the clinic and were unable to confirm if they were suitably encrypted and password protected.

There was no policy for the destruction of records. The manager could not clearly articulate how records would be destroyed or who would do it.

There were no monitoring processes for the quality or governance of records.

Medicines

The service did not store or administer medicines.

Incidents

The service had no recorded safety incidents. There was a policy that included an incident reporting form and reference to the duty of candour. The manager ensured actions from safety alerts were implemented and monitored.

The service had a significant incident and event policy, including a reporting form that contained prompts to identify causes of issues and learning from them. There had been no events recorded within the service.

Diagnostic and screening services

Inadequate

The manager understood the duty of candour (the legal requirement to apologise for harm caused in the event of a serious notifiable incident). The duty of candour is a general duty to be open and transparent with people receiving care in the event of a notifiable safety incident.

The manager received safety alerts from the Medicines and Healthcare products Regulatory Agency (MHRA) and reviewed these to identify if they were relevant to the service. The manager told us those received had not been relevant to the service provided.

Is the service effective?

Inspected but not rated

Evidence-based care and treatment

The service had policies and procedures based on national guidance and evidence-based practice. However, policies were not always followed.

The service had a suite of up to date policies. However, these were not always followed. For example, in relation to chaperone provision and clinical governance. The clinical governance policy described regular clinical audits being carried out, however, on the day of inspection clinical audits were not available and the manager told us they had not undertaken any.

The clinical governance policy described evidence based medical treatment, however, there was no reference to how this was applied in practice and no details of specific guidance followed.

The manager was a member of the British Medical Ultrasound Society (BMUS). We saw evidence they had attended an update course on fetal medicine advances in 2022. They had an understanding of the ALARA (as low as reasonably possible) principle, including having the equipment set to the lowest possible settings and using a maximum amount of time for the ultrasound scan.

Patient outcomes

The service did not monitor the effectiveness of care.

The service did not have a process for reviewing clinical outcomes. Although the clinical governance policy stated audits should be carried out, these were not being completed. Therefore, there was no assurance that the outcomes for patients were positive, consistent and met expectations, such as national standards.

The consent form was completed by patients patient on arrival at the clinic. However, information provided was not always complete. For example, we viewed forms that did not always include the patient's full name or details about past medical history or problems relating to the current pregnancy. There was no evidence to demonstrate the manager reviewed the forms or asked for further details or clarification where the forms did not include relevant information. There was no evidence to show the manager followed up on the information to ensure a complete assessment was undertaken prior to the scan. There was no evidence of quality review or improvement in relation to outcomes, and information was not used to improve care and treatment. There was no process for benchmarking the service or the quality of the scans carried out. Peer review audits were not carried out. The manager did not monitor the re-scan rate.

Inadequate

Diagnostic and screening services

Competent staff

The service did not make sure staff were competent for their roles.

There was one sonographer working at the service who was the registered manager. They completed relevant training in relation to their professional registration and received an annual external appraisal from their NHS responsible officer in relation to their GMC registration. However, there was no process of peer review of their scanning competency.

The manager told us no other staff were working at the service at the time of our inspection. However, they also described how they had used a previously employed staff member to undertake a single non-invasive prenatal test (NIPT) that had been carried out in the current year. However, they did not hold any current information about the clinician and had no service level agreement or appropriate checks in place. Although the manager knew the individual and told us they were a current registered midwife, the lack of relevant checks meant the manager could not provide evidence they were experienced, qualified and had the right skills and knowledge to meet the needs of patients.

Multidisciplinary working

The manager had links to external professionals to provide appropriate care for patients. However, we saw that referrals were not always made appropriately.

The service had a referral policy which stated that patients were to be referred to their local hospital in the event of abnormalities or where a second opinion was required. The manager told us they had not referred any patients to their local hospital in the last year. We viewed the record of one woman where an abnormality was seen on the scan where no referral was made.

The manage did not routinely communicate with patients' GPs. They told us that if a woman wished for results of the scan to be communicated with their GP, or that in the event of this being clinically appropriate then they would communicate by letter. The letter would be given to the woman to share with her GP. They told us of one example of this, where a woman had attended for a gynaecological scan and requested a summary to share with their GP.

As the manager worked alone at the service, regular multidisciplinary meetings to discuss patients and improve their care were not held.

Services were available to support timely patient care.

The manager could request support from doctors and other disciplines, including diagnostic tests. Non-invasive prenatal tests were carried out when requested by the woman to provide screening for the risk of chromosomal abnormalities in the pregnancy. The turnaround time for the test results was approximately 1 – 2 weeks.

Health promotion

The manager gave patients practical support and advice to lead healthier lives.

The manager told us they gave patients verbal advice and information to support healthier lives. The service had limited written information promoting healthy lifestyles and support in patient areas.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The service did not follow national guidance to gain patients' consent. The manager knew how to assess patients who lacked capacity to make their own decisions, however, training updates were not in date.

Diagnostic and screening services

The manager understood how and when to assess whether a patient had the capacity to make decisions about their care. The registered manager / sonographer had completed training in the Mental Capacity Act, however, this had expired in April 2023.

The service did not always gain consent from patients in line with legislation and guidance. The manage told us they informed patients of the scan procedure on arrival at the clinic. They had consent forms that doubled as patient information forms. However, some of the information on the forms was incomplete where the patient filled in the form and answered specific questions. There was no evidence the incomplete answers to questions were followed up by the manager. We saw patients were asked to sign the form prior to the scan. However, we viewed 2 early pregnancy scan forms that were unsigned. This was because the form did not request a signature and was referred to as an ultrasound booking form, however, the registered manager referred to it as a consent form.

There was no audit or monitoring processes in place for reviewing how consent was obtained and recorded.

Is the service caring?

Compassionate care

There was no evidence to suggest patients were not treated with compassion and kindness and their privacy and dignity were respected.

The manager was friendly and welcoming, and we received some positive feedback about their caring approach from a patient. However, we did not observe them interacting with patients as there were no scans booked in at the time of our inspection. They described to us occasions when they had provided additional support to patients, including when they were distressed or needed additional time during the scan.

The manager said they understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs. They were able to describe how they interacted with patients and their families, including when there were concerns and patients needed extra time and reassurance.

Emotional support

There was no evidence to suggest patients were not provided with emotional support. .

The manager said they gave patients and those close to them help, emotional support and advice when they needed it. They provided advice and support, including signposting to other services where necessary.

The manager said they understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. The manager was able to describe how they supported patients who were nervous or upset. This included allowing additional time for discussing their concerns.

Understanding and involvement of patients and those close to them

There was no evidence to suggest the manager did not support patients and families to understand their condition and make decisions about their care and treatment. However, the service did not actively seek feedback.

Inadequate

Diagnostic and screening services

The manager told us they made sure patients and those close to them understood their care and procedures. Information about specific scans was included on the consent/booking form. The manager told us any risks or concerns were discussed with patients prior to the scan, however, records relating to this were unclear and there were no scans on the day of our inspection for us to observe. We received feedback from one woman who told us they did not feel they had received adequate information and described the information they had received as 'misinformation'. They told us they would have sought a second opinion if they had been given more accurate information.

Patients and their families could give feedback on the service and their treatment, however, there were no formal feedback processes in place. The service did not actively collect feedback from patients about the service. We spoke with 2 patients who used the service and found feedback was mixed. We heard an example of one woman who described the approach of the manager as caring, including how they interacted with their child and involved them in the scanning process. Another woman told us they had previously had a positive experience of the service, but their most recent experience was difficult, and they would not use the service again. We viewed one online review of the service in the last 12 months that was positive about the experience and the support offered during a time of concern.

Is the service responsive?

Requires Improvement

We rated responsive as requires improvement.

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 manager planned and organised services so they met the changing needs of the local population. The service offered scanning appointments at flexible times to meet the needs of patients and their families, including evening and weekend appointments when required. The entrance to the service was at ground floor level and could accommodate a wheelchair if necessary.

The manager told us they had not had requests for scans from patients with additional needs such as physical disabilities or learning disabilities. However, they told us they would allow extra time where necessary should the need arise.

The service provided a wide range of scans including early pregnancy, gender scans, reassurance scans, and 4D baby scans.

Facilities and premises were appropriate for the services being delivered. The service had a waiting room with comfortable seating, a toilet and children's toys were available. The scanning room had an adjustable examination couch and hand washing facilities.

Meeting people's individual needs

The service did not always take account of patients' individual needs and preferences. The manager made some adjustments to help patients access services, however there were limited arrangements for meeting people's communication needs in the event of a disability or sensory loss.

Inadequate

Diagnostic and screening services

The service took account of patients' individual needs. Enough time was allocated for patients to ask questions. The woman's partner and other members of the family including their other children were encouraged to join in the experience. Provision was made for them to observe the baby scan in the ultrasound room.

There was no specific policy on meeting the information and communication needs of patients with a disability or sensory loss. There was no hearing loop and no formal provision for accessing translation services. The manager told us they would use online translation apps should the need arise.

The service had some information leaflets available, but these were not in different languages.

Access and flow

People could access the service when they needed it.

The service made sure patients could be seen when needed. We were told appointments were available 7 days a week and patients were booked in at a time suitable to them. Appointments could be booked through an online booking form from the service's website or by telephone. We saw an online review of the service in the last 12 months that detailed how the service had responded to a request for a reassurance scan on the same day.

The manager kept the number of appointments cancelled by them to a minimum. In the event of a cancellation this was rescheduled as soon as possible.

Patients received a verbal explanation of the scan along with keepsake images at the time of their appointments. The manager told us they wrote reports for patients to share with their GP or hospital services where there were abnormalities of information was requested by the woman. The manager told us in this situation they would email a letter to the woman within a few days of the scan, or in the case of them requiring more urgent information because of an abnormality this was provided for them to take with them. However, we did not see evidence of this as the manage told us they kept letters on a computer at home rather than in the clinic.

Learning from complaints and concerns

The service had a process for treating concerns and complaints seriously and investigation internally. However, there were no examples of patient feedback or learning as a result. There had been no complaints in the last 12 months.

The service had a policy on dealing with complaints. This included acknowledging the complaint within 48 hours and completing an investigation and response within 21 days. The manager told us there had been no complaints about the service in the previous 12 months.

There was no information visible within the clinic about how patients, relatives and carers could complain or raise concerns and no information about this on the service website.

The manager was unable to give examples of how patient feedback was used to improve daily practice.

Inadequate

Diagnostic and screening services

Is the service well-led?

Inadequate

We rated well led as inadequate.

Leadership

The manager did not clearly demonstrate they ran the service safely with good governance.

The manager did not demonstrate they recognised the risks associated with running the service. These included risks associated with being unable to demonstrate indemnity cover, insufficient equipment and premises maintenance, a lack of governance and feedback processes, and limited processes for monitoring performance.

There was a lack of action in relation to the challenges of quality and sustainability. The manager told us they were conducting limited scans which limited and reduced their focus on good governance and risk management.

Vision and Strategy

The service had a vision for what it wanted to achieve but no strategy to turn it into action.

The clinical governance policy stated there was a 5 year strategic plan. However, there was no evidence this had been produced. The manager told us they had a vision to develop the service and increase activity. However, they were unclear about how they would achieve this.

Culture

The service had an open culture where patients and their families could raise concerns without fear.

There were no staff working within the service other than the registered manager. The manager was friendly and approachable. There was a duty of candour policy and the manager recognised the need for open and honest information to be shared with patients and their families.

Governance

The manager did not operate effective governance processes. There was insufficient evidence of assessment of the quality and safety and effective monitoring of the service.

There was not an effective governance system in place for the service. Not all policies and procedures were being followed or adhered to. There was no feedback from patients about the service provided. The clinical records were not accurate or complete and not all were legible. There was no routine audit to be able to assess or monitor the service for quality and safety.

The manager was unable to provide evidence of medical indemnity insurance.

The establishment of the service and what was offered was not clear. The service did not have a clear inclusion or exclusion criteria for access to the service. For example, the manager said they did not currently carry out diagnostic or gynaecological scans as detailed on the service's website. However, we saw records indicating that gynaecological scans were carried out by the service and the service's statement of purpose stated gynaecological scans were carried out.

Inadequate

Diagnostic and screening services

Management of risk, issues and performance

The manager did not use systems to manage performance effectively. The service lacked processes to identify and manage risk on a continuous basis and actions to reduce the impact of risk were insufficient.

There were identifiable risks relating to the management of the premises and equipment. Some risk assessments had been carried out, however, actions were not consistently completed.

The service did not have a process to ensure the scans were being conducted effectively. There was no process to audit any rescans for patients. There was evidence the manager had not followed their referral process to an early pregnancy unit when a possible abnormality was seen on a scan.

Information Management

The service did not collect reliable data or analyse it. Data was not collected in accessible formats, to understand performance, make decisions and improvements. Not all information was secure. Information provided on the service's website was inaccurate.

The service did not have systems to collect data and use this to make decisions and improvements. Information about scans and patients using the service was not reliable or maintained in line with information governance guidelines. For example, information relating to scans provided was stored within the ultrasound machine including images. However, other information about patients accessing the service was in paper form as part of the consent process. This information was disordered and incomplete in some cases. It was not always possible to match consent/booking forms to scans within the ultrasound machine or booking information in the paper diary.

The service did not use information to understand performance. The clinical governance policy stated information from patients and clinical audit was used as a means of measuring performance. However, audits were not undertaken, and feedback was not actively sought.

The manager told us they stored correspondence about some patients on their computer at home. This was where the manager wrote summaries and correspondence for the service user to give to their GP, with the patient's consent if required. The manager was unable to provide assurance that their home computer was secure, password protected, encrypted or suitably backed up.

Information stored within the ultrasound machine included records that had been there for several years. The manager told us they had a policy to destroy records after 3 years. However, we saw images on the ultrasound machine that had been there beyond that time.

The service had information on its website about the cost of scans. In addition, cost details were also on the consent / booking forms patients completed on arrival at the clinic. The service also had details of the types of scans carried out on the website. However, this had not been updated and did not correspond with what the manager told us in terms of the scans they conducted. For example, they told us they conducted only pregnancy scans. However, there was information on the website about diagnostic scans as part of a gynaecological consultation. We also saw information about trans labial scans, in relation to stress incontinence or vaginal prolapse. The website also included inaccurate information about staff working at the service as there was reference to a midwifery manager, stating they were responsible for the daily management of the service. There was also reference to a team of clinical sonographers working at the service. However, this was not the case, and the registered manager was the only sonographer and member of staff.

Inadequate

Diagnostic and screening services

Engagement

The manager did not actively engage with patients to get their feedback.

The manager did not actively seek feedback from patients about the service they received. Their clinical governance policy described a service user group with an aim of using engagement with this group to improve the running of the service. However, the group was not in operation at the time of the inspection.

The manager told us they did not ask patients for feedback, but they had online and social media feedback they monitored. There was no formal process of analysis of any online or social media feedback, and we only found one feedback review online from the last year. The website contained a section on testimonials, however, these were either undated or dating back more than a decade.

Learning, continuous improvement and innovation

The manager was not able to demonstrate commitment to continually learning and improving the service.

There was insufficient evidence from good governance to show any commitment to improve the service. Although the clinical governance policy described quality improvement and some methodologies such as service user involvement and clinical audit, these had not been implemented within the service.

This section is primarily information for the provider

Enforcement actions

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 • The service did not ensure that medical information was completed on consent forms, in order to identify risks to the individual patient. • The service did not ensure that disposable equipment was in date and fit for use. • Environmental and equipment cleaning records were not maintained and there was visible dust in clinical areas. • There was not a clear protocol and record of the decontamination of the ultrasound transducer and cleaning equipment and supplies were not fit for purpose. Transducer sheaths were not in line with manufacturer recommendations and were not within the use by date. • Sharps bins for the storage of used needles and sharp instruments were not disposed of in line with National Institute for Health and Care Excellence best practice guidelines (2012) Healthcare-associated infections: prevention and control in primary and community care.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The provider did not ensure there was relevant medical indemnity insurance in place. • Medical records were not stored securely. • The provider did not ensure medical records were complete, legible, dated and signed. They did not consistently include clearly identifiable information about the service user, such as full name and date of birth.

This section is primarily information for the provider

Enforcement actions

Regulated activity	Regulation
	• There was no policy for the retention and destruction of medical records. • There were no regular quality assurance and improvement audits or reviews of the quality of treatment and care provided by the service in line with the service's clinical governance policy. • The service did not ensure it actively sought service user feedback to evaluate and improve the quality of the service provided

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing • The service did not ensure that regular training updates were completed.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment • The service did not ensure maintenance of equipment was carried out in line with the manufacturer's recommendations, ensuring that scanning machines are fit for purpose. • The service did not ensure environmental safety and fire safety maintenance was carried out in accordance with the recommendations of risk assessments and that risk assessments were carried out annually. • The service did not ensure that control of substances hazardous to health (COSHH) data sheets and risk assessments were held on the premises.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

This section is primarily information for the provider

Enforcement actions

- The service did not ensure any staff employed had full checks and reviews in line with employment law and statutory requirements, and a record of their employment was not maintained.