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	Inspected but not rated
Are services safe?	**Inspected but not rated**
Are services effective?	**Inspected but not rated**
Are services well-led?	**Inspected but not rated**

Summary of findings

Overall summary

Brayford Studio is an independent ultrasound clinic based in Lincoln, providing scanning services to self-funding patients.

We carried out a short notice announced focused inspection in September 2023 to follow up concerns we found at our inspection in July 2023, where we rated the diagnostic and screening core service as inadequate overall. This inspection on 12 December 2023 was a further focused inspection to follow up concerns found at the previous inspections.

We only inspected some of the key questions of safe, effective and well led as this is where the breaches of regulations were found. We did not inspect the safe, effective and well led key questions in full; instead, we focused on the key lines of enquiry where serious concerns had been previously identified to see if improvement had been made.

We did not re-rate the service as we only looked at areas based around the breaches. We inspected the service to determine if the service had made improvements.

We found that:

- Safe care was not provided at all times. The service did not control infection risk well, infection prevention and control audits were not robustly completed and did not identify all risks. Cleaning products were not appropriate for all procedures undertaken and there was visible dust and marks on clinical equipment. The service did not ensure there were effective processes to assess and respond to patient risk. There was limited reflection or evaluation of practice in relation to potential patient safety issues identified on previous inspections. There was limited review or evaluation of potential abnormalities shown on scans and subsequent referral processes to specialist services for follow up. Arrangements to improve the legibility of patient records were unclear and there were limited verification checks of patient information, leading to inconsistencies between paper and electronic records.
- The effectiveness of the service was not monitored. Audits to monitor patient outcomes were not carried out in line with the clinical governance policy. There was no benchmarking or review of the quality of scans. Training and competency checks were limited despite concerns raised at previous inspections about the quality and interpretation of scans.
- The service did not operate effective governance processes. There was insufficient evidence of assessment of quality, safety and monitoring of the performance of the service. The service lacked processes to identify and manage risk. There was limited evidence of continuous improvement and learning activities.

However, we found that:

- Mandatory training had been completed and was up to date.
- Single use ultrasound gel was available and gel decanting was no longer taking place.
- Repairs to the treatment room door had been carried out.
- There were no expired single use items within the clinic.
- Personal Protective Equipment (PPE) previously found discarded in drawers and cupboards had been removed.
- There was a clear policy for the management of records and the destruction of confidential waste.
- Computers and ultrasound equipment were password protected.
- The ultrasound machine was subject to quality assurance testing.

Summary of findings

Following this inspection, we identified that while some improvements had been made, these were insufficient and we issued a notice of decision to the provider where we imposed the following condition on their registration the condition we imposed was as follows;

The Registered Provider must not undertake any form of consultation or screening with any new or existing service users, without the prior written permission of the Care Quality Commission.

In addition, due to the insufficient improvements made in the time since the initial inspection in July 2023 and this inspection in December 2023, we issued a notice of decision to cancel their registration. Cancellation of the providers registration took effect from 26 March 2024.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	**Inspected but not rated**	See summary at the beginning of the report.

Summary of findings

Contents

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. 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.

At our previous inspection we found the following breaches of regulation:

- The service must ensure that infection prevention and control audits are completed in such a way that they identify risks and areas for improvement, 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 service must ensure quality assurance testing 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 checks are embedded within the service. They must ensure that all risks are identified, and action taken to mitigate them. (Regulation 15, premises and equipment).
- 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, scan findings and recommendations. (Regulation 17, good governance).
- The service must ensure there is a clear policy for the retention and destruction of records, including how destruction will be carried out in line with information governance and safety requirements. (Regulation 17, good governance).
- 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 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 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).

How we carried out this inspection

We completed an onsite visit to the service on 12 December 2023. The inspection team consisted of a CQC inspector and a specialist advisor in sonography.

Summary of this inspection

On the day of inspection, there were no services running due to action taken by CQC to suspend the providers registration because of the breaches to regulation.

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 reviewed 2 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 there are effective processes to assess and respond to patient risk. This must include a review of effective referral processes and an evaluation of this to ensure that patient risks are identified and appropriately acted on. (Regulation 12, safe care and treatment).
- The service must ensure that infection prevention and control audits are completed in such a way that they identify risks and areas for improvement, 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. (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 service must ensure environmental safety and fire safety maintenance checks are embedded within the service. They must ensure that all risks are identified, and action taken to mitigate them. (Regulation 15, premises and equipment).
- 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 17, good governance).
- The service must ensure records are complete, legible, dated, signed and must include clearly identifiable information of the service user, scan findings and recommendations. (Regulation 17, good governance).
- The service must ensure there is a clear process to identify and mitigate risks to patients. (Regulation 17, good governance).
- 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 service must ensure there are clear processes for the assessment of sonographer competency, including training updates, competency assessments and reflection on practice. (Regulation 18, staffing).

Summary of this inspection

- The provider must ensure there is a clear process and business plan for the employment of staff within the service. This must include clearly defined roles, 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:

- Ensure there is a clear protocol for the back-up of electronic information.
- Ensure that information on the service website is kept up to date.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated
Overall	Inspected but not rated	Inspected but not rated	Not inspected	Not inspected	Inspected but not rated	Inspected but not rated

Inspected but not rated

Diagnostic and screening services

Safe	Inspected but not rated
Effective	Inspected but not rated
Well-led	Inspected but not rated

Is the service safe?

Inspected but not rated

Cleanliness, infection control and hygiene

The service did not control infection risk well.

At the July 2023 inspection we identified concerns in relation to cleanliness, infection control and hygiene. At the September 2023 inspection we found clinical areas were mostly clean and had suitable furnishings which were clean and well-maintained. However, we saw clutter on the base plate of the ultrasound machine and there was visible dust. At this inspection we found that the clutter had been removed from the ultrasound machine, however, visible dust remained and there were gel marks on the machine.

At the September 2023 inspection we found there were no records of cleaning of the ultrasound transducer and the manager did not have a process in place to record this. Therefore, they could not evidence that regular cleaning was carried out. Cleaning wipes were not manufacturer recommended in line with British Medical Ultrasound Society (BMUS) decontamination guidance. Alcohol based wipes were available, however, the manager was unaware of the risks of the use of alcohol in relation to the potential degradation to the ultrasound probes. At this inspection we found that the alcohol-based wipes had been removed and replaced with wipes that were suitable for skin surface probe cleaning. However, these were not suitable for transvaginal probe cleaning and the manager was not aware of this.

At the September 2023 inspection we found items of PPE and paper towels discarded in drawers and a cupboard within the clinic. At the December 2023 inspection there were no discarded paper towels or discarded items of PPE within the clinic.

At the September 2023 inspection an infection prevention and control audit had been carried out the day before our inspection. However, this process failed to identify all infection control risks within the clinic, for example, the clutter and dust seen on the ultrasound machine. At this inspection we reviewed a September 2023 infection prevention and control audit and found it did not identify all the issues present. For example, the audit indicated that the label on the sharps bin had been appropriately filled in, but it had not. In addition, the audit indicated that that equipment was visibly clean, however we found visible dust and gel marks on the ultrasound machine.

At the September 2023 inspection we found that ultrasound gel was decanted from a 5-litre bottle which was in date, into a reusable gel container, which was not dated. This was not in line with a November 2021 MHRA alert about the risk of infection with the use of reusable gel containers. At this inspection we found that only pre-filled disposable containers of ultrasound gel were available, and that the provider had ceased using a larger container for decanting.

Inspected but not rated

Diagnostic and screening services

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 manager told us they carried out weekly tests of the fire alarm system, however, at our July 2023 inspection they were unable to provide records to demonstrate this. At the September 2023 inspection we saw that 1 test of the fire alarm system had been carried out in the week prior to our visit. The manager told us they had received a demonstration on how to test the alarm on this date from a fire safety specialist and had been given the appropriate equipment to carry out weekly testing themselves. However, this process was not yet embedded. At this inspection we saw records demonstrated that weekly testing of the fire alarm system had been carried out. However, a 6 monthly fire alarm service was due by the 19 December 2023, and this had not been booked.

The ultrasound machine in use had been calibrated in June 2023. There were no records of equipment handover forms in place to hand over to the engineer or receive back from the engineer. There was no evidence of routine quality assurance tests done on the machine to monitor the reliability of results and to check for deterioration in performance of the ultrasound scanner.

At this inspection we found that the manager had sought advice from the ultrasound machine contractor and had carried out quality assurance tests of the machine. However, there was no clear protocol for the frequency of quality assurance tests.

At the September 2023 inspection we found not all environmental risks had been mitigated. For example, the door to the scanning room was difficult to open from the inside. The manager told us that previously the door handle had come off. However, they had not taken action to repair the door and had not identified risks relating to potential entrapment within the scanning room. At this inspection we found the door to the scanning room had been repaired and there was no issue with opening and closing it.

At the September 2023 inspection we found PPE discarded in drawers and a cupboard. A sharps bin for the use of disposing of needles used to carry out non-invasive prenatal testing (NIPT) had been assembled but had no date or signature recorded on it which was not in line with national infection prevention and control guidance.

At this inspection there was no discarded PPE in drawers or cupboards. However, the sharps bin still did not have the appropriate record of assembly in line with infection prevention and control guidance.

At this inspection we found that most actions had been taken in relation to the environment and equipment concerns we had raised at our previous inspections. However, there continued to be a lack of proactive management of risks. The manager was unable to demonstrate clear processes for the identification and mitigation of risks in relation to the maintenance of the premises and equipment.

Assessing and responding to patient risk

The service did not effectively assess and respond to patient risk. The service's referral policy was not consistently followed.

At the July 2023 inspection we found 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, responses to these questions were not always complete. We saw that sonographer notes were written in the margin of the consent form and were sometimes illegible. This meant that the assessment of risk for individual patients could be unclear.

At this inspection, the manager was unable to demonstrate how they would improve the completion of consent forms and the quality and consistency of information obtained. They had not made changes to the consent form and had not reviewed the issues identified during the previous inspections with the aim of making improvements.

At the July 2023 inspection we found 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. At the September 2023 inspection we found ongoing concerns about how the provider identified and escalated potential risks to patients and the unborn baby.

At this inspection we reviewed 2 cases we had previously identified as potentially requiring onward referral due to potential abnormalities found during a scan. We found that an incident report had been completed for one of the cases; however, this did not sufficiently detail learning or potential changes to practice as a result. Action proposed did not include a clear plan to review sonographer practice, audit the quality of scans or review referral processes and whether concerns were escalated appropriately.

The second case raised as a concern at a previous inspection had not been recorded as an incident and there was no evidence that learning or improvements to practice had been considered. This case involved a potential abnormality as indicated by the baby measurements taken during the scan which could have been an indicator of maternal gestational diabetes (high blood sugar levels during pregnancy). There was no evidence of reflection on this case and no changes had been made to practice, identification of learning or ongoing improvement. Furthermore, the manager told us they had subsequently received information that indicated gestational diabetes had been diagnosed in this case. However, they did not identify that information as a trigger to review their own practice.

Records

Records of care and treatment are not managed in a safe and effective way.

At our previous inspection in July 2023, we found that patient notes were not comprehensive and were not stored securely. Consent forms were not fully completed, and sonographer notes were made in the margin of the consent forms and were sometimes illegible. Records were not stored securely. At the September 2023 inspection we found that following the July 2023 inspection, the manager had taken action to store consent forms in a folder in a locked drawer of a filing cabinet. However, we found loose consent forms containing patient information in a tray in the reception and 3 printed scan images with patient identifiable information discarded on the base plate of the scanning machine. At this inspection we found that records were stored securely within a locked filing cabinet and no loose consent forms or scan images were found.

At the July and September 2023 inspections the manager 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. We also found there was no password protection of the ultrasound scanning machine records. At this inspection we found that a laptop used by the manager was password protected. In addition, a back-up of electronic records had been carried out in November 2023, although there was no clear protocol for how regularly this would be done.

Inspected but not rated

Diagnostic and screening services

At the July and September 2023 inspections we found 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. The ultrasound scanner had records dating back to 2022 where the scanning images had been deleted, but the names and details of the patients were still visible. The manager was not able to demonstrate how records were deleted or why some patient information was retained when the images had been deleted.

At this inspection we found that action had been taken to remove historic patient information from the ultrasound machine. A destruction of paper records policy had been devised and a contract had been agreed for storage and destruction of confidential waste. However, during the inspection we noted irregularities between the names of patients recorded on consent forms and those recorded on the ultrasound machine. On further discussion with the manager, it was apparent there was no protocol in place for checking patient details and transcribing them onto the ultrasound machine accurately.

Incidents

Not all safety incidents were identified or recorded. Actions relating to safety incidents were not carried out within a clear timeframe to ensure improvement.

At the July 2023 inspection we found 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.

At the September 2023 inspection we found the service had no identified safety incidents recorded. However, an incident relating to a potential scan abnormality identified by CQC at the July 2023 inspection, which should have required an appropriate referral had not been identified by the provider as a safety incident.

At this inspection we found that the incident identified at the previous inspection, where a potential bleed had not been identified as an abnormality had been recorded in line with service policy. Action to address this issue included plans to book a sonographer training update, although the manager told us they had not yet taken action to explore training options or book a course. In addition, there continued to be no action proposed to review sonographer practice, seek external clinical input, audit the quality of scans or review referral processes and whether concerns were escalated appropriately.

A second incident where a potential abnormality was apparent on a scan, and where there were potential inaccurate foetal measurements recorded, had not been recorded as an incident. Therefore, there had been no review of the incident which may have led to the identification of areas for learning or improvement.

Is the service effective?

Inspected but not rated

Patient outcomes

The service did not monitor the effectiveness of care.

At the July and September 2023 inspections we found the service did not have a process for reviewing clinical outcomes. Information was not used to improve care and treatment. Although the clinical governance policy stated

audits should be carried out, these were not being completed. There was no process for benchmarking the service or the quality of scans carried out. peer review audits were not carried out and the manager did not monitor the re-scan rate. Therefore, there was no assurance that the outcomes for patients were positive, consistent, and met expectations, including national standards.

At this inspection we found the provider had not carried out audits in line with their clinical governance policy. The manager told us they had not carried out clinical audits because they had not been seeing patients. However, they did not recognise the benefit of undertaking audits on previous clinic activity with a view to identifying issues and areas for learning and improvement. Therefore, there continued to be no assurance that outcomes for patients would meet expectations.

At the July and September 2023 inspections we found consent forms were not always complete and there was no evidence to demonstrate the manager had reviewed the forms or asked for further details or clarification where the forms did not include relevant information.

At this inspection the manager was unable to evidence how they would monitor the use of consent forms and improve processes for recording and verifying information obtained during patient activities.

Competent staff

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

At the July and September 2023 inspection we found there was no process to review the scanning competency of the sonographer. The manager told us in September 2023 that they were planning to request support in reviewing their competency through the British Medical Ultrasound Society: However, at the inspection in December 2023 this had still not been carried out but the manager told us they were still intending to seek external support to review sonographer competency.

At the July 2023 inspection 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.

At this inspection, because the service was not undertaking any regulated activities, there were no other staff working at the clinic. The provider told us they would be looking to employ staff to undertake NIPT procedures, chaperone duties, sonography and reception duties when the service was running again. However, they did not have a clear staffing structure, clearly defined roles or a business plan to support this proposal.

Multidisciplinary working

Processes to ensure referrals were made appropriately were ineffective.

At the July 2023 inspection we found 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 patient where a potential abnormality was seen on the scan, and no referral had been made.

Inspected but not rated

Diagnostic and screening services

At this inspection we found the manager had not reviewed the referral policy and processes to identify any potential missed referral opportunities following our previous inspection. They had not reviewed the scan where an anomaly was found and had not reflected on their practice to identify opportunities for learning. We reviewed the scan of another patient where the baby's measurements could potentially give rise to concerns; however, the manager had also not identified this potential in relation to their referral policy.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Mental Capacity Act training had been completed.

At the July 2023 inspection 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 (MCA); however, this had expired in April 2023. At the September 2023 inspection we found that MCA training updates had yet to be completed. However, in the week following the inspection the manager sent us evidence that they had subsequently completed the training. At this inspection we saw that MCA training updates had been completed.

Is the service well-led?

Inspected but not rated

Leadership

There were not effective structures, processes, and systems of accountability to support the delivery of a good quality, sustainable service.

At the July and September 2023 inspections we found the manager did not demonstrate they recognised the risks associated with running the service. These included a lack of indemnity cover, poor infection prevention and control processes, insufficient equipment and premises maintenance and the identification of risk. The manager also did not consider a lack of governance and feedback processes, and limited processes for monitoring performance and patient outcomes as areas for concern.

At this inspection we found that some action had been taken to address areas of good governance, including obtaining medical indemnity cover, improving the security of patient records, and addressing premises risks identified at previous inspections. However, this was limited. There were ongoing risks relating to infection control, risk management, quality assurance and improvement, governance and feedback processes, as well as continued limited processes for monitoring performance.

Governance

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

At the July 2023 inspection 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 limited action to seek feedback from patients about the service provided. The clinical records were not secure, 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. At the September 2023 inspection we saw that ongoing safety risks were present in relation to infection control and the security and management of records. In addition, there were limited processes for managing performance; for example, in relation to identifying learning and improvement or the use of audits in line with the provider policy to improve the service provided.

At this inspection there were ongoing governance issues in relation to infection control. Fire safety maintenance was not sufficiently planned. The processes for managing performance remained limited. The manager told us of plans to audit records, but these had yet to be carried out and there was no clear process in place to improve the legibility of records.

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.

At the July 2023 inspection 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. At the September 2023 inspection we found ongoing risks relating to the premises. This included a door that was faulty, presenting a risk of potential entrapment and processes for fire safety checks that were not yet embedded. Infection control risks were still evident but the processes in place to identify and address these were insufficient.

At this inspection we found that the door previously identified as faulty had been repaired. However, the management of fire safety was not sufficiently robust to ensure that regular safety checks were carried out when required. Furthermore, the manager was unaware of the need for an upcoming check of the fire alarm in the week following the inspection. The infection control audit process did not identify all infection control risks and there were ongoing issues with cleaning of equipment. There was a lack of assurance that a clear process for identifying and mitigating risks relating to the safe use of equipment and premises was in place.

At the July 2023 inspection we found the service did not have a process to ensure the scans were being conducted effectively. There was no process to audit any re-scans for patients. There was evidence the manager had not followed their own referral process to an early pregnancy unit when a possible abnormality was seen on a scan. At the September 2023 inspection, there were ongoing concerns about the lack of processes in place to ensure scans were conducted effectively. It was not clear that learning from a previous concern about a lack of referral to an early pregnancy unit in response to a potential abnormality had taken place. There were no processes in place to audit scans for quality and safety and no peer review process in place. There was limited recognition of risks associated with the lack of these processes.

At this inspection there continued to no process to audit scans for quality and safety. There was no peer review process in place and the manager had not obtained a peer review of scans, despite stating they would do so following the September 2023 inspection. Mandatory training had been completed; however, there was a lack of assurance that ongoing training updates would be undertaken in a timely manner. Training relating to sonographer competency was identified as an action as part of an incident report where a potential abnormality had not been identified at the time of the scan. However, this training had not been sourced at the time of the inspection.

Information Management

The service did not collect reliable data or analyse it. Data was not collected or analysed to understand performance, make decisions and improvements. Information provided on the service's website was inaccurate.

Inspected but not rated

Diagnostic and screening services

At the July 2023 inspection we found 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. At the September 2023 inspection we found ongoing concerns about the security and reliability of patient records.

At this inspection we saw improvements to the security of patient records. However, there were ongoing concerns about the reliability of information. For example, patient names stored in the ultrasound machine did not always match what was written on the consent form by the patient. There were limited processes for verification of this information which presented a risk of error.

At the September 2023 inspection we found ongoing limitations in the use of 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.

At this inspection the manager told us they would audit scans and records in the future once the service was operational again. However, they did not have plans to audit historical activity, despite there being some concerns around the identification of abnormalities and the quality of images.

At the September 2023 inspection there was concern about a lack of security in relation to electronic records. For example, the ultrasound machine was not password protected and the manager was unable to evidence how they backed up records held electronically. The manager told us they stored correspondence about some patients on their computer at home.

At this inspection we found that computers and the ultrasound machine were password protected and had been backed up. However, the manager was unclear about how frequently these would be backed up in the future.

Information on the service website continued to be out of date and did not reflect the services offered.

Engagement

The manager had plans to actively engage with patients to get their feedback.

At the July and September 2023 inspection we found 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.

At this inspection, the manager provided us with a template of a patient feedback survey they were intending to give to all patients following an appointment.

Learning, continuous improvement and innovation

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

There continued to be insufficient evidence to demonstrate a commitment to improve the service. Some action had been taken to address concerns from our previous inspections, such as training and some aspects of health and safety.

Inspected but not rated

Diagnostic and screening services

However, there were areas where improvement was not evident, including in relation to quality assurance, some aspects of information management, infection prevention and control, reviewing clinical outcomes and management of risk. Furthermore, it was not clear if there was learning from incidents and there was limited evidence of how the service managed performance..

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 15 HSCA (RA) Regulations 2014 Premises and equipment Environmental safety and fire safety maintenance checks were not embedded within the service so that all risks were identified and action taken to mitigate them.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • Processes to assess and respond to patient risk we insufficient. Referral processes were not effective and risks to patients were not appropriately identified and acted on. • Infection prevention and control systems were not operating effectively. Audits were not appropriately completed and did not support the identification and management of risks. • There was visible dust on the ultrasound machine. • There was no a clear protocol or record of decontamination of the ultrasound transducer. safe • Sharps bins for the storage of used needles and sharp instruments were not managed in line with national guidance.

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

This section is primarily information for the provider

Enforcement actions

- Records were not consistently complete, legible, dated, signed and did not always include clearly identifiable information of the service user, scan findings and recommendations.
- The service did not ensure there was a clear process to identify and mitigate risks to patients.
- 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 there were clear processes for the assessment of sonographer competency, including training updates, competency assessments and reflection on practice.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed There was not a clear process and business plan for the employment of staff within the service, including clearly defined roles, full checks and reviews in line with employment law and statutory requirements, and employment records.