Boo Health Limited

Boo Baby Scan Bishop's Stortford

Inspection report

Sworders Yard
North Street
Bishop's Stortford
CM23 2LD
Tel: 01279501335
www.boobabyscan.co.uk

Date of inspection visit: 30 September 2022
Date of publication: 01/12/2022

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	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Inspected but not rated
Are services caring?	Outstanding
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

This was our first inspection for Boo Baby Scan Bishop's Stortford. We rated it as requires improvement because:

- The service was not using a log to document the cleaning of transvaginal ultrasound probes. This was not in line with national guidance.
- Cleaning records did not clearly demonstrate that all areas were cleaned regularly. The format of cleaning records did not allow staff to record the dates that daily cleaning had taken place or to detail the areas that had been cleaned.
- Staff had not gone through a process of identifying the hazardous substances being used by the service, of evaluating the potential risks to health of each substance, and of identifying and implementing appropriate control measures for each substance. This was not in line with the Control of Substances Hazardous to Health (COSHH) regulations.
- Staff did not always document regular safety checks of specialist equipment. The ultrasound machine was overdue for servicing. There was no maintenance plan for electrical equipment. Staff did not carry out regular checks of first aid equipment to ensure that the contents were complete and within their expiry date.
- Staff did not always keep up-to-date with their mandatory training.
- Staff did not complete any training on recognising and responding to patients with learning disabilities or autism. This became a requirement in July 2022.
- There were inconsistencies in incident reporting and investigation processes and policies.
- The registered manager was not always able to demonstrate that they had appropriate knowledge of applicable legislation and regulations.
- There were inconsistencies in the effectiveness of governance, information management and the management of risk, issues and performance.
- Data or notifications were not consistently submitted to external organisations as required.

However:

- The service had enough staff to care for patients and keep them safe. Staff assessed risks to patients, acted on them and kept good care records.
- Staff worked well together for the benefit of patients, advised them on how to lead healthier lives, and supported them to make decisions about their care.
- There was a strong, visible, person-centred culture. Staff were highly motivated and inspired to offer care that was kind and promoted people's dignity. Relationships between people who used the service, those close to them and staff were strong, caring, respectful and supportive. These relationships were highly valued by staff and promoted by leaders.
- The service planned care to meet the needs of local people and made it easy for people to give feedback. People could access the service when they needed it.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service engaged with patients and all staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement 	This is the first time we have rated this service. We rated it as requires improvement overall. We rated this service as requires improvement for safety and leadership. We rated caring as outstanding and responsive as good. We do not rate the effective domain in diagnostic and screening services. See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Boo Baby Scan Bishop's Stortford

Boo Baby Scan Bishop's Stortford is owned by the provider Boo Health Limited.

The service provides a range of non-diagnostic pregnancy ultrasound scans. Scans include early pregnancy reassurance scans, dating and growth scans, gender determination scans, 3D/4D bonding scans, and late pregnancy reassurance scans. Scans are provided from 7 weeks gestation onwards. This is a self-referral service which is provided 6 days a week. The service is provided to those aged 18 and over.

The premises are located in the centre of the town of Bishop's Stortford. The premises are made up of 3 rooms, which includes a reception area, an overflow waiting area or quiet room, and a scanning room. There is a disabled toilet with baby change facilities, kitchen and a storage room. All rooms are located within a ground floor, self-contained unit. The clinic has 1 adjustable scanning bed, along with the scanner. There is room for up to 5 adult guests and 2 children along with the woman being scanned.

Boo Baby Scan Bishop's Stortford was registered in 2020 and had not been previously inspected. The service had previously been provided under a franchise agreement but this ended in January 2022.

At the time of our inspection, the clinic employed 1 registered manager, 1 sonographer, and 2 administrative assistants. The service did not employ any medical staff. The clinic did not store or administer any medicines or controlled drugs.

The service had a registered manager in post and was registered to carry out the following regulated activities:

• Diagnostic and screening procedures

How we carried out this inspection

We carried out a comprehensive inspection of the service. The inspection team comprised of a lead CQC inspector and 1 other CQC inspector. We carried out a short notice announced inspection on 30 September 2022. A short notice announcement was made to ensure the service was open and the relevant members of staff were available at the time we planned to visit.

We spoke with the registered manager, the sonographer, and 1 administrative assistant. We observed 3 appointments. We observed the environment and spoke with 3 service users and their partners. We reviewed 5 patient records. We also looked at a range of policies, procedures and other documents relating to the running of the service.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this 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.

Summary of this inspection

Outstanding practice

We found the following outstanding practice:

- The service's sonographer had set up an informal out-of-hours telephone line for women who may be in particular need of reassurance. Women who were given access to this telephone number could contact the sonographer outside of the service's normal opening hours. If necessary, the sonographer would try to make arrangements to provide an out-of-hours scan for women.

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 that systems and processes are in place and implemented to ensure that equipment is properly maintained. (Regulation 12(2)(e), Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service must ensure that effective processes are in place for governance, information management, and management of risk, issues and performance. (Regulation 17, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)

Action the service SHOULD take to improve:

- The service should ensure that leaders are aware of and up to date with all the requirements placed upon the service by regulations. (Regulation 7, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should ensure that notifications are submitted to the Care Quality Commission as required. (Regulation 18, Care Quality Commission (Registration) Regulations 2009)
- The provider should ensure all staff complete mandatory training in a timely way. (Regulation 18, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should ensure that staff have completed training on recognising and responding to patients with learning disabilities or autism, at a level appropriate to their role. (Regulation 18, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should ensure that hazardous substances used by the service are risk assessed and that arrangements are regularly reviewed in line with the Control of Substances Hazardous to Health (COSHH) regulations. (Regulation 15, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should ensure that effective arrangements are in place for incident reporting and investigation. (Regulation 12, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should consider re-introducing face-to-face mandatory training courses, where appropriate.
- The service should consider the introduction of training for staff responsible for carrying out incident investigations.
- The service should consider the introduction of leaflets and other documentation in languages other than English, the introduction of any relevant communication aids which would help patients who may have difficulty with their speech or understanding become partners in their care, and the introduction of interpretation services.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Requires Improvement	Inspected but not rated	☆ Outstanding	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	☆ Outstanding	Good	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic and screening services

Safe	Requires Improvement
Effective	Inspected but not rated
Caring	Outstanding
Responsive	Good
Well-led	Requires Improvement

Are Diagnostic and screening services safe?

Requires Improvement

This is the first time we have rated this service. We rated safe as requires improvement.

Mandatory training

The service provided mandatory training in key skills to all staff but did not always make sure everyone completed it.

Staff did not always keep up-to-date with their mandatory training. The sonographer's mandatory training compliance was 100%. However, mandatory training compliance for administrative staff was 63.6% at the time of our inspection. The members of administrative staff had both been working for the service for around 6 months at the time of our inspection but had not yet completed all of their mandatory training. The service's recruitment employment policy stated that staff were required to complete their mandatory training within the first 3 months of their employment.

The mandatory training was mostly comprehensive and met the needs of patients and staff. Staff completed mandatory training on equality, diversity & inclusion, first aid, General Data Protection Regulation (GDPR), hand hygiene, health & safety, infection control, information governance, Mental Capacity Act & Deprivation of Liberty Safeguards (DOLS), safeguarding adults, safeguarding children & young people, and basic life support.

Staff received training in an e-learning format. Face-to-face training sessions were not being provided at the time of our inspection due to the COVID-19 pandemic.

Staff did not complete any training on recognising and responding to patients with learning disabilities or autism at the time of our inspection. From 1 July 2022, all health and social care providers registered with the CQC were required to ensure that their staff received training in how to interact appropriately with people who have a learning disability and autistic people, at a level appropriate to their role. We raised this concern with managers during our inspection, who said that they would review staff mandatory training courses.

Requires Improvement

Diagnostic and screening services

Managers informally monitored mandatory training and alerted staff when they needed to update their training. The registered manager said that due to the small numbers of staff employed by the service, they were able to maintain an awareness of mandatory training due dates without formally monitoring this through the use of a training completion log. However, our review of mandatory training completion demonstrated that staff did not always keep up-to-date with their mandatory training.

Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Staff had not always completed training on how to recognise and report abuse.

Staff had not always completed training specific for their role on how to recognise and report abuse. The registered manager and administrative assistants were required to complete training at level 2 in both adult and children's safeguarding. The sonographer was trained to level 3 in both adult and children's safeguarding. At the time of our inspection, there was a completion rate of 100% for adults safeguarding training. The completion rate for children's safeguarding training was 66.6%. This amounted to 1 member of staff who had not yet completed the children's safeguarding training. This member of staff had started their role at the service around 6 months prior to our inspection. The service's recruitment employment policy stated that staff were required to complete their mandatory training within the first 3 months of their employment.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff had not made any safeguarding referrals since the service opened. The registered manager had made appropriate links with local safeguarding professionals.

Staff followed safe procedures for children visiting the service. The service only scanned women who were aged 18 years or older. Women were permitted to bring younger children with them for appointments.

Staff had electronic access to safeguarding adults and children policies.

Cleanliness, infection control and hygiene

Staff kept equipment and the premises visibly clean. However, staff did not always document cleaning as required.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. The sonographer and administrative assistants carried out cleaning of the premises and equipment. Cleaning equipment was available and stored correctly.

Cleaning records did not clearly demonstrate that all areas were cleaned regularly. Separate cleaning records were completed for each area of the clinic and these demonstrated that cleaning had taken place on a weekly basis. Staff told us that cleaning was also being carried out on a daily basis but the format of the cleaning record documentation did not allow them to record the dates that daily cleaning had taken place or to detail the areas that had been cleaned. Staff provided evidence of new cleaning records that were introduced following our inspection, which addressed these concerns.

Requires Improvement

Diagnostic and screening services

Staff followed infection control principles including the use of personal protective equipment (PPE). Staff had access to appropriate hand washing facilities and sanitising hand gel was available. Staff adhered to 'bare below the elbows' principles. Personal protective equipment was readily available for staff to use.

Staff cleaned equipment after patient contact. However, they did not always document the cleaning that had been carried out. The service was not using a log to document the cleaning of transvaginal ultrasound probes. The Society of Radiographer's guidance 'Ultrasound Transducer Decontamination – Best Practice Summary' states that "A record of cleaning and disinfection and / or sterilisation must be kept for any transducer that has been in contact with anything other than intact skin". The lack of a cleaning log meant that we did not have evidence that probes were being cleaned as required. Staff provided evidence to demonstrate that they had implemented a cleaning log following our inspection. This therefore addressed our concerns.

Staff did not label equipment to show when it was last cleaned. For example, through the use of 'I am clean' stickers. However, information about when equipment had last been cleaned was available separately on cleaning schedule documentation.

The service had limited audits in place to monitor cleanliness, infection control and hygiene. The service had introduced a 6-monthly observational audit in May 2022 to monitor staff hand washing technique. The audit had been carried out on 1 occasion at the time of our inspection and had not raised any areas of concern. The service did not carry out any other regular audits to monitor cleanliness, infection control and hygiene. This may have limited the registered manager's ability to identify any areas of concern.

In the twelve months before the inspection, there had been no incidences of healthcare acquired infections at the location.

Environment and equipment

Staff did not always document regular safety checks of specialist equipment. The ultrasound machine was overdue for servicing, there was no maintenance plan for electrical equipment, and staff did not carry out regular checks of first aid equipment.

The design of the environment followed national guidance. For example, the scanning room had laminate flooring which meant that it could be easily cleaned if there were any spillages. Staff had access to a sink in the scanning room.

Staff did not always document regular safety checks of specialist equipment. Staff said that they would informally check ultrasound equipment on an ongoing basis and would address any concerns identified but this was not documented. This meant that we did not have evidence of regular safety checks being carried out. Society of Radiographers and British Medical Ultrasound Society's 'Guidelines for Professional Ultrasound Practice' (2021) state that ultrasound practitioners are expected to "Ensure that an agreed quality assurance programme is in place that incorporates the regular inspection of ultrasound machines and ancillary equipment."

Staff said that the sonographer had completed an informal competency assessment to show they had the knowledge and skills to use the equipment safely when they started in their role. This competency assessment was not documented and was not reviewed on a regular basis.

The service had enough suitable equipment to help them to safely care for patients. The service had 1 ultrasound machine which was purchased when the service opened in 2020. The machine purchase included a 5 year warranty and

preventative maintenance cover. However, the machine was 3 months overdue for an annual service at the time of our inspection. Staff said that the delay was due to an external organisation and was due to the provider no longer being part of the franchise which they had initially operated under. Staff were in regular contact with the external organisation to attempt to have the ultrasound machine serviced.

The service did not have a maintenance plan which set out the frequency or types of checks that would be carried out on the portable electrical equipment used by the service. Staff said that informal visual checks were carried out on a regular basis. The Health and Safety Executive 2013 guidance 'Maintaining portable electrical equipment' states that services should "Set up a maintenance plan for portable electrical equipment".

First aid equipment was readily available. However, staff did not regularly check the first aid equipment to ensure that the contents were complete and within their expiry date. We raised concerns regarding this during our inspection. Staff provided evidence to show that they had begun to carry out regular checks of first aid equipment after our inspection. This therefore addressed our concerns.

Staff disposed of clinical waste safely. The service stored clinical waste securely and an external organisation collected it regularly.

There was adequate and secure storage for consumables. All except 1 consumable item checked during our inspection were found to be in date for expiry. The item that was out of date was disinfectant for ultrasound probes. This was raised with staff during our inspection, who said that they would replace the item. Processes for ordering and replenishing consumable equipment meant there was enough equipment available.

The registered manager had identified environmental risks on a risk assessment spreadsheet. The provider had acted to lessen any risks or hazards identified by the risk assessment. The majority of risks had been identified when the service first opened. The registered manager stated that they would review risks on the risk assessment if they became aware of any changes but they did not review risks at regular intervals.

Staff confirmed that they had not gone through a process of identifying all of the hazardous substances being used by the service, of evaluating the potential risks to health of each substance, and of identifying and implementing appropriate control measures for each substance. Instead, the registered manager had included a general COSHH risk on the service's risk assessment spreadsheet, which had identified the potential risks and the control measures in place for the 'cleaning chemicals' in general used by the service. However, this was not in line with the Control of Substances Hazardous to Health (COSHH) regulations, which requires hazardous substances to be assessed individually.

The scanning environment was set up to avoid work related musculoskeletal disorders where possible.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration

Staff responded promptly to any sudden deterioration in a patient's health. The service had a first aid kit available. All staff working for the service were required to complete basic life support (BLS) training. In case of a medical emergency, staff called the emergency services via a 999 call.

Sonographers did not check 3 points of ID or use the Society of Radiographers "pause and check" system to ensure the right person received the right ultrasound investigation at the right time. Society of Radiographers and British Medical

Requires Improvement

Diagnostic and screening services

Ultrasound Society's 'Guidelines for Professional Ultrasound Practice' (2021) state that "while undertaking any ultrasound examination" ultrasound practitioners should "correctly identify the patient using their name, address, date of birth". The sonographer only confirmed the patient's name prior to beginning an ultrasound scan. This check had been introduced in December 2021 after a data protection incident had occurred.

Staff knew about and dealt with any specific risk issues. Women attending for pregnancy scans were advised to still attend their NHS scans as part of their maternity pathway. Women attending for pregnancy scans were provided with information about the risks of frequent scanning. The service did not have limits on the number of scans an individual woman could have. Re-scanning rates were monitored. There were clear processes to escalate unexpected or significant findings at the examination.

Staff shared key information to keep patients safe when handing over their care to others. All patients received copies of images from their scan and report to share with other health care professionals. If necessary, staff contacted relevant health care professionals by telephone to escalate concerns and arrange any appointments for follow-up.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care. Managers calculated and reviewed staffing levels.

The service had enough staff to keep patients safe. The service employed 1 sonographer and 2 administrative assistants. The administrative assistant manned the reception desk, supported the sonographer as required and worked as a chaperone.

Managers calculated and reviewed the number and grade of staff needed. Managers scheduled 1 sonographer and 1 administrative assistant for each clinic. The clinic would not go ahead unless these members of staff were available.

The manager could adjust staffing levels according to the needs of patients. The service normally made appointments available on the same days and times each week. However, staff said that if a woman made contact asking for an appointment for more urgent reassurance outside of these hours then they would work to open the clinic with the required staff members.

The number of staff matched the planned numbers. Staff said that there had only been 1 occasion in the year before our inspection where the number of staff had not matching planned numbers of 1 sonographer and 1 administrative assistant. The clinic would be cancelled if the number of staff did not match planned numbers. In the week before our inspection, a clinic had been cancelled due to administrative staff being unavailable.

The service did not have vacancy rates at the time of our inspection.

The service did not monitor turnover rates. We requested turnover rates following our inspection but this was not provided.

The service did not monitor sickness rates. We requested sickness rates following our inspection but this was not provided.

The service did not use agency staff at the time of our inspection. The service had used agency staff in the first year that the service was operating. The registered manager said that they had requested staff familiar with the service, who had received an induction and understood the service.

Requires Improvement

Diagnostic and screening services

Records

Staff kept detailed records of patients' care. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive and all staff could access them easily. Staff used a mix of paper records and electronic records. We reviewed 5 records and reports as part of our inspection and 9 consent forms. The documentation that we reviewed had been completed appropriately.

Sonographers could access previous reports or images when a patient attended multiple times.

When patients transferred to a new team, there were no delays in staff accessing their records. Patients received copies of their reports and images before leaving the premises.

Staff obtained sufficient information from patients prior to their scan. This included allergies and number of weeks pregnant.

Records were stored securely. Any paper records were stored in a locked filing cabinet. Electronic records were stored on an external hard drive which was removed from the premises and stored securely when staff left the premises each day. We observed that all computers were left locked when not in use. This ensured that patients' confidentiality was protected.

The service did not carry out any record keeping audits. This meant that the service may not identify areas of concern and take action to address these concerns. However, staff provided evidence following our inspection that they had introduced a monthly 'scan record' audit.

Medicines

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

Incidents

Staff recognised incidents and near misses. However, we identified some concerns in the processes and policies that were in place to report and investigate incidents. Managers shared lessons learned with the whole team. Staff were aware of the importance of being open and honest with patients and families when something went wrong.

Staff knew what incidents to report and how to report them. Staff provided some examples of what incidents they would report. Any incidents were logged on a 'something happened' spreadsheet. There was no separate incident report or incident investigation form at the time of our inspection. The 'something happened' log contained a brief 1 sentence summary of what had occurred and the action taken in response. This meant that very limited information was available about each incident. However, staff provided information following our inspection to show that they had introduced an incident report form. The form ensured that the same set of information would be recorded for each incident, including incident type and severity, an overview of what had occurred, details of any witnesses, clients and staff involved, and lessons learnt. This therefore addressed our concerns.

Staff did not clearly identify incidents on the 'something happened' log, which also contained information about patient feedback, complaints and referrals. This raised our concerns that staff would not be able to effectively monitor the type and number of incidents that had occurred. This has been reported on further in the well-led domain.

Requires Improvement

Diagnostic and screening services

Staff said that they had reported 2 incidents in the 12 months prior to our inspection. The incidents related to a data protection incident and an incorrect gender identification. The service had included these incidents on a 'something's happened' spreadsheet as described above. Staff were not able to provide any further documentation relating to the incidents, such as incident report forms or investigation reports. We were therefore not able to review the process that the registered manager had gone through to investigate the incidents.

Staff had reported no never events or serious incidents in the 12 months prior to our inspection.

The service did not have clear policies to support staff with reporting incidents and near misses. The service did not have a dedicated incident policy. Instead, the service had a Clinical Governance Policy and an Emergency & Significant Events Policy which both included an overview of the type of events that should be reported. The Clinical Governance Policy stated that "The situation should be investigated fully" but did not contain any further guidance for staff about how incidents should be investigated or the timeframe within which they should be investigated. In addition, the policies did not include information about grading the severity of the incident. The Emergency & Significant Events Policy set out the process for staff to follow when a never event was reported. However, this process was not up-to-date as it still referred to the franchise which the provider was no longer a part of.

Staff understood the principles of the duty of candour but had not had experience of putting this into practice. 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. Staff were aware of the importance of being open and honest with patients and families when something went wrong.

Managers of the service were responsible for conducting investigations into all incidents. Managers had not received any specific incident investigation training.

Staff met to discuss the feedback and look at improvements to patient care. Staff said that this would either be on an informal basis or as part of team meetings if appropriate.

There was evidence that changes had been made as a result of feedback. For example, after a data protection incident, protocols were changed so that the informed consent clipboard was taken into the room to confirm the woman's name.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not currently rate effective for diagnostic and screening services.

Evidence-based care and treatment

The service did not always provide care based on national guidance and evidence-based practice. Managers did not formally check to make sure staff followed guidance.

Staff followed up-to-date policies and staff said that the service based its policies on national guidance. All of the policies reviewed during our inspection were up-to-date for review. However, policies did not contain referencing to national guidance and this meant it was not always clear what guidance had been referred to when writing the policy.

The majority of policies had originally been written and developed by the franchise which the service had previously been a part of. The registered manager said that they had made slight amendments to policies to ensure they remained relevant to the service after they exited their franchise agreement. However, we found some examples where policies referred to processes which were no longer in place. For example, the Emergency and Significant Events Policy described the process that staff should follow after a never event had been reported, which included informing the franchise headquarters which they were no longer a part of.

Staff had access to policies and guidelines electronically and through a folder within the clinic. The registered manager had processes in place for regularly reviewing and updating policies. All staff had to sign to confirm they had read policies and protocols applicable for their role.

Care was not always being provided according to best practice and national guidance. For example, the service was not using a log to document the cleaning of transvaginal ultrasound probes. Society of Radiographer's guidance 'Ultrasound Transducer Decontamination – Best Practice Summary' states that "A record of cleaning and disinfection and / or sterilisation must be kept for any transducer that has been in contact with anything other than intact skin". In addition, sonographers did not check 3 points of ID or use the Society of Radiographers "pause and check" system to ensure the right person received the right ultrasound investigation at the right time. Society of Radiographers and British Medical Ultrasound Society's 'Guidelines for Professional Ultrasound Practice' (2021) state that "while undertaking any ultrasound examination" ultrasound practitioners should "correctly identify the patient using their name, address, date of birth".

Nutrition and hydration

Staff did not routinely offer food and drink to patients due to the nature of the service and due to the COVID-19 pandemic. However, staff had access to a selection of refreshments if necessary.

Pain relief

Patients undergoing an ultrasound scan do not routinely require pain relief. However, we observed that sonographers checked to ensure patients remained comfortable throughout their scans and tests, and made changes where required.

Patient outcomes

Managers and staff were not carrying out a comprehensive programme of repeated audits to monitor the effectiveness of care.

Managers and staff were not carrying out a comprehensive programme of repeated audits to monitor the effectiveness of care and to check improvement over time. The only audits being carried out at the time of our inspection were peer review audits and hand washing audits. Following our inspection, staff implemented additional audits, including a scan record audit.

The service carried out peer reviews on 5% of the sonographer's ultrasound images. This was to provide assurance about the quality of images across the service. The service provided evidence of peer reviews that had been carried out following our inspection. This demonstrated that whilst the service was reviewing the quality of images in line with guidance by the British Medical Ultrasound Society, they were not reviewing the accuracy and consistency of reporting across the service.

Outcomes for patients were positive, consistent and met expectations. We reviewed the most recent audit results as part of our inspection. These showed a high level of compliance regarding hand hygiene and image quality.

Requires Improvement

Diagnostic and screening services

Managers and staff used the results to improve patients' outcomes and improve care. Managers said that they would speak to staff if any concerns were identified about their practice as part of peer reviews or hand hygiene audits.

Managers shared and made sure staff understood information from the audits. Managers shared information on an informal basis as part of discussions during clinics.

If staff identified a suspected anomaly on a scan, they could not routinely confirm and review their suspected findings and apply learning to practice. Staff said that this was because they struggled to contact staff at early pregnancy units to discuss individual cases. In addition, women who had attended the service did not always provide consent for follow up calls to be made. However, if possible, a follow up call would be made with the woman to gather information about their outcomes. Staff recorded outcome information provided by patients on a referral log, which included information about scan findings, what action was taken to refer patients and the outcome.

Competent staff

The service did not always keep records to demonstrate that staff were competent for their roles. Managers had not always appraised staff's work performance or held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. The service employed 1 sonographer at the time of our inspection. The sonographer had appropriate qualifications and had 28 years of experience. The sonographer said that they maintained professional registration, even though there is no legal requirement for sonographers to be statutorily registered.

Managers said that they gave all new staff a full induction tailored to their role before they started work. However, this was not always documented. An onboarding form was completed for new staff. This included a section to confirm that all staff had received a general induction to the organisation, including a tour of the facilities, meeting the team and familiarisation with equipment. Staff said that administrative staff received a further induction tailored to their role and based on their previous experience. This had not been documented. The sonographer also stated that they had received a full induction tailored to their role. This included working on a supernumerary basis alongside another sonographer, who assessed her competence in all aspects of the role. However, this induction process had not been documented.

Managers did not always support staff to develop through yearly, constructive appraisals of their work. The sonographer had worked for the service for a year and a half at the time of our inspection but had not yet received an appraisal. The service also employed 2 administrative staff but they had been employed for less than a year and were therefore not yet due for their appraisals.

Managers supported clinical staff to develop through regular, constructive clinical supervision of their work. Regular peer review audits were carried out on sonographer's work and feedback was provided where any concerns were identified.

Managers mostly made sure staff attended team meetings or had access to full notes when they could not attend. Staff said that meetings were normally held on a quarterly basis. However, meeting minutes showed that the last team meeting had been held in April 2022, which was over 5 months prior to our inspection.

Requires Improvement

Diagnostic and screening services

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. For example, staff said that the induction process had been adjusted based on staff's previous working experience. One member of staff had not previously worked in healthcare and had therefore received additional training and support.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. For example, leaders had identified a member of staff who they felt had the right skillset to take on the registered manager role in the future. This member of staff was therefore being supported to develop their skills and knowledge.

Managers did not always have documentary evidence to show that staff had received any specialist training for their role. Managers did not hold equipment training records for staff who operated the ultrasound equipment. The registered manager told us that the sonographer had gone through a detailed induction process, which included training on the ultrasound equipment. However, this had not been documented.

Managers identified poor staff performance promptly and supported staff to improve. For example, peer review audits would assist in the identification of poor performance and additional support would be provided if necessary.

Multidisciplinary working

Staff worked together as a team to benefit patients. They supported each other to provide good care.

Staff worked well together and communicated effectively. We observed positive interactions between team members during our inspection and staff provided positive feedback about team working.

Staff held regular and effective multidisciplinary meetings to discuss and improve their care. This was confirmed through a review of meeting minutes following our inspection.

Staff worked across health care disciplines and with other agencies when required to care for patients. Staff communicated with other healthcare professionals if required. The provider had appropriate links with local safeguarding professionals. Staff told us they had good relationships with local NHS trusts.

Seven-day services

Key services were available to support timely patient care, but they were not available 7 days a week.

The service was open 6 days a week at the time of our inspection. Appointments were made available at weekends and in the evening. This offered flexible service provision to allow patients to attend around work and family commitments.

Patients were able to book appointments 7 days a week, 24 hours a day, using the booking system on the provider's website. Patients could also book appointments by telephone when the service was open.

Health promotion

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

The service shared relevant information promoting healthy lifestyles and support. The service used their social media channels to share information about topics such as healthy pregnancy and breastfeeding.

Requires Improvement

Diagnostic and screening services

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act and Mental Capacity Act 2005. Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff were able to explain the actions that they would take if they had concerns about a patient's capacity to make decisions about their care. However, staff told us that they rarely saw women who lacked capacity to make decisions about their care.

Staff gained consent from patients for their care in line with legislation and guidance. A written consent form was completed for all scans. Sonographers would also gain verbal consent to proceed with the ultrasound scan.

Staff made sure patients consented to care based on all the information available. Patients were asked to review and sign written information before their scan which included relevant information about the scan. This meant that patients could make an informed decision on proceeding with the scan.

Staff clearly recorded consent in the patients' records. We confirmed this through a review of 9 consent forms during our inspection.

Clinical staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards. The service only employed 1 sonographer at the time of our inspection and this individual was up-to-date with training on the Mental Capacity Act and Deprivation of Liberty Safeguards. The service's 2 administrative staff were also required to complete training on the Mental Capacity Act and Deprivation of Liberty Safeguards as they were involved in checking consent forms. However, neither of these staff members had completed the training at the time of our inspection. Both members of staff had been in post for about 6 months at the time of our inspection. The service's recruitment employment policy stated that staff were required to complete their mandatory training within the first 3 months of their employment.

Staff could describe and knew how to access policy on Mental Capacity Act and Deprivation of Liberty Safeguards. Staff had electronic access to these policies.

Managers did not monitor how well the service followed the Mental Capacity Act. For example, through an audit of documentation. This limited their ability to identify any areas of concern.

Are Diagnostic and screening services caring?

Outstanding ☆

This is the first time we have rated this service. We rated it as outstanding.

Requires Improvement

Diagnostic and screening services

Compassionate care

There was a strong, visible, person-centred culture. Staff were highly motivated and inspired to offer care that was kind and promoted people's dignity. Relationships between people who used the service, those close to them and staff were strong, caring, respectful and supportive. These relationships were highly valued by staff and promoted by leaders.

Feedback from people who used the service and those close to them was continually positive about the way staff treated people. People thought that staff went the extra mile and their care and support exceeded their expectations. Staff kept feedback cards they received from women who used the service. We reviewed 40 feedback cards during our inspection and they were 100% positive. Examples of feedback included "exceptional", "excellent service", "nothing negative to say, whole staff were perfect", "best sonographer". During our inspection we spoke with 3 women and 3 relatives, who all provided consistently positive feedback about the care provided by the service. For example, women and relatives told us staff were "friendly" and "informative". Feedback on social media was 100% positive. Examples of feedback included "The most amazing, intimate and personable experience of our pregnancy…(staff) go the extra mile to make you feel comfortable and reassured, answering any questions you may have and doing everything to make your experience special.", "amazing experience", "incredible", "magical", "(sonographer) was brilliant, she took her time, we had a laugh, she made us feel at ease it was such a positive and exciting experience."

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. Staff welcomed women and those joining them warmly and with compassion. We observed a friendly and jovial environment.

Staff followed policy to keep patient care confidential. For example, staff kept the door to the scanning room shut during the scan to ensure patients' privacy was maintained. Staff directed service users to separate waiting areas to ensure women had privacy before and after their scans. Women spoken to during our inspection confirmed staff respected their privacy and dignity.

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgmental attitude when caring for or discussing patients with mental health needs. Staff were able to provide examples of going above and beyond to understand and respect the individual needs of each service user. Staff provided an example of a woman who had attended the service after NHS scans had found that her baby had a cardiac abnormality, which sadly eventually proved to be fatal. The woman was having frequent scans in the NHS to monitor the cardiac abnormality. However, the woman felt that she was not given the opportunity to look at the baby's face during these scans. As a result, she attended Boo Baby Scan Bishop's Stortford and asked whether it would be possible to carry out a set of scans which would allow her to spend time looking at her baby's face. The sonographer adjusted their normal procedure during scans to spend the entirety of each appointment focusing on the baby's face, including time spent looking at the face in 4D, and working to get high quality images of the baby's face. This helped the woman emotionally connect and bond with the baby at a difficult time.

Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs. People's emotional and social needs were seen as being as important as their physical needs.

Emotional support

Staff went above and beyond to provide emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.

Staff gave patients and those close to them help, emotional support and advice when they needed it. If a potential concern was detected during the scan, staff described how they would allow extra time to help the patient understand the concern and to make support available to them. Women and their partners provided positive feedback about the support provided by staff and said that they felt able to discuss any concerns or worries with staff. We observed staff providing appropriate support to service users. For example, we observed a woman discussing their anxieties about the viability of their pregnancy with the sonographer. The sonographer took the time to reassure the patient through an explanation of the scan findings. The sonographer also signposted the patient to other healthcare professionals for further support. The patient described feeling "relieved" and "reassured" after their discussion with the sonographer.

Women provided positive feedback online about the emotional support that they had received from staff. For example, "They gave us so much joy during a moment of worry.", "…I have been worried about our baby…(the service) has given me peace of mind", "sonographer was reassuring".

Staff supported patients who became distressed in an open environment, and helped them maintain their privacy and dignity. Staff would provide support in the scanning room if women and their relatives became distressed during an appointment. Staff could also provide support in a quiet area which was separate to the main waiting area.

Staff understood the emotional and social impact that a person's care or condition had on their wellbeing and on those close to them. Staff were able to provide examples of going above and beyond to provide emotional support. For example, the service's sonographer had set up an informal out-of-hours telephone line for women who may be in particular need of reassurance. Women who were given access to this telephone number could contact the sonographer outside of the service's normal opening hours. If necessary, the sonographer would try to make arrangements to provide an out-of-hours reassurance scan for the woman. A recent example was provided where the sonographer had received a call from a woman who had concerns about her pregnancy on a Monday, when the service was normally closed. The sonographer had been on a day out with her family but had returned home in order to open the clinic and provide a scan for the woman. The scan had shown that the pregnancy remained viable and the sonographer had therefore been able to provide reassurance to the woman on the same day that her worries had arisen.

Understanding and involvement of patients and those close to them

Staff supported patients, families and carers to understand their condition and make decisions about their care.

Staff made sure patients and those close to them understood their care. Patients and relatives felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. Staff were able to provide examples of going the extra mile to ensure that service users understood their care. For example, staff had provided scans to a woman and her partner who were both living with learning disabilities. The service had booked hour-long appointments each time the couple attended the service to ensure that there was sufficient time to explain the scan, ensure that the couple understood their care, and allow them time to ask questions.

Patients and their families could give feedback on the service and their care and staff supported them to do this. The service asked service users to provide feedback on feedback cards immediately following their appointment. There were also signs in the waiting area asking service users to leave feedback on social media.

Requires Improvement

Diagnostic and screening services

Patients gave consistently positive feedback about the service. Reviews on social media were 100% positive, based on 56 reviews. Reviews on another website were 4.9 out of 5, based on 42 reviews. We reviewed 40 feedback cards during our inspection and these were 100% positive. Following our inspection, the service provided a summary of all feedback cards (40) received between May and September 2022. The overall satisfaction rate was 99.4% during this time, with 'friendliness', 'atmosphere', and 'quality' rated 100%.

Staff supported patients to make informed decisions about their care. Staff were observed providing clear explanations about what the scans involved, giving advice, and answering questions. Staff gave women copies of images from their scan and the report with information about the scan to allow them to decide who to consult for any further care or advice.

Staff held appropriate discussions about cost and said that if necessary they could make individual arrangements depending on the service user's circumstances, such as payment in instalments.

Are Diagnostic and screening services responsive?

Good

This is the first time we have rated this service. 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.

Managers planned and organised services so they met the changing needs of the local population. Boo Baby Scan Bishop's Stortford was not commissioned to provide any NHS services. Therefore service provision was driven by patient demand. People could access services and appointments in a way and at a time that suited them. The clinic location had been chosen as an easily reachable point in East Hertfordshire with transport links and nearby car parks. The service operated clinics on evenings and at weekends to fit with the needs of the patients they served. Patients could book an appointment to suit them either through the website or calling the clinic directly.

Facilities and premises were appropriate for the services being delivered. There was sufficient seating in waiting areas. Service users had access to a toilet which was accessible for wheelchair users and included a baby changing area. Children's toys and books were not available in the waiting areas due to the COVID-19 pandemic. Parking was not available directly outside the clinic. However, the clinic was located in a town centre location where service users had access to public car parks nearby. The clinic was accessible for service users with mobility problems and wheelchair users.

Managers did not formally monitor the number of missed appointments. The service charged a deposit as part of the appointment booking process to attempt to minimise the number of missed appointments.

Managers did not always contact patients who did not attend appointments. Managers said that this was to be sensitive to the woman's circumstances, as the reason for the missed appointment may be due to a miscarriage.

Requires Improvement

Diagnostic and screening services

Meeting people's individual needs

The service was inclusive and mostly took account of patients' individual needs and preferences. However, the service did not provide information in an accessible format for all patients.

Staff were aware of and responsive to the individual needs of patients living with mental health problems, autism and learning disabilities. However, staff said that they rarely had patients attend their clinics who had complex needs. Patients would provide information about any individual needs as part of the booking process. Staff said that they would then work to accommodate these on a case by case basis. For example, staff had booked hour-long appointments for a couple who were living with learning disabilities, to ensure that there was sufficient time to explain the scan and allow the couple time to ask questions.

Staff did not have access to any specific communication aids to help patients who may have difficulty with their speech or understanding become partners in their care and treatment. However, staff said that they very rarely had patients attend their clinics who had complex needs.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. Staff could use the booking system to record any information and communication needs. Staff provided examples of adjustments that had been made to support patients with a disability or sensory loss. For example, staff had made consent forms available in a larger font. Staff had also made arrangements to provide extra time during an appointment to read forms out to a patient who was not able to read.

The service did not have information leaflets or other documentation available in languages other than English. However, staff said that the electronic translation system that they used was able to translate individual documents if necessary.

Managers did not always make sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed. Staff used an electronic translation system to support patients whose first language was not English. This system allowed staff to speak into a microphone and the system would then translate this and produce audio in the chosen language. Staff did not have access to interpretation services. Staff said that women would be asked to bring a relative who could provide interpretation if necessary.

Access and flow

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

Managers did not formally monitor waiting times but made sure patients could access services when needed. The service did not have a waiting list. The service used an online booking system which allowed patients to view appointment availability and choose an appointment date and time that suited them. At the time of our inspection, patients would normally be able to book an appointment on the same week that they were requesting one. Patients received their ultrasound reports and images before they left the clinic.

Managers said that waiting times once patients arrived for their appointment were minimal. However, they did not formally monitor this. Reception staff monitored waiting times informally during each clinic and would provide updates to patients waiting for their appointment

Managers worked to keep the number of cancelled appointments to a minimum. Managers did not formally monitor data on cancelled appointments but they stated that appointments had only been cancelled by the service on 1 day in the last year. Appointments had been cancelled on this date due to administrative staff being unavailable. Staff said that they planned to recruit additional members of staff to avoid clinics being cancelled in future when staff were unavailable.

When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible.

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, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

Patients, relatives and carers knew how to complain or raise concerns. The service clearly displayed information about how to raise a concern in patient areas.

Staff understood the policy on complaints and knew how to handle them. Staff told us that they would attempt to resolve any complaints or concerns informally in the first instance.

Managers investigated complaints and identified themes. The service aimed to acknowledge a complaint within 2 working days of receiving it and would provide the complainant with a date by which the service expected to be able to respond fully. The registered manager stated that no themes had been identified as part of complaint investigations but they were able to provide an overview of the small number of complaints that had been received.

The service stated that they had received 2 complaints in the 12 months prior to our inspection. These related to a data protection breach and an incorrect gender identification.

The registered manager did not monitor complaints through a dedicated complaints log. Instead, staff said that complaints would be included on the 'something's happened' log, which also included information about positive feedback, incidents, and referrals. However, complaints were not clearly identified on the log and this meant that the registered manager may not be able to effectively monitor complaint themes and trends.

Managers were not able to provide documentation for recent complaint investigations to demonstrate that they had been dealt with appropriately. As part of our inspection, we asked to review the documentation relating to the 3 most recent complaint investigations and responses. However, this was not provided. This meant that we were not able to review the quality of the investigations carried out, how long it took for complaints to be resolved, and the feedback provided to complainants.

Managers shared feedback from complaints with staff and learning was used to improve the service. Staff said that feedback was often shared informally due to the size of the team. Feedback was also discussed at team meetings if appropriate. This was confirmed through the meeting minutes that we reviewed as part of our inspection. Staff were aware of complaints that had been received by the service and the action that had been taken in response.

Staff could give examples of how they used patient feedback to improve daily practice. For example, the service had received feedback related to the condition of the toilet area and staff had redecorated the area in response.

Requires Improvement

Diagnostic and screening services

The service had arrangements in place for the independent external review of complaints, through the Independent Services Complaint Advisory Services (ISCAS).

Are Diagnostic and screening services well-led?

Requires Improvement

This is the first time we have rated this service. We rated well-led as requires improvement.

Leadership

Leaders did not always have the skills and abilities to run the service. However, they were visible and approachable in the service for patients and staff. They supported staff to develop their skills.

There was a clear management structure with defined lines of responsibility and accountability. The service had a registered manager who held overall responsibility for the leadership of the clinic. The registered manager was also the co-owner of the business until April 2022, when the business was sold to the service's sonographer and their relatives. The registered manager had remained in their role after selling the business to ensure that the service's sonographer had sufficient time to develop the necessary skills and abilities to take on the registered manager role. The registered manager's involvement with the business had become more limited after April 2022 but they had continued to visit the clinic on a monthly basis and they made telephone contact on a weekly basis. The registered manager planned to formally hand over the registered manager role shortly after our inspection in September 2022.

The current registered manager at the time of our inspection had previous management experience and had completed relevant qualifications. However, they had not previously managed a healthcare service and they did not have a clinical background. They were supported in these aspects by the service's sonographer.

Leaders mostly understood the challenges to quality and sustainability, and could identify the actions needed to address them. The registered manager said that they reviewed the 'something happened' log, peer review audit outcomes and the risk assessment document to understand the challenges to quality and sustainability in the service. The registered manager demonstrated an understanding of the challenges or areas of concern highlighted in these documents. However, the registered manager had not identified all of the areas of concern that we identified as part of our inspection.

The registered manager could not always demonstrate that they had appropriate knowledge of applicable legislation and regulations. For example, risk assessments had not been carried out in line with the 'Control of Substances Hazardous to Health' (COSHH) regulations. In addition, the registered manager was unaware of new requirements which had come into force in July 2022 which meant that all staff were required to receive training in how to interact appropriately with people who had a learning disability and autistic people. In addition, the registered manager was not always clear about the notifications that had to be sent to external organisations. For example, a notification had not been made to the Care Quality Commission (CQC) about a change to the provider's directors and the registered address in April 2022.

Leaders were highly responsive to concerns identified during our inspection and took prompt action to address concerns raised.

Requires Improvement

Diagnostic and screening services

Staff told us that leaders were well respected, visible, and approachable. Staff felt confident to discuss any concerns with managers. The registered manager was available by telephone when they were not on site.

The service had considered leadership development and succession planning. For example, the registered manager had ensured that the sonographer had the necessary skills and abilities before officially handing over the role. The sonographer did not wish to take up the registered manager role on an ongoing basis and had identified another employee who was being trained to take up the role in the future.

Vision and Strategy

The service did not have a documented vision or strategy.

Staff were not able to provide a documented vision or strategy for the service. However, staff were focused on increasing service provision and were able to describe a range of actions that had been put in place to achieve this.

The service's values were 'joyful, relaxed, and professional'. During our inspection we saw that staff worked in line with the service's values. Staff we spoke to were committed to providing a high-quality service to all patients who used it.

Culture

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

Staff felt supported, respected and valued. Staff felt positive and proud to work in the organisation.

The culture was centred on the needs and experience of people who use services. Staff were highly motivated and inspired to offer care that was kind and promoted people's dignity.

There were cooperative, supportive and appreciative relationships among staff. We observed positive working relationships between managers, administrative assistants and sonographers throughout our inspection. Staff spoke positively about the working relationships with their colleagues.

The culture encouraged openness and honesty. Staff were aware of the importance of being open and honest with patients and families when something went wrong. The provider had processes and procedures in place to ensure they met the duty of candour, although this had not needed to be put into practice in the 12 months prior to our inspection.

Leaders and staff understood the importance of staff being able to raise concerns without fear of retribution. Staff said that they felt able to raise concerns if necessary. A whistleblowing policy and process was in place, but this had not been used in the 12 months prior to our inspection.

The mechanisms for providing staff with the development they needed, including high-quality appraisal and career development conversations, were not consistently implemented. For example, the service's sonographer was 6 months overdue for an appraisal.

The service did not have any staff well-being measures in place.

Governance

Leaders did not always operate effective governance processes. However, staff had regular opportunities to meet, discuss and learn from the performance of the service.

The registered manager had overall responsibility for clinical governance.

The service had a clinical governance policy in place. However, this did not set out the governance or leadership structure. The policy was focused on the way that feedback, incidents and other issues should be identified, investigated and monitored through the 'something happened' log. The registered manager was required to monitor the log on a monthly basis and make any changes to practice and policy based on any areas of concern identified. The registered manager demonstrated that they were continuing to undertake this role, despite their role becoming more limited after April 2022.

There were some inconsistencies in the effectiveness of governance processes. The service held annual leadership meetings for the business owners and the registered manager. The annual occurrence of these meetings meant that there was a risk that there would be delays in any areas of concern being escalated to and addressed by leaders. However, leaders said that due to the size of the leadership team and the relationships between them, they would still be able to informally escalate and communicate about any areas of concern in between meetings. However, this would not be documented. We reviewed the meeting minutes for the last 2 leadership meetings as part of our inspection. These demonstrated that there were discussions about service developments and a review of any themes and trends through the 'something happened' log. However, there was no discussion about audit outcomes, risks, workforce data, or other performance data. The service did not produce governance or performance reports. No actions were identified as part of the meeting and no action log was kept. We were therefore concerned that leadership meetings did not include a holistic review of risk, issues and performance. This may limit leaders' ability to identify and address areas of concern within the service.

Managers held quarterly team meetings for all staff. We reviewed the minutes from meetings during our inspection. This showed discussion about complaints, positive feedback and changes to processes.

Staff were clear about their roles and they understood what they are responsible for, and to whom.

Management of risk, issues and performance

Leaders and teams did not always use systems to manage performance effectively. They had not always identified and escalated relevant risks and issues and identified actions to reduce their impact.

There were some processes to manage current performance, but these were not always effective in identifying all areas of concern. Leaders used the 'something happened' log and audit outcomes to manage performance. However, these processes had not identified all of the areas of concern that were identified during our inspection.

The service's programme of clinical and internal audit to monitor quality and operational processes was limited. The audits carried out by the service at the time of our inspection were peer review audits to review image quality and hand hygiene audits. There were no documentation audits, no environmental cleanliness audits, and no audits to monitor the consent process. This would limit leaders' ability to identify all areas of concern.

There were some inconsistencies in the arrangements for identifying, recording and managing risks, issues and mitigating actions. The manager had completed a risk assessment spreadsheet to identify and review a range of risks within the service. The risk assessment identified the hazards, who or what was at risk, existing control measures in place, what further action was necessary, as well as who would complete the actions and by when. The risk assessment did not include a scoring of risks. The majority of risks had been identified when the service first opened in 2020. The manager said that they would review risks if they became aware of any changes but they did not re-assess risks on a regular basis. This meant that staff would not regularly review whether any additional actions were required to mitigate

the risk, or whether the risk still applied. For example, the risk assessment included a COVID-19 risk which had not been updated to reflect current practices. There was another risk relating to phlebotomists taking bloods for Non-Invasive Prenatal Testing (NIPT). The service was not offering NIPT at the time of our inspection and this risk therefore did not apply and did not need to remain on the risk assessment document.

Staff had not carried out individual risk assessments for substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations. This meant that the registered manager had not gone through a process of identifying all the hazardous substances being used, of reviewing potential risks to health of each substance, and of identifying and implementing appropriate control measures for each substance. This was not in line with the requirements of the COSHH regulations.

There was not always an alignment between the recorded risks and what staff said was 'on their worry list'. For example, leaders said that their worry list related to the potential for clinics being cancelled due to staff being unavailable. This had not been recorded as a risk on the risk assessment document.

Information Management

The service did not always collect reliable data and analyse it. Staff could not always find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. Data or notifications were not consistently submitted to external organisations as required.

There was not always a holistic understanding of performance within the service. The service used a 'something happened' log to monitor the service. The log included data about patient feedback, complaints, incidents, and referrals. The registered manager said that they used the risk assessment document and audit outcomes to monitor the service. The service did not produce any separate governance or performance reports. Leaders therefore did not formally monitor all data relevant to the quality and performance of the service. For example, the registered manager did not monitor data relating to access and flow, such as any delays once patients arrived for their appointment, cancellation rates, or did-not-attend rates. In addition, the manager did not monitor staffing related data such as sickness rates, turnover rates, mandatory training rates, or appraisal rates.

Staff mostly had sufficient access to information. For example, staff had electronic access to policies and processes.

Effective arrangements were not always in place to ensure that the information used to monitor quality and performance was accurate and reliable. For example, the information included in the 'something happened' log was not clearly identified, for example to indicate which information related to a complaint or which information related to an incident. This meant it would be challenging for the registered manager to monitor the number and type of complaints and incidents through the log.

Information technology systems were mostly used effectively to monitor and improve the quality of care. For example, sonographers could access information relating to a woman's previous scans. This information was also used to carry out peer review audits to review image quality.

Effective arrangements were not always in place to ensure that data or notifications were submitted to external bodies as required. For example, a notification had not been made to the Care Quality Commission (CQC) about a change to the provider's directors and the registered address in April 2022.

Requires Improvement

Diagnostic and screening services

There were robust arrangements to ensure the integrity and confidentiality of identifiable data, records and data management systems. Lessons were learned when there were data security breaches. The service stored electronic records securely and these were password protected. The service used an external hard drive which was removed from the premises overnight and stored in a secure location. Paper records were stored in a locked filing cabinet. There was a policy in place for the storage of images and reports and how these were securely maintained.

Effective arrangements were not always in place to ensure the availability of all relevant information. The service did not always formally document all relevant information. This meant that staff were not always able to provide evidence to confirm that they had completed actions as they had described. For example, the service did not have documentation relating to induction and competency assessments, equipment training records, transvaginal probe cleaning, or equipment quality checks.

A system was in place to ensure that patients were provided with a statement that included terms and conditions of the services being provided to them and the amount and method of payment of fees.

Engagement

Leaders actively and openly engaged with patients to plan and manage services. They collaborated with partner organisations to help improve services for patients.

People's views and experiences were gathered and acted on to shape and improve the services and culture. The service asked service users to provide feedback on feedback cards immediately following their appointment. There were also signs in the waiting area asking service users to leave feedback on social media.

Staff were engaged so that their views were reflected in the planning and delivery of services and in shaping the culture. Managers regularly held team meetings, which provided an opportunity for staff engagement. No staff surveys had been carried out since the service opened. However, due to the small number of staff working at the service, staff said that they regularly held informal discussions about issues affecting the service.

There were positive and collaborative relationships with external partners. The service had established good links with local NHS trusts.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Mangers were responsive to any concerns raised and sought to learn from them and improve services. Staff took time together informally and in team meetings to review the service's performance.

The service continuously sought feedback from patients to improve services. The service used patient feedback, complaints, and audit results to help identify any necessary improvements and ensure they provided an effective service.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance There were inconsistencies in the effectiveness of governance, information management and the management of risk, issues and performance.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment The service had not ensured that systems and processes were in place and implemented to ensure that equipment was properly maintained. Staff did not always document regular safety checks of specialist equipment. The ultrasound machine was overdue for servicing. There was no maintenance plan for electrical equipment. Staff did not carry out regular checks of first aid equipment to ensure that the contents were complete and within their expiry date.