

Ultrasound Care Ltd

# Cotton Exchange

## 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

Requires Improvement



Are services safe?

Inadequate



Are services effective?

Inspected but not rated



Are services caring?

Good



Are services responsive to people's needs?

Good



Are services well-led?

Requires Improvement



# Summary of findings

## Overall summary

We have not previously rated this location. We rated it as requires improvement because:

- The service did not monitor mandatory training in key skills. This meant the provider could not be assured staff training was up to date. The service did not always control infection risk well. The service did not always use control measures to protect women, themselves, and others from infection. The service did not always ensure specialist equipment was maintained. The service did not manage clinical waste well. The service did not complete and update risk assessments for women to remove or minimise risks. The service did not complete risk assessments for women at risk of deterioration. The service employed one person to undertake both the registered manager and sonographer role. This meant that many tasks and duties expected of a registered manager were not completed.
- The service did not always check to make sure policies were regularly reviewed and in line with the most up-to-date best practice guidelines. The service did not always collect outcome data or monitor the effectiveness of care. The service did not always assess the quality of scans. The service did not provide staff appraisals for work performance or supervision meetings to provide support and development. The service did not always work together as a team. The service did not always give women practical support and advice to lead healthier lives. The service did not support women to make informed decisions about their care and treatment. They did not follow national guidance to gain women's consent.
- The service did not always take account of women's individual needs and preferences. It was not always easy for people to find information on how to raise a concern. The service did not have an effective complaints policy in place to respond to concerns and complaints appropriately.
- Leaders did not always have the capacity to manage priorities effectively or in a timely way. Leaders did not always operate effective governance processes. Staff did not have formal meetings to discuss and learn from the performance of the service. Leaders did not always have systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to reduce their impact. The service did not always collect reliable data and analyse it to understand performance, make decisions and improvements.

However:

- The registered manager understood how to protect women from abuse and the service worked well with other agencies to do so. The service kept equipment and the premises visibly clean. The service had suitable facilities to meet the needs of women and their families. The registered manager made appropriate referrals in a timely manner when risk was identified. The service had enough staff to provide care and they were able to adapt the clinic times according to availability. The service kept detailed records of women's care and treatment. Records were clear, up-to-date, stored securely and easily available. The registered manager recognised incidents and knew how to report them appropriately.
- The service had an experienced and qualified lead sonographer who performed all the scans. The service worked with other stakeholders to benefit women. Services were available five days each week.
- The registered manager treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. The registered manager provided emotional support to women, families, and carers to minimise their distress and took account of their individual needs. The registered manager supported women, families, and carers to understand their condition.
- The service planned and provided care in a way that met the needs of some local people and the communities served. People could access the service when they needed it and received the right care promptly. Reasonable adjustments were made to help women engage with the service. Lessons learnt from complaints were identified and action was taken to prevent similar complaints happening.

# Summary of findings

- Leaders demonstrated that they had the skills and abilities to run the service. The service had a vision for what it wanted to achieve and a strategy to turn it into action. The registered manager felt respected, supported, and valued. They were focused on the needs of women receiving care. The information systems were secure. Staff actively and openly engaged with women to plan and manage services. Staff were committed to continually learning and improving services.

# Summary of findings

## Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement 	

# Summary of findings

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# Summary of this inspection

## Background to Cotton Exchange

Ultrasound Care Ltd was registered with the Care Quality Commission in March 2021 to provide the regulated activity of diagnostic and screening procedures. There has been a registered manager and a company director in place since initial registration.

The service provides a range of private ultrasound scans to self-funding women who are aged 16 and over. The scans offered by the clinic include; early pregnancy scans from six weeks gestation, reassurance and gender scans from 16 weeks and growth and 4D scans from 26 weeks.

All scans are performed by the registered manager who is also the lead sonographer. There are no other staff employed by the service.

The service is based on the ground floor in a grade II listed building located in Liverpool's commercial district. A receptionist is employed externally as a point of contact for all companies within the building.

We have not previously inspected the service.

## How we carried out this inspection

We inspected this service using our comprehensive methodology. We carried out an unannounced inspection on 15 June 2022.

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

One inspector and a specialist advisor carried out the inspection with off-site support from an inspection manager and head of hospital inspection. We spoke with four women and their families who attended the service on the day of our inspection. With their consent, we observed their ultrasound scans.

We interviewed the registered manager/lead sonographer, reviewed five scan records, and looked at a range of policies and procedures.

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:**

# Summary of this inspection

- The provider must have processes that assess the risks to the health and safety of service users receiving the care or treatment. (Regulation 12)
- The provider must do all that is reasonably practicable to mitigate any such risks. (Regulation 12)
- The provider must have processes in place to ensure that staff are suitably qualified, competent, skilled and experienced to provide a safe service. (Regulation 12).
- The provider must ensure that equipment is maintained and serviced in accordance with manufacturer's guidelines. (Regulation 12)
- The provider must have processes that assess the risk of, and prevent, detect, and control the spread of, infections, including those that are health care associated. (Regulation 12)
- The provider must ensure that when service users are asked for their consent, information about the proposed care and treatment must be provided in a way that they can understand. (Regulation 11)
- The provider must have systems and processes such as regular audits of the service and must assess, monitor and improve the quality and safety of the service. (Regulation 17)
- The provider must assess, monitor and mitigate the risks relating to the health, safety, and welfare of service users. (Regulation 17)
- The provider must ensure that their audit and governance systems remain effective.(Regulation 17)

## **Action the service SHOULD take to improve:**

- The provider should monitor and record staff training to ensure they are up to date in mandatory key skills.
- The provider should consider adapting the consent process for 16 and 17 year olds in line with best practice.
- The provider should develop a chaperone policy in line with best practice.
- The provider should have a first aid kit located in their clinic room.
- The provider should clearly display information on how to raise a complaint and signpost appropriately to the Independent Sector Complaints Adjudication Service (ISCAS).
- The provider should develop an equality, diversity and inclusion policy.

Following our inspection, we issued the provider with a warning notice for Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment. Warning Notices notify a registered person that we consider they are not meeting a condition of registration, a requirement in the Health and Social Care Act 2008, a regulation, or any other legal requirement that we think is relevant.

We also issued the provider with two requirement notices for Regulation 11 HSCA (RA) Regulations 2014 Consent and Regulation 17 HSCA (RA) Regulations 2014 Good governance. Details are at the end of the report.

# Our findings






## Overview of ratings

Our ratings for this location are:

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



# Diagnostic and screening services

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

## Are Diagnostic and screening services safe?

Inadequate 

We rated safe as inadequate.

### Mandatory training

**The service did not monitor mandatory training in key skills. This meant the provider could not be assured staff training was up to date.**

The registered manager did not monitor mandatory training to alert themselves when they needed to update it. At the time of inspection, the registered manager could not provide evidence that they were up to date in their mandatory training. After the inspection, they provided evidence that they had completed mandatory training. However, the certificates were dated the day after the inspection and previous evidence of mandatory training ranged from September 2019 to February 2021.

The training was comprehensive and was in line with the NHS Health Education England core skills training framework. Modules included infection prevention control (IPC), information governance, data security, moving and handling, preventing radicalisation, equality and diversity, fire safety and health and safety in health care.

The registered manager had completed adult basic life support up to level two in February 2021 which was valid for two years.

Following our inspection, the registered manager developed a training matrix table which monitored and recorded when their current mandatory training expired.

At the time of inspection there were no other staff that worked at the service.

### Safeguarding

**The registered manager understood how to protect women from abuse and the service worked well with other agencies to do so. The registered manager had training on how to recognise and report abuse and they knew how to apply it.**

# Diagnostic and screening services

The registered manager was the safeguarding lead and had completed safeguarding children training up to level two and safeguarding adults training up to level three. This level of training was appropriate and met the recommendations for someone with a central role in safeguarding situations.

The registered manager knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. They verbally described situations where they would need to make a referral and could give examples of how to protect children from harm such as when female genital mutilation was identified.

The registered manager knew how to make a safeguarding referral and who to inform if they had concerns. The service had referred one safeguarding concern to the local authority in the previous 12 months. This had been effective, timely and all necessary steps had been taken to safeguard the adult.

The service required all staff to have a Disclosure and Barring Service (DBS) check as part of their recruitment. We saw that the registered manager and company director had a DBS check completed within the last three years.

The safeguarding policy was up to date and covered all aspects of potential abuse such as female genital mutilation and forced marriage. However, it did not include information about how to make a referral or contact details for the local authority safeguarding team. We observed contact details for the local children and adult safeguarding team in the urgent findings policy.

The service did not have a chaperone policy and the registered manager told us that a receptionist could act as a chaperone if requested at the time of the scan. Generally, family members or friends would be used as chaperones which was not in line with best practice.

## Cleanliness, infection control and hygiene

**The service did not always control infection risk well. The service did not always use control measures to protect women, themselves, and others from infection. However, equipment and the premises were visibly clean.**

There was a policy for infection control with a review date of July 2021. This was subsequently reviewed after the inspection. The policy included principles for hand decontamination in line with best practice guidelines, cleaning procedures, decontamination, and disinfection of transabdominal and transvaginal transducers. The service also had a cleaning policy that covered equipment, a cleaning checklist and cleaning methods specific to transabdominal and transvaginal transducers. The methods described in the policy reduced the risk of cross infection and followed good practice guidelines.

However, the methods for cleaning transabdominal and transvaginal transducers in the IPC policy were different to the methods outlined in the cleaning policy. It was unclear after reading the two policies what methods should be adopted when cleaning the transducers.

The IPC policy did not include information on how to manage and dispose of clinical waste after transvaginal ultrasound scans.

Cleaning records outlined what should be cleaned and cleaning frequencies. However, the records were only signed weekly and did not evidence that the daily cleaning tasks had been undertaken.

# Diagnostic and screening services

The design of some chairs in the clinic room did not enable them to be effectively cleaned. This is because the chairs were fabric covered and not impermeable to dirt and liquid.

The service did not complete audits for IPC or the cleanliness of the environment. We observed an IPC audit document that covered areas such as hand hygiene, personal protective equipment (PPE), ultrasound machine, transducers, seating, hard surfaces, general environment, and waste but this had not been used. This was not in line with their IPC policy which states an audit log must be completed after each transvaginal transducer decontamination process. The registered manager told us that due to being the only staff member they had not audited themselves but would do so if they employed more staff in the future.

We observed that the registered manager cleaned the ultrasound bed, equipment and transducers in between appointments using low alcohol NHS approved anti-bacterial wipes. This was in line with their IPC policy but not in line with their cleaning policy.

The ultrasound bed was covered in disposable paper towel roll. We found the registered manager used and replaced this for most of the women but did use it on one occasion.

However, the registered manager followed infection control principles including the use of PPE. They wore a face mask during appointments and followed 'bare below the elbows' in line with IPC best practice guidelines.

There were handwashing facilities, elbow operated taps and hand sanitiser in the scan room. We saw the registered manager wash her hands prior to each scan.

Flooring was laminate throughout the clinic and was visibly clean with no dust present. The overall environment and equipment throughout the clinic were also visibly clean and well-maintained.

## Environment and equipment

**The service did not always ensure specialist equipment was maintained and did not manage clinical waste well. However, the service had suitable facilities to meet the needs of women and their families.**

The service did not complete all appropriate environmental, health and safety risk assessments. The service did not complete fire safety checks or fire risk assessments for their own environment. We saw a fire risk assessment for the building which included their scanning room, but this was dated June 2018 with a recommended in-house review date of April 2019 and an independent review date of April 2020.

We observed an environmental risk assessment that covered lighting, repetitive strain injury, computer workstation, floor covering, trip hazards and regular equipment checks. However, this assessment had never been used.

Electrical equipment, including the ultrasound scanning machine did not have portable appliance testing (PAT) stickers on. During inspection, the registered manager was not sure when the equipment had last been tested. Evidence provided at the time of registration showed that equipment had been PAT tested November 2020.

The provider did not monitor or record when the ultrasound machine had last been serviced or when the next service was. This meant there was a lack of assurance around the performance of the scanning machine. The registered manager told us they checked the machine probes, cables, and connectors, and cleaned the filters daily but there was

# Diagnostic and screening services

no record or dates to evidence that this was done every day. Following our inspection, the registered manager provided evidence to show the machine was booked to be serviced within the next two weeks. The machine had been serviced when the machine was first leased in February 2021 which meant the machine was out of date for servicing at the time of inspection and not in line with the specific servicing and maintenance requirements of every 12 months.

The service did not dispose of clinical waste safely. The service provided transvaginal scans and the registered manager told us that they disposed of transvaginal transducer covers in a glove which was then placed in the general waste bin. At the time of inspection there was no clinical waste bin or contract in place for removal. After the inspection, the registered manager evidenced they had set up a contract with a company to dispose of clinical waste and was now using the appropriate bags and a clinical waste bin in addition to general waste.

The service did not have its own first aid kit in the scanning room. The registered manager told us that they would use the first aid kit located at reception which was a few corridors away. This meant that if a woman attended their appointment alone and needed first aid, the registered manager would have to leave them unattended to acquire the first aid kit.

However, the service had suitable facilities to meet the needs of women and their families. The clinic was located within a grade II listed building with plenty of parking nearby and transport links. The main entrance and clinic were located on the ground floor with a reception and a large waiting area. The clinic was open plan with its own seating area, scanning area, viewing area, three storage cupboards and a sink. Accessible toilet facilities were in the reception area.

The clinic provided a screen for women to change behind if they had a transvaginal scan to maintain privacy and dignity.

During appointments, women and their families had the scanning environment to themselves. The waiting area was separate and located at reception. The open plan design of the scanning area, seating area and viewing area meant that women and their families could speak to the registered manager and view pictures in private.

There was a hand wash station in the scan room with appropriate hand gel and cleaning products were stored safely and securely in a locked cupboard. This was in line with Control of Substances Hazardous to Health 2002 (COSHH) regulations.

We saw the service had completed flooring assessments for the previous three months which looked at spillages, wires and whether the floor was sealed and flat.

The scan room contained an adjustable ultrasound bed which was wipe clean and well maintained.

## Assessing and responding to patient risk

**The service did not complete and update risk assessments for each woman to remove or minimise risks. The service did not complete risk assessments for women at risk of deterioration. However, the registered manager made appropriate referrals in a timely manner when risk was identified.**

The service did not assess the risks to the health and safety of women receiving care or treatment. The service did not collect any risk information such as physical health conditions, allergies, or pregnancy history prior to their appointment. We observed the registered manager ask women about their pregnancy history and if they were allergic to latex before their scan. However, the registered manager told us they did not ask women if they had any medical conditions prior or during the appointment and there were no risk assessments completed.

# Diagnostic and screening services

At the time of inspection there was no pathway or policy in place to assess or score risk levels for women who needed to attend an NHS hospital immediately after the scan due to unexpected findings. There was no risk assessment for deciding if it was safe for a woman to commute from the clinic when it was not an emergency.

There was no inclusion/exclusion policy outlining circumstances where women could or could not access the services provided. However, the registered manager told us that women who were under 6 weeks gestation or under the age of 16 would be excluded.

The service told women they should not treat their scan as an alternative to their NHS scans in the terms and conditions page at the time of booking. However, the terms and conditions were exceptionally long and not all information was specific to the scan itself. We did not observe this being explained verbally during any appointments to check that the woman had read and understood this.

However, the registered manager identified anomalies and unexpected findings from scans and responded in an appropriate and timely manner. The registered manager had collected information on women that were referred to an NHS hospital after unexpected findings. There had been twelve women recorded and monitored as to why they were referred followed by the outcome where applicable.

After the inspection, the registered manager developed an urgent medical review pathway which identified what action they should take depending on the severity of the risk. The pathway used a flow chart with clear indicators of when to call an ambulance and when to call a local NHS hospital for non-urgent action. This included the phone number, extension number, request the obstetric registrar on call and they would determine if the woman was safe to transfer to hospital based on information provided. In all cases, women received a copy of the scan report to show to their NHS care providers.

The service had an unexpected findings/urgent finding policy that included contact numbers for seven local NHS hospitals. It had contact numbers for early pregnancy units and alternative numbers for those women over 16 weeks gestation. The policy had phone numbers for local safeguarding teams and local police station for any young people under 18 years old with suspected female genital mutilation. The policy outlined what to do if unexpected findings were clinically urgent or not. For example, if a woman was in pain and/or bleeding they would ring 999 for an ambulance in an emergency.

The registered manager had completed adult life support training.

The registered manager asked all women if they had a latex allergy and used latex free gloves and transducer covers.

After the inspection, the registered manager provided evidence that they had added a section on 'relevant medical problems' to a newly adapted consent form. This meant they could now gain this information prior to women attending the clinic.

## Staffing

**The service had enough staff to provide care and they were able to adapt the clinic times according to availability. However, the service employed one person to undertake both the registered manager and sonographer role. This meant that many tasks and duties expected of a registered manager were not completed.**

The service employed one person to be both the registered manager and the lead sonographer.

# Diagnostic and screening services

There were seven appointments on the day of inspection. The registered manager told us that they completed between eight and fourteen appointments per day. We observed the registered manager undertake multiple tasks throughout the day in relation to their sonographer role. Their duties included meeting and greeting women and their families before a scan, cleaning equipment in between appointments, undertaking scans, writing scan reports, transferring and printing scan reports and images and taking payments.

There were many aspects of the registered manager role that had not been completed such as necessary risk assessments, completing audits, monitoring equipment, updating policies and processes.

## Records

**The service kept detailed records of women's care and treatment. Records were clear, up-to-date, stored securely and easily available.**

Records were stored securely, and scan reports were detailed. Paper scan reports were kept in a locked cupboard but were not in any order with a filing system. Electronic copies were saved on computer. We looked at five records saved in a file on an encrypted data storage memory stick. No other records apart from scan reports were kept on computer.

The registered manager could access records easily. During each scan, they stored the scan images and wellbeing report on the ultrasound scanning machine. At the end of the scan, they would copy the images and wellbeing report to a blank memory stick. The registered manager would use the computer and password protected software to upload the images and report which were then printed.

This meant there were copies of each scan and report stored on the ultrasound scanning machine and memory stick. The registered manager told us they could delete files from the ultrasound scanning machine when the storage was full because it was always backed up.

When making a referral to NHS services, women received copies of their records to share with relevant medical staff if they wanted to.

## Medicines

The service did not store or administer any medicines.

## Incidents

**The service had policies for safety incidents that were not dated. However, the registered manager recognised incidents and knew how to report them appropriately.**

The service had an accident and incident investigation policy, but this was not dated.

The registered manager gave examples of what incidents to report and knew how to report them. They told us that no incidents had occurred since the clinic opened and therefore had no incidents to record or report. The service also had an accident book but had not needed to report any accidents.

During the inspection we observed a duty of candour policy that was not dated. Duty of candour is a legal obligation for healthcare workers to be open and honest with patients when something goes wrong with their treatment or care.

# Diagnostic and screening services

The registered manager demonstrated that they understood and knew when they should apply duty of candour. They shared an example of when a woman had made a complaint and the registered manager had responded with an explanation, apologised, and shared the lesson learnt.

## Are Diagnostic and screening services effective?

Inspected but not rated 

We do not rate effective in diagnostic imaging services.

### Evidence-based care and treatment

**The service did not always check to make sure policies were regularly reviewed and in line with the most up-to-date best practice guidelines.**

At the time of inspection, the registered manager did not perform any audit activity and most policies that we looked at had review dates of July 2021. The service did not have a policy review schedule in place to ensure they regularly reviewed and updated policies. This meant that the service may not be following the most up to date guidance.

The registered manager showed us British Medical Ultrasound Society (BMUS) and Society of Radiographers (SoR) guidelines saved onto the clinic computer. They told us that they followed these documents to work in line with evidence based best practice guidelines and checked the websites for updates.

The clinic followed nationally recognised best practice, which recommends a two-week time gap between scans.

The fetal anomaly scan policy followed national guidance issued by the Fetal Anomaly Screening Programme (FASP) and ensured the registered manager knew when to refer women to the NHS.

### Patient outcomes

**The service generally did not collect any outcome data or monitor the effectiveness of care.**

We spoke with the registered manager about the monitoring of outcomes. There were no service level targets or performance indicators.

Scan times, gender accuracy, waiting times and outcome rates were not reviewed to monitor the effectiveness of the service.

However, since the clinic opened the service had collected data for 12 women relating to unexpected scan findings. The data was used to monitor the outcomes from the NHS hospital referrals and compare the outcomes to the registered managers scan results. For example, the registered manager had identified two ectopic pregnancies in the previous 12 months and the NHS hospitals had confirmed the same findings.

Following the inspection, the registered manager told us they had completed a gender accuracy audit with 43 women (86% response rate) and had 100% accuracy rate for gender. We saw evidence of this on the social media page.

# Diagnostic and screening services

## Competent staff

**The service did not provide staff appraisals for work performance or supervision meetings to provide support and development. The service did not always assess the quality of scans. However, the service had an experienced and qualified lead sonographer who performed all the scans.**

The service had a fit and proper persons requirement (FPPR) policy in place which stated that staff should have an annual appraisal by using external consultancy support. However, the registered manager told us they did not have professional supervision or appraisals with the company director or any external clinician. The registered manager told us they did not have any formal team meetings with the company director and no meeting minutes were ever taken. Instead, they had informal meetings over the phone and occasionally in person.

The recruitment policy in place had a review date of July 2021. It stated that 5% of all images and reports should be audited each month. However, the registered manager provided evidence of peer reviews of five scans dated December 2021 and told us this had been stopped due to the reviewer being off sick. The registered manager had received no peer reviews for the following six months to assess the quality of their scans and findings.

The registered manager had not recorded or monitored their continuing professional development since the clinic opened.

However, the registered manager was an experienced and qualified lead sonographer who performed all the scans. They were qualified in medical ultrasound and had worked for seven years as a lead sonographer in NHS services. The registered manager told us they kept up to date with their competencies by working for an NHS hospital on a monthly basis where they are audited for quality by clinical leads.

The company director and the registered manager had employment references and a valid Disclosure and Barring Service (DBS) check in the last three years. They both provided evidence of occupational health questionnaires to ensure that, after reasonable adjustments, they were able to perform their role properly and safely. This meant the company director and registered manager were employed in line with schedule 3 of the Health and Social Care Act 2008.

The registered manager provided evidence to show they were trained to use the ultrasound scanning machine and that they were registered with the Health and Care Professions Council (HCPC).

The service did not have any other staff employed at the time of inspection, but they had developed an induction pack should they decide to recruit more staff in the future. The induction pack included information about how they would screen, induct, and train new staff.

## Multidisciplinary working

**The service did not always work together as a team. However, they worked with other stakeholders to benefit women.**

The registered manager did not work with any other staff within the clinic, and they had not worked with their peer reviewer for six months.

The registered manager and company director did not meet regularly for any type of meetings. We asked the registered manager who was responsible for reviewing policies and they were unsure if it was them or if the company director had agreed for an external company to review them.



# Diagnostic and screening services

However, the service had processes in place for sharing information when they referred women to NHS services.

## Seven-day services

**Services were available five days each week.**

The clinic offered scans five days a week during weekdays and appointments could be made from 9am till 4.30pm. At the time of inspection there was no option for evening or weekend appointments.

Women and their families could book appointments through the website and contact the service by phone or via social media platforms at any time. Women we spoke with told us they found it easy to book an appointment.

## Health promotion

**The service did not always give women practical support and advice to lead healthier lives.**

There was no information on display in the clinic to promote healthy lifestyles.

The service did not collect any lifestyle information from women in order to offer advice in line with national priorities for health such as smoking, alcohol, or drug dependency.

However, on the website there was a blog on what exercise to do during pregnancy.

## Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

**The service did not support women to make informed decisions about their care and treatment. They did not follow national guidance to gain women's consent.**

The service did not gain consent from women for their care and treatment in line with legislation and guidance. The service only had a one stage consent process, and this was at the time of booking an appointment. Women using the service had implied consent when they booked their appointment, but the service did not ensure that informed consent was gained after this.

The service had a consent policy that was in date, but the consent process was not in line with this. It stated that when consent was given it must be recorded on the formal written obstetric report. This should include any decisions made (for example, declining a transvaginal scan). Women should also have signed a consent form prior to the scan being undertaken. However, the registered manager told us that the consent form within the consent policy had never been used since the clinic opened.

The consent process was not clear or presented in a way for people to understand. The service had a terms and conditions pop up window on their appointment booking page which was very lengthy. It had over twenty sections on numerous pages that included data protection and how the service uses people's data. The last few pages related to the actual treatment and scan. Consent was gained by ticking a box that service users had read the terms and conditions. There was no option or statement that related to a service users understanding of the information.

The service did not monitor that service user consent was taken in line with legal requirements. One woman we spoke with told us they had not signed any consent form prior to their appointment. They had been unaware that they had consented for treatment when they ticked the terms and conditions box.

# Diagnostic and screening services

The terms and conditions page stated that transvaginal scans can be used in early pregnancy and that service users can decline. The registered manager told us that verbal consent for transvaginal scans was gained at the time of the scan and that no written consent was taken at any stage. Consent for sharing information with the woman's GP or NHS hospital was also gained verbally at the time it was deemed necessary.

During the scans we observed, we did not see the registered manager gain verbal consent from any women prior to the scan commencing.

There was no consent form adapted for 16 and 17 year olds. For example, the consent process for this age range did not follow Gillick Competence or Fraser Guidelines to support children to make decisions about their treatment. Gillick competence is used to assess a child's capability to make and understand their decisions in relation to treatment. Fraser guidelines are applied specifically to advice and treatment that focus on a young person's sexual health and contraception.

However, the registered manager had completed level three safeguarding training which included the Mental Capacity Act.

The service did not treat anyone under 16 years old and we saw the registered manager check identification before carrying out scans.

After the inspection, the registered manager adapted a consent form to be used prior or during the appointment. The new consent form included consent for the scan itself, transvaginal scanning and sharing information with medical professionals.

## Are Diagnostic and screening services caring?

Good 

We rated caring as good.

### Compassionate care

**The registered manager treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.**

The registered manager was discreet and responsive when caring for women. They took time to interact with women and those close to them in a respectful and considerate way. We observed that the registered manager introduced themselves and showed effective communication skills.

Women and families we spoke with said that the registered manager treated them well and with kindness. We saw that they had an encouraging, sensitive, and supportive approach when delivering difficult news.

Some women we spoke with had visited the clinic before and told us they liked that the registered manager was familiar with them. The social media page showed that some women returned to the service months later to see the registered manager with their newborn baby.

# Diagnostic and screening services

The appointments involved women and their family. The scan room had a large viewing area with a big screen so everyone could view the images together.

The service ensured the privacy of women who used the service. The clinic had a privacy screen for women to use to change for transvaginal scans. The design of the clinic meant that women could talk to the registered manager without being overheard by other people in the waiting room. We observed that the registered manager locked the door during each appointment.

Scans were booked at 20-minute intervals but we observed that the registered manager took extra time if a woman needed emotional support and information after unexpected findings.

## Emotional support

**The registered manager provided emotional support to women, families, and carers to minimise their distress and took account of their individual needs.**

The registered manager gave women and those close to them help, emotional support and advice when they needed it. On the day of our inspection, one woman had unexpected findings from their scan. The registered manager was empathic, understanding and offered the woman a complimentary follow up scan in four weeks.

The registered manager was an experienced sonographer with the knowledge and skills required to have difficult conversations when delivering difficult news.

## Understanding and involvement of patients and those close to them

**The registered manager supported women, families, and carers to understand their condition.**

We observed four ultrasound scans with the women's permission and the registered manager always explained the procedure and what would happen throughout the scan. They were caring and answered all questions that were asked.

We also observed the registered manager explain the scan report to women and their families in a clear manner.

Women and their families could give feedback on the service and their treatment and the registered manager supported them to do this.

Women gave positive feedback about the service. We viewed some of the online reviews for the past 12 months and positive comments were made about the registered manager, the environment and quality of scan pictures. Women we spoke with shared similar comments and described the service as 'amazing,' 'a calm and relaxing experience' 'they made us feel comfortable' 'they were professional and explained everything to us.' We also saw several thank you cards sent to the registered manager.

The service offered various scan packages and this information was displayed on the website so that women could choose which package they wanted. The social media page shared information on various pregnancy topics such as missed miscarriages and ectopic pregnancies.

Women who used the service were able to bring along friends and family members, including children, to their scan. During our inspection, we observed the registered manager greet people in a friendly manner, including family members and children.

# Diagnostic and screening services

We saw that the registered manager encouraged women to leave reviews and they told us they were considering using an online survey to gather feedback over the next six months.

## Are Diagnostic and screening services responsive?

Good 

We rated responsive as good.

### Service delivery to meet the needs of local people

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

Facilities and premises were appropriate for the services being delivered. The reception, waiting area and clinic room were all located on the ground floor with no steps. The clinic had plenty of space to deliver scans and the design created a modern and relaxing environment.

The building and surrounding area had easy access for those with disabilities and had parking and transport links widely available.

However, the service did not offer scan appointments at evenings or weekends. This meant that people who worked Monday to Friday could not always access the service unless they took time off work.

### Meeting people's individual needs

**Reasonable adjustments were made to help women engage with the service. However, the service did not always take account of women's individual needs and preferences.**

The registered manager had completed training in equality and diversity. They were aware of protected characteristics and their responsibilities in line with the Equality Act 2010.

The registered manager gave an example of when they made reasonable adjustments for a woman living with a disability. They moved equipment around and cancelled some appointment slots to offer more time to fully cater for their needs.

The doorways in the waiting area and clinic were wide enough to accommodate a wheelchair and the environment allowed wheelchair users to safely use the facilities.

The ultrasound bed in the clinic was adjustable and could be lowered if women needed assistance to manoeuvre onto the bed safely.

The registered manager told us that there had been occasions when they had used 'google translate' on women's phones during appointments to translate information into other languages. It enabled them to type questions and receive answers in their own language.

# Diagnostic and screening services

However, the service did not provide leaflets or information on their website in other languages spoken by the local community.

The service did not have a policy which outlined how the service adapts to and meets the needs of those with mental health needs or learning disabilities.

We did not see evidence that the service had a policy for equality, diversity and inclusion.

The service did not have facilities to meet the needs of people with sight or hearing problems. There was no hearing loop and no information available in accessible formats.

## Access and flow

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

Women could access the appointment booking system online which generated an automated booking confirmation. Appointments could also be booked in person or by telephone.

The registered manager told us that they had not cancelled any appointments in the previous 12 months.

Women we spoke with told us that the booking system was easy and effective. They did not have to wait long once they had booked an appointment and some women had booked an appointment at short notice.

During the inspection, a woman had been able to book an appointment and have their scan the same day.

## Learning from complaints and concerns

**It was not always easy for people to find information on how to raise a concern. The service did not have an effective complaints policy in place to respond to concerns and complaints appropriately. However, lessons learnt were identified and action was taken to prevent similar complaints happening.**

We observed a complaints policy on the day of inspection that was due for review in July 2021. This was subsequently reviewed after the inspection but was still incomplete. It referenced the Parliamentary and Health Service Ombudsman (PHSO) which is for NHS patients and not appropriate for the women who use their service.

The service did not clearly display information about how to raise a concern in any of the clinic areas. It was not easy for women to find information on how to complain because it was not clearly displayed on the website. The email address to send complaints to was outlined on the website's terms and conditions page under section 21.

The complaints policy and complaints information on the terms and conditions page did not inform people that they could raise their concerns with the Independent Sector Complaints Adjudication Service (ISCAS) if they were not happy with the response they received from the service.

However, the service had one formal complaint in the previous 12 months which was dealt with promptly and lessons learnt were embedded into practice by adapting how certain scan findings are described. This was evidenced on the day of inspection when we observed the registered managers communication after a scan.

# Diagnostic and screening services

Requires Improvement



## Are Diagnostic and screening services well-led?

Requires Improvement



We rated well-led as requires improvement

### Leadership

**Leaders demonstrated that they had the skills and abilities to run the service. However, they did not always have the capacity to manage priorities effectively or in a timely way.**

The service had a fit and proper persons requirement (FPPR) policy in place. The policy outlined that the company director and registered manager would have the right level of qualifications, skills, and experience to undertake the roles and responsibilities of the position being offered.

The registered manager was supportive, visible, and approachable. Throughout the inspection, we saw them speaking with and supporting women.

The registered manager was the lead sonographer and was appropriately skilled and experienced to perform scans.

The registered manager recognised they needed time and support to develop systems and processes to ensure the service met regulatory requirements and they welcomed feedback to support them to do this

### Vision and Strategy

**The service had a vision for what it wanted to achieve and a strategy to turn it into action.**

The company director provided evidence of a business plan. The vision and strategy was to offer the best service they possibly can with trusted professionals to ensure all needs are met with the highest quality expert care. They aimed to make people feel welcome, safe, reassured, and provide people with a relaxed and enjoyable experience.

### Culture

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

The registered manager told us they felt respected and valued and that they were happy in their roles. They told us they felt supported by the company director and felt comfortable raising concerns.

The registered manager and company director spoke passionately about the service and the care they provided for women.

The service had a whistleblowing policy, but this was not dated.

### Governance

**Leaders did not always operate effective governance processes. Staff did not have formal meetings to discuss and learn from the performance of the service.**

# Diagnostic and screening services

The service had a governance policy in place that stated staff should have supervision and to discuss specific concerns and best practice. However, the registered manager told us they had not received any supervision since the clinic opened.

The service did not follow their quality assurance policy. It specified that the provider would ensure there was effective governance in place, including assurance, processes, and auditing systems. It stated that systems and processes would assess, monitor, and mitigate any risks relating to the health and safety of service users.

Most policies that we looked at during the inspection were not reviewed on time or not dated. The registered manager told us that an external company developed the policies before the clinic opened and they were not certain if it was their responsibility to review policies.

The registered manager did not have a professional annual appraisal with the company director or any external clinician. They told us they did not have any formal team meetings with the company director but would talk on the phone and have informal meetings sometimes in person. The company director told us that they held meetings monthly but there were no minutes taken at these meetings.

However, the registered manager took appropriate action in a timely manner to the concerns identified during the inspection.

## Management of risk, issues and performance

**Leaders did not always have systems to manage performance effectively. They did not always identify and escalate relevant risks and issues and identify actions to reduce their impact.**

The registered manager worked alone within the clinic. There was a comprehensive lone worker policy but at the time of inspection this did not have an issue date. We observed one lone worker assessment which was not dated, not signed and actions to mitigate risks had no completion date. No actions had been recorded as completed.

The company director provided an employer liability insurance certificate that was out of date.

Leaders had not developed a defined risk register with risks that were rated or graded in terms of impact or likelihood. Therefore, appropriate mitigations and reviews for any risks were not documented. The registered manager told us that the main risk was them being absent for a prolonged period of time. There was no plan in place to maintain the roles of sonographer and registered manager should this happen.

## Information Management

**The service did not always collect reliable data and analyse it to understand performance, make decisions and improvements. However, the information systems were secure.**

The service did not always collect or analyse performance data.

The service had a data protection policy that was comprehensive but not dated. We did not see any information in this policy that specified time frames for when scan images or scan reports would be destroyed.

However, this information was in the quality assurance policy and stated they would keep personal data for two years and then be securely destroyed.

# Diagnostic and screening services

After the inspection the registered manager completed a gender accuracy audit and had completed training in information governance.

Paper copies of scan reports were stored in a locked cabinet.

Terms and conditions were included on booking forms which were provided to all service users.

## Engagement

### **Staff actively and openly engaged with women to plan and manage services.**

The registered manager and company director maintained open lines of communication through text messaging, emails, phone calls and some face-to-face informal meetings.

Women were encouraged verbally at the end of appointments to provide feedback on their experience via google reviews and social media reviews.

The service had a public website which provided the public with information about what the service offered.

The service proactively used social media to engage with new, existing and potential service users.

## Learning, continuous improvement and innovation

### **Staff were committed to continually learning and improving services.**

We saw evidence the registered manager had started to implement changes after the feedback received during the inspection. They were keen to understand any potential shortfalls in their ability to meet regulatory requirements and use the inspection feedback as a catalyst for further improvements.

The registered manager told us that following a complaint, the process for explaining unexpected findings had been changed and we saw evidence of this on the day of inspection.

However, at the time of inspection, the service did not carry out any audits to drive improvements and performance data was not collected to enable them to change or improve practice.



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

Diagnostic and screening procedures

#### Regulation

Regulation 11 HSCA (RA) Regulations 2014 Need for consent

The provider did not ensure that the consent process was clear or presented in a way for people to understand.

#### Regulated activity

Diagnostic and screening procedures

#### Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

The provider did not have effective governance processes to ensure they were able to assess, monitor and improve the quality and safety of the service.

The provider did not assess, monitor and mitigate the risks relating to the health, safety, and welfare of service users.

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	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <p>The provider did not assess and mitigate the risk to the health and safety of people who use the service.</p> <p>The provider did not have processes in place to ensure that staff were suitably qualified, competent, skilled and experienced to provide a safe service.</p> <p>The provider did not ensure the premises and equipment used for providing care were safe for use.</p> <p>The provider did not assess the risk of prevention, detection and control of the spread of infections, including those that are health care associated.</p>