Wellbeing of My Baby Ltd

1a The Clock House

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?	Requires Improvement
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 rated this location as requires improvement because:

- Although we found the service largely performed well, it did not meet legal requirements relating to safe care and treatment, and good governance, meaning we could not give it a rating higher than requires improvement.
- Staff did not all receive the correct level of safeguarding training in order to safeguard people from the risk of abuse.
- The service did not ensure all staff completed mandatory training and that they were kept up-to-date.
- The service did not carry out quality assurance checks on equipment to ensure it was safe to use.
- The service did not have a process for assessing the quality and safety of the service.
- The service did not monitor referral rates to other healthcare providers.
- The service did not have a formalised process for recording and monitoring governance.

However:

- The service had enough staff to care for women and keep them safe. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records.
- Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of local people, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for their results.
- Staff felt respected, supported and valued. They were focused on the needs of women receiving care. Staff were clear about their roles and accountabilities.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires Improvement 	We rated this service as requires improvement. See the Overall summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to 1a The Clock House

1a The Clock House, also known as Wellbeing of My Baby, is operated by Wellbeing of My Baby Ltd. The service opened in February 2020. The service is located in Slough, Berkshire. The service primarily serves communities in Berkshire. It also accepts women from outside this area.

The service provides obstetric ultrasound services for self-paying women aged 18 years or over, offering early viability, late reassurance, gender, and 3D or 4D scans.

The location has a registered manager in post since February 2020. The service is registered to provide the regulated activity:

- Diagnostic and screening procedures.

Activity (April 2020 to May 2021)

- The service scanned 1653 service users, all of which were self-funded.

We have not previously inspected this location.

How we carried out 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.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a provider 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:

We told the service that it must take action to bring services into line with legal requirements. This action related to diagnostic and screening procedure services.

- The service must ensure all staff receive the level of safeguarding training as required for their role, so abuse can be recognised, and action taken to protect people. (Regulation 12 (1)).

- The service must ensure safety checks are carried out on equipment, to ensure equipment is safe to use. (Regulation 12 (1)).

- The service must ensure staff training is reviewed regularly and all staff are trained to the required level. (Regulation 12 (1)).

Summary of this inspection

- The service must ensure there are systems and process to assess, monitor and improve the quality and safety of the service provided. (Regulation 17 (1)).

Action the service SHOULD take to improve:

- The service should consider a process to monitor referral to other professionals, and the outcomes of these referrals to improve the quality and safety of the service. (Regulation 17 (1)).
- The service should consider developing a process to ensure the service is inclusive of all service users.
- The service should consider formalising and documenting meetings.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic imaging

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

Are Diagnostic imaging safe?

Requires Improvement

We rated this service as requires improvement.

Mandatory training

The service did not provide mandatory training in key skills to all staff. Not all mandatory training was kept up-to-date.

The service did not provide a mandatory training programme for all staff. There was no in-house training for staff for fire safety, manual handling or health and safety.

Clinical staff had completed mandatory training with another employer and provided evidence of completion. The modules included, but were not limited to; infection prevention control, fire safety, Mental Capacity Act, safeguarding adults and children, conflict resolution, manual handling, basic life support, information governance, and equality and diversity. However, some of these modules had expired and required refresher training to be completed.

Safeguarding

Staff understood how to protect women from abuse and recognised signs of abuse. Not all staff had been trained to the correct safeguarding level.

The service had policies for the safeguarding of vulnerable adults and children, which included the contact details for relevant authorities for making a safeguarding referral. The policy included information on female genital mutilation, and the service's reporting responsibilities.

Staff we spoke with had not had to make a safeguarding referral. Staff were able to tell us how they would identify a safeguarding issue and the appropriate actions to take.

Requires Improvement

Diagnostic imaging

Not all staff had the correct level of safeguarding training. Although, non-clinical staff had completed adult safeguarding training to level two, they had not completed training in safeguarding children. This was not in line with guidance; Safeguarding Children and Young People: roles and competences for health care staff, Intercollegiate Document Fourth edition: March 2019. The minimum training requirement was level one children's safeguarding for all staff working in healthcare, including those who did not treat children.

Clinical staff had received appropriate training for adults and children's safeguarding. Staff had completed level two for both adults and children's safeguard training.

Cleanliness, infection control and hygiene

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

The service had an infection prevention control policy, which provided staff with guidance and procedures to minimise the spread of infection. The registered manager was the lead for infection control at the service.

The service was clean and had furnishings which were clean and well-maintained. All areas of the service were visibly clean and free from clutter. Floors were not carpeted which enabled cleaning to prevent the spread of infection. The fixture and fittings could be cleaned effectively as they were visibly free from damage.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff completed daily cleaning schedules, in addition to deep cleaning that was completed once a week.

Staff followed infection control principles including the use of personal protective equipment (PPE). Clinical staff were seen to be bare below the elbow throughout the inspection. Bare below the elbow is a practice to reduce the spread of infections from clothing that could be contaminated and allowed staff to thoroughly wash their hands. During our inspection, staff were seen wearing PPE correctly.

Hand sanitising gel was available at reception and in the scanning room. We saw staff using sanitiser gel before and after service user contact. During our inspection women told us that they had observed the sonographer practicing good hand-hygiene.

The service had protocols in place to prevent the spread of COVID-19. Face masks were mandatory unless there was a medical exemption. Service users, and those attending in support were also required to have a temperature check. The service had added COVID-19 protocols to their website for women to review before attending an appointment.

Staff cleaned equipment after service user contact. We saw staff cleaning and sanitising scanning probes and equipment after performing a scan. Sonographers used single use probe covers when undertaking trans-vaginal scans. Probe covers were disposed of in the clinical waste bin after use. The probes were then cleaned with the recommended disinfectant.

Environment and equipment

Not all equipment was maintained safely. However, staff were trained to use the equipment. Staff managed clinical waste well.

Requires Improvement

Diagnostic imaging

Not all equipment was maintained safely. The service did not have a process for carrying out quality assurance checks on ultrasound equipment in line with the manufacturer's recommendation. Quality assurance checks evaluate the safety and performance of the ultrasound equipment, helping ensure information obtained in a clinical ultrasound procedure is accurate and clinical practices are safe.

The service had basic first aid equipment for use in cases of minor injury. We found out-of-date items in the first aid equipment. The service did not have a process for monitoring the content of this equipment.

Fire extinguishers were in date, stored safely on wall mounted brackets, and were accessible to use in case of a fire. During the inspection fire exits were clear from obstruction and safe to use in an emergency.

The service had one ultrasound scanner located in a designated clinic room. The room had adequate space to manoeuvre and accommodate those attending the scan. The scanning bench was adjustable making it suitable for a range of service users.

Women could watch scans on a large wall mounted screen which mirrored the images the sonographer was observing on the ultrasound scanner. Lighting was controllable allowing ultrasound scans to be seen clearly by women and those attending with them.

Staff disposed of clinical waste safely. Clinical waste was segregated from domestic waste and stored appropriately in a locked waste bin. The service had a service level agreement with an external company to collect clinical waste on a monthly basis or sooner if required.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. The service did not assess risks to woman who attended for frequent scans.

Women attending the service were asked to provide clinical details before a procedure, which the sonographer reviewed to assess if the scan was suitable. If the procedure was not suitable, the sonographer would discuss with the service user and refer them to NHS care.

Staff told women about the importance of attending their NHS scans and appointments. Staff made it clear that scans being performed at this service were in addition to the routine care they received as part of their NHS maternity pathway.

Due to the nature of the service, there was no emergency resuscitation equipment on site. The service told us that they would telephone 999 for urgent support if an emergency occurred on site.

The service had an in-date medical emergency policy. The policy contained contact details of the nearest emergency hospital, and listed referral criteria including ectopic pregnancy. Staff had good understanding of the policy, and the circumstances a referral to NHS services would need to happen.

The service did not assess the risk to women attending frequently for scans. Although ultrasound scans are considered safe, women were not informed of the need to balance the benefits of this type of scan against the possibility of unconfirmed risk to the unborn child. The service did not monitor the frequency a woman attended scans, which meant they could not effectively assess all risks to service users.

Requires Improvement

Diagnostic imaging

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 and treatment.

The service employed two members of staff, the registered manager who was also the sonographer, and a front of house assistant.

During opening hours, the registered manager and front of house assistant were always on site to ensure there was no lone working.

The service did not use bank, agency or locum staff. There were no staff vacancies at the time of our inspection.

Records

Staff kept detailed records of patients' care and treatment. Records were stored securely.

The service captured the medical history of service users prior to a scan. Staff collected information including, number of pregnancies, health conditions and the reason for the scan.

Records were clear, up-to-date and easily accessible to staff. We reviewed six sets of records; all were in line with Standards for the Provision of an Ultrasound Service set out by the Royal College of Radiologists. Records were completed with women's identification, date of scan, type of scan, details of the sonographer performing the scan, and procedure findings and recommendations.

Staff completed reports immediately after the scan to ensure information was accurately recorded.

All women received a printed copy of their scans. The service policy was to keep a copy of the scan and report for eight years, in case they needed to be referred to in the future. This was in line with the Records Management Code of Practice for Health and Social Care 2016 as set out by the Information Governance Alliance.

Records were stored securely. Staff stored records electronically on systems that were password protected. When a woman requested that images be transferred digitally, the staff checked and verified email addresses to ensure information went to authorised persons.

Medicines

No medicines were stored or administrated as part of the services provided.

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses.

1a The Clock House had an incident reporting policy. This policy was in date and described the process for the reporting of incidents and near misses, along with staff's duties and responsibilities.

Requires Improvement

Diagnostic imaging

Staff knew what incidents to report and how to report them. Staff reported incidents using a paper or electronic incident report form. The registered manager was responsible for conducting investigations, creating action plans and communicated with those concerned.

The service did not report any incidents or near misses in the 12 months before our inspection. Although there were no reports of incidents, staff could describe the process for reporting.

Staff understood duty of candour. Staff had not needed to notify women in line with duty of candour. However, they could explain the required actions under their duty of candour, following an incident which met the requirements. The service had an in date Duty of candour policy.

Regulation 20, Duty of Candour, of the Health and Social Care Act 2008 (Regulated Activities) 2014 was introduced in 2014. Duty of candour requires organisations to be open and transparent with a patient when things go wrong and the patient has suffered, or was at risk of suffering, moderate or severe harm.

Are Diagnostic imaging effective?

Inspected but not rated

We do not rate effective.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. However, the service did not have an audit process to review the effectiveness of care and treatment.

Staff followed up-to-date policies to plan and deliver quality care according to best practice and national guidance. Policies included details of the author, date of issue and date for annual review. The registered manager updated policies earlier should there be a change in legislation or guidance from the British Medical Ultrasound Society (BMUS), Society of Radiographers (SoR), or Royal College of Radiologists (RCR).

Nutrition and hydration

Food and drink were not routinely provided due to the nature of the service and the limited time women spent there. The service made bottled water available for women if required.

The service did advise women to eat and drink normally before a scan. They also advised to attend the scan with a full bladder to help ensure the best view of the baby.

Pain relief

No formal pain level monitoring was used due to the nature of the scans being performed. However, staff asked women if they were comfortable during the procedures.

Patient outcomes

Requires Improvement

Diagnostic imaging

The service did not monitor the effectiveness of care and treatment.

From April 2020 to May 2021 the service performed 1653 scans. The service was unable to say how many women had been referred to other health services, as this was not monitored. Monitoring referrals allows services to identify if outcomes matched the report findings and make improvements to service. However, staff were able to give examples of how they communicated with women and other healthcare professionals following a referral.

The service did not have a process to provide assurance of the quality and safety of the service. Peer review audits were not undertaken to review the quality and accuracy of the scans. This was not in line with recommendations made by The British Medical Ultrasound Society (BMUS).

Competent staff

The service made sure staff were competent for their roles. Although, there were no formal appraisals within the service.

The qualified sonographer was registered as a radiographer with the Health & Care Professions Council (HCPC). They worked in an acute setting in addition to this service to maintain their clinical practice and undertake professional development. The sonographer was responsible for obtaining consent, performing scans and communicating the results to women.

The service kept the required staff employment records. We saw that staff records held all relevant information including enhanced disclosure and barring service checks.

The service did not have a formal internal appraisal process. The front of house assistant had not received a formal appraisal due to the structure of the business. However, the sonographer had received an appraisal, within the last twelve months, through work in an acute healthcare setting.

The registered manager told us that should any training be required resources would be made available. They planned to expand the service by offering Non-Invasive Pre-Natal testing (NIPTs), in order to do this the registered manager was looking to acquire the correct competencies.

Multidisciplinary working

Staff worked together as a team to benefit patients.

During our inspection, staff described positive examples of working practices. The professional working relationship promoted a relaxed atmosphere to help put women and those attending the procedure at ease.

Seven-day services

1a The Clock house was not an acute service, therefore did not open every day.

The service held an evening clinic on Fridays from 5pm to 8pm. Clinics were also available on Saturday and Sunday from 10am to 1pm. Staff would create additional clinics should there be a need to do so.

Requires Improvement

Diagnostic imaging

All procedures were planned, with appointments arranged in advance.

Health promotion

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

Staff informed women that the image service was not a substitute for care as part of their antenatal pathway.

During our inspection women told us that the service had informed them to contact their GP or midwife should they develop any concerns during their pregnancy.

Further health promotion was not available at the time of the inspection. The service had removed leaflets due to coronavirus infection prevention control protocols.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Staff gained consent from women for their care and treatment in line with legislation and guidance. All women received written information to read and sign before their scan. We observed staff obtaining written consent and verbal consent.

The service had different consent forms for different scans. We saw consent forms for early pregnancy, late pregnancy and transvaginal ultrasound scans. Staff used booking forms and verbal communication with the women to ensure the correct consent form was used.

The service was only available to women of childbearing age, and over 18 years old. This was clearly stated in the service's terms and conditions. Staff checked the service users age during the consent process to ensure the woman was aged over 18 years old.

Staff obtained consent from women to share information with their GP, midwife or NHS care, should a scan show an anomaly.

Staff verbally gave women a detailed explanation of the procedures and informed them they could stop the scan at any time.

Clinical staff had completed training and understood their roles and responsibilities under the Mental Capacity Act (2005).

Are Diagnostic imaging caring?

Good

We rated this service as good.

Requires Improvement

Diagnostic imaging

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

During our inspection, we observed one scan and spoke with seven women who used the service. Staff introduced themselves, were friendly polite and informative. Staff responded to service user questions in a clear and understandable way.

During our inspection women told us staff respected their privacy and dignity. Feedback from women included comments such as 'they were respectful to my needs', and 'no one was allowed in and out the room…the sonographer explained the clothing that needed to be removed and the reasons why'.

Women said staff treated them well and with kindness. One woman told us 'their kindness could not have been better', another said that the service was 'very kind and compassionate'.

Staff followed policy to keep care and treatment confidential. We saw the scanning room remained closed during the entirety of the scan, including pre-scan discussions and when the sonographer was explaining the report.

The service had introduced a policy to allow one woman, and one other person to attend with them, in the clinic at any time. This was introduced as part of COVID-19 protocols. The service planned to maintain this practice to improve privacy and dignity for women.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress. However, the service was unable to offer a female chaperone.

Staff gave women and those close to them help, emotional support and advice when they needed it. Women who were anxious about attending a scan told us they were able to speak with the sonographer by telephone before attending the scan, which put them at ease.

All the women we spoke with told us that they were given the opportunity to ask questions. They felt staff answered those questions; one woman told us 'I had so many questions; they were very clear and knowledgeable'.

Staff undertook training on breaking bad news. Clinical staff had completed an antenatal charity course aimed at developing the skills of sonographers to deliver difficult news following the diagnosis of a fetal anomaly.

There was a chaperone service available and we saw staff offering this service to women. The front of house assistant acted as a chaperone and was aware of their responsibilities under the chaperone policy. However, the service was unable to offer a female chaperone. If a female chaperone was requested, staff told us they would be unable to perform the scan and would suggest other services that may be able to help.

Understanding and involvement of patients and those close to them

Requires Improvement

Diagnostic imaging

Staff supported and involved service users, families and carers to understand their condition and make decisions about their care and treatment.

Staff talked with women, and those attending in support, in a way they could understand. The sonographer explained the scan report and gave the woman, and the person accompanying them, time to ask questions.

Staff made sure women, and those close to them, understood their scan. Before conducting the scan, staff checked the woman's understanding of what they had booked. Staff described the scan process and purpose of the scan.

The service's full terms and conditions were made available for women to read. These were outlined on the back of the consent form and were agreed before any procedure could take place.

The costs of the scan were made clear. All bookings required an initial deposit to secure an appointment, with the balance due on the day of the scan. The service's booking system clearly displayed costs alongside the type of scan available. During inspection we observed staff confirming the costs prior to commencing the consent process.

Staff could give examples of how they used feedback to improve daily practice. The registered manager told us they had introduced an information leaflet on missed miscarriages after reviewing feedback and identifying how to improve.

Are Diagnostic imaging responsive?

Good

We rated this service 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.

Information about the services provided were accessible on the service's website. The service offered; viability, reassurance, wellbeing and gender scans. Women could book a 3D or 4D scan when their pregnancy reached the 26th week.

All women we spoke with during the inspection told us that they found it easy to get an appointment at a time and date they wanted.

Facilities and premises were appropriate for the services being delivered. The service was located on the ground floor of a building within a parade of local shops and was accessible to women and those accompanying them.

The waiting room had comfortable seating and toilet facilities for women and those accompanying them. At the time of the inspection the service had removed magazines and information leaflets as part of their COVID-19 precautions.

There was not a separate room for breaking bad news. However, the scanning room was spacious and had seating for women and those accompanying them should they need privacy.

Requires Improvement

Diagnostic imaging

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. However, not all individual service user needs were assessed during the booking process.

At the time of our inspection the service was allowing only one woman, and those accompanying them in the clinic at a time. Staff told us that this had provided a more private environment for those using the service.

The service offered set appointment times of 20 minutes. Appointment times included gaining consent, performing the scan and discussing the results. During our inspection all women told us that they had enough time to discuss scan results.

Staff were aware that scans may be difficult to perform depending on the position of the baby. The service offered to rearrange an appointment where it was not possible to meet the purpose of the scan.

The scanning room had a large wall-mounted screen which reproduced the scan images from the ultrasound machine. This screen enabled women, and the person attending with them, to easily view live images of the scan. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service December 2014).

The service was located on the ground floor which meant people did not have to use stairs or lifts to access the service. The toilet facilities were accessible and designed for wheelchair users. The scanning bench was adjustable in height which made it easier for service users to move on and off the bench. However, the service did not assess or monitor the mobility or communication needs of a service user during the booking process. This meant plans to meet individual needs could not be planned in advance.

The service was not able to offer information leaflets in other languages. Staff told us that this had not been requested by service users. However, they would consider providing information in other languages should they receive requests.

Access and flow

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

Women were able to self-refer to the service through an online booking system. The service made all available appointments visible on their online booking system. This meant women had full visibility of available appointments and could select a time and date that suited their needs. Confirmation of booking was automatically emailed to the person.

The service did not have a waiting list or back log for appointments and last-minute bookings could be accommodated. Staff would review bookings and add extra clinics where there was a need to create more availability.

The service did not monitor 'did not attend' rate. Staff would contact women who did not attend and offer another appointment where appropriate.

The service had not cancelled any clinics in the 12 months prior to the inspection.

Requires Improvement

Diagnostic imaging

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received.

Women knew how to complain or raise concerns. During our inspection most women told us that they knew how to make a complaint if needed.

Staff understood the policy on complaints and knew how to handle them. Staff accepted complaints in person, through telephone or by email. Staff said that they tried to resolve complaints at the point it was made. If this was not possible, the service would arrange a meeting at the complainant's convenience.

The service had an in-date complaints policy which set out the responsibilities of staff and the complaints process. In the event of a formal complaint being raised, a full investigation would be completed within 15 days, and the service aimed to fully resolve the complaint within 25 days.

The service did not have an external process for the independent investigation of complaints. However, the service offered independent mediation for complaints that could not be resolved internally.

The service had not received any complaints in the 12 months prior to the inspection.

Are Diagnostic imaging well-led?

Requires Improvement

We rated it as requires improvement.

Leadership

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

The registered manager had been in post since the service registered with the Care Quality Commission (CQC) in 2020. They understood their role and responsibilities within the service. Registered managers were appointed by the service to manage regulated activities.

The registered manager understood the challenges to sustainability of the business and had identified the actions needed to address them.

The registered manager also performed the role of a sonographer. This made them visible and approachable to everyone who used the service.

The front of house assistant spoke positively about how the registered manager ran the service. They said they had confidence in the work the registered manager did, and they worked together taking pride in what they did.

Vision and strategy

Requires Improvement

Diagnostic imaging

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders.

The service was developed by staff with the vision of operating a service for women over the age of 18, and of childbearing age, who wished to view ultrasound images during their pregnancy. The service aimed to be recognised as a trustworthy, safe and a reliable name for expectant mothers.

The registered manager, in collaboration with staff, was in the process of developing values and a new vision based around the health and wellbeing of women and babies.

The service was in the process of reviewing their business plan as a result of disruptions the coronavirus pandemic had brought to the service. Plans included offering non-invasive pre-natal testing (NIPT) and expanding the availability of clinics through recruitment.

The plans for sustainability were not recorded and succession plans for service continuity had not been developed.

Culture

Staff felt respected, supported and valued. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff spoke positively about the culture of the service. Staff were proud to work for the service and felt, as a team, they were able to spend quality time with service users and fulfil the services purpose.

We saw staff working well together. Staff demonstrated a common approach in providing the service.

The service had an in-date duty of candour policy. Staff developed the policy together using legislation. Staff had a good awareness regarding the duty of candour.

The service had developed a whistleblowing policy in preparation for the future growth of the service. Whistleblowing is the term used when someone who works for an employer raises a concern about malpractice, risk, wrongdoing or possible illegality, which harms, or creates a risk of harm, to people who use the service, colleagues or the wider public.

Governance

There was not a formal process to manage performance.

The registered manager was accountable for the clinical governance and quality monitoring of the service as out lined in the service's governance policy. This included monitoring feedback, complaints and investigating incidents.

The service did not have a formal governance reporting process, we were told this was due to the size and structure of the service. The registered manager and front of house assistant confirmed they had ongoing informal meetings to review feedback, complaints and investigations of incidents. They also reviewed appointments before and after clinics to informally discuss learnings. These meetings were not recorded which meant it was not possible to evidence discussions had taken place.

Requires Improvement

Diagnostic imaging

The service had in-date indemnity and medical liability insurance which covered all staff in the case of a legal claim.

Managing risks, issues and performance

The service did not always have the systems to identify and manage risk in order to reduce their impact.

The service did not have a process for identifying and managing all risks. The service did not complete quality assurance checks on equipment, this meant that there may have been unknown risks associated with the quality and safety of equipment.

The service had created a risk register to monitor and manage the risks associated with the coronavirus pandemic. The service had identified risks within the service and placed mitigation in place to control the spread of the disease. All staff had completed a COVID-19 personal risk assessment.

There was no risk register for non-COVID-19 risks. The service had conducted environmental risk assessments for legionella, electrical instillation, and fire safety. Staff were aware of the risk assessments.

The staff did not complete any audits, for example image scan quality, scan result and reports which did not provide assurance of quality of its service or inform risks and improvements.

Managing information

The service collected, managed and used information well to support its activities, using electronic systems securely.

There was a system to ensure women received and read the service's terms and conditions prior to their scan. Costs of scans were clearly stated on the service's website with a non-refundable deposit taken at the point of booking and full payment taken on site.

The service collected the contact details for each woman's GP. Staff discussed with women how the data they provided would be used should the scan show an anomaly.

Records were easily accessible and stored securely. Women completed consent forms on paper, these were immediately scanned to store as electronic records within a password protected system. Paper records were immediately destroyed and treated as confidential waste. Scan images were stored electronically on a separate password protected system. The service had a policy of storing records for eight years.

The service shared scan information with women securely. Women accessed the service via an online booking process and were required to supply an email address where confirmation of the booking would be sent. Staff used this email address to share electronic scan images as it could be verified to belong to the woman who made the booking.

During our inspection all computer systems were logged off when devices were not being used.

Engagement

Requires Improvement

Diagnostic imaging

Staff openly engaged with women to plan and manage the service. However, the service did not actively engage with service users.

The service used social media and internet review sites to monitor customers' feedback. At the time of our inspection, one internet review site had 23 separate reviews. We saw evidence of the service engaging in an open and honest way with customers who did not feel satisfied with the service. However, the service did not have a system or process to actively seek views of those who use the service.

The service demonstrated changes they made as a result of feedback. Staff created a leaflet for women who had suffered a missed miscarriage allowing women to review information in their own time and signpost women to support.

Learning, continuous improvement and innovation

There was limited evidence that the service gathered information in order to improve or innovate. However, the service was in the planning stage for the development of an app that would allow service users to review scan images securely and access support information.

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 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service must ensure all staff receive the level of safeguarding training as required for their role, so abuse can be recognised, and action taken to protect people. (Regulation 12 (1)). • The service must ensure safety checks are carried out on equipment, to ensure equipment is safe to use. (Regulation 12 (1)). • The service must ensure staff training is reviewed regularly and all staff are trained to the required level. (Regulation 12 (1)).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service must ensure there are systems and process to assess, monitor and improve the quality and safety of the service provided. (Regulation 17 (1)).