Baby Scan Clinic Limited

Window to the Womb Aylesbury

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

Summary of findings

Overall summary

Our rating of this location stayed the same. We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care to women. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information. Women were able to access key services in a timely way.
- 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 the individual needs of women, 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 a diagnostic procedure.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of women receiving care. Staff were clear about their roles and accountabilities. The service engaged well with women and the community to plan and manage services and all staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	Our rating of this service stayed the same. We rated it as good . See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Window to the Womb Aylesbury

Window to the Womb is operated by Baby Scan Clinic Ltd. As part of the agreement, the franchisor Window to the Womb Ltd provides the service with regular on-site support, access to their guidelines and policies, training and the use of their business model and brand.

Window to the Womb Aylesbury opened in October 2018 and provides diagnostic pregnancy ultrasound services to self-funding women, who are more than six weeks pregnant and aged 16 years and above, across Buckinghamshire. All ultrasound scans performed at Window to the Womb are in addition to those provided through the NHS.

Window to the Womb was separated into two clinics: the 'firstScan' clinic, which specialises in early pregnancy scans, and 'Window to the Womb' clinic which offers later pregnancy and wellbeing scans. From 1 September 2020 to 31 August 2021 the service had performed 2640 'firstScans' and 2637 Window to the Womb scans.

The 'firstScan' clinic offers the following scans:

- Reassurance, viability, dating and specialist scans from six to 15+6 weeks gestation.

The Window to the Womb clinic offers the following scans:

- Wellbeing scans from 16 to 40 weeks' gestation.
- Wellbeing and gender scans from 16 to 23 weeks 'gestation.
- Growth and presentation scans from 26 to 42 weeks' gestation.
- 4D baby scans from 24 to 34 weeks' gestation.

All women accessing the service self-refer to the clinic and are all seen as private women (self-funding).

The service runs six clinics a week, Tuesday evenings, Wednesday during the day, Thursday and Friday evenings, Saturday all day and Sunday mornings.

The service has had a registered manager in post since October 2018 and was registered with the CQC to undertake the regulated activity of diagnostic and screening procedures.

We have inspected this service once before on 13 November 2019. We rated the service as Good.

How we carried out this inspection

We undertook this inspection as part of a random selection of services rated Good and Outstanding to test the reliability of our new monitoring approach.

During the inspection, we spoke with five staff including the registered manager, a sonographer and scan assistants. We spoke with five women and two relatives. During our inspection, we observed four scans and reviewed five patient records.

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

Summary of this inspection

Areas for improvement

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

- The service should consider updating the sink in the ultrasound room to a clinical sink.
- The provider should update the complaints policy to direct women to an independent adjudication or resolution service in the event the service cannot resolve a complaint. The complaints policy should not direct women to the Care Quality Commission (CQC) as this organisation does not provide a complaint service.

Our findings

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Good

Our rating of safe stayed the same. We rated it as good.

Mandatory Training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

Staff received and kept up to date with their mandatory training. Mandatory training subjects included: infection prevention and control, fire safety, information governance, safeguarding adults and children, chaperoning, and the Mental Capacity Act 2005. This ensured all staff had information to care for people with a diverse range of needs.

The service had a mandatory training policy which detailed the expectations of mandatory training required for scan assistants and sonographers. We saw records that evidenced that all staff, except one who had recently started, were up to date with their mandatory training.

The mandatory training was comprehensive and met the needs of women and staff. The service provided mandatory training on a rolling programme basis and staff accessed the training by e-learning modules or face to face sessions during their team meetings.

Managers monitored mandatory training and alerted staff when they needed to update their training. Staff confirmed they either completed training at home, or they were given time to complete at work.

Safeguarding

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

Staff received training specific for their role on how to recognise and report abuse. Staff were familiar with the service's safeguarding policy and how to access it.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. They could tell us the procedure to follow if they had safeguarding concerns.

The franchisor had recently improved their national safeguarding policy, which was applicable to all locations. The new policy provided up to date guidance on recognising abuse and escalating concerns in the specific context of the service. The policy included processes for staff to obtain support in the event a child under the age of 16 attempted to obtain a scan.

A separate female genital mutilation (FGM) policy provided staff with clear guidance on how to identify and report FGM. Child sexual exploitation and FGM was included in safeguarding training.

The service displayed information regarding safeguarding from abuse in the toilet. This reflected good practice as it meant women could discreetly access important information.

Cleanliness, infection control and hygiene

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

Staff followed infection control principles including the use of personal protective equipment (PPE). The sonographer wore an apron, gloves and a mask when undertaking scans. All other staff were wearing masks. To minimise risks in relation to Covid-19, staff had continued to wear face masks when not providing care directly to women despite them not being mandatory from 19 July 2021, and encouraged women and their companions to do the same.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Staff kept the equipment and premises visibly clean. They used control measures to prevent the spread of infection. The ultrasound room had washable flooring and wipe-clean furnishings. Staff placed paper towelling on the couch for each woman and changed this in between women.

The service stopped undertaking gender scans and 4D scans during the height of the Covid-19 pandemic to minimise risk of women being exposed to the risk of Covid-19.

Staff cleaned and safely stored equipment such as probes used for intimate ultrasound investigations (for example, trans vaginal investigations). Staff covered the probes during investigations and cleaned them with the recommended wipes post ultrasound scan. This minimised the risk of cross infection between women using the service.

The World Health Organisation (WHO) hand hygiene guidance was posted above each sink to provide a visual guide to handwashing. We saw staff cleaning their hands WHO guidance before and after patient care. The service carried out hand hygiene audits which showed 100% compliance. Staff were below bare the elbows, so there were no shirt sleeves or jewellery getting in the way of effective hand hygiene, as recommended by the Department of Health. However, the hand basin was small so there was a risk of splashing and dispersal of contaminated droplets. The tap had to be physically turned on and off, rather than lever or sensor-operated, so there was a risk of contamination of their hands.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

Good

Diagnostic and screening services

Staff carried out daily safety checks of specialist equipment. Sonographers completed daily quality assurance checks for the ultrasound machine to ensure the equipment was safe to use.

The service had suitable facilities to meet the needs of women's families. People using the service arrived in the reception area which included comfortable seating and a water-cooling machine. There was a print room for families to choose their photograph and video's, the scanning room and a small office/storage room.

The service had enough suitable equipment to help them to safely care for women. The service had purchased a new ultrasound machine on 28 November 2018. The registered manager had ensured the machine was serviced yearly.

Staff disposed of clinical waste safely. Staff followed correct procedures to handle and sort different types of waste. The service had an agreement with a clinical waste removal company to remove clinical waste monthly.

Staff stored cleaning materials in a locked cabinet in the storeroom in line with the Control of Substances Hazardous to Health Regulations 2002 (COSHH). COSHH is the legislation that requires employees to control substances which are hazardous to health. We saw risk assessments relating to the use of COSHH products were up to date and reviewed regularly.

There were suitable arrangements in place for fire safety, including a fire risk assessment and clear instructions for staff to follow in the event of a fire. Staff kept all fire exit doors clear of obstructions.

Assessing and responding to patient risk

Staff identified, responded to and removed or minimised risks to patients. Staff identified and quickly acted upon women at risk of deterioration.

Staff told us what action they would take if a patient became unwell or distressed while waiting for, or during, an ultrasound scan. The action taken depended on the specific situation and staff provided examples which showed they would take the right action.

On booking their appointment, the service asked women to bring their NHS pregnancy records with them. This meant the sonographers had access to the woman's obstetric and medical history. It also meant if there were any concerns staff could contact the women's relevant medical provider and GP.

Staff told women about the importance of still attending their NHS scans and appointments. The sonographers made sure women understood the ultrasound scans they performed were in addition to the routine care they received as part of their NHS maternity pathway. We heard staff reminding women about the importance of still attending for their NHS scans at the four ultrasound scans we observed.

Staff completed a pre-scan questionnaire for each woman, which included questions about health conditions and if a known latex allergy, using a health declaration and consent process.

To safeguard people against experiencing the incorrect type of ultrasound scans we saw staff asking women to confirm their names and date of birth and the scan they were expecting to attend for. This evidenced staff followed best practice and used the British Medical Ultrasound Society's (BMUS) 'Have you paused and checked' checklist.

Good

Diagnostic and screening services

Staff shared key information to keep women safe when handing over their care to others. There were clear processes and pathways in place to guide staff on what actions to take if the sonographer found unusual findings on the ultrasound scan. We saw evidence sonographers made rapid referrals to the local NHS early pregnancy unit or fetal medicine as appropriate, when they found concerns about a woman's health. When asked, staff were clear on what these actions were and gave two examples.

Sonographer and scan assistant staffing

The service had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care. Managers regularly reviewed and adjusted staffing levels and skill mix.

The service had enough staff to keep women safe. The service employed four scan assistants on zero hour contracts. There were three sonographers working various hours to support the clinic.

Scan assistants were responsible for manning the reception desk, managing enquiries, appointment bookings, acting as a chaperone for women during their scan, supporting the sonographers during the ultrasound scans, and helping the families print their scan images.

All staff we spoke with felt staffing levels were adequate. At all times there were at least three staff in the clinic, this included two scan assistants and a sonographer. No staff member worked alone.

All staff including sonographers employed by the franchisor underwent a local induction which covered all aspects of the service. Staff records we reviewed showed all staff had completed an induction.

Records

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

Staff ensured before scans were undertaken women had signed to confirm they agreed to the terms and conditions. This included women giving consent for medical information relating to their pregnancy being passed on to their NHS provider. The registered manager audited compliance monthly. The latest audit showed compliance was 100%.

Patient notes were comprehensive and all staff could access them easily.Sonographers kept a detailed electronic record of scans and referrals to NHS services.

Records were stored securely. They were stored electronically. All computers and the ultrasound machine were password protected and we observed staff locked them when not in use which ensured there was no unauthorised access.

We reviewed five records including referral forms from the 'firstScan' and 'Window to The Womb' clinics. Staff recorded information in a clear and accurate way. This included women's estimated due date, the type of ultrasound scan performed, the findings, conclusions, and recommendations as well as the women's consent to the scan.

Good

Diagnostic and screening services

When women transferred to another service, there were no delays in staff accessing their records. Where appropriate, and with consent, the sonographer would also provide a paper copy of the scan report for a woman's GP or other relevant healthcare professionals when making a referral.

Staff saved the ultrasound images onto a memory stick, which they uploaded to a mobile phone application ('app') accessible for free to the women. The app enabled women to have instant access to their scan images and any video recordings made. Once staff uploaded the images, they deleted the images from the memory stick.

Women having a 'firstScan' could receive an electronic report written by the sonographer at the time of the scan by entering an individualised code into the app. Women having Window to the Womb scans received electronically a foetal wellbeing report which detailed the baby's position, gender (if requested), foetal anomaly sweep, a check of the brain amniotic fluid, lungs and heart, abdomen and limbs, growth and placental position. The service stored a copy of the information, as per their records retention policy, in case they needed to refer to the data in the future.

Incidents

The service managed patient safety incidents well. Staff recognised and reported incidents and near misses. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave women honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.

All staff knew what incidents to report and how to report them. The service used a paper-based reporting system and had an accident and incident book available in the clinic for staff to access. The registered manager was responsible for conducting investigations into all incidents.

Staff we spoke with knew how to report incidents and could give examples of when they would do this. If an incident occurred, managers told us they would investigate them and share lessons learned with the whole team and other locations.

Staff met to discuss feedback and look at improvements to patient care.Senior staff shared the lessons with other locations through a newsletter called 'OpenWindow' circulated when there was information that needed to be shared across the franchise. For example, one incident related to a data management problem and staff reviewed the chain of events that led to the occurrence. Staff changed their practice following the incident.

Staff understood the duty of candour. They were open and transparent and gave women and families a full explanation when things went wrong. The service had not needed to do this but staff we spoke with were aware of the term and the principle behind the regulation and the need to be open and honest with women where incidents occurred. Duty of candour training was part of the staffs' mandatory training requirements.

The service had no never events. Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.

Are Diagnostic and screening services effective?

Good

Diagnostic and screening services

Inspected but not rated

We do not currently rate the effective domain for diagnostic imaging services.

The service provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women subject to the Mental Health Act 1983.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.

The registered manager monitored staff compliance to policies. Staff signed and dated a checklist to confirm they had read policies as part of their induction and when the service updated policies. We saw evidence of these completed checklists.

We reviewed five local policies which were up to date. The clinical lead, a diagnostic sonographer and clinical nurse specialist from the franchise wrote the policies and protocols, and the lead sonographer and a consultant in obstetrics and gynaecology reviewed them. They followed national guidance from the Royal College and Society of Radiographers, the foetal abnormality screening programme standards and British Medical Ultrasound Society. For example, the service did not offer transvaginal scans to women over 10 weeks gestation in line with BMUS guidance. All policies and protocols had a date when a review required.

The service followed 'as low as reasonably achievable' (ALARA) principles outlined by the British Medical Ultrasound Society (BMUS). The service kept scanning times to a minimum and did not offer scans that lasted longer than 10 minutes. Sonographers did not repeat scans within seven days of the earlier scan, which reduced any risks that prolonged scans may cause to the unborn baby. We observed staff spoke with women during appointments explaining this principle if needed.

The service had an audit programme to assure itself of the quality and safety of the clinic. The franchisor completed yearly sonographer competency assessments and a yearly clinic audit. The registered manager completed monthly clinic audits. Included in this audit were the signed terms and conditions to ensure staff had requested all women to read and sign the conditions. Also, that current policies printed off, for example in the scan room, the scan room hygiene policy.

Staff protected the rights of women subject to the Mental Health Act and followed the Code of Practice. They completed Mental Capacity Act training as part of mandatory training. This included the importance of open discussions to ensure the person understands all information presented to them such as the scan and the terms and conditions. This included people with learning difficulties or early onset dementia.

Nutrition and hydration

Staff made sure women did not fast for too long before diagnostic procedures. Staff took into account women's individual needs where food or drink were necessary for the procedure.

Staff made sure women had enough to drink. Staff gave women information on drinking water before a scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the unborn baby.

A water fountain was available in the reception area for women.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for women.

The director of ultrasound and the clinical lead used audit and review processes to monitor performance and outcomes.

Sonographers were part of a peer review process to ensure the accuracy and quality of ultrasound scan images, videos, and reports. Sonographers reviewed colleague's scans against internal targets and considered areas for improvement, such as scan times and gender or health inaccuracies. These were shared and discussed at monthly review meetings and with the director of ultrasound.

A clinical lead was always on call when the clinic was open to provide support to sonographers. The franchisor's IT system meant the clinical lead could access scans and results digitally and provide real-time input into scan analysis. This ensured women received accurate, timely interpretation of their scans.

The franchisor reported a 99.9% accuracy rate for their gender confirmation scans. There was a rescan guarantee in place for when it was not possible for the sonographer to confirm the gender of the baby. From 1 October 2020 to September 2021 staff had undertaken 155 rescans.

The service used key performance indicators to monitor performance, which the franchisor set. This enabled the service to benchmark themselves against others. Data was collected and reported to the franchisor every month to monitor performance. This included information about the number of scans completed including the number of rescans, and the number of referrals made to other healthcare services. The registered manager told us the service was above average in all performance indicators measured with respect to other to other clinics in the franchise. As the inspection was about Aylesbury clinic, the directors were not able to provide commercial comparison with other clinics.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Managers gave all new staff a full induction tailored to their role before they started work. We saw evidence of the induction checklist which included for example, mandatory training, an introduction to the 'firstScan' and Window to the Womb service.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. Sonographers were interviewed by senior clinical staff on commencing with the service. As part of the interview process their clinical knowledge was assessed to check a sonographers' clinical competency. This included the review of ultrasounds during the interview, alongside sonographers' registration, indemnity insurance and revalidation status. The sonographers, when they first commenced, were observed by an experienced sonographer. Senior clinical staff requested to see a random selection of their ultrasounds weekly when they first started to check their quality and accuracy. When senior staff were satisfied with a sonographers' performance, the sonographers had a yearly competency assessment with the lead sonographer for the franchisor.

Good

Diagnostic and screening services

We saw evidence of sonographers working for the service having correct and up to date Health and Care Professions Council registrations. The sonographers also belonged to the Society and College of Radiographers.

There was also a system of sonographers completing peer reviews. The senior team recognised the sonographer peer reviews were not always producing quality reports. In response to this, the service implemented two changes; peer reviews were to be completed by sonographers from other clinics, remotely and anonymously and to be completed online so they would be readily available.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff reported they had the opportunity to discuss training needs with their line manager. The registered manager supported staff to develop their skills and knowledge.

Managers supported staff to develop through yearly, constructive appraisals of their work. These had been completed except for one member of staff who had been in post for less than a year. Staff we spoke with had found the appraisal helpful.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. The registered manager printed out all team meeting minutes and placed them in a folder. A sonographer we spoke with told us about online meetings they attended to support the role. The week before our inspection there had been a discussion around ectopic pregnancy and communication at a team meeting.

The registered manager attended update meetings with the franchisors twice a year which included mandatory training sessions. The registered manager explained they were unable to attend the meeting due in October 2021, however they had already requested a copy of the presentations. If further clarification was needed, they planned to approach the franchisor's operations manager.

Managers identified poor staff performance promptly and supported staff to improve. Clinical leads managed performance issues of sonographers or scan assistants. The IT system meant clinical leads could securely support sonographers on or off site and randomly check scans completed by sonographers, to identify where to target support.

Multidisciplinary working

Sonographers and scan assistants worked together as a team to benefit women. They supported each other to provide good care.

During the inspection, we saw the team worked well together and observed positive communication between the scan assistant and sonographer.

The service had liaised with local NHS trusts to ensure their referral pathways were effective.

Seven-day services

Services were available at different times during the week and at weekends to support timely patient care.

The service ran six clinics a week. Tuesday evening, Wednesday during the day, Thursday and Friday evenings, Saturday all day and Sunday mornings. The service designed clinic sessions to accommodate the needs of women and their families, for example evening and weekend appointments enabled working mothers and siblings to attend.

Good

Diagnostic and screening services

Women and their partners could book appointments online or by telephone at a time to suit them.

Health promotion

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

The service had relevant information promoting healthy lifestyles and support in women's areas. The service provided families with information about pregnancy specific issues or concerns, for example morning sickness, keeping healthy, foods to avoid and complications in pregnancy and what to do.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff received and kept up to date with training in the Mental Capacity Act, as part of their induction and mandatory training. There was a Mental Capacity Act (2005) policy for staff to follow, which clearly outlined the service's expectations and processes.

Staff gained consent from women for their care and treatment in line with legislation and guidance. Staff clearly recorded consent in the women's records. All women were required to complete a consent form prior to undergoing ultrasound scanning. Consent form information included terms and conditions, scan limitations, referral consent and use of data.

Staff made sure women consented to treatment based on all the information available. Consent forms for 'firstScans' and Window to the Womb scans were sent to women as appropriate. Women were sent email reminders to read and complete information needed online before arrival if possible, to give them time to discuss with their partner if they wished. Staff told us most women completed forms before their appointments.

During our inspection, we saw that women's verbal consent was also sought before the sonographer commenced the ultrasound scan. Staff were aware women have a choice.

Are Diagnostic and screening services caring?

Good

Our rating of caring went down. We rated it as good.

Compassionate care

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

Good

Diagnostic and screening services

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed staff were warm, kind and welcoming when they interacted with women and their families. If women received bad news, this was given in the privacy of the scanning room.

Women said staff treated them well and with kindness. We observed four scans. Staff ensured privacy for women when needed, with the use of a privacy screen and disposable covering sheets. A scan assistant acted as a chaperone for all women during their scans.

Women and their companions were also able to leave feedback on open social media platforms, which the registered manager said were frequently monitored. On one platform there were 104 reviews, with the service highly rated. On another with 94 reviews, the service was rated 4.8. The comments were nearly all positive. Several reviews described most staff as 'lovely' and 'warm' and 'kind'.

During our inspection, we spoke with four women and their companions and they all described the service positively. For example, they said staff had been 'friendly and welcoming' and they came away feeling very reassured.

Staff followed policy to keep patient care and treatment confidential. Following a 'firstScan', staff went through the electronic report with the women in the privacy of the scan room, to ensure women understood the language and content used in the report. Staff then checked the understanding of the women and asked them if they had any questions.

Feedback forms (comment forms) were available in the clinic for women and their companions to complete. The registered manager advised us that feedback forms from 1 January 2021 to 30 September 2021 scored 4.85 out of 5. The registered manager explained some women had felt rushed.

Emotional support

Staff provided emotional support to women, families and carers to minimise their distress. They understood women's personal, cultural and religious needs.

Staff gave women and those close to them help, emotional support and advice when they needed it. People using services during our inspection told us they felt reassured by the information they received before their appointment and that it helped them prepare for their scan.

Staff informed us that women and their partners remained in the scanning room if the scan showed abnormal results whilst the scan assistant made the referral to an NHS provider. The woman and their partner could remain in the room for as long as they needed. The service had access to written patient information to give to women who received difficult news.

Staff provided reassurance and support for anxious women during their scan appointment. Staff showed a calming and reassuring demeanour so as not to increase anxiety for women and their partners.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. At the 'firstScan' clinic the sonographer said at the start of the scan 'sorry about the silence' whilst they carefully visualised structures present. We saw the sonographer providing reassurance throughout an ultrasound scan when women were anxious about the viability of their pregnancy. Both the scan assistant and the sonographer offered kind words of reassurance to both the woman and her partner.

Good

Diagnostic and screening services

Staff undertook training on breaking bad news. The registered manager explained staff had received training in May 2021 about how to give bad news, going through what to do before, during and after. The training underlined the principles of staff being calm, open and honest.

Understanding and involvement of women and those close to them

Staff supported and involved women, families and carers to understand their condition and make decisions about their diagnostic procedures.

During our inspection, we saw staff treated women and their families treated with kindness and respect. Staff welcomed women and their families including children to the service and there was enough room to accommodate eight guests with the service user in the clinic room. This may help children to bond with their unborn sibling.

Staff made sure women and those close to them understood their care and treatment. Staff took time to explain the procedure before and during the scan. We saw the sonographer fully explain what was going to happen throughout the scan. They used appropriate language to explain the position of the unborn baby and the images on the monitors. They asked people using services if they had any questions throughout and at the end of the scan.

Before the scan, staff asked people using services if they wanted to know the gender of the baby. If they didn't, they advised them they would ask them to look away from the screen when the baby's genital area was scanned. By warning them in advance, this avoided any anxiety or surprises.

For 'firstScan' appointments the two viewing screens in the scan room remained off until the sonographer had found a heartbeat. If the sonographer could not locate a heartbeat, they would ask the people using services if they would like to view the scan which enabled the women and their family to feel empowered in the decision-making process.

When people using services arrived in the clinic, scan assistants reviewed the prices of the scans with the people using services to ensure they had booked the correct scan for their requirements and were aware of the charges.

The franchisor had developed a smart device application which allowed women to securely view their scan images and videos remotely. The application enabled women to share their images and video to social media sites, or other individuals, as they so wished

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

Women and their companions were also able to leave feedback on open social media platforms, which the registered manager said were frequently monitored. On one platform there were 104 reviews, with the service highly rated. On another with 94 reviews, the service was rated 4.8. The comments were nearly all positive. Some women had been unhappy with the photographs.

Are Diagnostic and screening services responsive?

Good

Our rating of responsive stayed the same. We rated it as good.

Good

Diagnostic and screening services

Service planning and delivery to meet the needs of the local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Staff planned and organised services so they met the changing needs of people who used the service. The service had a range of packages with different price options which it clearly displayed on the website. People using services could book appointments online or over the phone. The service offered out of hours appointment times, in the evenings and during weekends. The service offered a re-scan service if 4D images could not be obtained at the planned time. The service saw only self-funding people using services. They did not see any NHS people using services.

Facilities and premises were appropriate for the services being delivered. The service provided information on travelling to the clinic on their website. The clinic was close to public transport links and provided free parking. Comfortable seating was provided in reception. The clinic was accessible for wheelchair users. The toilets were situated outside of the unit but were easily accessible for wheelchair users.

The scanning room could comfortably accommodate up to eight people and included a scanning couch, privacy screen, comfortable seating and two large screens for people using services to view the images. At the height of the Covid-19 pandemic the number of guests had been reduced to three, to ensure social distancing.

The service had developed an innovative mobile phone application which enabled women to document and share week-by-week images of their pregnancy 'bump' with their family and friends and create a time-lapse video of their pregnancy journey. Scan assistants saved any scan image taken during a Window to the Womb appointment onto the application. This enabled women to have instant access to their scan images.

Staff discussed the packages with the women and their partners upon entering the clinic, and the service displayed clearly each package on the website. All packages included a wellbeing scan.

Managers monitored and took action to minimise missed appointments. The booking system sent out automatic reminders ahead of appointments and the service offered a grace period for late attendances caused by unforeseen circumstances.

The people using services we spoke with said the clinic was easy to find, and provided a calm, professional environment.

If a service user did not attend for their appointment the service would not follow up due to the risk the service user may have miscarried. However, if a service user contacted the service to say they had miscarried the service would offer a full refund of all deposits paid.

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They coordinated care with other services and providers.

Managers made sure women and their loved ones and carers could get help from interpreters or signers when needed. Information on the scans provided and the consent process were available electronically in different languages, speak

aloud or enlarged font on an electronic device at the reception desk. All staff completed equality and diversity training that helped them deliver care in line with the franchisor's diversity policy. This ensured people with protected characteristics defined by the Equality Act (2010) received care free from bias. Each woman completed a health declaration form on which they could declare any reasonable adjustments they needed to safely and comfortably attend the appointment.

The examination couch in the scan room could accommodate women with a weight of up to 240 kg. This meant they were suitable for bariatric women using services.

The service could accommodate women in wheelchairs for an ultrasound scan as staff could control the examination couches electronically to enable the service user to transfer to the couch safely (if the service user could safely transfer themselves).

The ultrasound scan room provided a calm and relaxing atmosphere with dimmed lighting to ensure the people using services were able to view the scan picture on the screens clearly.

Staff were able to extend and change clinics to support people using services. For example, the service would often accommodate women who required reassurance for a last-minute scan on the same day. On the day of our inspection, there were two on the day bookings.

Staff gave information leaflets to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy, a second scan that confirmed a complete miscarriage or an inconclusive scan. The leaflets contained a description of what the sonographer had found, advice, and the next steps they should take.

All people using services we spoke with reported their appointment times were long enough for them to ask questions and gain reassurance. It also allowed time for the women to go for a walk to encourage the foetus to move to improve the scan image. On the day of our inspection we saw this happen in practice.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to test and from test to results were in line with national standards.

The service did not have a waiting list for appointments. Women could self-refer to the service on the same day if required. We saw some same day appointments booked on the inspection. Women could book their scans through the website 24-hours, seven days a week, via telephone or email.

The booking system was flexible and featured a range of packages for people to choose from. . People who used services paid a small deposit upon booking the scan and could change the package when they attended for their scan appointment if they wished.

On the day of inspection, we saw people using services arrive in the reception area and wait no longer than five minutes for their scan. Scan assistants advised people using services to arrive 10 minutes early for their scan to ensure time to complete the paperwork and to discuss the scan procedure.

The sonographer gave the results of the ultrasound scans to the service user immediately after the scan which enabled them to discuss their results with the relevant health care professional in a timely manner.

Good

Diagnostic and screening services

Staff ensured there was time between scans for cleaning and rescanning, such as if baby was not in the optimum position for a clear image. This kept delays and waiting times to a minimum. If a sonographer could not obtain a clear image during a scan due to the position of baby, staff encouraged women to take a walk and have a drink. We saw this happen during our inspection. The appointment structure meant a rescan could take place quickly. Staff facilitated fast access to scan images and made these available to women immediately.

The franchisor employed a full-time sonographer who was available via telephone to review real time scans if the sonographers needed a second opinion. Response times varied from 10-15 minutes to half an hour.

If a staff member went off sick the service did not use bank or agency staff instead, the scan assistants and sonographers would cross-cover between themselves to help prevent clinic cancellations. There were two days when this had not been possible. To ensure patient safety women were rescheduled.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included women in the investigation of their complaint.

Women and those accompanying them knew how to complain or raise concerns. The complaints policy was displayed in the clinic. They could speak with staff, including a manager, on request. Staff provided complaint forms and women could also submit a complaint through the service's website.

Managers investigated complaints and identified themes. The service had received 17 complaints since 1 October 2020. Themes identified by the registered manager included concerns about the quality of the image and lack of urgency, bedside manner, care and concern.

Managers shared feedback from complaints with staff and learning was used to improve the service. This was shared through a staff newsletter in April 2021 and customer care training. The information included recent complaint trends, and what staff could do differently to ensure a positive patient experience. The registered manager had placed the letter in staff records, which we could see they had read, signed and dated. Since the newsletter there had been four complaints and none in August or September 2021.

Staff knew how to acknowledge complaints and women received feedback from managers after the investigation into their complaint. The franchisor's policy was to acknowledge receipt of a complaint immediately and then provide a resolution or update by the seventh working day.

The franchisor's complaints' policy included clear escalation for women to follow if they were dissatisfied with the outcome, including contact details for a director. However, the policy directed women to submit unresolved concerns to the Care Quality Commission (CQC). CQC does not mediate complaints and instead the policy should refer to an independent service. The terms and conditions which people using services signed before their scan, provided information about contacting the service if they had a complaint and an independent resolution service. CQC does ask people to tell them about their experience of care, good or bad, to understand the quality of care people get from services.

Are Diagnostic and screening services well-led?

Good

Diagnostic and screening services

Good

Our rating of well-led stayed the same. We rated it as good.

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 women and staff. They supported staff to develop their skills and take on more senior roles.

The leadership team was well defined. The registered manager was the franchisee owner and operator and held overall responsibility for regulatory compliance, with support from directors. An area manager was responsible operationally for clinics in the local network and a clinic manager led the individual service on a day to day basis. Staff told us this structure worked well and they felt supported by readily accessible, visible leadership.

Senior staff working nationally consisted of directors and a clinical lead. The clinical lead worked nationally to support sonographers and scan assistants with clinical care. An additional experienced sonographer, with over 40 years NHS experience, had recently joined the senior clinical team. The plan was for them to support the clinical lead on remotely assessing and reviewing scans on a monthly basis and providing feedback to sonographers via clinic owners and managers.

The directors and senior clinical staff provided oversight of policies and compliance with national guidance and best practice. During our inspection, we saw visible leadership and that managers readily engaged with women and those accompanying them.

The registered manager oversaw the sonographers and scan assistants and was responsible for the everyday running of the clinic. The registered manager shared business information with the directors of the franchise. We observed clear management and reporting arrangements in place.

The registered manager attended six monthly national franchise meetings. During these formal meetings, there was an opportunity to network and share best practice ideas as well as receive ongoing training and have discussions around clinic compliance, performance, audit, and best practice. The registered manager told us the franchise operations manager for their area was readily available if needed for advice.

The registered manager was always available via telephone if there were any service user or staff concerns or in the event of an adverse incident.

Staff told us the registered manager was accessible and approachable if they wanted advice or to make suggestions. The registered manager kept staff informed of any developments for the service.

Staff could access support, advice and guidance from three clinical leads employed by the franchisor. This included a consultant radiographer and specialist nurse in early pregnancy. The clinical lead for the franchisor assessed all new sonographers and had over 35 years NHS sonography experience. The specialist nurse in early pregnancy provided clinical leadership regarding ‘firstScan’ early pregnancy scans and completed a yearly annual check of the clinic.

Good

Diagnostic and screening services

Vision and Strategy

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 vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.

The registered manager's vision was to provide people using services with easily accessible, high quality imaging using ultrasound technology, in a caring and professional manner.

The service had also identified values, which underpinned their vision. Their values included: Focus, dignity, integrity, privacy, diversity, safety and staff. All staff we spoke with were aware of the values and embedded them into everyday practice. Staff told us their purpose was to provide a positive customer experience.

There were also aims, which identified what the service needed to do to achieve their vision. Examples included: "to provide pregnant ladies with medically relevant ultrasound findings by way of an obstetric report", and "to report any suspected abnormalities identified using the pathways we have established with our local NHS hospitals".

Culture

Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where women, their families and staff could raise concerns without fear.

The franchisor had a freedom to raise a concern guardian, a freedom to speak out policy and a whistleblowing policy which staff were aware of. Staff told us they could make comments and suggestions, could talk freely and felt supported to drive improvements by the registered manager. A member of staff suggested a list of foetal health referral addresses along with early scan referral addresses. The member of staff told us their suggestion was acted on promptly, with the additional referral addresses now available.

Staff told us they worked well together as a team and there was an open and honest culture. We saw a 'no blame' approach to the investigation of complaints and the registered manager addressed performance issues through open and honest one to one feedback with staff.

All staff spoke proudly about their roles within the service and staff felt supported in their work. Staff told us they felt valued and supported by colleagues and the registered manager. Staff told us they enjoyed coming to work.

There was a strong emphasis on the care of the women and their families. Staff promoted openness and honesty and understood how to apply the duty of candour. Staff were aware of what the term duty of candour meant.

The registered manager told us if they recognised a strength in a staff member, they would encourage growth and development to move them up to a more senior role. For example, the registered manager had identified a scan assistant with leadership potential and had promoted them to a senior scan assistant role in February 2021.

Governance

Good

Diagnostic and screening services

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The service had a clear governance process to continually improve the quality of service provided to women and their families. Staff understood their roles and responsibilities in relation to governance. The service improved service quality through regular audits and clinical reviews by lead clinicians employed by the franchisor.

The registered manager followed a robust recruitment process for all staff, which included reviewing application forms for employment gaps, references and Disclosure and Barring Service checks. The recruitment of sonographers was undertaken by clinical staff employed by the franchisor, as the registered manager did not have a clinical background.

There were policies and procedures in place for the operation of the service and these were available to staff in a folder in the clinic. All policies were up-to-date and reviewed yearly by the franchisor. The registered manager explained staff could feedback verbally or by email if they had any comments to make about policies. They had not fed back themselves but following feedback from other franchisees about the title 'Fetal Abnormality Policy', the policy was retitled 'Fetal Ultrasound Policy'.

The franchisor employed a consultant radiographer to advise the board on compliance with national standards and ensured policies and strategy was in line with best evidence-based practice.

The clinical governance panel sent updates to franchisees when scan protocols updated. The latest update dated 11 August 2021 had been printed and was in the communications folder for staff to read.

The franchisor had indemnity and medical liability insurance which covered all staff working for the franchisor, in the case of a legal claim and was in date until October 2021. The registered manager was waiting for the renewed indemnity and medical liability insurance to arrive.

The franchisor had a clear governance policy which outlined the responsibility of board members, the relationship between franchisor and franchisor and the requirement for regular audits.

The audit programme included monthly local audits, yearly audits and peer review audits. Yearly compliance audits included premises checks, health and safety, emergency planning, accuracy and completion of scan reports, completion of pre-san questionnaires, professional registration and staff records.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events. Staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

The registered manager had an awareness of the service's performance and challenges. They could describe actions to address these challenges. For example, the challenge of finding, assessing at interview and keeping good staff which resulted in a high quality service.

The service did not have a risk register however, we saw evidence the registered manager reviewed all risk assessments monthly to ensure they documented any changes or identified new risks. We saw up-to-date and complete risk assessments for fire, health and safety, legionnaires' disease and the Control of Substances Hazardous to Health (COSHH). The registered manager recorded risk assessments on a form which identified the risk and control measures and the member of staff responsible for monitoring and managing the risk. We saw risk assessments were easily accessible to all staff and all staff had seen them.

At the last inspection, the risk of scan assistants caring for children whilst their mother was in the scan room had not been risk assessed and not detailed in the risk assessments. Staff discussed this risk with us. The registered manager advised this request by mothers was unlikely as mothers were encouraged to take their children into the scan room. If for any reason a scan assistant was required to look after a mother's children it would be at the request of the mother, and children would be looked after in the reception area where other staff and people using services were also present.

People using services were strongly recommended in the terms and conditions to access all antenatal services made available by the NHS, and that they were available free of charge. We observed four people using services and their companions being reminded to access all the antenatal services made available to them through the NHS.

To reduce the risks of lone working, there were always at least three staff on site when the service was open.

The service used key performance indicators to monitor performance, which the franchisor set. This enabled the service to benchmark themselves against the 36 others in the franchise.

The audit program undertaken by the registered manager helped them to identify any risks to the provision of a quality service rating to performance and adherence with policies and guidance.

Information Management

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

The franchisor was registered with the Information Commissioner's Office (ICO), in line with The Data Protection (Charges and Information) Regulations (2018). The ICO is the UK's independent authority set up to uphold information rights. Women consented for the service to use their personal data in providing a service. This was part of their signed agreement within the form detailing the ultrasound process. This demonstrated the service's compliance with the General Data Protection Regulation (GDPR) (2018).

The service had an up to date privacy notice policy which referred to all relevant legislation regarding staff responsibilities, documentation standards and the retention of records.

Staff could see how many scans the service had completed and how many women the sonographers had referred to maternity services for ongoing care. The service recorded each referred service user and reported back to the franchisor. Staff could view the numbers monthly.

There was enough information technology equipment for staff to work with across the service. This meant staff had access to the required information at the time they needed it.

Good

Diagnostic and screening services

Engagement

Leaders and staff actively and openly engaged with women, staff, equality groups, the public and local organisations to plan and manage services. They collaborated with partner organisations to help improve services for women.

Staff told us they felt involved in the running of the service and were able to give feedback and suggestions. Staff worked closely with colleagues in another of the franchisor's clinics in the region to help support capacity and learning. Managers reviewed and responded appropriately to feedback from women in real time. The brand had an active social media presence and managers monitored this to ensure feedback was captured and confidentiality maintained.

Staff told us managers were visible and easy to communicate with through secure messaging, phone or in person. The franchisor held conferences twice yearly for franchisee owners and registered managers. This was a structured opportunity to keep up to date with the operation of the business and to share learning, experiences, and challenges with colleagues from clinics across the country.

The franchisor produced a newsletter called 'open window'. Open Window contained information on what was happening across the franchise and updates on e-learning and policies. The service kept copies in a communication folder. The newsletter was produced when there was information and updates to share.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

The registered manager supported continuous improvement. The franchisor had recently updated the policy, 'Policy for Reacting to a Missed or Incorrect Diagnosis'. The registered manager had put information detailing the additions and reasons for the additions in the staff communications folder, to ensure staff were aware and understood the additions.