Baby Scans Cheshire Limited

Window To The Womb

Inspection report

115 Station Road
Ellesmere Port
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Tel:

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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. 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 effective care and treatment. 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.
- 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 long for their results.
- 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 continuous improvement.

However:

- The provider needed to ensure that they obtained the appraisals for Sonographers working at the service whose substantive post was in the NHS or another provider.

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 location. 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 effective care and treatment. 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. • 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 long for their results. • 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 continuous improvement. However:

Summary of findings

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Summary of findings

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Summary of this inspection

Background to Window To The Womb

The clinic is in Ellesmere Port, Cheshire and is owned by Baby Scans Cheshire Limited, trading as Window to the Womb (Ellesmere Port). The clinic has one scan room, a reception area /waiting room and an area where service users can choose their photographs and keepsakes. It is located on the ground floor of a building very close to the rail station and is fully accessible. The clinic is registered to provide the following regulated activities:

• Diagnostic and screening procedures

There was a registered manager for the clinic who had been in post for around one year. There had been a registered manager in post since the clinic opened in 2018.

We had not inspected or rated this location previously.

Window to the Womb in Ellesmere Port is part of a franchise group. The franchise headquarters is in Stockport and the franchisees who own the clinic also own two other Window to the Womb franchise clinics.

The clinic provides pregnancy ultrasound services to women aged 16 to 65.

Window to the Womb has separated their services into two clinic types. 'Firstscan' clinic sessions specialise in early pregnancy scans from seven weeks up to 16 weeks gestation. 'Window to the Womb' clinic sessions offer later pregnancy scans. The Firstscan and Window to the Womb sessions take place at different times. All women were given a scan to check the well-being of the foetus but women could also receive gender identity scans and 4D bonding scans up to 30 weeks of pregnancy.

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

The clinic was open on two weekdays and at weekends.

At the time of our inspection the clinic employed one registered manager, four sonographers and four scan assistants. There was also an area manager who worked there one to two days per week.

In the reporting period January 2021 to December 2021 the service carried out 2,621 scans on women who were 16 to 40 weeks pregnant and 1,450 scans on women from seven to 16 weeks pregnant.

How we carried out this inspection

Our inspection was short announced (staff were told that we were coming during the week of our inspection) to ensure that we could speak to the registered manager and a sonographer and to enable us to observe routine activity. We inspected this service using our comprehensive inspection methodology.

Two inspectors carried out the inspection on 19 January 2022 with off-site support from an inspection manager. During the inspection, we met with the registered manager, area manager a sonographer and scan assistant. We also spoke with three service users and their partners.

Summary of this inspection

We reviewed four client records and five staff records. We also reviewed policies and procedures held by the provider and other associated 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.

Outstanding practice

The service purposely ran early pregnancy and later pregnancy clinics at different times to ensure that women who had experienced pregnancy loss or were anxious about their pregnancy did not share the same area with women who were much later in their pregnancy.

Areas for improvement

Action the service SHOULD take to improve:

- The provider should ensure that they obtain the appraisals for Sonographers working at the service whose substantive post is elsewhere in the NHS or another provider.
- The provider should ensure that there is access to independent interpreters to assist women whose first language is not English or who may have a hearing impairment to ensure that a relative does not act as an interpreter where there may be a safeguarding concern such as suspected forced marriage or FGM.

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

We had not inspected this service before. 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.

The mandatory training was comprehensive and met the needs of women and staff. Mandatory training requirements, including topics covered and frequency of training for each role were defined in the mandatory training policy.

The training included e-learning courses in Window to the Womb induction; firstscan (early pregnancy scan) induction; breaking bad news; child protection (child safeguarding); adult safeguarding; chaperone training and decontamination training. The decontamination training taught staff how to correctly use decontamination products used on the internal probe for trans-vaginal scans. The manager, assistant manager and team leader also undertook first aid training which was also optional for sonographers and scan assistants.

Managers monitored mandatory training and alerted staff when they needed to update their training. The service kept a training matrix that clearly showed when the training was due to be undertaken by each staff member. We reviewed the training matrix and saw that staff were up to date with their mandatory training.

Sonographers undertook the Window to the Womb mandatory training courses but also supplied evidence of their NHS mandatory training and Continuing Professional Development (CPD) log to the clinic manager.

In addition to the annual training courses the staff received training in a “topic of the month” delivered in a monthly team meeting. These included safeguarding refresher training twice yearly; fire and health and safety training annually.

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.

Good

Diagnostic and screening services

Staff received training specific for their role on how to recognise and report abuse. The manager and assistant manager had received level three training in children and adult safeguarding, as had the regional manager. The team leader, sonographers and scan assistants had all received at least level two training in children and adult safeguarding. Sonographers had generally received level three training in their NHS role. Staff could complete the training in the clinic or were paid to complete it in their own time. There were safeguarding refresher topics covered at team meetings during the year. There was always someone trained to level three in the clinic.

Staff could give examples of how to protect women from harassment and discrimination, including those with protected characteristics under the Equality Act.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff knew how to make a safeguarding referral and who to inform if they had concerns.

The manager described several examples of where appropriate safeguarding referrals had been made to the local authority. The manager was also the designated safeguarding lead for the service.

Staff followed safe procedures for children visiting the service.

The service scanned women over 18 years of age and women aged 16 to 18 years of age who were accompanied by a parent or guardian. They did not scan below the age of 16. Women were asked for a date of birth and the patient record system flagged those women who were between 16 and 18 so that additional safeguarding measures could be put in place.

The service had policies for safeguarding adults; child protection (children's safeguarding); female genital mutilation and Gillick competencies. They contained contact details of local authority safeguarding teams covered by the clinic. Policies and procedures were written centrally by the provider and disseminated to individual clinics who were part of the franchise. The provider had taken advice from a CQC safeguarding lead when reviewing the policies, to ensure that they covered all that was necessary. The policies were in date and had recently been updated. The policies covered child sexual exploitation and the PREVENT government strategy, that was developed to assist in signposting organisations where there was a suspicion of an adult or child having been radicalised.

The service required all staff to have a Disclosure and Barring Service (DBS) check as part of the recruitment process. The service repeated the check every three years for the registered manager and scan assistants and annually for sonographers. We checked staff files and in the five files we checked the DBS check was documented in the files.

There was a DBS policy that stated that two members of staff should be present when any scans were undertaken.

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.

Clinical areas were visibly clean and had suitable furnishings which were clean and well-maintained. All furniture in the clinic had wipeable surfaces and all floors were washable. There were no carpets. During the pandemic, toys had been removed from the waiting area to reduce the risk of infection.

Couches in the waiting area were sufficiently spread out to maintain social distancing

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. The clinic underwent a monthly deep clean. All staff took part in cleaning the premises.

Staff followed infection control principles including the use of personal protective equipment (PPE). The scanning room had ample personal protective equipment and staff wore gloves, masks and aprons when in the scanning room with women.

There was a handwashing sink in the scanning room, and we saw that staff washed their hands before and after scanning the women.

Staff cleaned equipment before and after client contact. Staff cleaned the trans vaginal and ultrasound probe with specialist disinfection foam and wipes after each use. We saw that staff had received training in use of the products to ensure maximum protection of women.

We saw that disposable paper towel roll was used to cover the examination couch and this was changed, and the couch cleaned between scans.

Staff followed the World Health Organisation 'Five Moments for Hand Hygiene' and arms 'bare below the elbows' guidance. Hand sanitising gel was also available for staff, women and visitors to use at the reception desk.

The clinic manager carried out hand hygiene audits quarterly and these showed that 100% of hand hygiene moments had been adhered to by staff.

All posters and policies displayed in the clinic were laminated to make them easy to clean and prevent the spread of infection.

The service had policies on scan room safety and hygiene (detailing the way that they ensured their scan room was safe, clean and hygienic and the cleaning schedule to be displayed in the clinic); infection control (detailing how they minimised the risk of infection); clinic cleaning and laundry policy and a mobile sink cleaning policy. The infection control policy had been updated in line with COVID-19 precautions and restrictions.

Environment and equipment

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

Staff kept substances which met the Control of Substances Hazardous to Health (COSHH) regulations in a locked cupboard. We saw that these were stored appropriately. A risk assessment was completed and would be repeated every year. COSHH training was part of the health and safety mandatory training.

Staff carried out daily safety checks of specialist equipment. Training on use of the scanning machine was delivered to sonographers new to the service, by the clinical lead of the Window to the Womb franchise provider. The machine was serviced annually, and the service was due to take place the day after our inspection.

The couch in the scanning room was adjustable and could be lowered and raised. There were service records in place for the couch.

Good

Diagnostic and screening services

All electrical equipment in the clinic was PAT tested (portable appliance testing) annually and this was next due in April 2022.

Fire equipment was tested, and staff knew what to do in case of a fire. The service carried out fire drills and there were fire extinguishers on the premises.

An annual risk assessment of the premises was carried out and this included a fire risk assessment.

There were appropriate bins for clinical waste disposal in the clinic. These were emptied into a clinical waste bin in a secure area outside the premises. The manager was aware that the lock on this bin was broken. They have since arranged for a new bin to be delivered by the waste collection contractor.

The clinic kept a first aid box, and this was in date. There were three trained first aiders and always one on site when the clinic was open.

Assessing and responding to patient risk

The service had appropriate arrangements in place to assess and manage risks to women, their foetus and families. Staff knew what to do and acted quickly when there was an emergency.

Staff completed risk assessments for each woman on arrival. The service advised all women to bring their NHS pregnancy notes with them, so sonographers had access to their pregnancy and medical history. Staff told us if a woman did not bring her notes they would call her GP or midwife before carrying out a scan. Staff made sure women understood that the ultrasound scans they provided were in addition to their routine maternity care and advised any woman who had missed a 12-week scan to register with a midwife.

All women completed a pre-scan questionnaire that included pregnancy history. This included a declaration signed by the woman which gave consent to pass medical information to an NHS care provider if needed and a confirmation that she was receiving appropriate pregnancy care from the NHS.

Women were also asked to confirm whether they had received a scan within the previous 14 days. Affirmative answers were highlighted in red on the patient record system and women would be contacted before attending the clinic to find out when the scan had been. In urgent cases, a scan would be considered but not if a woman had received a scan within the last seven days. The manager was able to give an example of where a woman had been refused a scan for this reason.

Women who attended for a scan were asked if they had a latex allergy.

The service followed the ‘as low as reasonably achievable’ principles outlined by the Society and College of Radiographers. This meant that sonographers did not scan for longer than 10 minutes and would not repeat scan within seven days of the previous scan.

The clinic would not scan any women who were more than 16 weeks pregnant and were not on an NHS antenatal pathway.

Good

Diagnostic and screening services

The service used the 'Pause and Check' list devised by the British Medical Ultrasound Society and Society of Radiographers. We saw the sonographer completed the checks during scans, which included confirming the woman's identity (name, address and date of birth) and consent, providing clear information and instructions, and informing the woman about the results. The pause and check list was clearly displayed in the scanning room and could be seen by the sonographer.

There was a policy in place and staff knew what to do in the event of any sudden deterioration in a woman's health. If a woman was suspected as having an ectopic pregnancy an ambulance was called to transport them to hospital as an emergency.

Staff knew about and dealt with any specific risk issues. The service had clear processes and pathways with local NHS providers for staff to follow if any abnormalities were found on an ultrasound scan. We noted that the screens in the scanning room were not turned on by the scan assistant until the sonographer had detected a heartbeat for the foetus.

Staff told us if an abnormality was detected they would call the local early pregnancy unit, triage unit or emergency gynaecology department, with the woman's permission. An appointment would be made. If an abnormality was detected the sonographer would give an explanation to the woman and their partner and the assistant would write up the report. The woman and their partner would stay in the scan room to ask any questions.

Staff shared key information to keep women safe when handing over their care to others. The woman was provided with a report to take with them to the hospital.

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. Staff received a full induction and there was an induction policy in place.

The service had enough staff to keep women safe.

The clinic was managed by the registered manager with an area manager who covered three clinics owned by the franchisees.

There were four sonographers who worked for the service. All worked in substantive posts in the NHS. One of the sonographers also worked part time at another Window to the Womb clinic. The sonographers were registered with the Health and Care Professions Council as diagnostic radiographers

There were four scan assistants, one of whom acted as assistant manager and one of whom acted as team leader and would run the clinic in the registered manager's absence. The role of the scan assistants was to run the reception, assist in the print area, brief the sonographer on the next customer and act as a chaperone in the scanning room.

There was also an administrative assistant who worked remotely for the clinic and two others owned by the franchisees, taking bookings and giving advice to potential customers.

For each shift at the clinic there was a manager present, a sonographer and two scan assistants.

Good

Diagnostic and screening services

The clinic opening hours were worked around the availability of the sonographers. If a sonographer was unavailable, the clinic could try to get a sonographer from elsewhere in the clinic group to cover a clinic. The service did not use bank or agency staff.

The clinic had a lone working policy although staff did not work alone in the clinic. There was a panic alarm in the clinic, and this enabled a security company to listen to the clinic environment and call for assistance if necessary.

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.

Client care records were comprehensive and all staff could access them easily. The clinic used an electronic records system to store pre-scan questionnaires, referrals to NHS services and completed well-being scan documents.

The pre-scan questionnaire was comprehensive and gathered details about the woman's NHS details, reason for appointment and patient history, such as number of previous pregnancies and births, caesareans, miscarriages, ectopic pregnancies, reversed sterilisation and so on. The questionnaire also gathered details of the woman's last menstrual period, first positive test, previous scans and latex allergies. The woman was also able to make any comments in a free text box on the questionnaire.

Appointments on the records system were clearly flagged for females under the age of 18; with a pregnancy calculated at under six weeks or over 30 weeks who wanted a 4D scan as it may not have been appropriate to perform scans on these women.

Women were provided with a copy of their well-being report at the end of the scan.

When it was necessary to make a referral to the NHS for a woman to receive further advice or treatment, the woman was provided with a full report of the concerns and a referral letter to take with them to the early pregnancy unit or other hospital department.

Referrals were arranged by telephone by the sonographer before the woman left the clinic wherever possible.

The clinic had originally kept paper records, and these were stored securely. There was an ongoing process of digitally archiving the records.

There was a phone application for staff and service users were given a unique access code so that they could access their images. Women had instant access to their scan images and could share them with whoever they wanted to.

Medicines

The service did not use any medicines or controlled drugs.

Incidents

The service managed 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.

Good

Diagnostic and screening services

The clinic had an incident policy. This included how to respond to any clinical incidents, including what constitutes a serious incident and a serious incident report template.

There was also a policy for responding to a missed or incorrect diagnosis, an incorrect gender identification policy and a duty of candour policy.

The clinic kept an incident log. Incidents were reviewed and managed by the clinic manager. Incidents were investigated thoroughly. Women and their families were involved in these investigations. The service recorded very few incidents. There had been no incidents of moderate harm or above in the last 12 months and no requirement to apply duty of candour.

Staff knew what incidents to report and how to report them.

Staff raised concerns and reported incidents and near misses in line with the service's policy.

Staff understood the duty of candour.

Staff received feedback from investigation of incidents, both internal and external to the service.

Staff met to discuss the feedback and look at improvements to a client's care. Incidents were reviewed and discussed at team meetings and clinic manager meetings.

The manager gave an example of actions undertaken following a missed spina bifida diagnosis where all the sonographers carried out refresher training, reviewed the scan video and carried out reflection and feedback.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not rate the effective domain for diagnostic services.

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

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

Local policies and protocols were up-to-date, written for all Window to the Womb franchise clinics centrally by the franchisor clinical lead, a diagnostic sonographer and clinical nurse specialist. They were reviewed by the lead sonographer and a consultant in obstetrics and gynaecology. They followed national guidance from the Royal College and Society of Radiographers, the foetal abnormality screening programme standards and British Medical Ultrasound Society.

The franchise made individual clinics aware when there were changes to guidelines and updated and disseminated update policies and procedures.

Policy updates were sent to staff via an electronic e-signature document that staff had to sign to say that they had read and understood the policy or procedure. Updates to procedures were discussed at team meetings.

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

Patient outcomes

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

The service monitored outcomes for service users and experience, through monthly clinic audits and client satisfaction feedback cards and complaints. Positive feedback from women and low numbers of complaints and incidents indicated that most women had a positive experience.

The service did not participate in any local or national clinical audits but did benchmark against the other clinics owned by the franchisees.

The service monitored the reasons for self-referral for early pregnancy scans to look for trends. The main reason for self-referral was anxiety.

Managers and staff carried out a comprehensive programme of repeated audits to check improvement over time.

We reviewed the monthly clinic audits for November and December 2021 and saw that the clinic had received no complaints and there were no incidents. The clinic had a target of meeting a less than 8% rescan rate for customers. This target had been consistently met.

Managers and staff used the results to improve women's outcomes and made sure staff understood information from the audits. We saw that audit results were discussed at monthly area managers meetings and team meetings and suggestions for improvements were made and agreed.

As well as monthly monitoring, the franchisor carried out a comprehensive compliance audit every year. Areas covered in the audit were physical clinic inspection, health and safety, infection control, emergency planning, operational delivery, policies and procedures, client feedback and staff including the sonographers. Following the audit action plans were put in place with dates for completion of those actions.

We reviewed the last clinic compliance audit, carried out in November 2020 which showed that the clinic had been given the highest rating and was fully compliant in all areas.

Sonographers received a clinical review by the franchisor clinical lead once a year. There was also a process in place for peer review of scan reports to gain assurance that scan procedures were carried out in line with the service's policies. Each sonographer peer reviewed four randomly selected scan records from one of the other sonographers every three months.

The clinic manager carried out a service and care assessment for staff every three months.

The dates of assessments due for each member of staff were logged on the training record.

Good

Diagnostic and screening services

Every scan started with a diagnostic well-being scan to give reassurance to the women that the pregnancy was developing normally and to check the well-being of the foetus.

The service reported that there had been a total of 75 referrals made to NHS services from January to December 2021 as a result of unexpected findings during scan procedures. Nine of these had been for women over 16 weeks pregnant and 66 for women who were under 16 weeks pregnant.

Competent staff

The service made sure staff were competent for their roles. Managers appraised the work performance and held supervision meetings with non-sonographers to provide support and development, however, they did not have processes in place to carry out or review appraisals for sonographers working in the clinic.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women.

Newly appointed staff underwent an induction process and competency assessment following the commencement of employment. Scan assistants underwent a probationary period.

We checked five staff files and found that they were complete. We saw that employment checks had been completed and that references had been taken up for each member of staff. There was a statement from each NHS trust that employed the sonographers about their suitability for the role. All induction training had been completed and the initial assessment for the sonographers had been completed.

The sonographers had received competency based training as part of their substantive NHS roles and each sonographer maintained their individual competencies as part of their continual professional development (CPD). This was held on staff files. All the sonographers were registered with the Health Care Professions Council (HCPC) and we saw evidence of this in the staff files and training logs.

Managers supported scan assistants to develop through yearly, constructive appraisals of their work. Staff had objectives and targets. A performance plan was put in place where more support was needed. Managers identified poor staff performance promptly and supported staff to improve.

There was no formal process for appraisal or supervision of sonography staff in the service. The sonographers underwent annual appraisal as part of their substantive NHS roles. The registered manager told us the individual sonographers held their appraisals individually and these were not routinely requested or reviewed as part of the service's assurance processes.

Managers made sure staff attended team meetings or had access to full notes when they could not attend.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge.

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. One member of staff had attended a course, at their own request, to improve their knowledge of invitro fertilisation (IVF).

Managers made sure staff received any specialist training for their role. The clinical lead for the franchise trained staff on the scan equipment in use in the clinic

Good

Diagnostic and screening services

Multidisciplinary working

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

We saw that all the staff worked well together. The scan assistants greeted people as they arrived at the service and supported them to fill in the paperwork. A scan assistant worked with a sonographer in the scanning room and each was aware of their role in the scanning process. They supported each other to form a good rapport with the women and their relatives. On completion of the scan the women were moved back into the waiting room to the area where they could pick their photographs and buy extra items.

The service worked with local NHS maternity services if they needed to refer women with any abnormalities on their ultrasound scan. The clinic had built relationships with early pregnancy units, foetal medicine, labour wards and maternity day units at local NHS hospitals. We were told that the early pregnancy units were happy to take telephone referrals from the clinic following a discussion with the sonographer about their concerns.

The service had an electronic computer application to assist them to make safeguarding referrals to local authority safeguarding teams in the area that the clinic covered.

Seven-day services

Services were available to support timely care.

The clinic was not open seven days a week but the manager told us that they had tried to give as much flexibility as possible in opening hours to enable women to make a convenient appointment time, whether this being in the evening, during a weekday or at the weekend. The telephone line was staffed seven days a week.

At the time of our inspection, the clinic was open every weekend from 9am to 5pm; one evening a week from 3pm to 9pm and one day a week from 9am to 5pm. The telephone was staffed every day from 9am to 7pm.

Health promotion

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

The service had relevant information promoting healthy lifestyles and support.

The clinic stocked a range of leaflets on conditions and health promotion in pregnancy. We saw leaflets on the scan report they would receive; sickness in pregnancy; inconclusive scans; information following a scan suggesting a missed miscarriage; second scans that have confirmed a complete miscarriage; sub-chorionic bleeds and pregnancies of unknown locations.

The service worked with two companies who had mobile phone and computer applications. One was a midwifery application providing the answers to the most common questions for expectant women. The other was an application that aided mental and physical health promotion and well-being in pregnancy, including mood management, stress levels and tracking key pregnancy metrics such as the expected size of the foetus and physical and mental changes that could be expected at different stages of the pregnancy. Women were signposted to these applications for further support.

Consent and Mental Capacity Act

Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent. Staff followed the service policy and procedures when a woman could not give consent.

Good

Diagnostic and screening services

Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. The service had a Mental Capacity Act policy in place which staff knew how to access.

When women could not give consent, they were referred back to the NHS for any scanning procedures because the service did not carry out any procedures without signed consent.

Staff gained consent from women for their care and treatment in line with legislation and guidance.

Staff made sure women consented to treatment based on all the information available.

Staff clearly recorded consent in the women's records.

All women received written information to read and sign before their scan. This included a technology and safety briefing, terms and conditions, information on scan limitations, a crib sheet on what is and is not included in the scan package, information on medical records, consent and use of data. We looked at three care records and saw that they showed written consent had been obtained from women and that planned scans were delivered with their agreement.

Women receiving a transvaginal scan were asked to give verbal consent to the sonographer after they had received an explanation of what this entailed.

There was no separate consent for women aged 16 or 17 but service users of these ages had to bring a parent or legal guardian with them who signed the consent form.

Staff understood Gillick Competence guidelines and had received training in this. The service had a Gillick Competencies policy in place.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 and the Children Acts 1989 and 2004 and they knew who to contact for advice.

The sonographers had received mental health act training as part of their training within their NHS roles.

Are Diagnostic and screening services caring?

Good

We had not inspected this service before. 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.

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 saw the scan assistants chatting with the women and explaining the processes of the scanning and the images. They showed women the phone application and how they could get their images and how they could share them.

Privacy and dignity were protected as there was always a scan assistant in the scanning room with the woman who acted as a chaperone. The scan room door was locked when women were having an intimate scan and there was a privacy screen, so the woman could undress. The women were covered with a large towel during the scan.

During the scans we observed, women were treated sensitively, and the sonographer was professional, respectful, and supportive at all times.

Women said staff treated them well and with kindness. We reviewed 50 feedback cards completed by women after their scan and everyone gave a five star rating for all areas that included the initial welcome received, the care provided during their scan and the overall experience. We saw that the clinic had also received 100% positive reviews on a social media page and on a customer review website. The service monitored reviews on social media and responded to reviewers.

We spoke with three women and their loved ones. They described the care they had as being excellent and said they felt reassured. They said they had enough information before coming to the clinic and the appointment had been easy to book.

Staff followed policy to keep client care and treatment confidential.

Staff understood and respected the individual needs of each woman and showed understanding and a non-judgmental attitude. Women were offered a free rescan where it had not been possible to obtain clear images of the foetus.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs.

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.

Staff supported women who became distressed in an open environment and helped them maintain their privacy and dignity.

All staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations.

When the sonographer had to deliver bad news to a woman, they were kept in the scanning room whilst receiving an explanation of what had been found and remained in there whilst a report was produced for them to take away and an appointment was made with the hospital or early pregnancy unit.

The sonographer told us that on one occasion the clinic had been closed and appointments cancelled when there was a woman with an ectopic pregnancy awaiting an ambulance because the care of the woman came first.

Good

Diagnostic and screening services

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.

Understanding and involvement of women and those close to them

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

Staff made sure women and those close to them understood their care and procedures.

Staff talked with women, families and carers in a way they could understand, using communication aids where necessary. We observed that staff took time to explain the procedure before and during the scan. We saw the sonographer fully explained what was happening throughout the scan. They used appropriate language to explain the position of the unborn baby and the images on the monitors and asked women if they had any questions throughout and at the end of the scan.

Relatives of women were encouraged to accompany the woman during their scan. We saw that women's relatives were involved and accompanied women during the scan procedures we observed on the day of the inspection. At the time of our inspection, a woman could attend with five relatives (including children). During the pandemic lockdown periods, this had been restricted to a woman and partner or one other relative only.

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

Staff supported women to make informed decisions about their care.

Women gave positive feedback about the service.

Are Diagnostic and screening services responsive?

Good

We had not inspected this service before. We rated it as good.

Service delivery to meet the needs of local people

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

The service offered a range of ultrasound scan procedures for private fee paying pregnant adult women and for females aged 16 and 17.

Managers planned and organised services so they met the changing needs of the local population. Clinic opening times meant those people who were working could book an appointment in the evening or at the weekend and there were limited appointments available on two weekdays.

Good

Diagnostic and screening services

Facilities and premises were appropriate for the services being delivered. The service had a suitable environment for providing scan procedures to women. There was enough capacity in the waiting area that to allow for social distancing and privacy. The treatment room was spacious and provided a suitable and relaxed environment for women and their loved ones to undergo scan procedures whilst maintaining their privacy and dignity.

The premises were on a main road, there was ample parking in the vicinity, and they were located close to the local train station. It was convenient for women to travel there by public transport from The Wirral, Liverpool and Cheshire areas.

Appointments were booked in advance, online or by telephone, and this allowed staff to plan the scan procedures before women attended their appointment.

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 directed women to other services where necessary.

The service ensured that there were separate sessions for women receiving early pregnancy scans. This ensured that women who were there for reassurance about their pregnancy, for example those who had suffered previous miscarriages, did not have to share the waiting room with women who were much later on in their pregnancy.

The service had an equality policy and sonographers had received equality and diversity training within their NHS role.

Information leaflets in the clinic were only available in English but similar information was available on the company website and the website was able to be translated into numerous different languages. Staff were able to print off the leaflets from the website in a woman's chosen language.

The service was able to use Google Translate to communicate with women and their families whose first language was not English. They did not have access to an interpreter company but encouraged women who could not speak English well to arrange for an interpreter to be present if they felt this was needed.

The service did not have a hearing loop for women with hearing impairments or access to information in braille for women with sight impairments. The manager told us that when deaf people attended they would wear visors rather than masks if the person was able to lip read.

The service was accessible for persons with limited mobility on the ground floor of a building with wide doorways and access directly from the street.

Although toys for children had been removed from the waiting room for infection control purposes, the clinic offered children attending with their parents colouring sheets and pens to take away with them.

The service did not have specific admission or exclusion criteria, but the clinic would not scan women who were unable to give consent or could not be safely scanned, such as bariatric women who exceed the weight-bearing maximum of the scanning couch.

Ultrasound scan prices were clearly displayed on the service's website. There was information for prospective clients about what to do before arriving at the clinic, what would happen on arrival and the scan itself. There were also frequently asked questions on the website. Women could also telephone for additional information.

Good

Diagnostic and screening services

The service did early pregnancy scans from six to 15 weeks and six days and Window to the Womb scans from sixteen weeks onwards.

There was a telephone application where women could view their scan images and have instant access to their images. Women were able to print scan pictures at home if they were unable to or did not wish to print them in the clinic.

The service offered women a range of baby keepsake and souvenir options, which could be purchased for an extra fee. This included additional images and soft toys.

Access and flow

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

All women attending the service were self-referred. Women could book their appointments at a time and date of their choice in advance. Appointment bookings were made in person, by telephone or women could directly book their appointment through the provider's website.

Women were given appointments based on their preference. There was no waiting list for appointments and women could be seen promptly (including the same day in some instances). Women who had to cancel their appointments were given an alternative date and time.

Managers monitored and took action to minimise missed appointments. Women who had booked a scan were sent a text message reminder a day or two in advance.

Women were routinely given a 30-minute appointment slot, but this could be extended if needed.

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, relatives and carers knew how to complain or raise concerns. Information about how to complain was displayed clearly in the scanning room and waiting area.

Staff understood the policy on complaints and knew how to handle them. The complaints policy was in date and had a review date.

Managers investigated complaints and identified themes. The service had received eight complaints in 2021 about a range of matters, such as, scan image quality; late running of the clinic; the wrong coloured bear given following a gender scan; the wrong gender reveal scratch card given; the way the woman was treated by the sonographer and the refusal to carry out a scan because they had received a scan in the NHS within the previous seven days.

Staff knew how to acknowledge complaints and women received feedback from managers after the investigation into their complaint.

Managers shared feedback from complaints with staff at team meetings and learning was used to improve the service.

Good

Diagnostic and screening services

Where customers were not satisfied with the outcome of a complaint, they were directed to an independent body used by the company as an alternative dispute resolution provider where they could submit a complaint for consideration by the independent body.

Are Diagnostic and screening services well-led?

Good

We had not inspected this service before. 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 service was managed on a day to day basis by the registered manager who had been in post for approximately one year. They were supported by two scan assistants who acted as assistant manager and team leader.

There was an area manager who looked after the three clinics in the franchise who had a background in nursing and sonography. They attended the clinic once or twice per week.

The clinic was owned with two other clinics by the franchisees. The franchisor employed a clinical lead who could provide clinical and leadership support to all of the clinics in the franchise.

Staff we spoke with told us that the clinic was well-managed, and they said that managers were supportive and responsive.

The registered manager said that they felt they had been supported to gain the skills, knowledge and experience to run and manage the clinic safely.

Managers were able to cover for their line manager. A manager was always available to resolve any issues at the earliest opportunity.

Vision and Strategy

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

The service had a statement of purpose with a number of aims and objectives and values.

Examples of the aims and objectives were:

- To meet the demand to provide pregnant ladies with a private obstetric ultrasound service in an easily accessible local environment.
- To provide pregnant ladies with medically relevant ultrasound findings by way of an obstetric report.

- We only employ HCPC certified sonographers who are provided with training and protocols to complete safe and medically relevant services.

The clinic had eight core values that were based on focus; dignity; integrity; honesty; privacy; diversity; safety and staff.

The Window to the Womb franchise had an organisational strategy and vision for 2022. This included a short-term strategy to expand the business and build on the medical and diagnostic credentials; to introduce additional diagnostic scans and to introduce additional diagnostic or medical services to complement the current ultrasound services.

There was also a medium to long-term strategy that included building closer relationships with the NHS to minimise the need for the NHS to use valuable resources for non-urgent or unnecessary scans in the first trimester of pregnancy.

Culture

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

The registered manager and area manager we spoke with were highly motivated and positive about their work. They told us there was a friendly, client-focused and open culture and that they regular feedback to aid future learning.

The registered manager told us all the sonographers and reception staff worked well as a team. Staff told us that they enjoyed working in the service.

There was freedom to raise a concern policy that staff could access if they wished to raise a concern.

Governance

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 policy which outlined the responsibility of board members, the relationship between franchisor and franchisee and the requirement for regular audits.

The registered manager had overall responsibility for clinical governance and quality monitoring and reporting this to the franchisee. This included investigating incidents and responding to complaints.

The service had policies and procedures 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 annually. Policies were well ordered, indexed and were readily available to view in paper format and electronic format.

There were staff meetings every month. We looked at the records for three meetings and saw that they included agenda items such as clinical updates, guidelines from professional bodies around scan times and miscarriage training for staff. Staff also discussed any complaints, incidents, service changes and client feedback.

There were monthly meetings where the mangers from the different locations met to share their learning on issues such as complaints, incidents and good practice.

Good

Diagnostic and screening services

There was an audit programme in place which included monthly local audits, annual audits and peer review audits. Annual compliance audits included premises checks, health and safety, emergency planning, accuracy and completion of scan reports, completion of pre-scan questionnaires, professional registration and staff records. We saw clear actions were identified and agreed with the clinic.

The service had statutory professional indemnity insurance arrangements, in accordance with British Medical Ultrasound Society (BMUS) guidelines.

The service had a fit and proper persons policy that all staff were required to comply with. We saw evidence that the registered manager underwent recruitment checks, such as enhanced disclosure and barring service (DBS) checks. There were up to date DBS checks in place for all staff.

The recruitment policy outlined the recruitment checks to be carried out for reception staff prior to commencing employment, such as identification checks and references. We looked at the four five staff files. These included information such as identification checks, contact details, curriculum vitae (CV's), references and employment contracts.

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.

We saw up-to-date risk assessments were completed for fire, health and safety, legionnaires' disease and the Control of Substances Hazardous to Health. Risk assessments were recorded on a form which identified the risk and control measures and the member of staff responsible for monitoring and managing the risk. Risks were regularly reviewed by the registered manager and area manager.

There was a corporate risk register that covered all clinics in the franchise. This was maintained by staff in the head office of the franchise. There were six risks on the corporate risk register, including sonographer availability; scan machine failure; failure of ambulance to arrive for an emergency; customer self-discharging following an ectopic pregnancy diagnosis; PPE shortages and customers refusing to wear face masks. Each risk was scored for impact and probability and there were mitigations for each risk.

The service had employer's liability insurance and group medical malpractice insurance.

The service had appropriate emergency action plans in place in event of incidents such as power loss or fire. These outlined clear actions staff were to take and contact details of relevant individuals or services.

The registered manager compiled a monthly performance report. Performance against key performance indicators was shared with staff in the monthly team meeting.

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.

Good

Diagnostic and screening services

The service 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.

The company had received advice from a consultant with the changes to the General Data Protection Regulations and had appropriate and up-to-date policies for managing women's personal information that were in line with relevant legislation and the requirements of the General Data Protection Regulations.

Staff received training for information governance and the General Data Protection Regulations.

Computer terminals were password protected, and the scanning machine was also password protected for each sonographer.

The telephone application for the sharing of images had a unique access code for each woman to access their images. The application was also used for staff communication.

Passwords for equipment and computers were changed if members of staff left the business and the key codes to open doors in the premises.

Scan images were stored on the scanning machine for no more than two weeks and on the clinic record system for no more than three months.

Well-being and referral reports were kept for 21 years, in line with best practice guidance.

The service had a policy on the Caldicott principles, and the franchise had a senior person responsible for protecting the confidentiality of people's health and care information and making sure it is used properly.

Engagement

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

Staff routinely engaged with women during their scan procedures to gain feedback about the services.

The registered manager told us client feedback was regularly reviewed. Comments cards were available at the reception area and all women were encouraged to provide feedback about the service.

The service was mainly promoted through their website, social media platforms and through word of mouth from women that had used the service.

Staff engagement took place through daily communication and routine staff meetings. The scan assistant told us they received good support and from the sonographers.

The franchise collaborated with two partner organisations who provided information on pregnancy care and physical and mental health promotion and wellbeing for women. Clients were signposted to these organisations for further support.

Good

Diagnostic and screening services

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.

There was a culture of continuous learning and development in the service.

The service sought suggestions from staff at all levels to improve the customer experience.

The registered manager was open to the franchise introducing new areas of focus to clinics, such as early pregnancy scans to confirm viable pregnancies in IVF women.