

Anaservices Alton Ltd

Window To The Womb

Inspection report

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Date of inspection visit: 19 April 2022
Date of publication: 06/07/2022

This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location

Requires Improvement



Are services safe?

Requires Improvement



Are services effective?

Inspected but not rated



Are services caring?

Good



Are services responsive to people's needs?

Good



Are services well-led?

Requires Improvement



Summary of findings

Overall summary

We had not previously rated this service. We rated it as requires improvement because:

- The service did not carry out updated fire risk and safety assessments
- The service did not have policies that reflected current guidance, legislation or best practice for staff
- The service did not ensure that staff adhered to policies
- The service did not always take account of women's individual needs
- Leaders were not always aware of their legal accountability regarding the Health and Social Care Act 2008

However,

- The service had enough staff to care for women and keep them safe. Staff had training in key skills. The service demonstrated management of infection risk well in practice. The service managed safety accidents well and learned lessons from them.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service. Staff worked well together for the benefit of women and provided access to good information.
- Staff treated women with compassion and kindness, respected their privacy and dignity. They provided emotional support to women.
- The service planned care to meet the needs of local people. The service 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 their results.
- Leaders supported staff to develop their skills. Staff felt respected, supported and valued. They were focused on the needs of women. Staff were clear about their roles and responsibilities. The service engaged well with women and staff were committed to improving services continually.

We rated this service as requires improvement because it was requires improvement for safe and leadership. It was however good for caring and responsive and not rated for effective.

Summary of findings

Our judgements about each of the main services

Service

Rating

Summary of each main service

Diagnostic imaging

Requires Improvement



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Summary of findings

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Summary of findings

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Summary of this inspection

Background to Window To The Womb

Window to the Womb, Alton, is operated by ANA Services Ltd and operates under a franchise agreement with Window to the Womb (Franchise) Ltd. The service provides wellbeing pregnancy ultrasound services to self-funding women across Alton and surrounding areas. All scans carried out include wellbeing as the primary purpose.

Window to the Womb has separated their services into two clinics: the 'First-scan' clinic, which specialises in early pregnancy scans and a 'Window to the Womb' clinic which offers later pregnancy and wellbeing scans (Window scans).

The service provides ultrasound baby imaging for pregnant women. This includes four dimensional (4D) and two dimensional (2D) early scans starting from 6 week gestation, foetal health and gender scans from 16 weeks, baby growth scan from 26 weeks. The service provides wellbeing imaging for adults over the age of 16 years. It is registered to provide the regulated activity of diagnostic and screening procedures.

The service had a registered manager in place. We have not inspected this service before.

We inspected this service using our comprehensive inspection methodology.

How we carried out this inspection

We carried out a short notice, announced inspection using our comprehensive inspection methodology on the 19 April 2022.

The service registered with CQC in August 2020 and had not previously been inspected. The registered manager has been in post since October 2021.

During our inspection we visited the reception area, the scanning room, administrative areas and other rooms used within the business. We spoke with five members of staff including the CQC registered manager. We also spoke to two patients and their partners. We also observed a scanning appointment. We also reviewed the policies, records and procedures of the location.

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

Areas for improvement

Action the service MUST take to improve:

- The service must carry out risk assessments in relation to any changes to use of fire exits. (Reg 12(2))
- The service must secure COSHH storage facilities when not in use. (Reg 12(2))
- The service must ensure policies reflect current national guidance, legislation and best practice and that staff adhere to policies. Such as for: information governance, data protection, control of substances hazardous to health (COSHH), infection prevention and control, maintaining equipment, data protection and complaints. (Reg 17(2))

Summary of this inspection

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

- The service should ensure that all staff and service related records are dated. (Reg 17(2))
- The service should ensure risk assessments for the handling of used personal hygiene including sanitary protection and nappy waste are carried out. (Reg 12 (2))
- The service should ensure actions following audits are complete, detailed and reviewed with outcomes documented. (Reg 17(2))
- The service should ensure provisions are made for those with visual or hearing disabilities. (Reg 10(2))
- The service should ensure all patient records, including digital images, are stored for a minimum length of time in line with national guidelines. (Reg 17(2))






Our findings

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

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

Are Diagnostic imaging safe?

Requires Improvement 

The service did not have a previous rating. We rated it as requires improvement.

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. Staff training documents showed all staff had completed e learning inductions, safeguarding children and adults, mental capacity act, chaperoning and communication. The staff matrix showed 100% compliance for mandatory training.

The mandatory training was comprehensive and met the needs of patients and staff. Mandatory training was a one day session and covered Health and Safety, Fire Safety, Equality and Diversity, Infection control, food hygiene, basic life support, moving and handling, Safeguarding Children and Adults levels one and two for scan assistants and Sonographers, with managers trained to level three, lone working and complaints. The staff training matrix showed all staff had completed e learning inductions, safeguarding children and adults, mental capacity act, chaperoning and communication. Training was carried out quarterly for fire safety, six monthly for infection prevention and control and safeguarding and annually for equality and diversity, health and safety, information governance, Mental Capacity Act and lone working. The mandatory training policy itself did not always demonstrate gender neutrality.

Sonographer training included face to face and e learning. New sonographers also underwent shadowing from a clinical lead sonographer from the franchise head office. New sonographers attended the head office and received training in policies, processes and protocols. They also received practical scanning training using an ultrasound machine and a training simulator for transabdominal and transvaginal scans.

First Aid training was not required for all staff but Window to the Womb guidance was to have one First Aid trained member of staff on duty whenever the clinic was open. We saw named First Aid staff displayed on the clinic wall.

Diagnostic imaging

New staff had to complete all mandatory training before starting work and underwent a three day induction process. Staff felt they had enough training for their role and felt they could ask for additional training if they needed it. Managers said sonographers could have additional training opportunities offered, such as new techniques, processes, developments and these were communicated from head office and in peer group meetings.

Managers monitored mandatory training and alerted staff when they needed to update their training. Staff were updated on their training needs through team meetings. Staff said they could access e learning at any time to update skills.

Safeguarding

Staff understood how to protect patients from abuse. 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. The registered manager was trained in safeguarding level three in children and adult safeguarding. All other staff received training in children's and adult's safeguarding level two.

Staff knew how to identify adults and children at risk of, or suffering, significant harm. Leaders shared learning from safeguarding from other locations via training, staff newsletters and staff meetings.

Staff knew who to inform if they had concerns. Staff knew who their safeguarding lead was and could name them. Staff had access to a safeguarding policy electronically. There were paper copies of the policy which referenced contact details for local authority safeguarding and the franchise lead for safeguarding. Franchise leaders reviewed this policy annually to ensure it was up to date. However, we viewed the policy and the safeguarding flowchart did not give full clarity to the roles and responsibilities for staff and managers and did not always reflect their role as referrers. The flow chart did not reflect appropriate steps in the safeguarding process and may cause delays in ensuring the safety of adults was protected.

Managers told us all staff had Disclosure and Barring Service (DBS) checks carried out. Managers and sonographers had enhanced level DBS checks and scan assistants had standard level DBS checks. Managers told us DBS checks were carried out by the franchise the staff would be working in, but staff could work at other franchise sites if required. DBS checks were part of monthly audits carried out. The audit for April 2022 showed there were no actions required for DBS checks.

Cleanliness, infection control and hygiene

The service did not always control 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 prevention and control (IPC) principles including the use of personal protective equipment (PPE). Staff used PPE and uniforms were bare below the elbows. Hand sanitisers were present throughout, with signs prompting its use. We saw staff handwashing before and after patient interactions. However, we did not see a handwashing audit in the service. Monthly clinic audits were seen but did not include handwashing audits, so leaders cannot be assured that staff are adhering to handwashing procedures. We reviewed the Infection Prevention and Control policy for the service, and it does not adhere to evidence based standard infection prevention and control precautions.

Diagnostic imaging

In line with COVID-19 governmental guidance there were COVID-19 symptom information signs and QR codes for the COVID-19 NHS check in. Signs for face coverings were present and were visible for people entering the clinic. Staff requested those entering the clinic to wear a face covering. Proof of face covering exemption were not requested. There were face coverings available for people using the service. COVID-19 notices were displayed.

Staff disposed of clinical waste safely. Managers told us clinical waste bins were emptied daily and placed into locked clinical waste bins outside to await collection by their contracted provider. We saw a contract with the provider for fortnightly collections.

Feminine hygiene bins had been under a contract to be collected, but a new contract was being sought due to non collection of bins. Managers told us staff were managing the disposal of bins in the interim. However, there were no feminine hygiene bins present so it was not clear how clinical waste was being disposed of and we did not see a risk assessment for staff to carry out this task.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. All areas were visibly clean, tidy and well maintained. Cleaning records were up-to-date and showed all areas were cleaned when the clinic was open with areas having hourly checks done and signed. Staff did a two-weekly deep clean following a cleaning checklist. The service had a colour scheme for the use of specific coloured mops and buckets for specific cleaning areas with signs to ensure staff were clear on the colour coding.

Staff cleaned equipment after patient contact. We saw staff clean equipment between patients and in line with IPC policy.

The transvaginal probe was cleaned after each use and the cleaning was documented in each woman's notes. All staff had received specific training on the cleaning of the transvaginal probe. Documents seen for transvaginal scans included the type of scan carried out, batch information for decontamination gel, patient details and which sonographer performed the scan. The record of any products used, the service felt would allow them to respond to any allegations of contamination

It did not contain the serial number of the transvaginal probe, but there was only one probe in use at the clinic.

The service provided a small handwashing sink in the scan room and staff washed their hands in line with national guidance.

There were data safety sheets for cleaning materials and scanning gels.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always keep people safe. Staff were trained to use them. Staff did not always manage clinical waste well.

The design of the environment followed national guidance and the service had suitable facilities to meet the needs of patients' families. The unit layout aided privacy for people using the service by having doors between the reception waiting area and scanning room. Patients had a comfortable waiting area with activities for children and a quiet area should women and their families need it. Patient waiting areas were clean and tidy and had easy clean seating and there were activities for children to do in waiting areas.

Diagnostic imaging

Facilities had access for those with a disability, the toilet had a wall mounted handrail and equipment for baby changing needs. However, the door lock only opened from the inside which may pose a risk to anyone stuck inside who required help. This was brought to the attention of staff who advised they would act on this. There was not an emergency pull cord in place but this has been highlighted as a risk and evidence was seen to show this was planned to be in place by May 2022.

The service documented the substances in use at the clinic, in a Control of Substances Hazardous to Health folder. The service stored control of substances hazardous to health (COSHH) in a locked cupboard with a clear sign on it. However, the cupboard was unlocked at the time of our inspection but staff advised they had opened it to carry out checks.

Risk assessments were completed for all chemicals but did not contain exact details of the risks or what happens in spillages, contamination or exposure to hazardous materials or what precautions would be required for use of those hazardous materials.

Staff did not carry out regular quality checks of specialist equipment. The ultrasound machine and probes did not undergo any regular quality checks. The Medicines and Healthcare products Regulatory Agency (MHRA) and The British Medical Ultrasound Society (BMUS) guidance and recommendations are that equipment should have a regular quality assurance (QA) program between regular servicing to ensure the optimum performance of equipment and to spot any potential drops or loss of performance or artefacts that might be detrimental to image quality and visual value of the scans.

The maintaining equipment policy stated that the service should carry out regular checks but did not state what those regular checks were. The provider however informed us all equipment had visual checks by staff. Also, the scan machine was not used intensively enough for drops in performance levels within the interim timescales between major services.

A service level agreement for the maintenance of equipment was in place. An external company carried out annual servicing on specialist equipment, such as the ultrasound machine, and we saw documents to show the last service was in date. However, there was not a fault recording system in place for equipment, but staff could report faults to the manager. This is not adhering to the providers policy on maintaining equipment which states that a clear fault reporting system should be in place. Staff could contact the external company who would respond to any issues raised. However, there were no system in place for staff to communicate the status of the equipment and any changes or modifications made or errors fixed or not fixed, so staff could not be assured their equipment was operating as it should.

We saw portable electrical appliance testing (PAT) documents showing tests had been carried out annually. Equipment had stickers on showing the test dates and due tests dates.

During our inspection managers told us that the rear fire exit was not in use due to being blocked by construction materials related to another building occupant. We asked managers if they had carried out a separate risk assessment for this or sought advice but they had not. We saw an updated handwritten note on the fire risk assessment floor plan that advised staff the rear fire exit was not in use, the date on that floor plan was printed as 13/02/20201(sic), so it was unclear when exactly that was written. It was also not clear how this was disseminated to staff as January and February team meeting minutes made no mention of it and nor did March and April clinic audits. However, we found no updated fire risk assessment for the closure of the rear fire exit and although we requested the fire safety policy and updated risk assessment for the rear fire exit, they were not sent to us.

Diagnostic imaging

Additionally, within the current fire risk assessment, it identifies combustible materials and the process for reducing fire ignition sources, which was to remove cardboard immediately. We found stacks of cardboard in the rear of the building. Therefore, staff were not adhering to their fire risk control methods within their risk assessments.

Managers said the fire exit was locked and they had taken steps to cover up fire exit signs but during the inspection signs for both fire exits were still visible by those using the building. The rear fire exit was open during our inspection as managers had shown us the access route and construction materials, but the fire exit door was later locked.

Following a fire safety inspection, the service was advised to change the type of fire extinguishers they had and we saw the new fire extinguishers securely attached to the wall.

Managers told us there was monthly testing of smoke detectors and fire drills were carried out three monthly.

The service had an emergency carry chair on site but it did not have a service check sticker on to show when it was last safety checked or serviced.

Assessing and responding to patient risk

Women completed a health questionnaire at the time of booking online. Staff reviewed this when women arrived for their scan. Women had the chance to complete this on site if they had not done so before arrival.

Staff told us they would not normally repeat scan a woman within two weeks of a previous scan but their website states possible reasons why they may do this, such as psychological or physical concern, and this would be done at least seven days after a previous scan, or they may offer an alternative type of scan. We saw evidence of a woman being declined a scan as it was within the two week period, so an appointment was rearranged to ensure the two week interval was adhered to. Staff asked women when they arrived when their last scan was and advised of the risks of frequent scanning. There were visible signs in the clinic for patients to see regarding the advice on frequency of scans.

Women signed a self-declaration stating they were receiving or intended to receive maternity care through the NHS. The service asked women to bring their NHS maternity medical record with them when they came to the clinic but said they would scan people without their NHS records. This was to help assure the service that the woman was on an NHS maternity pathway. Staff advised women to continue with their NHS scans as part of the maternity pathway.

There was a clear escalation process for unexpected or significant findings and referral details of local NHS trusts, for patients to be referred to. In the event of an emergency, staff would call 999. Details of scans with urgent issues were sent to the reception screen, which alerted staff to call emergency services and guided them with instructions to communicate with emergency services.

Sonographers were able to contact the Window to the Womb franchisor clinical leads for advice and support during clinics. The clinical leads were employed by the franchisor and were available to review ultrasound scans remotely when needed. Women would be referred to their local NHS Early Pregnancy Unit if a scan identified concerns. Women were provided with a completed report outlining the details of scan findings along with a referral letter.

The service requested a parent or responsible adult or carer to accompany young women attending the service who were aged between 16 and 18 years. If there were any concerns regarding the legitimacy of the responsible adult, the service requested identification documents.

Diagnostic imaging

Staff shared key information to keep patients safe when handing over their care to others. Staff completed referrals on a dedicated form and kept a log with basic information. Sonographers signed all referrals which contained all the information needed for transfer between services. Staff said most referrals were completed during clinic hours by clinic staff, but any referrals completed out of hours were done by head office. It was not clear if there was complete oversight by head office of all referrals made and there did not seem a robust system of correlating the referrals log to the correct patient.

The service did not require a resuscitation trolley. The service had a first aid box stored in the reception area. Clear signs showing staff who were trained in First Aid were visible in the reception area. Staff were up to date with adult and children's first aid training.

Staffing

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

The service had enough staff to keep women safe. Staff received training covering adult and children safeguarding, communications, chaperoning and the Mental Capacity Act. All staff underwent an induction which also covered e learning introduction to the service modules and optional first aid learning. Experience of staff with the service varied depending how long they had been with the service.

Managers said they did not often use agency staff but if they did, they would undergo the same induction process. Managers could access staff from other locations for staff cover, for example due to annual leave or staff sickness. Policies and processes were the same in the Window to the Womb franchise, which made working at different clinics easier.

Managers calculated and reviewed staffing numbers and scan appointments and adjusted the number of staff needed for each shift. Staff rotas were created monthly in advance.

The service operated with a qualified sonographer, clinic manager and scan assistants. For most clinics, there were two scan assistants and a sonographer routinely rostered. A scan assistant acted as a chaperone for all women alongside the sonographer while in the scan room.

Staff recruitment was both national and international with franchise staff arranging national recruitment and an agency arranging international recruitment with franchise oversight.

All staff had current disclosure and barring service checks (DBS). These were checked and signed by the manager.

Records

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

Diagnostic imaging

Patient notes were comprehensive and all staff could access them easily. Women transferred between services had their referral information with them and managers told us they sometimes emailed referrals to NHS partners. Managers told us they did not have an NHS email account but told us their emails were securely sent. This was not inline with the providers Information Governance policy which states that “Personal data should never be emailed as this form of communication is not secure”.

Patient records and staff information were paper and stored securely in a locked cabinet in the customer quiet room area. Records were clear and dated. Scan images were stored digitally and archived to external hard drives and kept at the franchise head office. Staff reported there were no delays in accessing women’s records.

Patient information from the clinic diary was issued to the staff each day. Once the clinic ended, staff notes were shredded. However, we asked how confidential waste was disposed of and were told it goes in non confidential waste.

The scanning machine stored ultrasound images but staff told us these were sometimes deleted by the sonographer to increase storage space. The data retention policy covers the scope of scanned images but does not address this action of deleting images. This was raised with the provider who stated they would look into their policy. Women completed a self-declaration which gave consent for staff to share clinical information with their NHS service, if needed.

We observed a woman’s scan, and the sonographer checked their identification by showing them a screen and asking if those details were correct. This was not following guidance set out by the Society of Radiographers and could pose a risk of breaching general data protection regulations (GDPR) if the wrong patient details were on the screen.

Incidents

Staff recognised incidents and near misses and reported them appropriately. When things went wrong, staff apologised and gave patients honest information and suitable support.

Staff knew what incidents to report and how to report them. Staff recorded any incidents in a logbook. There had been no incidents recorded. However, the incident logbook did not have a start date on it, so staff could not be assured how many incidents may have occurred over time.

Managers told us they shared learning from any incidents with all staff and used monthly staff meetings to provide feedback to all staff. Managers told us any learning from incidents was also shared with the Window to the Womb franchise management group but as there had been no incidents recorded, we were not able to see evidence of this.

The service also kept an accident book. There had been one recent accident where a clinic visitor tripped and injured themselves. Staff took appropriate action at the time, documented the issues and made changes to the environment to minimise further risks.

The service had no never events or serious incidents in the past year.

Medicines

There were no medicines held or administered at this location.

Are Diagnostic imaging effective?

Diagnostic imaging

Inspected but not rated 

In accordance with our current methodology, we do not rate effective in Diagnostic Imaging

Evidence-based care and treatment

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

Managers told us policies were created and reviewed annually by the franchisor and any changes or updates were shared with staff via emails and team meetings. Policies we saw had creation and review dates within them. We reviewed team meeting notes which documented these areas were discussed at monthly team meetings.

Clinical leads completed competency assessments remotely of sonographers. The assessors would access the scanned images and reports created by sonographers and produce a report for the sonographer to read. These competency assessments were part of the internal and external checks to ensure sonographers were competent and formed part of the clinical audit completed by the franchisor throughout the year.

Sonographers also completed peer reviews to monitor each other's practice and knowledge.

The registered manager completed monthly clinic audits. Areas checked included training, policies, risk assessments, equipment, documentation and staff. Audit outcomes were shared and discussed with staff at team meetings. However, the actions in the audit did not identify who was responsible for implementing any identified actions, the timescale of those actions or whether those actions had been completed.

We reviewed the safeguarding policy as the franchise was given feedback by the CQC in 2021, following a review that highlighted issues and concerns with the policy. We saw evidence that changes had been made following the 2021 CQC feedback.

Pain relief

Staff monitored women to check if they were comfortable.

The service did not provide pain relief due to the nature of the services offered, but sonographers ensured that women were comfortable throughout their scan.

Patient outcomes

Staff monitored the effectiveness of the service. They did not always use the findings to make improvements and achieve good outcomes for women.

Yearly compliance audits were completed by the franchisor to monitor the clinic's performance and to identify any areas where improvements could be required, such as training, infection prevention and control, staffing and complaints.

Diagnostic imaging

Managers and staff used audits to improve women's experiences. Lead sonographers in the franchise group regularly reviewed scans remotely to check for quality and diagnosis and produced performance reports on sonographers. Any sonographers below standard would have further support from clinical leads. Sonographers had access to clinical leads for advice and reviews. Sonographers also attended monthly meetings with their peers to discuss issues and share learning but we did not see minutes of these meetings.

Managers and staff carried out a programme of repeated audits to check compliance with expected standards. Audits included training, policies, risk assessments, equipment, documents and scan reports. Audit tools contained a free text box to record any identified actions.

However, we saw that actions had been identified, but did not identify who would carry out those actions, or if those actions had been carried out, or a completion date. Therefore, staff could not be assured those actions had been completed and neither could auditors. An example of this was the action recorded as "reference resent" and a staff members name next to that, another example was "safeguarding training, first aid" and a staff members name next to that and a reference to "decontamination training" and a staff members name next to that. None of these actions had any further documentation to show if, and when they were carried out and completed or by whom, so managers and staff could not be assured if any actions had been addressed and completed.

Managers shared information from the audits discussed these at staff team meetings.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance.

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

Managers gave all new staff a full induction specific to their role before they started work. The induction included location specific information as well as information about the provider.

Staff had specific training on chaperoning and supporting women after unexpected results from scans.

Managers supported staff to develop through yearly, constructive appraisals of their work. Managers also supported sonography staff to develop through regular, constructive clinical supervision of their work and this was done remotely. Staff told us the franchise clinical educators supported the learning and development needs of sonographers and produced assessment reports following reviews of scans with performance categories of good, satisfactory and requires improvement. The assessment reports had free text boxes for the assessors to make comments on performance.

Staff said felt they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

Multidisciplinary working

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

The team worked well together and communicated well with each other. The registered manager worked closely with the clinic manager and staff told us there was a good relationship between all staff at the service.

Diagnostic imaging

Staff had contact details of local NHS maternity departments and were able to contact them on behalf of women if they needed an urgent referral. Staff told us they had good relationships with local NHS trusts. The service liaised with maternity services to ensure their referral pathways were effective and appropriate. Staff communicated referrals at times by telephone, email and referral form. The service used a printed referral template and hand wrote the woman's details and reason for referral. Staff told us a copy of the scan report and images were attached to referrals.

Staff held regular team meetings to discuss patients and improve their service. Staff team meeting minutes covered a range of topics. Minutes were not always detailed but feedback from staff was documented.

Seven-day services

The service was not an acute service and did not offer an emergency service. The service was on demand and offered appointments in the evening and on weekends to enable woman to book scans at a time that suited their lifestyle.

At the time of our inspection the service operated on Tuesday, Thursday and Saturday with varied opening times according to the demand.

Health promotion

The service did not provide information for women to lead healthier lives.

The service had relevant information on issues in pregnancy and support. The service provided leaflets that contained information for women and their families. It was not clear if the leaflets were produced in different languages but the website contained similar information and people could select from a wide range of languages. There was also a pregnancy app developed to offer support for mood management in pregnancy.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff were aware of the Mental Capacity Act.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff were aware of the Mental Capacity Act and its application although they could not recall a time when they had a concern about a woman's capacity.

Women received written information to read and sign before their scan. This included information about ultrasound scanning and safety information, a pre-scan questionnaire and declaration form which included terms and conditions. The service gave women additional information for early pregnancy scans that told them more about the scan and information should the sonographer need to perform a transvaginal scan due to the early stage of the pregnancy.

Staff gained consent before scanning women. Women were asked to sign a consent form which detailed the scan, any risks and unexpected outcomes. The sonographer explained the scan to women and obtained verbal consent before commencing scanning.

Are Diagnostic imaging caring?

Good 

The service did not have a previous rating. We rated it as good.

Diagnostic imaging

Compassionate care

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.

One woman we spoke to told us staff treated them well and with kindness. We saw feedback from customers, stating they had positive experiences from staff at the clinic.

Staff followed policy to keep patient care and treatment confidential.

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

Emotional support

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

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff were able to support women following bad news. Staff could help women to book appointments at the local NHS hospital if needed and signpost them to support networks.

Staff supported patients who became distressed in an open environment and helped them maintain their privacy and dignity. Staff would take those in distress to a dedicated quiet room where women could be supported by staff or their partners and families.

Staff undertook training on breaking bad news and understood empathy when having difficult conversations. Staff gave an example of supporting a couple who had received bad news, where the sonographer had explained the issue and staff supported and gave the couple time to digest the news and then answer any further questions they had.

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. Staff showed compassion and understanding when talking about the people using their service and understood the emotional needs for those attending for scans.

Understanding and involvement of patients and those close to them

Staff supported patients, families and carers to understand their condition.

Staff talked with women, families and carers and made sure women and those close to them understood their care. For any language barriers during a scan, staff said they would use Google translate to aid communication.

Patients and their families could give feedback on the service and their treatment via quick response (QR) codes or via Google reviews and staff supported them to do this.

Diagnostic imaging

Patients gave positive feedback about the service with online reviews. Feedback seen on web based review platforms and social media, gave positive feedback regarding staff being supportive, knowledgeable, engaged and kind to women and their partners. Some reviews showed that they had used the service on more than one occasion and would be happy to return.

Are Diagnostic imaging responsive?

Good 

The service did not have a previous rating. 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.

Managers planned and organised services so they met the changing needs of the local population. Women could book appointments to suit them both day and evening. The service operated three days a week.

Facilities and premises were appropriate for the services being delivered. A dedicated quiet room provided privacy and dignity for women and their partners who may have received distressing news. There was wheelchair access to the clinic. Baby changing facilities were available.

Managers monitored and took action to minimise cancelled appointments and had contingency plans in place. Managers ensured that patients who had cancelled appointments were contacted and new appointments arranged.

The service provided women with leaflets about pregnancy related issues such as, bleeding, sickness, pregnancies of unknown locations and miscarriage. This information was also on the website and available in different languages. Staff provided women with contact details of local hospitals early pregnancy units in an information pack. Information booklets for group B Streptococcus in pregnancy and new born babies were available in the clinic.

However, the service did not have a hearing loop or any provisions for visually impaired people using their services.

Meeting people's individual needs

The service was not always inclusive of patients' individual needs and preferences. Staff did not always make reasonable adjustments to help patients access services.

Staff did not always apply the policy on meeting the information and communication needs of patients with a disability or sensory loss. There were no provisions for people with visual or hearing impairments.

The service did not have information leaflets available in the clinic, in languages spoken by the patients and local community, but leaflets were available on the website and people could self select their chosen language. Staff said they would use Google translate for any languages issues once patients were in the clinic.

The clinic had information about the Miscarriage Association. There were cards that staff could pass on to women with information about how they could access support.

Diagnostic imaging

Staff had limited access to communication aids to help patients become partners in their care and treatment. There were no facilities for patients with hearing or visual impairments.

We reviewed the equality policy which recognised the needs and rights of those with a disability but did not fully address how the service would meet the needs of those with a disability using the service.

Access and flow

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

The service is an on demand service and women could book an appointment within the same week.

Learning from complaints and concerns

It was not always easy for people to give feedback and raise concerns about care received. The service did not always treat concerns and complaints seriously. The service investigated them and shared lessons learned with all staff. The service communicated with customers regarding their complaint.

We reviewed complaints for the previous 12 months. The service clearly displayed information about how to raise a complaint or concern in the clinic. The complaints policy was visible in the clinic waiting room and showed the named contact and address for complaints. Staff told us they aimed to deal with complaints within 21 days or sooner. People could complain in person and via the website.

However, the address to write to on the Window to the Womb website was missing from the contact us and complaints section on the website, but people could telephone to make complaints as well.

Staff told us complaints were initially dealt with internally, then escalated to the franchise. However, the escalation process in the clinic policy did not reflect this and directed people to two organisations that do not deal with complaints. The electronic policy we received and reviewed did not state at what stage the escalation of a complaint would occur and placed the onus of escalation on the customer.

Staff did not understand or follow the policy on complaints. We saw in a mini clinic audit that covered checks such as bins, stock, infection prevention and control (IPC), risk assessments and complaints, that staff were told in written form, “not to worry too much about logging image quality complaints but more serious complaints”. This would not provide the service with oversight of any themes or trends in complaints and may limit addressing issues and concerns people using the service may have.

Managers investigated complaints but did not always identify themes. Evidence showed that staff were encouraged to document more serious complaints, rather than complaints of other natures deemed less serious by managers. This did not follow the customer complaints policy which states customers can complain about any aspect of the service provided.

Evidence of complaint handling was provided but indicated the discussion of the complaint was via telephone and was not included in the evidence we were provided. It did show a timely response to the complaint and the offer of a complimentary re scan.

Are Diagnostic imaging well-led?

Diagnostic imaging

The service did not have a previous rating. We rated it as requires improvement.

Leadership

Leaders did not always demonstrate the skills and abilities to run the service. Leaders did not always understand and manage the priorities and issues the service faced. They were not always visible but were approachable in the service for staff.

The clinic manager ran the service day to day with the support of the registered manager, who was responsible for several other clinics. The regional manager had oversight responsibility for the clinics operated by the franchisee. The regional manager and franchisor supported the registered manager with day to day tasks.

Staff told us the registered manager was approachable and were happy to go to them with any concerns or queries. The registered manager was available by telephone when they were not on site. The registered manager told us that the provider level team were available for support if needed.

However, leaders did not always have the awareness of the regulatory responsibilities and accountabilities they hold to ensure the service was meeting the fundamental standards of care. This was clear from the number of policies in use that did not reflect current guidance, legislation or best practice for staff, and was also demonstrated in the absence of risk assessments for staff and environmental risks. It was also clear in the minimising of complaints which would not allow leaders to identify themes in complaints and would not be able to address them or improve upon them.

Vision and Strategy

The service and location had a vision for what it wanted to achieve.

There was a provider level vision and this was underpinned by provider values. The service values included focus, dignity, integrity, privacy, diversity staff and safety. At a location level, managers told us they wanted to extend the days of operational opening and were monitoring their plans to do this.

During our inspection we saw that staff worked in line with the services values. Staff we spoke to were committed to providing a high-quality service to all women who used it. The service aimed to become a five day a week service.

Culture

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

Staff were proud to work for the service and invested in the service they delivered. We observed a caring and respectful culture with staff demonstrating a caring approach to service users and each other.

Staff felt confident they could raise concerns with the registered manager and told us there was a supportive culture in the service. Women we spoke to felt staff were positive, professional and supportive.

Staff were friendly, welcoming and open with their communications.

Diagnostic imaging

Women and their partners felt supported, respected and well treated by staff and this was reflected in external reviews of the clinic.

Governance

Leaders did not always operate effective governance processes throughout the service. 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 registered manager had overall responsibility for clinical governance, quality monitoring and reporting this to the franchisee and the franchisor. This included investigating incidents and responding to patient complaints.

The regional manager and franchisor supported the registered manager. Franchise meetings discussed clinic compliance, performance, audits and best practice. There was an audit programme which included monthly local audits, annual audits and staff peer review audits. Annual compliance audits included premises checks, health and safety, emergency plans up to date, accuracy and completion of scan reports, completion of pre-scan questionnaires, professional registration and staff records. However, the service did not demonstrate how the audit process was linked to any outcomes in improving the service and ensuring staff were all adhering to policies, processes and practices.

The franchisor held monthly manager meetings attended by senior staff across the franchise group. Managers discussed and documented performance, complaints, compliments, training and compliance with policies and procedures.

All staff attended monthly local team meetings at the clinic. Staff meeting minutes were not detailed but showed discussion topics of compliance with policies and procedures, audit results, complaints, incidents and patient feedback were covered.

However, there were a number of issues with policies in the service. The safeguarding policy did not give full clarity to the responsibilities of the managers and staff in the service with regards to their safeguarding process and clarity of responsibilities. The safeguarding flowchart did not reflect the feedback from the CQC 2021 review and had not been updated to reflect this.

The mandatory training policy referred to female staff only in training scenarios, so excluded some staff.

Although the policies and procedures were developed and written by the franchisor, they are not registered with the care Quality Commission. The registered provider Ana Services Limited and the registered manager, as the persons registered with CQC, are legally accountable in ensuring policies and procedures meet the needs of people using the service and the needs of the service, and that they reflect current national guidance and laws.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They did not always identify relevant risks. Issues were identified but actions were not always taken to reduce their impact. They had plans to cope with unexpected events.

Managers told us staff had annual appraisals. Staff told us they could raise any objectives and employment needs at any time.

Remote assessments of sonographer's scans and reports were carried out by franchise clinical leads and reports published with benchmark statements of performance.

Diagnostic imaging

The registered manager recorded risk assessments on a form which identified the risk and control measures. Some risk assessments were limited in their detail and did not always address or identify relevant risks, such as the COSHH risk assessment and this was not in line with their own policy. Risk assessments were easily accessible to all staff but they were not always completed.

However, the regional manager and registered manager told us they reviewed all risk assessments and documented any changes or identified new risks but we did not evidence of this with regards to the rear fire escape.

The service had a clinic contingency plan to identify actions to be taken in the event of an incident that would impact the service, for example, extended power loss, severe weather events, short notice staff sickness and equipment failure. The contingency plan included contact details of relevant individuals or services for staff to contact.

Information Management

The service collected 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.

The service had both paper and electronic records. Staff stored paper, electronic records and scan reports securely. The service retained records in line with General Data Protection Regulations (GDPR). However, staff told us that confidential records would be shredded but placed in non confidential waste bins with generic waste. The service policy for information governance did not provide clear and specific guidance on confidential waste handling.

The service stored electronic records securely and these were password protected. The service had an information governance policy and all staff had completed mandatory information governance training. Managers monitored key performance indicators and used these to make improvements.

A number of metrics were considered at monthly team, managers and regional meetings to ensure consistency across the region. This included complaints, feedback from women and audit results.

Engagement

Leaders and staff actively and openly engaged with women, staff.

Women could leave reviews on the services website and through social media sites. We viewed several social media platforms and saw that staff interacted with those leaving reviews and feedback. The service suspended paper-based feedback following national guidance during the COVID-19 pandemic.

When dealing with complaints, we saw timely responses to their customers concerns and complaints and measure to compensate any customer inconvenience.

Managers shared information with staff informally daily and formally via monthly team meetings. Staff also received information via email.

Learning, continuous improvement and innovation

All staff were committed to continually learning.

Diagnostic imaging

Improvement for those using the service were evidenced by the development of a wellbeing app to provide support for pregnant women. The app provided tracking systems for mental wellbeing, “kicks tracking” for babies and access to scan images. The app used password protection and users had unique identification codes.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>The service did not have policies that reflected current national guidance, legislation and best practice and that staff adhere to policies.</p>

Regulated activity	Regulation
Diagnostic and screening procedures	<p>Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment</p> <ul style="list-style-type: none">• The service did not carry out risk assessments in relation to any changes to use of fire exits.• The service did not secure COSHH storage facilities when not in use