

Window to the Womb

Quality Report

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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Good



Are services safe?

Good



Are services effective?

Are services caring?

Good



Are services responsive?

Good



Are services well-led?

Good



Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Summary of findings

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Overall summary

Window to the Womb is operated by D Ventress Ltd, and is located in Farsley; a town in the city of Leeds metropolitan borough, West Yorkshire. The service operates under a franchise agreement with Window to the Womb (Franchise) Ltd. The service is an independent healthcare provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients over 16 years of age.

Window to the Womb (Farsley) has separated their services into two clinics. These are comprised of a 'Firstscan' clinic, which specialises in early pregnancy scans (from six to 15 weeks of pregnancy), and a 'Window to the Womb' clinic, which offers later pregnancy scans (from 16 weeks of pregnancy).

We inspected the service using our comprehensive inspection methodology. We carried out a short-announced inspection on 11 April 2019; giving staff two working days' notice. We had to conduct a short-announced inspection because the service was only open if patient demand required it.

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

Throughout the inspection, we took account of what people told us and how the provider understood and complied with fundamental standards.

Services we rate

We had not previously inspected this service. We rated it as **Good** overall.

We found the following areas of good practice:

- The service made sure staff were competent for their roles. Staff had the right qualifications, skills, training

and experience to keep people safe from harm and deliver effective care and treatment. There were established referral pathways to NHS antenatal care providers.

- Staff understood how to protect patients from abuse and the service had systems to do so.
- There were clear processes for staff to raise concerns and report incidents; and staff understood their roles and responsibilities. The service treated concerns and complaints seriously, and had systems to investigate them. Lessons learned were shared with the whole team and the wider service.
- The environment was appropriate for the service being delivered, was patient centred, and was accessible to all women.
- Staff cared for patients with kindness and compassion. We saw considerable evidence of positive feedback from women who had used the service.
- Staff provided emotional support to patients to minimise their distress. Scan assistants acted as chaperones during ultrasound scans to ensure women felt comfortable and received optimum emotional support.
- Staff understood the importance of obtaining informed consent, and involved patients and those close to them in decisions about their care and treatment. To help ensure good standards of communication, scan assistants periodically assessed sonographers for their quality of customer care and service, standard of communication, and overall customer experience.
- Managers in the service had the right skills and abilities to run a service providing high-quality sustainable care and promoted a positive culture.

Summary of findings

- The service was committed to improving services, had a vision for what it wanted to achieve, and engaged well with patients and staff to plan and manage services.

However:

- Written information that was provided to women at the service about the safety of ultrasound scanning sometimes contradicted Public Health England (PHE) guidance.

Following our inspection, we told the provider that it should make some improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Deputy Chief Inspector of Hospitals (North)

Ellen Armistead

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

Window to the Womb (Farsley) is an independent healthcare provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients over 16 years of age. The service offers an early pregnancy clinic (from six to 15 weeks of pregnancy), and a later pregnancy clinic (from 16 weeks of pregnancy). Depending on the type of scan performed, these might involve checking the location of the pregnancy, dating of the pregnancy, determination of sex, and fetal presentation at the time of appointment. Patients are provided with ultrasound video or scan images, and an accompanying verbal explanation and written report.

Summary of findings

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Good



Window to the Womb

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Window to the Womb

Window to the Womb is operated by D Ventress Ltd, and is located on the outskirts of Farsley town centre. The service operates under a franchise agreement with Window to the Womb (Franchise) Ltd. The service is an independent healthcare provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients aged over 16 years of age. The service primarily serves the communities of Leeds, Bradford, Wakefield and outlying areas.

As part of the agreement, the franchisor (Window to the Womb Ltd) provides the Farsley service with regular on-site support, access to their guidelines and policies, training, and the use of their business model and brand.

The service has had a registered manager in post since May 2016. The service had recently had a change of registered manager, and the current registered manager had been in post since March 2019. Prior to this, the registered manager had undertaken other roles in the service, and had been employed by the service since it had opened in March 2016. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on 11 April 2019. We had not previously inspected this service.

Our inspection team

The team that inspected the service comprised a CQC lead inspector. The inspection team was overseen by Sarah Dronsfield, Head of Hospital Inspection (North East and Cumbria).

Information about Window to the Womb

Window to the Womb (Farsley) separates their services into two clinics; a 'Firstscan' clinic, which specialises in early pregnancy scans, and a 'Window to the Womb' clinic, which offers later pregnancy scans.

Services at the location are provided according to patient demand. However, clinics typically run on a Wednesday and Thursday evening, and on Saturday and Sunday during the day.

The Firstscan clinic offers early pregnancy (reassurance, viability and dating) scans to women from six to 15 weeks of pregnancy. The Window to the Womb clinic offers later pregnancy (wellbeing, gender, growth and presentation) scans to women from 16 weeks of pregnancy. Wellbeing and gender scans are offered from 16 weeks of pregnancy, and growth and presentation scans are offered from 26 weeks of pregnancy.

Scans available at the location are offered as an additional service, and are provided to complement NHS

pregnancy pathway scans. The service does not offer diagnostic anomaly scans, but there are established pathways to refer women to primary antenatal (NHS) providers; should a potential anomaly or concern be identified.

The service does not currently provide any additional diagnostic services, such as non-invasive pre-natal testing (NIPT) or endometrial thickness measuring (for women undergoing fertility treatment).

Activity:

- From 1 January to 31 December 2018, the later pregnancy (Window to the Womb) service performed 2,757 ultrasound scans.
- Of these, 1,562 were gender determination scans, 874 were 4D baby scans, 177 were well-being scans, and 144 were growth and presentation scans.

Summary of this inspection

- Over the same period, the early pregnancy (Firstscan) service performed 1,040 ultrasound scans.

Track record on safety during the reporting period 1 January to 31 December 2018; in this timeframe there were:

- No patient deaths.
- No never events.
- No serious incidents.
- No duty of candour notifications. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- No safeguarding referrals.

- No incidence of healthcare acquired infections.
- No unplanned urgent transfer of a patient to another health care provider.
- No appointments were cancelled for a non-clinical reason.

From 1 January to 31 December 2018, the service reported it had received three complaints.

During our inspection, we spoke with four members of staff; these included the registered manager, a sonographer, and scan assistants. We also reviewed 10 staff records. We observed two ultrasound scans, and spoke with these two patients and their companions. We reviewed a total of eight patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before our inspection. We had not previously inspected this service.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We had not previously inspected this service. We rated safe as **Good** because:

Good



- The service made sure staff were competent for their roles. Staff had the right qualifications, skills, training and experience to keep people safe from harm and deliver effective care and treatment.
- Staff understood how to protect patients from abuse and the service had systems in place to do so.
- There were processes for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents. Lessons learned were shared with the whole team and the wider service.
- The service had suitable premises and equipment and looked after them well. Staff kept the equipment and the premises clean. The environment promoted the privacy and dignity of women.
- Staff completed and updated risk assessments for each patient and kept detailed records of patients' care and treatment. Records were securely stored and available to all staff providing care.

However:

- Written information that was provided to women in a 'technology and safety' brief sometimes contradicted Public Health England (PHE) guidance. Following our inspection, the service provided evidence that the information had been amended in line with PHE guidance.

Are services effective?

We do not currently rate the effective domain for diagnostic imaging services, however, we found:

- The service used current evidence-based guidance and good practice standards to inform the delivery of care and treatment.
- Staff had the skills, knowledge and experience to deliver effective care and treatment; and staff of different disciplines worked together as a team to benefit women and their families.
- Staff understood the importance of obtaining informed consent, and when to assess whether a patient had the capacity to make decisions about their care.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.

Summary of this inspection

Are services caring?

We had not previously inspected this service. We rated caring as **Good** because:

- Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.
- Staff provided emotional support to patients to minimise their distress.
- Staff involved patients and those close to them in decisions about their care and treatment.

Good



Are services responsive?

We had not previously inspected this service. We rated responsive as **Good** because:

- The service planned and provided services in a way that met the needs of local people.
- The service took account of patients' individual needs.
- People could access the service when they needed it.
- The service treated concerns and complaints seriously, and had systems to investigate them, learn lessons from the results, and share these with all staff.

Good



Are services well-led?

We had not previously inspected this service. We rated well-led as **Good** because:

- The registered manager had the right skills and abilities to run a service providing high-quality sustainable care. They promoted a positive culture, creating a sense of common purpose based on shared values.
- The service had systems to identify risks, and plans to eliminate or reduce them.
- The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent care to flourish.
- The service engaged well with women, staff and the public to plan and manage appropriate services and collaborated with partner organisations effectively.
- The service had a vision for what it wanted to achieve and workable plans to turn it into action; and was committed to improving services by learning from when things went well or wrong, and promoting training and innovation.

Good



Detailed findings from this inspection






Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	Good	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Notes

Diagnostic imaging

Safe	Good 
Effective	Good 
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We rated the safe domain as **good**.

Mandatory training

- **The service provided mandatory training in key skills to all employed staff; and ensured contracted (self-employed) staff had undertaken relevant training.**
- The service had an up to date mandatory training policy. Mandatory training requirements included fire safety awareness, infection control, information governance, health and safety at work, equality and diversity, safeguarding adult, and safeguarding children training.
- Records we reviewed showed the registered manager, five scan assistants, and one administration assistant employed at the location were compliant with mandatory training requirements.
- Six sonographers worked for the service on a self-employed basis. All sonographers completed their mandatory training with their substantive (NHS) employer. We saw the registered manager had oversight of what mandatory training sonographers had completed with their substantive employer; and we saw evidence sonographers had been provided with a formal induction to the service.
- It was company policy (mandatory) for all sonographers to be registered with a professional regulatory body. We reviewed staff files and saw that

all six sonographers contracted at the service were registered with the Health and Care Professions Council (HCPC). Some sonographers were also registered with other professional regulatory and national bodies; such as, the Nursing and Midwifery Council (NMC) and British Medical Ultrasound Society (BMUS).

- The registered manager informed us that the ultrasound machine used by the service was an updated version of machines frequently used in the NHS. As such, sonographers at the location were already familiar with the machine prior to commencing employment. However, use of the equipment was monitored during initial training and shadowing sessions, and the ultrasound manufacturer was available to train sonographers to use the machine, should they require it.
- The registered manager had attended external mandatory training courses provided by the franchisor. Courses covered important topics such as: basic life support, fire safety, information governance, complaints handling, conflict resolution, and moving and handling training.

Safeguarding

- **Staff understood how to protect patients from abuse and the service had systems in place to do so.**
- There were up-to-date safeguarding adults and children's policies for staff to follow, which included the contact details of local authority safeguarding teams, and local advocacy services and voluntary

Diagnostic imaging

organisations. We saw that staff had initialled safeguarding policies to show they had been read. Safeguarding information was also displayed in the waiting area.

- We also saw that the service held copies of safeguarding referral forms and guidance issued by local authorities, for staff to use or refer to, if needed.
- A separate female genital mutilation (FGM) policy provided staff with guidance on how to identify and report FGM.
- We saw that the registered manager had undertaken a safeguarding quiz with scan assistants, to further check their understanding.
- The service had a designated lead for both children and adults' safeguarding, who was the registered manager. The registered manager had completed adults and children's level three safeguarding training. They were available during working hours to provide support to staff.
- We reviewed staff files and saw that all other staff at the service had received level two adults and children's safeguarding training at a minimum.
- Staff we spoke with were able to articulate signs of different types of abuse, and the types of concerns they would report or escalate; they were aware of the service's safeguarding policies.
- In the reporting period January to December 2018, we saw that no safeguarding referrals had been made by the service. However, given the nature of the service, this was not cause for concern.
- A risk assessment for the location had been undertaken. This stated that all staff had to have a Disclosure and Barring Service (DBS) check. The risk assessment stipulated that staff DBS checks had to be renewed every three years; with the exception of sonographers, which were to be renewed annually. Enhanced DBS checks used for NHS employment were deemed to be acceptable. We saw 100% of staff who had worked at the service longer than six weeks had a DBS check in place. One scan assistant and one administration assistant had recently been employed by the service; their DBS checks were in progress and we saw evidence of this.

- We reviewed personnel files and saw that all staff had an up to date curriculum vitae on file, and the service had obtained references for all staff. We also saw employment offer letters, contracts, evidence of induction, proof of address, and copies of photographic identification were kept on file.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept the equipment, and the premises clean.**
- The service had infection prevention and control (IPC) policies and procedures, which provided staff with guidance on appropriate IPC practice. We saw that all staff had received mandatory IPC training.
- During our inspection, we saw that clinic rooms, toilets, reception and waiting areas were visibly clean.
- We saw staff completed a daily cleaning log. We also saw that staff undertook frequent (hourly) cleanliness visibility checks of clinical areas throughout their shifts; documenting and remedying any areas of concern as necessary.
- The service had appropriate handwashing facilities and sanitising hand gel was available. During our inspection, we observed clinical staff were bare below the elbows and adhered to the World Health Organisation's (WHO) 'Five Moments for Hand Hygiene'. We also saw that the service conducted handwashing compliance audits every quarter. The most recent was conducted in February 2019 and identified the six staff observed were 100% compliant.
- We saw that cleanliness, hygiene, and personal and protective equipment (such as latex-free gloves and antiseptic wipes) were readily available at the service.
- The sonographers followed the manufacturer's and IPC guidance for routine disinfection of equipment. Staff decontaminated the ultrasound equipment with disinfectant between each woman and at the end of each day. We observed staff cleaning equipment and machines during our inspection.
- There were appropriate facilities for the disposal of clinic waste, and the service had an agreement with a third-party disposal company.
- During the Firstscan clinic, which performed transvaginal scans, the couch in the treatment room

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used by patients was covered with disposable cloth which was changed between patients and the couch wiped with an antibacterial wipe before laying out a new disposable cloth. During the later pregnancy (Window to the Womb) clinic, which only performed transabdominal scans, a washable fabric cover was placed on the couch; however, this was covered with a disposable cloth which was changed between patients.

- Women were given a towel to use during their ultrasound scan to help maintain their dignity. Following each appointment, the used towels were placed in a laundry bin, and were laundered at a minimum temperature of 60 degrees.
- The service had processes for dealing with blood and body substance spills, and a spill kit was available at the location; at the time of our inspection, there had been no need to use this to date.
- In the twelve months prior to inspection there had been no incidences of healthcare acquired infections at the location.
- An annual risk assessment for Legionnaires' disease was undertaken in May 2018. The assessment identified actions the service was taking to mitigate the risk; such as water temperature and flushing monitoring. Legionnaires' disease is a serious pneumonia caused by the legionella bacteria. People become infected when they inhale water droplets from a contaminated water source such as water coolers and air conditioning systems.

Environment and equipment

- **The service had suitable premises and equipment and looked after them well. The environment promoted the privacy and dignity of women using the service.**
- The ultrasound machine at the location was less than 12 months old, and as such, had not yet undergone an annual service. The service had contracted an external engineering company; and if faults arose, staff were able to call out engineers to assess and perform repairs.
- Staff told us that they regularly checked stocks at the location, and we saw there was adequate storage facilities for consumables.

- The service had produced a property file, which contained key documentation. We saw that there was a health and safety policy at the service, and managerial staff at the location had undertaken a range of environmental risk assessments; most recently, in March 2019. The service had produced an emergency action plan for contingency planning.
- The service had undertaken a 'control of substances hazardous to health regulations' (COSHH) risk assessment in February 2019. We saw that substances that met COSHH (Health and Safety Executive, 2002) criteria were securely stored; and a sign indicating storage of COSHH materials was clearly displayed on the cupboard door.
- Electrical equipment was regularly serviced and safety tested to ensure it was safe for patient use. An electrical installation condition assessment was undertaken by an external company in December 2018; and all forty pieces of equipment tested were found compliant.
- The service had contracted an external company to undertake a fire risk assessment in January 2019; and there was an emergency evacuation procedure. At inspection, we saw fire extinguishers were accessible, stored appropriately, and had all been inspected and serviced within the date indicated (January 2019). Fire and evacuation drills were held each month, with the most recent drill completed in March 2019.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient. They kept clear records and asked for support when necessary.**
- The service only provided ultrasound scans to women over 16 years of age. The service did not offer emergency tests or treatment.
- We saw that written information provided by the service strongly advised women to attend scans as part of their NHS maternity pathway. As part of giving consent, women had to declare that they were receiving appropriate antenatal care from an NHS provider.
- When booking their appointment, women were advised to bring their NHS pregnancy records with them to their appointment. This meant the

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sonographers had access to women's obstetric and medical history, if required. It also meant that staff could contact the most relevant medical provider if a concern was detected; which women agreed to as part of consent procedures at the service.

- A different pre-scan questionnaire was in use at the Firstscan service. This required women to provide GP details, and the details of their local NHS hospital. Women were also required to provide pregnancy information. For example, number of previous pregnancies, ectopic pregnancies, and miscarriages, date of last menstrual period, and date of first positive pregnancy test.
- Sonographers were required to document if women had provided their pregnancy records, or the details of their antenatal care provider or GP, on consent forms. In addition, sonographers had to record whether they were satisfied the service was appropriate for the woman, and could therefore be offered.
- We observed that written information and verbal information given to women who utilised the service was clear as to the limits of diagnostic services provided. For example, women had to declare that they understood that scans were not exhaustive and that sonographers at the service could not confirm possible anomalies; but would refer them to NHS antenatal care providers.
- We saw that scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for 'as low as reasonably achievable' (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency of ultrasound waves. This meant that sonographers used minimum frequency levels for a minimum amount of time to achieve the best result.
- However, we saw that information provided by the service to women in a 'technology and safety' brief sometimes contradicted Public Health England (PHE) guidance. PHE advise that although there is no clear evidence that ultrasound scans are harmful to the fetus, parents-to-be must decide for themselves if they wish to have ultrasound scans and balance the benefits against the possibility of unconfirmed risks to the unborn child. Although safety information given in the service brief was contextualised by various ultrasound methods and research sources, some of the language used was sometimes definitive; for example, "... you and your baby are completely safe", and "having an ultrasound scan won't affect your baby". We observed that the information concluded with findings from the Advisory Group on Non-ionising Radiation (2010), which stated: "although there is insufficient evidence of harm resulting from scans, there is a possibility of unconfirmed risks to the unborn child, and it called for more research". This latter statement was in line with PHE guidance, but appeared at odds with some earlier statements (as described). Following our inspection, the service provided evidence that the information had been amended in line with PHE guidance.
- We saw BMUS 'pause and check' guidance was displayed in the scan room and the sonographer we observed followed this guidance. The guidance is designed to act as a ready reminder of the checks that need to be made when any ultrasound examination is undertaken.
- We saw a sonographers' handbook and a hospital pathways folder were in use at the service. There were clear processes to guide staff on what actions to take if potential abnormalities were identified on ultrasound scans; this included defined care pathways for sonographers to follow to refer women to appropriate NHS antenatal healthcare providers. For example, if women required referral to the antenatal clinic at a local NHS trust. Guidance documents contained contact numbers for local hospital antenatal care providers. If the sonographer suspected higher-risk conditions or concerns (such as, placental abruption or an ectopic pregnancy) they were instructed to immediately dial 999 for emergency assistance.
- Sonographers at the service were able to contact a lead sonographer for advice and support during clinics. The lead sonographer was employed by the franchisor and was available to review any ultrasound scan remotely within two hours.
- Staff documented referrals on dedicated referral forms, which were reviewed by the registered manager and kept on file. We saw the service maintained a referral log, which detailed patient information, the date of the scan, the date the referral was made, and a summary of the possible anomaly or concerns

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identified. From 1 March 2018 to the date of our inspection, we saw the later pregnancy scan (Window to the Womb) service had made five referrals and the Firstscan clinic had made 53 referrals to NHS antenatal care providers.

- During our inspection, we reviewed 10 referral forms (five from the early pregnancy clinic and five from the later pregnancy clinic), which detailed patient information, scan findings, reason for referral, and who the receiving healthcare professional was. We saw sonographers were required to document their work contact details and HCPC registration number on the referral form. Reasons for referral included potential anomalies and concerns such as, possible hernia, small for gestational age, possible talipes of foot (baby has a turned-in or club foot), irregular gestational sac, missed miscarriage, and no fetal heartbeat. Staff at the service offered to call NHS antenatal care providers on behalf of patients, to refer them and explain potential findings; this helped to ensure continuity of care. We saw accompanying written reports and scan images were provided to NHS antenatal healthcare providers, as appropriate.
- It was company policy for someone who was first aid trained to always be on duty, and personnel files showed staff had completed first aid at work and the registered manager had completed basic life support training. Staff had access to a first aid box on site. There was also clear guidance for staff to follow if a woman suddenly became unwell whilst attending the clinic. If staff had concerns about a woman's condition during their ultrasound scan, they would stop the scan and telephoned 999 for emergency support.
- The service reported there had been no unplanned urgent transfers of a patient to another health care provider, and no appointments had been cancelled for a non-clinical reason in the reporting period January to December 2018.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- The registered manager was responsible for the day-to-day running of the clinic. There were five scan

assistants and one administration assistant employed at the location. Scan assistants were responsible for managing enquiries, appointment bookings, supporting the sonographers during the ultrasound scans, and helping to support women and make them comfortable. Day-to-day management of scan assistants was undertaken by the registered manager.

- Six sonographers worked for the service on a self-employed basis. All sonographers held substantive posts in the NHS and had previous obstetrics and gynaecology experience. We saw that all sonographers at the service were registered with the HCPC. Some staff also held additional registrations; for example, with the NMC and BMUS.
- The ultrasound clinics were scheduled in advance and the sonographers assigned themselves to the clinics.
- All staff we spoke with felt that staffing was managed appropriately. Staff told us that the service only operated with a minimum of two scan assistants (or the registered manager and a scan assistant) and a qualified sonographer on duty per shift.
- The pool of staff available at the service was adequate to cover absenteeism, such as holidays and sickness cover.
- The service did not make use of any bank or agency staff.
- The registered manager monitored staff sickness rates. From January to December 2018, there had been no staff sickness absences.

Records

- **Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.**
- The service had an up to date information governance policy, and a data retention policy.
- The registered manager was the information governance lead for the service.
- We saw that all staff at the service had completed information governance training.
- Pre-scan questionnaires and consent forms at the service ensured sufficient information was obtained from women prior to their scans; for example, in

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relation to number of weeks pregnant, and number of previous pregnancies. Women were also required to declare medical conditions that might affect their scan.

- As part of consent taking processes at the service, women agreed to the service contacting NHS antenatal healthcare providers (such as GP or NHS antenatal services) should a potential anomaly or concern be identified.
- Sonographers were responsible for obtaining the informed consent of women and completing ultrasound (paper) reports, with the assistance of scan assistants. A copy of which was provided to the patient to take away. The service retained a copy of the scan report, in case they needed to refer to the document in future. The service retained a digital copy of scan images for a period of 30 days, in order to rectify any issues following the scan.
- The franchisor had developed a smart device application that allowed women to securely view their scan images and videos remotely. The application enabled women to share their images and video to social media sites, or other individuals, as they so wished.
- We saw that paper documents were securely stored in lockable filing cabinets, and computers were password protected.
- The franchisor had hired an EU General Data Protection Regulation (GDPR) consultant in 2018 to ensure the services record systems and digital applications were compliant.

Incidents

- **Processes were in place for staff to raise concerns and report incidents. Staff understood their roles and responsibilities to raise concerns and record safety incidents. Lessons learned were shared with the whole team and the wider service.**
- The service had an up to date incident reporting policy, which detailed staff obligations to report, manage and monitor incidents.
- The service used a paper-based reporting system, and an incident log was available in the clinic. We reviewed the incident log, which ran from January 2019, and

saw one incident had been recorded in the 12 months prior to our visit. This involved a patient becoming briefly locked in the bathroom due to the inside handle breaking; we saw evidence the lock had been fixed the following day.

- The registered manager was responsible for conducting investigations into all incidents at the location, and submitted a monthly incident return to the franchisor.
- Staff we spoke with described the process for reporting incidents and provided examples of when they might do this. Staff we spoke with said they would be open and honest with patients should anything go wrong, and give patients suitable support. The registered manager could explain the process they would undertake if they needed to implement the duty of candour following an incident.
- We saw that the registered manager reviewed incidents to identify any themes and learning. We saw services within the wider franchise shared learning from incidents and events through the national network, and via team meetings and through service circulars. For example, staff we spoke with were aware of the recent emergency transfer of a woman at another (franchise) location, following detection of a live ectopic pregnancy.
- In the reporting period January to December 2018, there were no patient deaths, never events, or serious incidents at the location. In the same period, there was no duty of candour notifications.

Are diagnostic imaging services effective?

Good 

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

Evidence-based care and treatment

- **The service used current evidence-based guidance and good practice standards to inform the delivery of care and treatment.**

Diagnostic imaging

- Staff were aware of how to access policies, which were stored electronically on an internal computer drive. We also saw paper copies were collated in folders and were accessible to staff.
- Local policies and protocols were in line with current legislation and national evidence-based guidance from professional organisations, such as the National Institute for Health and Care Excellence (NICE) and the BMUS.
- All policies and protocols we reviewed contained a next renewal date, which ensured they were reviewed by the service in a timely manner.
- Scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for ‘as low as reasonably achievable’ (ALARA) principles for safety in ultrasound scanning; and sonographers followed BMUS ‘pause and check’ guidance.
- There was an audit programme in place to provide assurance of the quality and safety of the service. Clinic and local compliance audits were undertaken regularly; for example, with respect to patient experience, cleanliness, health and safety, ultrasound scan reports, equipment, and policies and procedures. Additional assurance was provided by external audits undertaken by the franchisor. We saw deviation from processes documented and improvement actions agreed, which were timebound and checked. For example, we saw a recent February 2019 audit had identified some sonographers would require an annual review by the clinical lead in the near future.
- The service was inclusive to all pregnant women and we saw no evidence of any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.

Nutrition and hydration

- **Food and drinks were available to meet patients’ needs.**
- To improve the quality of the ultrasound image, women were asked to drink extra fluids on the lead up to their appointment. Women who were having a gender scan were encouraged to attend their

appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. It was also included in the ‘frequently asked questions’ on the service’s website.

- Drinking water was available on site. However, due to the nature of the service, food and drink was not routinely offered to women. However, there were local convenience stores nearby, should women or their companions wish to purchase any food or drink.

Patient outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.**
- The registered manager had overall responsibility for governance and quality monitoring.
- The service used key performance indicators to monitor performance, which were set by the franchisor. This enabled the service to benchmark themselves against other franchised clinics. Data was collected and reported to the franchisor every month to monitor performance. This included information about the number of ultrasound scans completed including the number of rescans, and the number of referrals made to other healthcare services.
- From 1 March 2018 to the date of our inspection, the service had referred 58 women to antenatal (NHS) care providers due to the detection of potential concerns.
- The Window to the Womb franchise reported a 99.94% accuracy rate for their gender confirmation scans; this figure was based on over 20,000 gender scans completed at the 36 franchised clinics across the UK. Data provided by the location showed that three inaccurate gender ultrasound scans had been performed in a twelve-month period, equating to a gender accuracy rate of 99.89%.
- There was a rescan guarantee for when it was not possible for the sonographer to confirm the gender of the baby at the time of the appointment. If the woman received incorrect information with regards to their baby’s gender, they were offered a complimentary 4D baby scan. The sonographer involved also received additional support from the lead sonographer, who was employed by the franchisor.

Diagnostic imaging

- From January to December 2018, 46 gender rescans were completed. The gender rescan rate for the later pregnancy (Window to the Womb) clinic was 3% of the total number of gender scans completed. Most of the rescans were completed because it was not always possible for the sonographer to confirm the gender of the baby at the time of the initial appointment. However, this rate also included some rescans where the woman was asked to mobilise for a short period at the clinic, or to drink cold fluids, to encourage baby to reposition and enable a clearer image.
- We saw that service activity audit results and patient feedback were discussed at monthly team meetings. As all sonographers at the service were substantively employed in the NHS, they struggled to attend clinic team meetings. We saw team meeting minutes were emailed to sonographers, and a paper copy was displayed in the staff area; which sonographers initialled to indicate these had been read.

Competent staff

• **Staff had the skills, knowledge and experience to deliver effective care and treatment.**

- We reviewed staff files and saw each staff member had completed a local induction, which included mandatory and role-specific training. Staff accessed their role-specific training through the service's electronic training portal. Training records confirmed that all staff had completed their appropriate role-specific training.
- Staff files we reviewed all contained evidence of a curriculum vitae, recruitment, interview and selection processes, references from previous employment, picture identification, employment contract, and Disclosure and Barring Service (DBS) checks.
- Information provided by the service showed there was a 100% appraisal compliance rate for the three scan assistants at the service that had been employed for more than 12 months; and we saw evidence of this.
- Four sonographers at the location had been contracted for more than 12 months. The service did not formally appraise these self-employed staff. However, we saw sonographers received competency

assessments from the clinical lead; and the registered manager checked the sonographers' registration, indemnity insurance and revalidation status on an annual basis.

- We saw it was company policy (mandatory) for all sonographers to be registered with a professional regulatory body. We reviewed staff files and saw that all sonographers contracted at the service were registered with the Health and Care Professions Council. Some sonographers were also registered with other professional regulatory and national bodies; such as, the NMC and BMUS.
- We reviewed staff files and saw evidence of sonographers undertaking continuous professional development and additional formal qualifications; for example, a number of sonographers held or were working towards specialised post-graduate degrees. We also saw sonographers had recently attended a regional franchisor event to share best practice.
- The franchise had recently introduced sonographer peer review audits (November 2018). The sonographers peer reviewed each other's work and determined whether they agreed with their ultrasound observations and report quality. This was in line with BMUS guidance, which recommends peer review audits are completed using the ultrasound image and written report. At our inspection, we reviewed five peer review audits that had been completed at the location since November 2018. We saw peer assessment covered feedback on topics such as effective use of equipment, observations, and report quality. We found that no concerns had been identified; however, peer assessments did highlight learning. For example, one peer assessment recommended "using depth before zooming might make [the] image clearer".
- The franchisor produced video training logs (VLOGs), these were used as additional training and continuing professional development tools for sonographers, and scan assistants who wanted to learn more about sonography.

Multidisciplinary working

- **Staff of different disciplines worked together as a team to benefit women and their families.**

Diagnostic imaging

- We observed positive examples of the registered manager, sonographer and scan assistants working well together.
- We saw evidence that staff engaged in team meetings. For staff members unable to attend, copies of meeting minutes were available for them to read on the staff notice board.
- If a possible anomaly or concern was detected, the service had established pathways to refer women to their primary antenatal care providers; for example, their GP or local NHS trust.

Seven-day services

- **Services were available that supported care to be delivered seven days a week, if necessary.**
- Services were supplied according to patient demand. This meant the location was not necessarily open seven days a week. Clinics typically ran on a Wednesday and Thursday evening, and on Saturday and Sunday during the day. This offered flexible service provision for women and their companions to attend around work and family commitments. The service had capacity to extend service provision as and when the need arose; and ran additional clinics on Friday evenings, if needed.

Health promotion

- **The service promoted opportunities for healthy living.**
- The service offered women patient information leaflets and antenatal care packs. These included information about keeping healthy, foods to avoid, and health promotion questions to ask their midwife (such as booking of flu jabs, and breastfeeding support).
- The service also carried a range of national charity information leaflets, for example, one detailed information encouraging women to understand and be mindful of baby's normal movements during pregnancy.
- We saw that information about local antenatal classes was available.

Consent and Mental Capacity Act

- **Staff understood the importance of obtaining informed consent, and when to assess whether a patient had the capacity to make decisions about their care.**
- Staff completed training in relation to consent, and the Mental Capacity Act (2005), as part of their induction and mandatory training programme.
- There was a Mental Capacity Act (2005) policy for staff to follow, which clearly outlined the service's expectations and processes.
- Women's consent to care and treatment was sought in line with legislation and guidance. All women were required to complete and sign a consent form prior to undergoing ultrasound scanning. Consent form information included terms and conditions, such as scan limitations, referral consent, and use of data.
- Staff were aware of consent procedures for those aged under 18 years of age; for example, the use of the Gillick competency test.
- During our inspection, we saw that the sonographer checked information women had provided, asked questions to clarify any issues, and sought women's verbal consent before the sonographer commenced with the ultrasound scan.
- Information on the service's website could be accessed in (changed to) any language. The service also offered a 'read out loud system' to allow the visually impaired to gain information with ease. The service had contracted a (telephone) language interpretation service, that could be utilised for consent taking processes, if needed.

Are diagnostic imaging services caring?

Good 

We rated the caring domain as **good**.

Compassionate care

- **Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.**

Diagnostic imaging

- The scan room afforded patients privacy and dignity. We saw the service had recently fitted a privacy curtain, should women wish to use it. The scan room had three wall-mounted monitors. This meant women's companions could easily view ultrasound images, should women opt to use the privacy curtain.
- During our inspection, we observed staff were warm, kind and welcoming when they interacted with women and their companions.
- Feedback forms (comment cards) were available in the clinic for patients and their companions to complete. During our inspection we reviewed 12 comment cards completed. Patients and companions were able to rate the overall service provided from one to five stars, and we saw all women (100%) had rated the service as 'five stars'. Qualitative feedback was overwhelmingly positive, for example, patients described they were "made to feel so welcome" and staff were "so friendly" and "great", care was described as "amazing".
- Patients and their companions were also able to leave feedback on open social media platforms, which the registered manager said were frequently monitored. We viewed a selection of feedback on these sites and saw feedback was overwhelmingly positive. The service was "highly recommended", and staff were described as "welcoming" and "friendly and professional".
- During our inspection, we spoke to two patients and their companions. All patients and companions we spoke with during our inspection described the service positively. For example, they said the service was "wonderful".
- As part of their mandatory training, staff received communication training; which included the emotional aspects of delivering and receiving bad news.
- Emotional and communication guidance was available at the service for staff to follow. We also saw that staff received training to understand and appreciate parents needs and feelings when receiving challenging news, and to offer appropriate emotional support.
- Staff told us that if possible anomalies were identified, or concerns arose, women would be supported (by the sonographer, supported by the scan assistant) in the scan room. Staff said that any women awaiting appointments would be informed that scans might be delayed.
- Window to the Womb separated their services into two clinics: the 'Firstscan' clinic, which specialised in early pregnancy scans; and the 'Window to the womb' clinic, which offered later pregnancy scans. Clinics purposely ran 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.
- The service had access to written patient information to give to women who had received challenging news. This included a range of patient information leaflets produced by national miscarriage, stillbirth and infant bereavement charities.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
 - We observed scan assistants and the sonographer were very reassuring, and interacted with women and their companions in a professional, respectful, and supportive way.
 - The scan assistants acted as chaperones during ultrasound scans to ensure women felt comfortable and received optimum emotional support.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
 - The scan room was large, and patients could bring up to six companions with them, if they desired. The scan room benefitted from three large wall mounted monitors, so women and their companions could see detailed pictures of ultrasound scans.
 - We observed that staff took time explaining procedures to women before and during ultrasound scans, and left adequate time for patients and their companions to ask questions, and have these satisfactorily answered.

Diagnostic imaging

- Patients we spoke with at inspection said that they had received detailed explanations of scan procedures, and accompanying written feedback.
- We saw that staff adapted the language and terminology they used when discussing the procedure to the needs of individual women and their companions.
- To help ensure good standards of communication, scan assistants periodically assessed sonographers for their quality of customer care and service, standard of communication, and overall customer experience. The sonographer received verbal and written feedback, and the registered manager ensured any identified learning points were implemented. We reviewed ten of these assessments undertaken at the location during our inspection. We saw scan assistants had rated setting up of the scan room for clinic, sonographer's infection prevention and control practice, quality of welcome and introductions, and explanation of the scan process. The scan assistant also sought feedback from the patient and their companions. For example, one stated they "had a really good experience" and another said that they had "found everything they needed to know".
- Women and companions we spoke with during our inspection described the sonographer gave sufficiently detailed descriptions of scan images. For example, one said they had "told us more than at the hospital".

Are diagnostic imaging services responsive?

Good 

We rated the responsive domain as **good**.

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
- The environment was appropriate for the service being delivered and was patient centred. The scan

room was large with ample seating and additional standing room for up to six guests, and children of all ages were welcome to attend. Baby change facilities were also available.

- Information about services offered at the location were accessible online. The service offered a range of ultrasound scans for pregnant women; such as wellbeing, viability, growth, presentation, and gender scans.
- Women were given relevant information about their ultrasound scan when they booked their appointment, such as needing a full bladder. There was also a link to a 'frequently asked questions' section on the service's website.
- The service provided payment details in a booking confirmation email prior to appointment. Ultrasound scan prices were detailed on the service's website, and we observed staff clearly explaining costs and payment options to women during their appointments.
- Services were delivered to meet patients' needs, offering appointments after working hours during the week, and at weekends.

Meeting people's individual needs

- **The service took account of patients' individual needs.**
- Women received detailed written information to read and sign before their scan appointment. Key information about what different ultrasound scans involved were available on the service's website, and could be accessed in any recognised world language.
- The service had contracted a telephone interpretation service, for staff to use during appointments with non-English speaking women. We were also told that the franchisor was developing a bespoke mobile phone application for staff and women to use in these circumstances. Once developed, the application would be capable of translating both verbal and written information.
- The service website offered a 'read out loud system' to allow the visually impaired to gain information with ease.

Diagnostic imaging

- Staff described that they had a woman who was deaf attend the service for an ultrasound scan. The woman's needs were identified at the time of booking. Staff described that they had altered their communication techniques to meet the woman's needs. For example, they had been mindful to face the patient when speaking and clearly articulated words (for lipreading), and had utilised visual diagrams to aid communication.
- The service was located on the ground floor, with direct access from the street; and off-street parking was available. Accessible bathroom facilities were situated adjacent to the clinic and waiting area. There was a reception area with ample seating for women awaiting appointments, and their companions.
- The scan room was large and airy, with ample seating and additional standing room for up to six guests. The scan room was lit with mood lighting to create a relaxing and calming environment for the woman and her companions. There was an adjustable medical bed in the scan room, which staff used to support women with limited mobility.
- We saw that children were welcomed in the clinic, and toys were provided in the waiting area to entertain them.
- We saw that information leaflets were given to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy; a second scan that confirmed a complete miscarriage; or an inconclusive scan. These leaflets contained a description of what the sonographer had found, advice, and the next steps women should take.
- Window to the Womb separated their services into two clinics: one for early pregnancy scans, and one for later pregnancy scans. This meant that women who may have previously experienced a miscarriage did not share the same area with women who were much later in their pregnancy.
- The service operated an equality and diversity policy. Equality and diversity training was mandatory for all staff, and we saw training compliance was 100% at the time of inspection.
- **People could access the service when they needed it.**
- All women self-referred to the service. The service offered different booking methods. Women could book their scan appointments in person, by phone, or through the service's website. The franchise had also developed a secure smart device application that had an appointment booking facility.
- The service opened according to patient demand, and typically ran on a Wednesday and Thursday evening, and on Saturday and Sunday during the day. The service had capacity to extend service provision as and when the need arose; and ran additional clinics on Friday evenings, if needed.
- At the time of our inspection, there was no waiting list or backlog for appointments. From January to December 2018, the service conducted 3,797 ultrasound scans. The later pregnancy (Window to the Womb) service had performed 2,757 ultrasound scans. The early pregnancy (Firstscan) service had performed 1,040 ultrasound scans.
- At the time of inspection, the service did not formally monitor rates of patient non-attendance. However, staff we spoke with said there was a low rate of non-attendance because the service requested a non-refundable deposit payment on appointment booking. If a woman suffered a miscarriage before their appointment, staff would refund the deposit payment immediately.
- Patients we spoke with at the inspection were positive about the availability of scans, and said that they had received suitable appointments in a timely fashion. We also saw this reflected in written feedback we reviewed. During our inspection, we observed that clinics ran on time.
- In the reporting period January to December 2018, no planned appointments were cancelled for a non-clinical reason; such as breakdown of equipment.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, and had systems in place to investigate them and learn lessons from the results, and share these with all staff.**

Access and flow

Diagnostic imaging

- The service had an up to date complaints policy, which outlined procedures for accepting, investigating, recording and responding to local, informal, and formal complaints about the service. The policy confirmed that all complaints should be acknowledged within three working days and resolved within 21 working days.
- All had staff completed a mandatory training course on customer care and dealing with complaints.
- We saw information about how to complain was displayed in the clinic reception area. Information on how to make a complaint was also available on the clinic website, and on the reverse of the consent forms and scan reports.
- The registered manager had overall responsibility for reviewing and responding to complaints. They collated complaints in a complaint log. The manager described that the complaints and concerns received were usually minor in nature and most often communicated to the service via social media channels, which were frequently monitored.
- The registered manager described that there was a minimum of two scan assistants and one sonographer on duty at all times; this helped to ensure there was enough staff to interact personally with every client. The service actively encouraged staff to identify any potential dissatisfaction whilst the client was still in the clinic, and resolve complaints or concerns locally.
- The service had received three formal complaints from January to December 2018. All three complaints related to sonographer communication; for example, one woman felt that the sonographer had not offered enough reassurance. We saw that complainants had received a formal apology from the registered manager, and had fed back details of the complaint to the sonographer involved.
- We saw that complaints and concerns were discussed at team meetings; and meeting minutes were made available to staff unable to attend.
- The complaints policy contained the name and contact details for a member of staff at head office; whom patients could contact, if they felt their complaint or concern had not been satisfactorily resolved at local level. We also saw that the franchise

offered an alternative dispute resolution service, which was provided by an independent body; patients could approach this service if they felt their complaint had not been resolved locally or by the franchisor.

- The service actively encouraged feedback, through comments cards available in clinics, and via open platform social media sites. We saw that the service had responded to feedback. For example, they had added a dignity curtain in the scan room, and adjusted opening times to reflect patient demand.

Are diagnostic imaging services well-led?

Good 

We rated the well-led domain as **good**.

Leadership

- **The registered manager had the right skills and abilities to run a service providing high-quality sustainable care.**
- The registered manager, although relatively new to the role, had worked at the service in another capacity for approximately three years; and had good awareness of the service's performance and needs.
- The franchisor was contractually responsible for providing the registered manager with ongoing training, which was undertaken at clinic visits, training events, and biannual national franchise meetings.
- The franchisor offered management development to staff; this included, customer service skills, manager induction, negotiating and influencing, problem solving and performance appraisal training. The registered manager had undertaken this training in July 2018.
- The sonographers reported to the registered manager for matters of administration and to the lead sonographer for clinical matters. Scan assistants reported to the registered manager.
- Staff knew the management arrangements and told us they felt well supported. The lead sonographer was available for advice, and could review any ultrasound scans remotely within two hours.

Diagnostic imaging

- We saw that the registered manager interacted well with staff, and was friendly, approachable, and effective in their role.

Vision and strategy

- **The service had a vision for what it wanted to achieve and workable plans to turn it into action.**
- The service aimed to “to provide pregnant ladies with a private obstetric ultrasound service in an easily accessible local environment” and “to enhance [the] customer’s experience by offering a homely, safe and comfortable environment”.
- The service had identified values, which underpinned their vision. Their values included: dignity, integrity, privacy, diversity, and safety. The location also sought to promote “excellence in ultrasound imaging services by ensuring accuracy, efficiency, compassion and professional integrity”.
- Staff we spoke with could reiterate the ethos of the service’s vision and values.
- The service had a detailed business strategy which outlined what it wanted to achieve over the upcoming year.

Culture

- **The registered manager promoted a positive culture, creating a sense of common purpose based on shared values.**
- We spoke with three members of staff who all spoke positively about the culture of the service. Staff felt supported, respected, and valued, and proud to work for the service.
- The service operated an open and honest culture to encourage team working within the organisation. There was a corporate ‘Freedom to raise a concern’ policy. It detailed the types of concerns that might be raised, and contained the contact details of the company’s national Freedom to Speak Up Guardian.
- Any incidents or complaints raised had a ‘no blame’ approach to the investigation. However, all staff we spoke with said they were open and honest with

women in circumstances where errors had been made, and apologies would always be offered, and the manager ensured steps were taken to rectify any errors.

- The registered manager was aware of the duty of candour regulation; however, they had not had any incidents which met the criteria where formal duty of candour had been required to be implemented.
- Equality and diversity training was incorporated into the service’s induction and mandatory training programme.

Governance

- **The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent care to flourish.**
- There was a governance policy, and the service had a clear local governance structure.
- There were effective recruitment, training and performance review processes, and the registered manager ensured staff were appropriately qualified and trained to deliver good quality care.
- The registered manager had overall responsibility for clinical governance and quality monitoring. This included investigating incidents and responding to patient complaints. The registered manager was supported by the franchisor and attended biannual national franchise meetings; where clinic compliance, performance, audit, and best practice were discussed.
- The service did not hold formal clinical governance meetings. However, staff meeting minutes and service circulars demonstrated that complaints, incidents, audit results, patient feedback, and service changes were discussed and reviewed.
- All staff were covered under the service’s medical malpractice insurance, which was renewed in October 2018. The sonographers also all held their own professional indemnity insurance.

Managing risks, issues and performance

- **The service had systems in place to identify risks, plans to eliminate or reduce them, and cope with both the expected and unexpected.**

Diagnostic imaging

- There were up to date health, safety and environment risk assessments; these included fire, health and safety, legionnaires' disease, and the Control of Substances Hazardous to Health Regulations (COSHH) risk assessments. These detailed risks identified, mitigating/control measures, the individual responsible for managing the risk and the risk assessment review date.
- There were appropriate policies regarding business continuity and major incident planning; which, for example, outlined clear actions staff needed to take in the event of extended power loss, a fire emergency, or severe weather conditions.
- The service used key performance indicators to monitor performance, which were set by the franchisor. This enabled the service to benchmark themselves against other clinics in the peer group.
- There was an audit programme to provide assurance of the quality and safety of the service. Local audits, such as clinical and compliance audits were undertaken regularly; and additional assurance was gained through external (franchisor) audits of the service.
- Sonographer peer review audits were undertaken in accordance with recommendations made by the British Medical Ultrasound Society, and the franchisor employed a clinical lead to complete annual sonographer competency assessments.
- The service used patient feedback, complaints, and audit results to help identify any necessary improvements and ensure they provided an effective service.

Managing information

- **The service had policies and procedures in place to promote the confidential and secure processing of information held about patients.**
- We saw that appropriate and accurate information was effectively processed, challenged and acted upon. Key performance, audit, and patient feedback data was collated and reviewed to improve service delivery.
- There were up to date information governance, and data retention policies at the service. These stipulated

the requirements of managing patients' personal information in line with current data protection laws. We saw paper and electronic patient records and scan reports were securely stored.

- The service had registered with the Information Commissioner's Office (ICO) in February 2019, which is 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 franchise had consulted with an EU General Data Protection Regulation (GDPR) consultant in 2018 to ensure information use and records storage (including in relation to digital applications) were compliant.

Engagement

- **The service engaged well with women, staff and the public to plan and manage appropriate services and collaborated with partner organisations effectively.**
 - The service actively encouraged patients to provide feedback; and patients could provide verbal feedback, and leave written reviews on comment cards at the service, and on open social media platforms.
 - Staff told us that that they regularly reflected on information and feedback gathered from women and their companions to improve quality of care and service delivery, and we saw evidence of this. For example, they had added a dignity curtain in the scan room, and provided early pregnancy scans and adjusted opening times to reflect patient demand. We saw complaints about sonographer communication and behaviour had been fed-back and acted upon.
 - The service held monthly team meetings, and staff we spoke with said they felt engaged in service planning and development. We reviewed team meeting minutes and saw that patient feedback (such as, complaints, concerns and compliments) were discussed with the team during staff meetings. Sonographers were unable to attend the team meetings due to other work commitments. Therefore, the team meeting minutes were circulated by email and a paper-copy was available for staff to view in the service. Sonographers initialled team meeting minutes to indicate these had been read.

Diagnostic imaging

- The franchisor produced a monthly newsletter called 'Open Window'; which included new developments and important updates; such as, new clinics that had opened, changes to training delivery, and good practice developments.
 - We also saw the service had introduced a location specific sonographer newsletter, which, for example, contained updates regarding incidents and service learning; this was emailed to sonographers each month. The registered manager evidenced that the newsletter had been read by sonographers by asking them to return email it had been 'read and understood'.
- Learning, continuous improvement and innovation**
- **The service was committed to improving services by learning from when things went well or wrong, and promoting training and innovation.**
 - As described earlier, staff we spoke with could provide examples of improvements and changes made to processes based on patient feedback and staff suggestion.
 - The service made use of a smart device application that allowed women to remotely and securely book appointments, access scan images and videos, and share these with friends and family; if they so wished.
 - We saw sonographers and scan assistants undertook continuous professional development.
 - The franchisor produced video training logs (VLOGs), these were used as additional training and continuing professional development tools for sonographers, and scan assistants who wanted to learn more about sonography.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should consider amending definitive statements about the safety of ultrasound scans in their 'technology and safety' brief to comply with Public Health (PHE) guidance.