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 Judge Limited, and is located in Balby; a suburb of Doncaster, in the county of South 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 (Doncaster) 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 21 May 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 and 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.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	Window to the Womb (Doncaster) 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 anearly 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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Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Window to the Womb

Window to the Womb is operated by Judge Limited, and is located in Balby, a suburb of Doncaster. 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 Doncaster and outlying areas (such as, Pontefract, Goole, Scunthorpe, Worksop, and Rotherham).

As part of the agreement, the franchisor (Window to the Womb Ltd) provides the Doncaster (Balby) 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 it opened in January 2017. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on 21 May 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 (Doncaster) 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 Tuesday and Thursday afternoons and evenings, and during the day on Saturday and Sunday.

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 4 February 2018 to 4 February 2019, the later pregnancy (Window to the Womb) service performed 2825 ultrasound scans.
- Of these, 1974 were gender determination scans, 823 were 4D baby scans, and 28 were growth and presentation scans.

Summary of this inspection

- The early pregnancy (Firstscan) service became operational at the service on 23 May 2018, and from 23 May 2018 to 04 February 2019 performed 436 ultrasound scans.

Track record on safety during the reporting period 4 February 2018 to 4 February 2019; 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.
- There had been one unplanned urgent transfer of a patient to another (NHS) health care provider.
- 18 appointments were cancelled for a non-clinical reason (all within the same weekend due to sonographer sickness).
- From 4 February 2018 to 4 February 2019, the service reported it had received two formal complaints.

During our inspection, we spoke with four members of staff; these included the registered manager, the clinical manager, and a sonographer, and scan assistant. We also reviewed 15 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?

Good

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

- The service provided mandatory training in key skills to all employed staff; and ensured contracted (self-employed) staff had undertaken relevant training.
- 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.

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.

Are services caring?

Good

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.

Summary of this inspection

- 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.

Are services responsive?

Good

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.

Are services well-led?

Good

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

- The registered manager and clinic 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.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Good

Diagnostic imaging

Safe	Good
Effective	
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, clinic manager, and five scan assistants employed at the location were compliant with mandatory training requirements. Notably, an additional scan assistant had commenced employment at the service in May 2019 and was still in their induction period at the time of inspection.
- Eight sonographers worked for the service on a self-employed basis. One sonographer worked exclusively in private practice and we saw they were fully compliant with induction and mandatory training requirements. Seven sonographers were substantively employed in the NHS and completed their mandatory training with their substantive (NHS) employer. Where applicable, 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 five sonographers contracted at the service were registered with the Health and Care Professions Council (HCPC). Two sonographers were registered with The Public Voluntary Register of Sonographers (managed by the Society and College of Radiographers (SCoR)). 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). All sonographers at the service were members of the SCoR.
- The registered manager and the clinic 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 policies for staff to follow, which included the

contact details of local authority safeguarding teams, and local advocacy services and voluntary organisations. Safeguarding information was also displayed in the service.

- A separate female genital mutilation (FGM) policy provided staff with guidance on how to identify and report FGM.
- The service had a designated lead for both children and adults' safeguarding, who was the registered manager. The registered manager and the clinic manager had completed adults and children 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 completed level two adults and children safeguarding training.
- 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 4 February 2018 to 4 February 2019, 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. Enhanced DBS checks used for NHS employment were deemed to be acceptable by the service. We saw 100% of staff who had worked at the service longer than six weeks had a DBS check in place.
- 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.
- There was a monthly deep clean of the service, and a comprehensive check list had been produced to monitor and document compliance with this.
- The service had appropriate hand washing 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 hand washing compliance audits every quarter. An audit conducted in January 2019 identified the 14 staff observed during the period 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 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 removable 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 February 2019. The assessment identified the service was taking preventative measures to mitigate the risk; such as frequent water temperature and flushing monitoring. Legionnaires' disease is a serious pneumonia caused by the legionella bacteria. People can 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.**
- We saw evidence that the ultrasound machine at the location was last serviced in February 2019. 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 February 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 September 2018; and all 52 pieces of equipment tested were found compliant.
- The service had undertaken a fire risk assessment in February 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 (25 May 2018). Fire and evacuation drills were held each month, with the most recent drill completed in April 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 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.

- Pre-scan questionnaires were in use at the service. These 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.
- We saw the sonographer we observed followed BMUS 'pause and check' 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 identified. From 4 February 2018 to 4 February 2019, we saw the later pregnancy scan (Window to the Womb) service had made eight referrals to NHS antenatal care providers. The early pregnancy scan (Firstscan) service became operational at the service on 23 May 2018. From 23 May 2018 to 04 February 2019, the Firstscan service had made 28 referrals to NHS antenatal care providers.
- During our inspection, we reviewed 12 referral forms (nine from the early pregnancy clinic and two 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 professional registration number on the referral form. Reasons for referral included potential anomalies and concerns such as, pregnancy of unknown location, 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 the registered manager and clinic manager had completed level three emergency first aid at work

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 stopped the scan and telephoned 999 for emergency support.

- The service reported there had been one unplanned urgent transfers of a patient (suspected ectopic pregnancy) to an NHS health care provider in the reporting period 4 February 2018 to 4 February 2019.

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 had overall responsibility for running of the service, supported by a clinic manager. The clinical manager was responsible for the day-to-day running of clinics. There were six scan assistants 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.
- Eight sonographers worked for the service on a self-employed basis. Seven sonographers held substantive posts in the NHS, and one worked exclusively in private practice. We saw that all sonographers had previous obstetrics and gynaecology experience. We saw that all sonographers at the service were registered with the HCPC, NMC and/or SCoR. Some also held additional registrations, for example, with 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 three members of staff on duty per shift; which included the registered manager or clinic manager and a scan assistant, and a qualified sonographer.
- The pool of staff available at the service was adequate to cover absenteeism, such as holidays and sickness cover; although this was not always possible in emergencies.
- The service did not make use of any bank or agency staff.
- The registered manager monitored staff sickness rates. From 4 February 2018 to 4 February 2019, there had been one staff sickness absence.

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 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 an electronic (spreadsheet) incident log. We reviewed the incident log for the 12 months prior to our visit and saw one incident had been recorded. This involved the emergency transfer of a patient to NHS care by ambulance, due to suspected ectopic pregnancy. We saw staff involved had followed service procedures for this type of incident.
- 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.
- In the reporting period 4 February 2018 to 4 February 2019, there were no patient deaths, never events, or serious incidents at the location. In the same period, there were no duty of candour notifications.

Are diagnostic imaging services effective?

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.**
- 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 British Medical Ultrasound Society (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. For example, we saw a local service audit undertaken January 2019 identified staff who required appraisals

in the near future, and identified that fire, legionnaires disease, and health and safety risk assessments were due for renewal by February 2019. We saw these had been completed at the time of our inspection.

- Additional assurance was provided by external audits undertaken by the franchisor. We saw deviation from processes was documented and improvement actions agreed, which were timebound and checked. For example, we saw a (franchisor) compliance audit undertaken July 2018 had identified a small number of scan reports reviewed were not clearly signed and dated by the sonographer, and this practice needed to be fully embedded with immediate effect. At our inspection, we saw the practice had been embedded, and all scan reports we reviewed were clearly signed and dated by a sonographer.
- 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 cafes 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 4 February 2018 to 4 February 2019, the service had referred 36 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. The registered manager at the location informed us that there had been two inaccurate gender ultrasound scans (of 1974 gender scans performed) at the location in a twelve-month period; this equated 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.
- We saw that service activity audit results and patient feedback were discussed at monthly team meetings. Some sonographers at the service struggled to attend clinic team meetings, and we saw team meeting minutes were emailed to sonographers, and a paper copy was displayed in the staff area; which staff 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 employed for more than six weeks had completed 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 an 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.
- We saw there was an 100% appraisal compliance rate for the three sonographers at the service that had been employed for more than 12 months. In addition, we saw sonographers received induction 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 (HCPC), Nursing and Midwifery Council (NMC), and/or the Society and College of Radiographers (SCoR). Some sonographers were also registered with other professional national bodies, such as the 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.
- We reviewed staff files and saw evidence of sonographers undertaking continuous professional development and additional formal qualifications; for example, a number of sonographers held 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 ten 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 greater "use [of] sector width to focus in on specific areas when doing wellbeing checks". Another suggested "use cardiac setting for heart views".
- 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.**
- 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

Good

Diagnostic imaging

- **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 Tuesday and Thursday afternoons and evenings, 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 provision 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, exercise, and baby sensory classes were 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. In addition, the registered manager told us that young women (of 16 to 17 years of age) who wanted to use the service had to attend with someone with parental responsibility; and the individual with parental responsibility was required to countersign their consent form. We saw evidence of this.
- 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.**
- The scan room afforded patients privacy and dignity. We saw the service provided towels for women to use whilst being scanned, and there was a privacy screen available. The scan room had three wall-mounted monitors. This meant women and their companions could easily view ultrasound images, should they opt to use the privacy screen.

Good

Diagnostic imaging

- During our inspection, we observed staff were warm, kind and welcoming whey 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 20 completed comment cards. 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 very positive, for example, patients described the service as "amazing" and "fantastic" and staff as "lovely people" and "friendly and professional".
- 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 also very positive. For example, people said they "would highly recommend a 1000 times over!", and staff were described as "Great and friendly … just so welcoming and helpful".
- 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 they were "very happy" with the service.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- We observed scan assistants and the sonographer were reassuring and interacted with women and their companions in a professional, respectful, and supportive way. One woman we observed having a scan said to staff that they had "put my mind at ease a lot".
- We viewed a selection of feedback from women and their companions, who overwhelmingly described feeling supported. For example, they said they "felt so at ease", were "given time" and "the whole team were very reassuring."
- The scan assistants acted as chaperones during ultrasound scans to ensure women felt comfortable and received optimum emotional support.
- 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 difficult 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.
- The scan room had a fire exit that led directly to the car park. Staff said that women could choose to use this exit if they had received difficult news and did not want to walk back through the clinic and use the main entrance.
- 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.

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 five 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.

Good

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.
- Examples of patient feedback (comment cards) we reviewed on site demonstrated staff ensured good understanding and involvement of women and their companions. For example, one woman described that the "sonographer was really patient with us", and another commented that staff had "made my young children feel part of the experience". We also saw examples of comment cards completed by children who had attended with their expectant mothers.
- 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 six of these assessments. 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. For example, one identified that the sonographer was "very welcoming and friendly … engaged well with customers" another commented on the sonographer's "welcoming and professional body language". Learning was also identified. For example, feedback suggested the sonographer could have provided a more in-depth "overview of process before scan". However, recognised the "good explanation throughout the scan". Scan assistants also sought feedback from the patient and their companions. We saw, for example, women and their companions had commented that the sonographer was "very friendly" and they would "highly recommend the service". Another commented that the sonographer "seemed very professional … tried everything to get the baby to move".

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 standing room for up to five guests, and children of all ages were welcome to attend.
- Information about services offered at the location was 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.

Good

Diagnostic imaging

- The service had contracted a telephone interpretation service for staff to use during appointments with women for whom English was not their first language. 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.
- The service was located on the ground floor, with off-street parking available. Bathroom facilities were situated in a corridor between the scan room and waiting area. There was a reception area with ample seating for women awaiting appointments, and their 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.

Access and flow

- **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 Tuesday and Thursday afternoons and evenings, 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 4 February 2018 to 4 February 2019, the service conducted 3261 ultrasound scans. From 4 February 2018 to 4 February 2019, the later pregnancy (Window to the Womb) service performed 2825 ultrasound scans. The early pregnancy (Firstscan) service became operational at the service on 23 May 2018, and from 23 May 2018 to 04 February 2019 performed 436 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 4 February 2018 to 4 February 2019, 18 planned appointments were cancelled for a non-clinical reason. All 18 appointments were cancelled within the same weekend, as the sonographer who was meant to be on duty was ill and a replacement could not be found at short notice. Just under half of the patients who had their appointment cancelled chose to reschedule.

Learning from complaints and concerns

Good

Diagnostic imaging

- **It was easy for people to give feedback and raise concerns about care received.** The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.
- 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 service only operated with a minimum of three members of staff on duty per shift; which included the registered manager or clinic manager and a scan assistant, and a qualified sonographer. The registered manager described that 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 reported they had received two formal complaints from 4 February 2018 to 4 February 2019. During our inspection, we reviewed the complaints log and saw an additional complaint had been received in April 2019. In all cases, we saw that complainants had received a formal apology from the registered manager and the registered manager had fed back details of the complaint, and any learning, to staff involved. Two cases broadly involved concerns raised about practitioner communication. One case involved a potentially missed anomaly. We saw that a full and formal investigation had been initiated by the registered manager, and the case had been escalated to and reviewed by the franchisor's clinical lead. The investigation and review found that the sonographer had carried out all appropriate checks for baby's gestational age.
- We saw that discussion of feedback (from compliments, complaints and concerns and peer reviews) was a standing agenda item 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 patient and staff feedback. For example, they had introduced early pregnancy scans, and increased staffing and opening hours, to reflect the growth in service demand. A privacy screen had also been added to scan room, following a complaint at another franchise location.

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 (and owner) had been with the service since it opened in early 2017; and had good awareness of the service's performance and needs. The registered manager was supported by a clinic manager, who had also been with the service since it had opened.

Good

Diagnostic imaging

- The sonographers reported to the registered manager and clinic manager for matters of administration and to the lead sonographer for clinical matters. Scan assistants reported to the clinic manager on a day-to-day basis; although the registered manager had overall responsibility for all staff.
- 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.
- We saw that the registered manager and clinic manager interacted well with staff, and were friendly, approachable, and effective in their roles.
- 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. We saw that both the registered manager and clinical manager had completed this training.

Vision and strategy

- **The service had a vision for what it wanted to achieve and workable plans to turn it into action.**
- The service's aims included "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 four 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. 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.

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.**
- 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) (due for renewal September 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 introduced early pregnancy scans,

and increased staffing and opening hours, to reflect the growth in service demand. A privacy screen had also been added to scan room, following a complaint at another franchise location. The registered manager had also taken the decision to reconfigure the internal layout of the service to enhance the customer experience. We saw complaints and concerns raised by patients 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.
- The service produced its own monthly staff circular and had implemented a staff (secure) messaging group; to inform staff about service updates and practice developments.
- The franchisor also 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 best practice developments.

Learning, continuous improvement and innovation

- **All staff were committed to continually learning and improving services.**
- 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.