Window to the Womb Darlington

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	Outstanding ☆
Are services safe?	Good ●
Are services effective?	
Are services caring?	Outstanding ☆
Are services responsive?	Good ●
Are services well-led?	Outstanding ☆

Summary of findings

Letter from the Chief Inspector of Hospitals

Window to the Womb is operated by D I Harries Limited, and is located on the outskirts of Darlington 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 over 16 years of age.

Window to the Womb has separated its 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 1 March 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 **Outstanding** 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 service operated an open and honest culture, and there was a national freedom to speak up guardian, and an alternative (independent) dispute resolution service; if needed.
- The environment was appropriate for the service being delivered, was patient centred, and was accessible to all women.
- We saw extensive evidence of positive feedback from women who had used the service; including from women who had received difficult news, and those who had previously experienced pregnancy loss.
- Staff understood the importance of obtaining informed consent, and involved patients and those close to them in decisions about their care and treatment.
- The service had a vision for what it wanted to achieve, and consistently engaged well with patients and staff to plan and manage services.

We found the following areas of outstanding practice:

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- There were high levels of emotional support available to women and their companions. Scan assistants acted as chaperones, to ensure women felt comfortable and received optimum emotional support. All staff received communication training to offer emotional support. We also saw scan assistants periodically assessed sonographers for their quality of customer care and communication skills, and findings were fed-back to them. The service purposely ran early pregnancy and later pregnancy clinics at different times to ensure that women who had experienced pregnancy loss or were anxious about their pregnancy did not share the same area with women who were much later in their pregnancy. Staff had received enhanced bereavement and communication training. The service also benefited from a dedicated 'quiet room', which could be used if women and their companions had received difficult news.
- The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent care to flourish. The registered manager was a registered bereavement midwife of ten years standing with extensive of practice in large NHS teaching hospitals; they brought this breadth of experience to leadership of the service. Leaders strived to deliver and motivated staff to succeed; personal and professional staff development was positively encouraged and there was a deeply embedded system of leadership development and succession planning. The service was committed to promoting training, research and innovation. For example, the service had collaborated with a local (Russel group) university and had assisted them with research scans exploring the effects of hyperemesis and smoking on the fetus. The service was also involved with an upcoming study, exploring the effects of domestic violence on fetal wellbeing.

However, we found the following issues that the service provider needed to improve. These findings were fed back at the time of inspection:

- The location's website provided a link to frequently asked questions on the franchisor's website; and we saw the information offered was not in line with Public Health England (PHE) guidance. This was immediately remedied (removed) by the franchisor at the time of inspection.
- During the early pregnancy (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. However, during the later pregnancy (Widow to the Womb) clinic, which only performed transabdominal scans, a fabric cover was placed on the couch; this was not changed between patients nor covered with a disposable cloth. This was not in line with good infection control practice.

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.

Ellen Armistead

Deputy Chief Inspector of Hospitals (North)

Overall summary

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Outstanding ☆	Window to the Womb (Darlington) 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.

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Background to Window to the Womb

Window to the Womb is operated by D I Harries Limited, and is located on the outskirts of Darlington 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 Darlington and outlying areas.

As part of the agreement, the franchisor (Window to the Womb Ltd) provides the Darlington 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 December 2016. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on 01 March 2019. We had not previously inspected this service.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and a team 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 (Darlington) 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 Monday, Wednesday and Friday 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 2,988 ultrasound scans.
- The early pregnancy (Firstscan) service had been operational since October 2018; and from October to December 2018 performed 126 ultrasound scans.

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

Summary of this inspection

- 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 informal complaints, but had not received any formal complaints.

During our inspection, we spoke with six members of staff; these included the registered manager, area manager, a sonographer, and scan assistants. We also reviewed ten staff records. We observed three ultrasound scans, and spoke with these three patients and their companions. We reviewed a total of six 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 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.
- Staff understood how to protect patients from abuse and the service had systems to do so.
- The service had suitable premises and equipment and looked after them well. The environment promoted the privacy and dignity of women using the service.
- Staff completed and updated risk assessments for each patient. Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date and easily available to all staff providing care.
- There were clear 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.

However:

- The location's website provided a link to frequently asked questions on the franchisor's website; and we saw the information offered was not in line with Public Health England (PHE) guidance.
- During the later pregnancy (Window to the Womb) clinic, which only performed transabdominal scans, a fabric cover was placed on the scanning couch; this was not changed between patients nor covered with a disposable cloth. This was not in line with good infection control practice.

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.
- Referral pathways to other agencies were in place for staff to follow to benefit patients.
- Managers monitored the effectiveness of care and treatment and used the findings to improve them.

Summary of this inspection

- The service made sure staff were competent for their roles. 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.

Are services caring?

Outstanding ☆

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

- Staff cared for patients with compassion. We observed staff were warm, kind and welcoming whey they interacted with women and their companions. There was significant feedback from patients, which was overwhelmingly positive, and confirmed that staff treated them well and with kindness.
- Sonographers took time explaining procedures to women before and during ultrasound scans, left adequate time for patients and their companions to ask questions, and provided detailed explanations, and accompanying written feedback. Scan assistants acted as chaperones during ultrasound scans to ensure women felt comfortable and received optimum emotional support.
- Staff provided emotional support to patients to minimise their distress. Emotional and bereavement guidelines and patient information was available; and staff received training to deliver difficult news and offer emotional support. Although not practising under the qualification at the location, there was access to a registered midwife who specialised in bereavement. The service benefited from a dedicated 'quiet room', which could be used if women and their companions had received difficult news.
- 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 Window to the Womb service at the location had worked alongside a local charity to hold 'meet the mummies' tea and coffee mornings for new mothers who had used the service to meet each other. Staff had also facilitated special events for service users; for example, gender reveals and engagement proposals.

Are services responsive?

Good ●

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

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- 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, patient centred, and accessible to all women.
- 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 website also offered a 'read out loud system' to allow the visually impaired to gain information with ease. The service had contracted a telephone interpretation service, for staff to use during appointments with non-English speaking women. All staff had received mandatory equality and diversity training.
- 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, "bumpies"; which had a booking facility. There were low rates of non-attendance (less than 1%). If a woman suffered a miscarriage before their appointment, staff would refund the deposit payment immediately.
- The service treated concerns and complaints seriously, and had effective systems to investigate them and learn lessons from the results, and share these with all staff. Patients could contact head office or an independent dispute resolution service, if they felt their complaint had not been satisfactorily resolved by the registered manager.

Are services well-led?

Outstanding ☆

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

- Leaders at all levels demonstrated the high levels of experience, capacity and capability needed to deliver excellent and sustainable care. There was a deeply embedded system of leadership development and succession planning. The registered manager had a deep understanding of issues, challenges and priorities in their service, and beyond.
- The registered manager promoted a positive culture, creating a sense of common purpose based on shared values. Leaders strived to deliver and motivated staff to succeed. Staff at all levels were proud of the service as a place to work and speak highly of the culture.
- The service had systems to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. Leaders regularly reviewed how the service functioned and ensured that staff at all levels had the skills and

Summary of this inspection

knowledge to use systems and processes effectively. The service used local audit and key performance data to monitor and improve service quality, and safeguarded high standards of care by creating an environment for excellent care to flourish.

- The service had policies and procedures in place to promote the confidential and secure processing of information held about patients. The information used in reporting, performance management and delivering quality care was consistently found to be accurate, valid, reliable, timely and relevant.
- There were consistently high levels of constructive engagement with staff and people who use services. The service engaged well with women, staff and the public to plan and manage appropriate services and collaborated with partner organisations effectively.
- There was a fully embedded and systematic approach to improvement. The service was committed to improving services by learning from when things went well or wrong, and promoting training, research 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	☆ Outstanding	Good	☆ Outstanding	☆ Outstanding
Overall	Good	N/A	☆ Outstanding	Good	☆ Outstanding	☆ Outstanding

Outstanding ☆

Diagnostic imaging

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

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 area manager and clinic manager, and all four scan assistants employed at the location were 100% compliant with mandatory training requirements.
- Four sonographers worked for the service on a self-employed basis. Two sonographers completed their mandatory training with their substantive (NHS) employer. Two sonographers were solely employed in private practice and completed their mandatory training with a Window to the Womb clinical lead. We saw the registered manager had oversight of what mandatory training sonographers had completed; and in all cases (100%), sonographers at the location had completed mandatory training requirements.
- 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 four 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).
- Sonographers had been trained by the ultrasound manufacturer to competently use the ultrasound machine at the service. The manufacturer provided additional training approximately twice a year to the service.
- The registered manager, who was NMC registered, attended an 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. We saw that staff mandatory training included six-monthly review and understanding checks of Window to the Womb safeguarding policies.
- A separate female genital mutilation (FGM) policy provided staff with guidance on how to identify and report FGM.

Diagnostic imaging

- The service had a designated lead for both children and adults' safeguarding, who was the registered manager. The registered manager, area manager, and clinic manager had completed adults level three 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 three sonographers at the service had received level three adults and level three children's safeguarding training. One sonographer (who was substantively employed in the NHS) had received level two adults safeguarding training.
- We saw all four scan assistants were compliant with safeguarding adults and safeguarding children level two 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 to the registered manager; they were aware of the service's safeguarding policies.
- In the reporting period January 2018 to December 2018, we saw that no safeguarding referrals had been made by the service. 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 worked at the service had an up to date DBS check.
- 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, and evidence of induction training were kept on file.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept the equipment, and the premises clean**.
- There was 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 were 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 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. The service used a microbicide gel to further limit the possibility of sexually transmitted diseases.
- 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. However, we saw that during the later pregnancy (Widow to the Womb) clinic, which only performed transabdominal scans, a fabric cover was placed on the couch; which was not changed between patients nor covered with a disposable cloth. This was not in line with best practice, and we fed this back during our inspection.

Diagnostic imaging

- 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.
- There were 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. 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 had been purchased within the last 12 months; as such, the machine had not yet required 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 a property file, which contained key documentation. We saw that there was a health and safety policy, and managerial staff at the location had undertaken a range of environmental risk assessments in late 2018. The service had produced an emergency action plan for contingency planning.
- A 'control of substances hazardous to health regulations' (COSHH) risk assessment was undertaken in October 2018. 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. We reviewed eight pieces of equipment and found all equipment had been serviced within the date indicated. An electrical installation condition assessment was undertaken by an external company in November 2018.
- A fire risk assessment was undertaken in November 2018; and there was an emergency evacuation procedure in place. At inspection, we saw fire extinguishers were accessible, stored appropriately, and had all been inspected and serviced within the date indicated (April 2018). Fire drills were held each month, with the last drills completed in January and February 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. If women were aged 16 or 17 years of age, they were required to attend with a responsible adult (for example, someone with parental responsibility). 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. The service was clearly marketed as an "additional baby scan service … that worked in parallel with the NHS". 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.

- 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. Prior to our inspection, we saw that the service's website contained a link to the frequently asked section of the company's (franchisor's) website. We saw the question, "Can ultrasound hurt my baby?" displayed. The answer provided was, "this is something that has been asked numerous times by expectant mums, and the answer is NO. Despite extensive studies in recent years, ultrasound has not been shown to cause any harm to mum or baby". This was not in line with 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. We saw this was immediately actioned (removed) by the franchisor on the day of our inspection. This showed good partnership working between the franchisee and franchisor.
- 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 1 January 2018 to the date of our inspection, we saw the later pregnancy scan (Window to the Womb) service had made 10 referrals to NHS antenatal care providers; eight of these were to pregnancy assessments units (PAUs), and two were to fetal medicine units (FMUs). We saw that the Firstscan clinic (which had been operational at the service since October 2018) had made 10 referrals to early pregnancy assessment units (EPAUs) from November 2018 to the date of our visit.
- During our inspection, we reviewed three referral forms, which detailed patient information, scan findings, reason for referral, and who the receiving healthcare professional was. We saw sonographers were required to indicate and document their work contact details and HCPC or NMC registration number on the referral form. Reasons for referral included

potential anomalies and concerns such as, fetal dilated bowel, oligohydramnios (a condition in pregnancy characterised by a deficiency of amniotic fluid), and intrauterine fetal death (after 24 completed weeks of pregnancy). Staff at the service told us that they always offered to call NHS antenatal care providers on behalf of patients, to refer them and explain potential findings. Staff said this helped to ensure duty and continuity of care, and helped limit any distress. 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 managers had completed emergency first aid at work (level three) 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 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 2018 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 and service owner was a registered midwife, who specialised in bereavement midwifery and still practised in the NHS; although, they no longer held a substantive role.
  - The registered manager employed an area manager responsible for the day-to-day running of four clinics in the area. The area manager supervised a clinic manager employed at the location.
  - There were four scan assistants employed at the location. They were responsible for managing enquiries, appointment bookings, supporting the sonographers during the ultrasound scans, basic administrative tasks, helping to support women and make them comfortable, and helping the families print their scan images. Day-to-day management of scan assistants was undertaken by the clinic manager.
  - Four sonographers worked for the service on a self-employed basis. We reviewed staff records and saw that all sonographers had previous obstetrics and gynaecology experience. We saw that all sonographers at the service were registered with the HCPC. Some were also held additional registrations; for example, with the NMC and BMUS. Two of the sonographers held substantive posts in NHS trusts, and two of the sonographers worked solely in private practice.
  - 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 a clinical manager, two scan assistants, 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 area manager was available to work across different Window to the Womb franchise locations in the local area, if needed. If necessary, emergency sonographer and scan assistant cover could also be provided from these Window to the Womb franchise locations.
  - 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.
  - Information provided by the service showed that four members of staff had left the service in the 12 months prior to our inspection. We spoke with the registered manager during our inspection, who explained that two sonographers had left the service in the last 12 months. The manager said that one sonographer had relocated and had taken up employment at another (out of area) Window to the Womb clinic, and another

sonographer had taken parental leave. We saw that the service had replaced staff who had left, and had recruited additional staff to match expanded service provision.

Records

- **Staff kept detailed records of patients' care and treatment. Records were secure, 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 GPs 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 support of scan assistants. A copy 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 ("bumpies") which allowed women to securely view their scan images and videos remotely. The application enabled women to share their images and video to social media sites, or other individuals, as they so wished.
- We saw that paper documents were securely stored in lockable filing cabinets, and computers were password protected.
- The service had consulted with an EU General Data Protection Regulation (GDPR) consultant in 2018 to ensure the service and digital applications developed 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 and saw three incidents had been recorded in the 12 months prior to our visit. One incident related to a power cut, one to adverse weather conditions, and one related to a relative of a patient being verbally abusive to staff.
- The registered manager was responsible for conducting investigations into all incidents at the location, and submitted a monthly incident return to the franchisor.
- We saw that the registered manager reviewed incidents to identify any themes and learning. We saw learning from incidents was shared with staff, at team meetings and through service circulars. For example, following an incident when the relative of a patient became verbally abusive at the location, we saw that this had been discussed at a team meeting, and actions discussed with staff should the situation reoccur.
- The registered manager explained that services within the wider franchise also shared learning from incidents and events through the national network.
- Staff we spoke with described the process for reporting incidents and provided examples of when

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they might do this. Scan assistants tended to explain that if they identified an incident, they would escalate this to a more senior member of staff; such as the clinic manager or a sonographer.

- 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.
- In the reporting period January 2018 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?

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.
- The service followed the ALARA (as low as reasonably achievable) principles, outlined in the 'Guidelines for professional ultrasound practice, 2017' by the Society of Radiographers and BMUS. This meant that sonographers used minimum frequency levels for a minimum amount of time to achieve the best result.
- There was an effective audit programme that provided assurance about 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 local December 2018 audit had identified some sonographers required additional peer assessment scans, to comply with quality auditing; we saw these had been completed at inspection.
- 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.
- Due to the nature of the service, food and drink was not routinely offered to women. However, there was a drinking water dispenser in the waiting area, which was accessible to women and visitors. There was also a fridge containing soft drinks and confectionary, which could be purchased by the women and their families for a small fee.
- We saw baby friendly initiative posters displayed in the main reception area that promoted breastfeeding; and which informed women they were "welcome to breastfeed here".

Patient outcomes

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- **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 January 2018 to the date of our visit, the service had referred 20 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. Window to the Womb services at the location reported performing two incorrect gender scans since becoming operational; equating to a success rate of 99.99%.
- The service offered 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.
- From January to December 2018, the rescan rate for the later pregnancy (Window to the Womb) clinic was 9% of the total number of 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 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. The Firstscan clinic had not completed any rescans since becoming operational at the location in October 2018.
- We saw that service activity audit results and patient feedback were discussed at monthly team meetings.

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 that had been employed for more than 12 months; and we saw evidence of this.
- As sonographers at the location had not yet been contracted for 12 months, they were yet to receive an appraisal or competency assessment. However, we saw that the lead sonographer had conducted an initial competency assessment when sonographers had first joined the service. Competency assessments included checking the sonographers' registration, indemnity insurance and revalidation status.
- 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 four 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 National Midwifery Council (NMC) and BMUS.

- We reviewed staff files and saw evidence of sonographers undertaking continuous professional development. For example, we saw that some sonographers held fetal medicine, growth, anomaly and doppler qualifications. In other cases, we saw that sonographers had attended specialist conferences or workshops. 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 found the sonographer needed to "ensure appropriate zoom to optimise image techniques".
- 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.**
- During our inspection, we observed positive examples of the registered manager, area manager, clinic manager, sonographer and scan assistants working well together.
- We saw evidence that staff engaged in team meetings, and that when available, sonographers attended these. For staff members unable to attend, meeting minutes were available.
- We saw evidence that the service had formally contacted screening coordinators in local NHS trusts to inform them of services being provided at the location. The registered manager described that a consultant from one local trust had visited the service to meet with them and see the clinic.
- 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. Services at the location were typically provided on Monday, Wednesday and Friday evenings, and on Saturday and Sunday's. This offered flexible service provision for women and their companions to attend around work and family commitments.

Health promotion

- **The service promoted opportunities for healthy living.**
- The service offered women patient information leaflets ('Information for mums to be'), which detailed information about keeping healthy, foods to avoid, health promotion questions to ask their midwife (such as provision booking of flu jabs, and breastfeeding support), and information about normal baby movements after 24 weeks of pregnancy.
- The service displayed information in the main waiting area about a national charity that raises awareness among women to understand and be mindful of baby's normal movements during pregnancy.
- We saw the service displayed a poster about local 'nurturing your bump' swimming classes, which were available in the local area.

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.**

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- 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. Sonographers we spoke with could give examples of when and how they might assess mental capacity.
- Women's consent to care and treatment was sought in line with legislation and guidance. All women were required to complete 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.
- During our inspection, we saw that women's verbal consent was also sought 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?

Outstanding ☆

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

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 observed staff were very 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 25 comment cards completed from January 2019 to February 2019. Patients and companions were able to rate the overall service provided from one to five stars, and we saw all had rated the service as 'five stars'. Qualitative feedback was very positive, for example, patients described the care as "excellent", "fabulous" and staff as "lovely" and "very friendly and helpful".
- Patients and their companions were also able to leave feedback on open social media platforms, which the registered manager said were frequently monitored. We reviewed a selection of reviews (from the several hundred available) and found the service was very highly rated, and feedback was overwhelmingly positive. For example, responses included statements such as: "staff were absolutely amazing", "staff cannot be praised high enough", and "wonderful from start to finish! Would 100% recommend".
- During our inspection, we spoke to three 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" and staff were "very warm and caring".

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- 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. We also saw that staff removed purchasable items, such as heart beat bears, out of the waiting area before the Firstscan clinic commenced.
- 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.

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- As part of their mandatory training, staff received communication training; which included the emotional aspects of delivering and receiving difficult news.
- Emotional and bereavement guidance was available at the service for staff to follow. We also saw that sonographers received training to understand and appreciate parents needs and feelings when receiving difficult news, and offer appropriate emotional support.
- We saw that a staff bereavement study day was planned for May 2019, organised by a national bereavement charity.
- Although not practising under the qualification at the location, the registered manager was a registered midwife, who specialised in bereavement; and was available to advise and guide staff, as needed. The registered manager was also available to speak with patients, if required. The registered manager's skills and experience enhanced the services available at the location, should they be needed.
- The service benefited from a dedicated 'quiet room', which could be used if women and their companions had received difficult news. The quiet room could be accessed through a side door leading from the scan room, with another exit leading to the reception area. This meant that women and their companions who had received difficult news did not have to see people waiting for appointments until they were ready to do so.
- We reviewed a scan assistant's appraisal and saw they had reflected on how they had helped to support a young couple who wanted a 4D scan of their baby who had passed away in utero.
- We also reviewed written feedback from parents who had received difficult news and had been referred to NHS antenatal care providers. We saw that parents spoke very positively about the service, despite some of the challenging outcomes they encountered. For example, one woman had written, "…thank you for the support you gave me and my family. It just wasn't meant to be. But we will be back again. Thank you for being so kind and nice".
- The service had access to written patient information to give to women who had received difficult news. As well as information produced by national charities, the service had developed their own pregnancy loss patient information leaflets for both women, and for those that accompanied them.
- The service was in the process of working with another national charity, who work to support families through premature and traumatic births. The service had agreed to donate 'heartbeat bears' (these are toy bears which play audio recordings of baby's heartbeat, recorded during scans) to parents whose babies will not survive long outside of the womb, or will have long standing complications.

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 very large, and patients could bring up to 10 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 also saw that children were welcomed in the clinic.
- 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.
- 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 two of these assessments undertaken at the location

during our inspection. We saw the scan assistant had rated setting up of the scan room for clinic, sonographer's IPC 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, "mum and dad said [sonographer] was lovely and explained … more than at hospital".

- The Window to the Womb service at the location had worked alongside national charity to hold 'meet the mummies' tea and coffee mornings. These were for women who had ultrasound scans at the location to meet with other new mothers. They raised over £600 for the charity.
- Staff we spoke with also told us about how they had arranged special events at the request of service users. For example, they had helped to facilitate gender reveals and engagement proposals.

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 10 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 franchise director hoped the application would be implemented by March 2019.
- 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 first floor of a business centre with lift access, and an accessible bathroom was also available. The scan room was large and airy, with ample seating and additional standing room for up to 10 guests. There was an adjustable medical bed in the scan room to support women with limited mobility. There were three wall-mounted monitors, including a large (100 inch) monitor; these enabled women and their companions to view the baby scan more easily.

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- We saw that information leaflets were given to women when they had a pregnancy of an unknown location, for example, an ectopic pregnancy, or an inconclusive scan. These leaflets contained a description of what the sonographer had found, advice, and the next steps women should take.
- The service also had access to written patient information to give to women who had received difficult news. This included a 'feelings after pregnancy loss' leaflet, which detailed how other women who had experienced pregnancy loss reported feeling. We also saw that a range of information leaflets produced by national miscarriage, stillbirth and neonatal death charities were available. The service had also developed a 'support for partners' information leaflet, for the partners of women who had experienced pregnancy loss.
- 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. Although the Firstscan clinic was operated within Window to the Womb and was provided by the same staff, appointments were offered at different times. This meant that women who may have experienced a miscarriage did not share the same area with women who were much later in their pregnancy. The service had a dedicated 'quiet room', which could be used if women and their companions had received difficult news.
- 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, "bumpies"; which had an appointment booking facility.
- The service opened according to patient demand, and typically operated three evenings per week, and on Saturday and Sunday day times. The service had capacity to extend service provision as and when the need arose. We saw that the clinic had extended evening opening hours to meet demand.
- At the time of our inspection, there was no waiting list or backlog for appointments. From January to December 2018, the later pregnancy (Window to the Womb) service performed 2988 ultrasound scans. The early pregnancy (Firstscan) service had been operational since October 2018; and from October 2018 to December 2018 had performed 126 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. Following our inspection, the service provided non-attendance information, which showed the rate was approximately 1%. 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 2018 to December 2018, no planned appointments were cancelled for a non-clinical reason; such as breakdown of equipment. During our inspection, we viewed an incident book log that detailed a clinic had been delayed for approximately 30 minutes due to a power cut in 2018; this was beyond the service's control. We viewed actions taken, which showed staff had telephoned patients booked in to warn them of possible delays.

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.**

Outstanding ☆

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- 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 into a complaint log, which detailed the contents of the complaint, immediate actions taken, actions to be implemented, and was used to identify any themes and learning.
- The registered manager described that there was a minimum of two scan assistants, one sonographer, and one clinic manager 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 registered manager described that complaints received were usually minor in nature and most often communicated to the service via social media channels, which were frequently monitored. The service had received three informal complaints from January to December 2018. No formal complaints were received over this period.
- We reviewed the informal complaints and saw one related to a woman who had been referred to a NHS antenatal care provider, because staff were concerned about a lack of fetal movements. The baby was subsequently found to be well, and the woman felt that the service had unnecessarily provoked stress and anxiety. We saw that the registered manager had contacted the woman to apologise for making her feel this way, but explained that staff had to follow protocol as they had a duty of care. We saw the complaint was resolved following this contact; the complainant had reflected on the initial complaint and follow-up information, and had developed a better understanding of why the service had made the referral.
- 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, the service had purchased bigger couches for the reception and waiting area to accommodate larger families who attended the service. The service had also introduced early pregnancy scans (Firstscan clinics), and had extended opening times to meet patient demand.

Are diagnostic imaging services well-led?

Outstanding ☆

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

Leadership

- **Leaders at all levels demonstrated the high levels of experience, capacity and capability needed to deliver excellent and sustainable care. There was a deeply embedded system of leadership development and succession planning. The registered manager had a deep understanding of issues, challenges and priorities in their service, and beyond.**
- The registered manager was a registered bereavement midwife of ten years standing with experience in both a major London teaching hospital and other NHS services

in the North East of England. They brought this breadth of experience to leadership of the service; whilst maintaining face-to-face contact with clients and health professionals. The registered manager had an in-depth understanding of the service's performance, challenges, and priorities; and insight of wider developments in diagnostic and ultrasound practice.

- The franchisor was contractually responsible for providing the registered manager with ongoing training, which was undertaken at clinic visits, training events and the biannual national franchise meetings. The registered manager had successfully completed the leadership course, which included customer service skills, negotiating and influencing, problem solving and performance appraisal training. In addition, the registered manager had attended other (external) continuous professional development training courses relevant to their practice and leadership of the service.
- The registered manager had implemented a three-tier leadership system that positively encouraged staff development and supported succession planning. In addition to the registered manager, there was an area manager who had oversight of three locations, and a clinic manager responsible for day-to-day oversight of services at the location. The area manager had undertaken relevant leadership training; as well as more specialised training, such as bereavement and communication training. The clinic manger had also been provided with additional leadership training to ensure the safe and competent running of the clinic.
- Staff knew the management arrangements and told us they felt very supported. The clinic manager reported to the area manager, who reported to the registered manager. Scan assistants reported to the clinic manager on a day-to-day basis. However, the registered manager had ultimate responsibility for oversight of all staff at the service. The sonographers reported to the registered manager for matters of administration and to the lead sonographer for clinical matters. The lead sonographer was available for advice and could review any ultrasound scans remotely within two hours.
- Staff we spoke with said the registered manager and clinic manager were very friendly, approachable, and effective in their roles. Staff said they felt confident to discuss any concerns they had with them; and were able to approach the registered manager directly, should the need arise.

Vision and strategy

- **The service had a vision for what it wanted to achieve and workable plans to turn it into action.**
- The service offered a "private and personal service which works in parallel with the NHS".
- 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 service aims and ethos of the service's vision and values.
- The registered manager was very mindful of staff satisfaction and retention rates (which were high) and had implemented training and succession planning strategies that supported staff development and internal promotion.
- The service had a detailed business strategy which outlined what it wanted to achieve over the upcoming year; for example, business areas it wanted to develop in line with the wider health economy, and horizon scanning to ensure best practices and technologies were implemented and utilised.
- Senior staff at the service we spoke with said that they had been approached by NHS commissioners, to provide ultrasound scanning services. At the time of inspection, provision of these (Firstscan clinic) services was under consideration.
- At the time of inspection, the service was looking to introduce a new scan package at their Firstscan clinic to measure the endometrium in a pre-pregnancy state, to help women who were trying to conceive.

Culture

- **The registered manager promoted a positive culture, creating a sense of common purpose based on shared values. Leaders strived to deliver and motivated staff to succeed. Staff at all levels were proud of the service as a place to work and spoke highly of the culture.**

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- We spoke with six members of staff who were exceptionally positive about the culture of the service. Staff said they felt supported, respected, and valued, and all reported that they felt very proud to work for the service. Staff were passionate about the service they provided to women and their families.
- We observed strong collaboration, team-working and support across all functions of the service; and a common focus on improving the quality and sustainability of care and people's experiences. For example, sonographers peer-reviewed and appraised each other's clinical practice, and scan assistants periodically reviewed the patient-centredness and quality of sonographers' communication techniques. The service highly valued patient feedback, which could be provided through a variety of channels; and used this to improve patient experience.
- We saw staff at all levels were actively encouraged to speak up and raise concerns, and all policies and procedures positively support this process. 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 understood 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.**
- Structures, processes and systems of accountability were clearly set out, understood and effective. Staff at all levels were clear about their roles and accountabilities. The service had a governance policy and there was a clear local governance structure. The registered manager cited an advantage of the franchisee system was that of a detailed procedural model, with regular review and updating. Governance arrangements across the franchise were proactively reviewed by franchise directors to help ensure these reflected best practice.
- There was an effective audit programme that provided assurance about 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.
- 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.
- Due to the size and nature of the service, the registered manager did not hold formal clinical governance meetings. However, we saw staff meeting minutes demonstrated that complaints, incidents, audit results, patient feedback, and service changes were documented, discussed and reviewed. In additional, there was a local audit programme, monthly audit results were fed back to head office, and additional assurance was provided via external (franchisor) audits of the service.
- 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 to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected. Leaders regularly**

reviewed how the service functioned and ensured that staff at all levels had the skills and knowledge to use systems and processes effectively. Problems were identified and addressed quickly and openly.

- There were up to date health, safety and environment risk assessments in place; 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 outlined clear actions staff needed to take in the event of extended power loss, a fire emergency, severe weather, or other major incident.
- The service used key performance indicators to monitor performance, with key quality measures set by the franchisor. This enabled the service to benchmark themselves against other clinics in the peer group.
- Local audits, such as clinical and compliance audits were undertaken regularly; data was collected and reported to the franchisor every month to monitor performance. Additional assurance was gained through quarterly and unannounced external (franchisor) audits of the service. Where issues were identified, we saw these were and addressed quickly and openly.
- There was an effective audit programme to provide assurance of the quality and safety of the service. Sonographer peer review audits were undertaken in accordance with recommendations made by the British Medical Ultrasound Society, and the franchisor completed 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. The information used in reporting, performance management and delivering quality care was consistently found to be accurate, valid, reliable, timely and relevant.**
- We saw that appropriate and accurate information was effectively processed, challenged and acted upon. Key performance, audit, and patient feedback data was frequently collated and reviewed to improve service delivery.
- There was a demonstrated commitment at all levels to sharing data and information proactively to drive and support internal decision making, as well as system-wide working and improvement. Performance and clinical audit data were submitted to the franchisor on a monthly basis; and we saw issues identified at other locations were shared by the franchisor and acted on at local level.
- There were up to date information governance, and data retention policies in place 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 was registered with the Information Commissioner's Office (ICO), 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

- **There were consistently high levels of constructive engagement with staff and people who use services. The service engaged well with women, staff and the public to plan and manage appropriate services and collaborated with partner organisations effectively.**
- Feedback from service users and partner organisations was welcomed and seen as a vital way of improving service provision and quality. 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.
- There was a demonstrated commitment to acting on feedback. Staff 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, the service had purchased a room divider (screen) for use in the Firstscan clinic; to maintain patient dignity whilst performing transvaginal scans when women were accompanied in the scan room by relatives.

- The service held monthly team meetings, and staff we spoke with said they felt engaged in service planning and development. The service had implemented digital forums for staff to communicate service performance, consult on delivery, and to acknowledge staff contributions. We reviewed team meeting minutes and saw that patient feedback (such as, complaints, concerns and compliments) were discussed with the team during staff meetings. The sonographers were sometimes 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 at the location.
- 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 best practice developments.

Learning, continuous improvement and innovation

- **There was a fully embedded and systematic approach to improvement. The service was committed to improving services by learning from when things went well or wrong, and promoting training, research and innovation.**
- Staff we spoke with could provide examples of improvements and changes made to processes based on patient feedback and staff suggestion.
- The service demonstrated a strong commitment to professional development; which included online and site based continuous professional development training designed to provide ladders for personal and professional growth. For example, enhanced emotional and bereavement training was offered to staff, and we saw the service had arranged a bereavement study day with a national charity.
- Safe innovation was celebrated. There was a clear, systematic and proactive approach to seeking out and embedding new and more sustainable models of service delivery and care. For example, the service made use of a smart device application ("bumpies") 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.
- The service had implemented dedicated IT systems with appropriate safeguarding and oversight, to ensure accurate comprehensive recording.
- 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.
- There was a strong record of sharing work locally, nationally and internationally. For example, the service had collaborated with a local (Russel group) university in the 12 months prior to our inspection, and had assisted them with research scans exploring the effects of hyperemesis and smoking on the fetus. We also saw that the location was due to assist with an upcoming study, exploring the effects of domestic violence on fetal wellbeing.

Outstanding practice and areas for improvement

Outstanding practice

- There were high levels of emotional support available to women and their companions. Scan assistants acted as chaperones, to ensure women felt comfortable and received optimum emotional support. All staff received communication training to offer emotional support. We also saw scan assistants periodically assessed sonographers for their quality of customer care and communication skills, and findings were fed-back to them. The service purposely ran early pregnancy and later pregnancy clinics at different times to ensure that women who had experienced pregnancy loss or were anxious about their pregnancy did not share the same area with women who were much later in their pregnancy. Staff had received enhanced bereavement and communication training. The service benefited from a dedicated 'quiet room', which could be used if women and their companions had received difficult news.
- The service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent care to flourish. The registered manager was a registered bereavement midwife of ten years standing with extensive of practice in large NHS teaching hospitals; they brought this breadth of experience to leadership of the service. Leaders strived to deliver and motivated staff to succeed; personal and professional staff development was positively encouraged and there was a deeply embedded system of leadership development and succession planning. The service was committed to promoting training, research and innovation. For example, the service had collaborated with a local (Russell group) university and had assisted them with research scans exploring the effects of hyperemesis and smoking on the fetus. The service was also involved with an upcoming study, exploring the effects of domestic violence on fetal wellbeing.

Areas for improvement

Action the provider SHOULD take to improve

- The provider should consider ensuring that information they present to women regarding the safety of ultrasound pregnancy scanning is in line with Public Health England guidance.
- The provider should consider ensuring that the fabric cover placed on scanning couch is always covered with a disposable sheet or changed between patient use in the later pregnancy clinic, in line with good infection prevention and control practice principles.