Window to the Womb

Quality Report

Unit 3
Station Road
Chester le street
DH33DY
Tel: 0191 640 2269
Website: https://windowtothewomb.co.uk/studios/newcastle-baby-scan-studio/

Date of inspection visit: 27 June 2019
Date of publication: 09/09/2019

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 ☆

Overall summary

Window to the Womb is operated by D I Harries Limited, and is located in central Chester-le-Street, a town in County Durham. 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

Summary of findings

short-announced inspection on 27 June 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 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:

- We saw all staff at the service (including scan assistants) had received safeguarding children and young people, and safeguarding adults' level three training. In addition to this, we saw that staff mandatory training at the location included documented six-monthly review and understanding checks of Window to the Womb safeguarding policies.
- 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

Summary of findings

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 formed a collaboration with a local (Russel group) university and assisted them with performing research scans for fetal research. They had participated in a study exploring auditory simulation in the womb, and another study exploring the effects of hyperemesis and smoking on the fetus. At inspection, we saw that the service was currently involved in a study exploring fetal taste preferences. They were also due to assist with an upcoming study exploring the effects of maternal anxiety and depression on fetal neural development.

Ann Ford

Deputy Chief Inspector of Hospitals (North)

Summary of findings

Our judgements about each of the main services

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

Summary of findings

Contents

Outstanding ☆

Window to the Womb

Services we looked at Diagnostic imaging

Summary of this inspection

Background to Window to the Womb

Window to the Womb is operated by D I Harries Limited and is located in central Chester-le-Street, a town in County Durham. 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 Washington, Durham, Sunderland, Newcastle, and outlying areas.

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

The service has had a registered manager in post since it began operating in 2016. The service is registered for the following regulated activities:

- Diagnostic and screening procedures

We conducted a short-announced inspection of the service on 27 June 2019. We had not previously inspected this service.

Our inspection team

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

Information about Window to the Womb

Window to the Womb (Chester-le-Street) 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 ran on Monday, Tuesday, Wednesday, Thursday and Friday evenings, and all day Saturday and Sunday.

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

Scans available at the location are offered as an additional service and are provided to complement NHS pregnancy pathway scans. The service does not offer diagnostic anomaly scans, but there are established pathways to refer women to primary antenatal (NHS) providers; should a potential anomaly or concern be identified.

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

Activity:

- From June 2018 to June 2019, the later pregnancy (Window to the Womb) service performed 2538 ultrasound scans.
- In the same period, the early pregnancy (Firstscan) service performed 1308 ultrasound scans.

Summary of this inspection

Track record on safety during the reporting period 28 January 2018 to 28 January 2019; in this timeframe there were:

- No patient deaths.
- No never events.
- No serious incidents.
- No duty of candour notifications. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- No safeguarding referrals.
- No incidence of healthcare acquired infections.
- No unplanned urgent transfer of a patient to another health care provider.
- No appointments were cancelled for a non-clinical reason.

In the reporting period, the service reported it had identified or received five informal complaints (concerns) but had not received any formal complaints.

During our inspection, we spoke with five members of staff; these included the registered manager, area manager, clinic manager, a sonographer, and a scan assistant. We also reviewed nine staff records. We observed three ultrasound scans and spoke with these three women and their companions. We reviewed a total of 23 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.

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.
- 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 caring as **Outstanding** because:

Summary of this inspection

- 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 worked alongside a local charity to hold quarterly '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:

- 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

Summary of this inspection

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; which had a booking facility. There were very 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 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.

Summary of this inspection

- 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 staff and made sure everyone completed it.**
- 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 five scan assistants employed at the location were 100% compliant with mandatory training requirements.
- Two sonographers worked for the service on a self-employed basis; one did so full-time and one did so part-time. The part-time sonographer held a substantive post in an NHS trust, and the full-time sonographer worked solely in private practice at the location. We saw that both sonographers had completed mandatory training with Window to the Womb, and their practise was supervised and monitored by the franchisor clinical lead. We saw the registered manager also had oversight of what mandatory training the sonographer substantively employed in the NHS had completed.
- 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.
- We saw it was company policy (mandatory) for all sonographers to be registered with a professional regulatory body, and to hold professional qualifications. We reviewed staff files and saw that all both sonographers contracted at the service were registered with the Health and Care Professions Council (HCPC). They were also registered with other regulatory bodies; these included, the Society and College of Radiographers (SCoR), the Nursing and Midwifery Council (NMC) and British Medical Ultrasound Society (BMUS). The full-time sonographer contracted at the location had previously qualified as a medical doctor (Bachelor of Medicine, MD) before deciding to retrain and become a sonographer. Both held post-graduate qualifications in ultrasound practice.
- The registered manager, who was Nursing and Midwifery Council (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.
- We also saw that the area manager had completed external mandatory training courses provided by the franchisor.

Safeguarding

Diagnostic imaging

- **Staff understood how to protect patients from abuse and the service had systems in place to do so.**
- There were up-to-date and service specific safeguarding adults and children's policies for staff to follow, which included the contact details of local authority safeguarding teams. In addition, other (external) safeguarding information was available to staff; these included a local authority safeguarding adults interagency partnership policy, and a national charity safeguarding children and young people tool kit.
- A separate female genital mutilation (FGM) policy provided staff with guidance on how to identify and report FGM.
- The service had a designated lead for both children and adults' safeguarding, who was the registered manager. The registered manager, 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 also saw that all sonographers and scan assistants at the location had received level three adults and level three children's safeguarding training. In addition to this, we saw that staff mandatory training at the location included six-monthly review and understanding checks of Window to the Womb safeguarding policies; and this was documented.
- Staff we spoke with were able to clearly 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 28 January 2018 to 28 January 2019, 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 proof of identification, residence, and 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, qualifications, and professional membership were kept on file.

Cleanliness, infection control and hygiene

- **The service controlled infection risk well. Staff kept the equipment, and the premises clean**.
- There were infection prevention and control (IPC) policies and procedures, which provided staff with guidance on appropriate IPC practice. We saw that all staff had received mandatory IPC training.
- During our inspection, we saw that clinic rooms, toilets, reception and waiting areas were visibly clean.
- We saw staff completed a daily cleaning log. We also saw that staff undertook frequent (hourly) cleanliness visibility checks of clinical areas throughout their shifts; documenting and remedying any areas of concern as necessary.
- There was a monthly deep clean of the service, and a comprehensive check list had been produced to monitor and document compliance with this. We reviewed the last six checklists dating back to January 2019 and saw 100% compliance was achieved.
- Cleaning materials were colour coded for use in different areas of the premises.
- 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 the service had introduced hand hygiene audits in January 2019; audits monitored ten staff over a period of several days. The latest audit showed 100% compliance. Metrics included; 'key moments' for

hand hygiene, bare below the elbows, appropriate covering of any cuts and grazes, hand washing technique, and disposal of paper towels (without touching the bin lid).

- 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 clinics, 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.
- We saw that scan assistant's periodically assessed sonographers for their quality of customer care and service, and overall customer experience; and as part of this, assessed sonographer's infection prevention and control (IPC) practice. We reviewed ten of these assessments that showed sonographers had set up the clinic room to company standard and had followed correct IPC protocols.
- 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 (and was last completed in April 2019). 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 over 12 months prior to our inspection; and we saw that it had received an annual service (August 2018). The service contracted an external engineering company to do this; 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 the last twelve months. 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 April 2019. We saw that substances that met COSHH (Health and Safety Executive, 2002) criteria were securely stored; and a sign indicating storage of COSHH materials was clearly displayed on the cupboard door.
- Electrical equipment was regularly serviced, and safety tested to ensure it was safe for patient use. We saw an external company had tested all (25 pieces) of electrical equipment in May 2019.
- An annual fire risk assessment was last undertaken in May 2019; and there was an emergency evacuation procedure in place (last updated in February 2019). At inspection, we saw fire extinguishers were accessible, stored appropriately, and had all been inspected and serviced in May 2019. We saw that fire alarms and

smoke detectors were checked on a monthly basis, and this was documented. Fire drills were held each month, and evidence of this was documented, with the last drill completed in June 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.
- Pre-scan questionnaires were in use at the service. These required women to provide GP details, and the details of their local NHS hospital. Women were also required to provide pregnancy information. For example, number of previous pregnancies, ectopic pregnancies, and miscarriages, date of last menstrual period, and date of first positive pregnancy test.
- Sonographers were required to document if women had provided their pregnancy records, or the details of their antenatal care provider or GP, on consent forms. In addition, sonographers had to record whether they were satisfied the service was appropriate for the woman, and could therefore be offered.
- We observed that written information and verbal information given to women who utilised the service was clear as to the limits of diagnostic services provided. For example, women had to declare that they understood that scans were not exhaustive and that sonographers at the service could not confirm possible anomalies; but would refer them to NHS antenatal care providers.
- We saw that scans were conducted according to British Medical Ultrasound Society (BMUS) recommendations for 'as low as reasonably achievable' (ALARA) principles for safety in ultrasound scanning; for length of scan and frequency of ultrasound waves.
- We saw BMUS 'pause and check' guidance was displayed in the scan room and the sonographer we observed followed this guidance. The guidance is designed to act as a ready reminder of the checks that need to be made when any ultrasound examination is undertaken.
- Written and verbal advice given to women about ultrasound scanning was 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 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 an antenatal clinic or fetal medicine unit 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 June 2018 to June 2019, we saw the later pregnancy scan (Window to the Womb) service had made 33 referrals to NHS antenatal care providers. Over the same period, we saw that the early pregnancy (Firstscan) clinic had made 88 referrals to NHS antenatal care providers.
- During our inspection, we reviewed 20 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 registration number on the referral form. Reasons for referral included potential anomalies and concerns such as, suspected fetal abnormality (for example, duodenal atresia, a congenital absence or complete closure of the bowel adjoining the stomach), oligohydramnios (a condition in pregnancy characterised by a deficiency of amniotic fluid), polyhydramnios (an excessive accumulation of amniotic fluid), intrauterine fetal death, pregnancy of unknown location, and missed miscarriage.
- 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; and we saw documented evidence of this. 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 28 January 2018 to 28 January 2019.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.

- The registered manager 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.
- In addition to these staff, there were five 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.
- Two sonographers worked for the service on a self-employed basis; one did so full-time and one did so part-time. We reviewed staff records and saw that sonographers had previous obstetrics experience and were registered with the HCPC. The part-time sonographer held a substantive post in an NHS trust, and the full-time sonographer worked solely in private practice; having previously qualified as a medical doctor (MD) and retrained to become a sonographer.
- The ultrasound clinics were scheduled in advance and the sonographers assigned themselves to the clinics; with the full-time sonographer undertaking most clinics.

Diagnostic imaging

- All staff we spoke with felt that staffing was well managed. 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 other 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 2018 to January 2019, there had been no staff sickness absences.
- Information provided by the service showed that one (part-time) sonographer had left the service in the 12 months prior to our inspection. We spoke with the registered manager during our inspection, who explained that the sonographer had retired. We also saw that one sonographer had taken parental leave.

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 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.
- Passwords and key codes were changed frequently, and whenever a member of staff left the service.
- 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 one incident had been recorded in the 12 months prior to our visit. This related to clinic power loss for a period of 40 minutes in February 2019.

- 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 at other locations they were responsible for; to identify any themes and learning to share with other clinics. We saw learning from incidents at other locations was shared with staff at the service, at team meetings and through service circulars.
- 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 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 28 January 2018 to 28 January 2019, 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 monthly; 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 (the most recent was undertaken at the location in March 2019). We saw deviation from processes documented and improvement actions agreed, which were time-bound and checked. For example, we saw a local audit in May 2019 had identified the fire extinguishers required servicing in the near future; and we saw this 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, free bottles of drinking water were available in the waiting area.
- There were food outlets located nearby, should women or their companions wish to purchase food and drinks.
- 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". We also saw that posters were displayed detailing a national breastfeeding telephone helpline.
- We also saw baby friendly initiative posters displayed about 'responsive bottle feeding'.

Patient outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.**
- The registered manager had overall responsibility for governance and quality monitoring.
- The service used key performance indicators to monitor performance, which were set by the franchisor. This enabled the service to benchmark themselves against other franchised clinics. Data was collected and reported to the franchisor every month to monitor performance. This included information about the number of ultrasound scans completed including the number of rescans, and the number of referrals made to other healthcare services.
- From June 2017 to June 2018, the service had referred 121 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 no incorrect gender scans in the 12 months prior to our inspection; equating to a success rate of 100%.
- 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.
- From June 2017 to June 2018, the rescan rate for the later pregnancy (Window to the Womb) clinic was 8% of the total number of scans completed (203 of 2538 scans). We saw rescans were completed because fetal position or maternal habitus prevented completion of all wellbeing checks and/or determination of baby gender, at the time of the initial appointment. In most instances, the woman was asked to mobilise for a short period of time at the clinic, or to drink cold fluids, to encourage baby to reposition and enable a clearer image.
- The early pregnancy (Firstscan) clinic routinely completed rescans, and we saw that approximately one in four women who attended the service were required to re-attend. This was predominantly because women had attended too early in pregnancy to determine viability (that is, they believed they were later along in pregnancy than they actually were). In line with NICE clinical guideline CG154, these women were booked to re-attend in two weeks (10 to 14 days) time.
- 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.

Diagnostic imaging

- 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 area manager, clinic manager and three scan assistants that had been employed for more than 12 months at the location; and we saw evidence of this
- We saw that the lead sonographer conducted an initial competency assessment of sonographers at the location when they had first joined the service. We saw sonographers at the location who had been contracted for more than 12 months received an annual appraisal by the registered manager and a competency assessment by the franchisor's clinical lead; which included checking their 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 both sonographers contracted at the service were registered with the Health and Care Professions Council (HCPC). They were also registered with other professional regulatory and national bodies; these included the Society and Council of Radiographers (SCoR), the Nursing and Midwifery Council (NMC) and British Medical Ultrasound Society (BMUS). We also saw that the full-time sonographer employed at the service had qualified as a medical doctor (MD) and had decided to retrain as a sonographer.
- We reviewed staff files and saw evidence of sonographers undertaking continuous professional development; for example, specialist ultrasound courses provided by BMUS and SCoR. In addition, we saw that both sonographers held ultrasound post-graduate qualifications. We also saw sonographers had attended a regional franchisor event to share best practice.
- The franchise had introduced sonographer peer review assessments (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 seven peer review audits that had been completed at the location since December 2018. We saw peer assessment covered feedback on topics such as effective use of equipment, observations, and report quality. We found that no concerns had been identified; however, peer assessments did highlight learning. For example, one peer assessment recommended the sonographer needed to "ensure appropriate zoom to ensure best measurements are obtained".
- 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.
- 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 all

day, seven days a week. Services at the location were typically provided on Monday, Tuesday, Wednesday Thursday and Friday evenings, and all day Saturday and Sunday. 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.
- In addition, information posters from another national baby loss prevention charity were displayed; that encouraged women to contact their midwife or seek medical assistance in a range of circumstances.
- 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.**
- 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.
- Staff were aware of consent procedures for those aged under 18 years of age; for example, the use of the Gillick competency test. In addition, we saw that young women (of 16 to 17 years of age) who wanted to use the service had to attend with a responsible adult (for example, someone with parental responsibility); and the responsible adult was required to countersign their consent form.
- 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.
- Women were given a large disposal cloth to use during their ultrasound scan to help maintain their dignity. A privacy screen was also available in the scan room, should women wish to use it; for example, if they were having a transvaginal scan and/or attending with friends or relatives.

Diagnostic imaging

- Feedback forms (comment cards) were available in the clinic for patients and their companions to complete. During our inspection we reviewed seven comment cards at random. 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" and described staff "went above and beyond".
- We saw a host of thank you cards had been received by the service from women and their families. We reviewed a dozen of these and saw feedback was overwhelmingly positive. For example, women described an "amazing" and "brilliant experience", and described staff as "lovely, professional and kind". They also said that "your kindness won't be forgotten" and "you really went the extra mile for us". We also saw thank you cards from children who had attended the service with their mothers.
- 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 hundreds available) and found the service was very highly rated (five stars), and feedback was overwhelmingly positive. For example, responses included statements such as: "truly amazing and friendly staff, couldn't recommend enough".
- 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, and we observed them thanking staff for the service provided.

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.
- 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 staff had attended a bereavement study day in May 2019, organised by the registered manager in conjunction with 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' when clinics were in progress, which could be used if women and their companions had received difficult news. We saw that the 'quiet room' had ('before and after') baby scan images and new born baby photographs on display. However, we observed that a bespoke blind had been fitted to the display wall to completely conceal these images, if needed. In addition, we saw that the room benefited from slated blinds, which were closed when the room was in use; to maintain privacy and confidentiality.

Diagnostic imaging

- We 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, a woman who was induced at an early stage following identification of potential concerns and was referred to NHS antenatal care services said, "[baby] is very poorly but I still want to thank you for taking the time and making me feel comfortable". We also saw that a relative of another woman who had been referred to NHS antenatal care from the service had written, "on behalf of [names] and all our family, I would like to say a massive thank you for all you do during the appointment and for the care and support offered to [woman] afterwards".
- 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 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. We saw this had been launched in June 2019, and a press release had been issued.

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 several 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 and scan room.
- 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 ten of these assessments undertaken at the location during our inspection. We saw the scan assistants 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 woman said, "[sonographer] was very nice, made me feel completely at ease and it was lovely to hear the heart beat". Others commented, "really lovely, felt at ease throughout the scan and everything was explained to us", and "felt very reassured by the scan and not rushed".
- Feedback on social media and online review platforms was overwhelmingly positive. For example, the most recent review we saw said "The staff were truly amazing told you everything that was happening and going on keeping you reassured throughout. They were very patient with me with me and waited for my family …".
- The Window to the Womb service at the location worked alongside a national charity to hold quarterly 'meet the mummies' tea and coffee mornings. These were for women who had ultrasound scans at the location to meet with other new mothers.

Diagnostic imaging

- 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.

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

Meeting people's individual needs

- **The service took account of patients' individual needs.**
- Women received detailed written information to read and sign before their scan appointment. Key information about what different ultrasound scans involved were available on the service's website, and could be accessed in any recognised world language.
- The service had contracted a telephone interpretation service, for staff to use during appointments with non-English speaking women. We were also told that the franchisor was developing a bespoke mobile phone application for staff and women to use in these circumstances. Once developed, the application would be capable of translating both verbal and written information.
- The service website offered a 'read out loud system' to allow the visually impaired to gain information with ease.
- The service was located on the ground floor of a business centre, and an accessible bathroom was also available. The scan room was large and airy, with ample seating and additional standing room for several guests. There was an adjustable medical bed in the scan room to support women with limited mobility. There were three large wall-mounted monitors; these enabled women and their companions to view the baby scan more easily.
- 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, and service had developed a 'support for partners' information leaflet, for the partners of women who had experienced pregnancy loss. We also saw that a range of information leaflets produced by national miscarriage, stillbirth and neonatal death charities were available.
- 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. 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 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; which had an appointment booking facility.
- The service opened according to patient demand, and typically operated Monday, Tuesday, Wednesday, Thursday and Friday evenings, and all-day Saturday and Sunday. 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.
- From June 2018 to June 2019, the later pregnancy (Window to the Womb) service performed 2538 ultrasound scans. In the same period, the early pregnancy (Firstscan) service performed 1308 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 very low rate of non-attendance (estimated as less than 1%) because the service requested a non-refundable deposit payment on appointment booking. If a woman suffered a miscarriage before their appointment, staff would refund the deposit payment immediately.
- Patients we spoke with at the inspection were positive about the availability of scans and said that they had received suitable appointments in a timely fashion. We also saw this reflected in written feedback we reviewed. During our inspection, we observed that clinics ran on time.
- We observed that the service had built in gaps between appointment slots, so that appointments did not run 'back to back'. This contingency time enabled staff to maintain appointment times and minimise waiting times, should an appointment overrun. As observed at inspection, we also saw that this enabled staff to offer women re-scans if needed; for example, if the sonographer could not get a clear picture of baby and had asked the woman to mobilise for a short period of time.
- In the reporting period 28 January 2018 to 28 January 2019, no planned appointments were cancelled for a non-clinical reason; such as breakdown of equipment.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, and had systems in place to investigate them and learn lessons from the results, and share these with all staff.**
- 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 or self-identified by the service via social media channels and online review sites, which were frequently monitored. The service had self-identified or received five informal complaints (concerns) from 28 January 2018 to 28 January 2019. No formal complaints were received over this period. At inspection, we saw no additional complaints or concerns had been received or identified in the intervening period, to the date of our inspection.
- We reviewed the informal complaints and saw two of these related to quality of images, and the availability of specific merchandise. Three informal (low level) concerns related to sonographer communication. In all cases, we saw that a manager had responded to the woman and apologised and had offered a full refund or complementary rescan by means of recompense. In all instances we saw that informal complaints and concerns had been satisfactorily resolved. We saw that the concerns raised had been fed back to staff; and in the case of sonographer communication, the staff member involved had been asked to complete additional training.
- 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 introduced a privacy screen for women, if required. 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 four 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.**
- We spoke with five 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 supported 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 monthly 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.
- Employers liability insurance was in place and was last renewed March 2019.

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. We saw these metrics, and policy compliance and training were discussed at monthly team meetings; with actions and completion dates documented.

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.
- Passwords and key codes were changed frequently, and whenever a member of staff left the service.

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. 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. We saw that copies of these were held in a file at the location, and staff had signed these to indicate they had been read and understood.

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 staff had attended a bereavement study day organised in conjunction with a national charity.
- Despite not being required, we saw that all staff at the service (including scan assistants) had been received safeguarding children and young people, and safeguarding adults', level three training.
- 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 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 and 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 formed a collaboration with a local (Russel group) university and assisted them with performing research scans for fetal research. They had participated in a study exploring auditory simulation in the womb, and another study exploring the effects of hyperemesis and smoking on the fetus. At inspection, we saw that the service was currently involved in a study exploring fetal taste preferences. They were also due to assist with an upcoming study exploring the effects of maternal anxiety and depression on fetal neural development.

Outstanding practice and areas for improvement

Outstanding practice

- We saw all staff at the service (including scan assistants) had received safeguarding children and young people, and safeguarding adults' level three training. In addition to this, we saw that staff mandatory training at the location included documented six-monthly review and understanding checks of Window to the Womb safeguarding policies.
- 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 formed a collaboration with a local (Russel group) university and assisted them with performing research scans for fetal research. They had participated in a study exploring auditory simulation in the womb, and another study exploring the effects of hyperemesis and smoking on the fetus. At inspection, we saw that the service was currently involved in a study exploring fetal taste preferences. They were also due to assist with an upcoming study exploring the effects of maternal anxiety and depression on fetal neural development.