

D.I. Harries Darlington Limited

Window to the Womb Darlington

Inspection report

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

Ratings

Overall rating for this location

Outstanding 

Are services safe?	Good 
Are services effective?	Inspected but not rated 
Are services caring?	Outstanding 
Are services responsive to people's needs?	Good 
Are services well-led?	Outstanding 

Summary of findings

Overall summary

Our rating of this location stayed the same. We rated it as outstanding because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them. Staff collected safety information and used it to improve the service.
- Staff provided good care to women that was based on an ethos of continuous improvement and excellence. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information. Key services were available flexibly.
- Women were truly respected and valued as individuals. Staff empowered them as partners in their care, practically and emotionally, by delivering an exceptional and distinctive service.
- The service planned care to meet the needs of people who used the service, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for a diagnostic procedure.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of women who used the service. Staff were clear about their roles and accountabilities. The service engaged well with women to plan and manage services and all staff were committed to improving services continually.
- The leadership, governance and culture were used to drive and improve the delivery of high-quality person-centered care. The leadership team actively sought opportunities for improvement and evidence-based development through specialist collaboration.

We last inspected the service in March 2019. We told the service it should act to ensure the information presented to women regarding ultrasound safety was in line with Public Health England guidance. We asked the service to consider a change of infection prevention and control processes in the scanning room. At this inspection we found the registered manager had addressed both areas.

Summary of findings

Our judgements about each of the main services

Service

Diagnostic and screening services

Rating

Outstanding



Summary of each main service

Window to the Womb Darlington is an independent healthcare provider offering antenatal ultrasound imaging and diagnostic services to self-funding or private patients over 16 years of age. The service offers an early pregnancy clinic (from six to 15 weeks of pregnancy), and a later pregnancy clinic (from 16 weeks of pregnancy). Depending on the type of scan performed, these might involve checking the location of the pregnancy, dating of the pregnancy, determination of sex, and fetal presentation at the time of appointment. Patients are provided with ultrasound video or scan images in 2D, 3D or 4D, and an accompanying verbal explanation and written report. The service is led by innovation in technology-based care and has clinical oversight for referring women onward to NHS services.

Summary of findings

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Summary of this inspection

Background to Window to the Womb Darlington

Window To The Womb is operated by D I Harries Limited. The clinic opened in 2018 and provides private ultrasound services to self-funding women who are over the age of 16 and more than six weeks pregnant. Ultrasound scans are separate from NHS standard care pathways. The service operates from a dedicated clinic with step-free access and car parking.

The service has a registered manager in post.

The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures. We last inspected the service in March 2019 and rated it outstanding overall.

How we carried out this inspection

We carried out a comprehensive inspection of the service under our regulatory duties. The inspection team comprised of a lead CQC inspector and an offsite CQC inspection manager. We gave the service short notice of the inspection because we needed to be sure it would be in operation at the time we planned to visit.

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

Outstanding practice

We found the following areas of outstanding practice:

The service provided a unique opportunity for women to have their scan digitally livestreamed, with audio commentary from the sonographer, to relatives or friends anywhere in the world. This took place with secure information management and effective governance. Staff had acted on early feedback to improve the service with better interaction and narration to help remote viewers understand the video.

The clinical lead worked extensively with scan assistants and sonographers to enhance standards of communication when delivering bad news. This demonstrated attention to detail and included learning from national examples of incidents of complaints. This was part of a wide-ranging, persistent focus on ensuring emotional support was delivered in a structured manner by staff who were compassionate and trained in evidence-based support strategies.

Staff were demonstrably passionate, enthusiastic and committed to the development of women's health care and supporting good health outcomes. They worked with regional universities to support leading edge research on baby scanning services and foetal abnormalities and proactively engaged with artificial intelligence and digital platforms to improve women's experiences.

The clinical lead recognised the importance of building effective, managed relationships with local NHS services, including early pregnancy units and maternity wards. They liaised directly with staff to ensure they understood the nature of this service and the provider's standards. This helped to address misconceptions of the independent healthcare sector and meant women experienced more streamlined referrals between this service and secondary care.

Summary of this inspection

Areas for improvement

Action the provider SHOULD take to improve:

- The provider should update the complaints policy to direct patients to an independent adjudication or resolution service in the event the service cannot resolve a complaint. The complaints policy should not direct patients to the Care Quality Commission (CQC) as this organisation does not provide a complaints service.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Good	Inspected but not rated	<div>☆ Outstanding</div>	Good	<div>☆ Outstanding</div>	<div>☆ Outstanding</div>
Overall	Good	Inspected but not rated	<div>☆ Outstanding</div>	Good	<div>☆ Outstanding</div>	<div>☆ Outstanding</div>



Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Good



Our rating of safe stayed the same. We rated it as good.

Mandatory training

The service provided mandatory training in key skills to all staff and made sure everyone completed it.

The mandatory training was comprehensive and met the needs of patients and staff.

The clinic manager monitored training compliance and had adapted access to training courses to ensure there were no gaps in compliance due to the COVID-19 pandemic.

Records showed compliance with training was consistently above 90% and staff had protected time to complete this.

Managers monitored mandatory training and alerted staff when they needed to update their training. Staff completed training in forced marriage awareness and recognising female genital mutilation. They also completed training in providing care for patients with mental health needs and learning disabilities.

Safeguarding

Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse and they knew how to apply it.

Staff received training specific for their role on how to recognise and report abuse. Staff provided examples of scenarios in which they would seek help from a safeguarding professional. Staff undertook refresher training three times each year or more often if there was specific learning from an incident or a new policy to incorporate.

The provider had a standardised safeguarding policy that meant all staff maintained training to level 3 in child and adult safeguarding.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act.



Diagnostic and screening services

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff were trained to recognise the signs of forced marriage and female genital mutilations at different stages of the patient journey, including in waiting areas and during intimate scans.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. Staff gave examples of how they had worked with the local safeguarding team when they had identified concerns about a patient's welfare.

The service displayed information regarding safeguarding from abuse in the toilets. This reflected good practice as it meant patients could discreetly access important information.

The provider had recently improved the safeguarding policy applicable to all locations. The new policy provided up to date guidance on recognising abuse and escalating concerns in the specific context of the service. The policy includes processes for staff to obtain support in the event a woman under the age of 16 attempted to obtain a scan.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained.

The infection control policy included clear guidance on the cleaning and disinfection of transvaginal probes, cleaning and storage of mops, cleaning of the sink, cleaning of the floorings and hand washing. We saw staff followed this guidance in practice.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly.

The clinic manager had implemented a new daily cleaning schedule to maintain safety and hygiene standards to address the risks presented by COVID-19. Staff had designated cleaning responsibilities and had extra time between scans and at the end of the day for cleaning.

The clinic manager carried out daily and weekly checks of cleaning standards and the area manager audited local records. We saw the clinic performed consistently well.

Staff followed infection control principles including the use of personal protective equipment (PPE).

The service had hand washing facilities for sonography staff to decontaminate their hands and equipment following scans. World Health Organisation (WHO) hand hygiene guidance was posted above each sink to provide a visual guide to handwashing.

Staff had completed coronavirus and infection control awareness training and the clinic manager carried out monthly hand hygiene checks on each member of staff to check compliance with hand hygiene at key stages of care. The team achieved 100% compliance in audits for the previous six months.

Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. We observed sonography staff cleaned the transvaginal probes in line with British Medical Ultrasound Society (BMUS) and manufacturer guidelines. This meant the service reduced the risk of cross infection.



Diagnostic and screening services

We observed appropriate COVID-19 infection control procedures such as hand washing, hand sanitisation, use of personal protective equipment (PPE) and social distancing. Staff performed lateral flow tests in line with national guidance.

The service had updated the COVID-19 policy to provide guidance for staff to help reduce the risk of spread of infection. Staff asked about any COVID-19 symptoms or known exposure, ensured they wore masks and sanitised their hands.

Women were provided with information about COVID-19 restrictions at the time of booking. There were posters on display at the entrance of the clinic reminding everyone to wear masks and not to enter if they were experiencing COVID-19 symptoms.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.

The service had suitable facilities and had enough suitable equipment to meet the needs of women. Staff completed regular checks of stock, first aid kit and equipment.

Staff carried out daily safety checks of specialist equipment. Electrical equipment had undergone safety testing in the previous 12 months in line with the provider's safety policy.

The service had suitable facilities to meet the needs of women and the people who accompanied them.

The service had enough suitable equipment to help them to safely care for patients. Managers followed a clear process for the service, maintenance and repair of scanning equipment. A contingency plan was in place to reduce delays in the event of equipment failure.

Staff disposed of clinical waste safely. Staff carried out waste streaming in line with Department of Health and Social Care Health Technical Memorandum 07-01, which reflected national best practice.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff acted quickly to reduce risks in emergencies.

Staff responded promptly to any immediate risks to women's health. The provider had health and safety policies that included a deteriorating patient policy. This meant that staff knew what to do and acted quickly when there was an emergency.

Staff completed risk assessments for each woman, such as allergies and health conditions, using a health declaration and consent process.

Staff had completed mandatory training in health and safety, emergency first aid and fire safety. The clinic manager carried out weekly fire safety checks and monthly unannounced fire drills. This enabled them to monitor staff reaction in the event of an evacuation.



Diagnostic and screening services

The service provided clear guidance for sonographers to follow when they identified unexpected results during a scan. Staff gave examples of redirecting women who were experiencing pain or bleeding to their local NHS clinical team. We reviewed four referral letters which showed that staff shared key information to keep women safe when referring any concerns to the NHS. We saw evidence sonographers made rapid referrals when they found concerns about a woman's health and documented their phone calls with NHS services to maintain an audit trail of referrals.

Staffing

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

The service had enough staff to keep women safe. The clinic manager planned staffing levels to meet demand on the service, measured by the number of bookings made in advance. The provider required each shift to have a sonographer, a scanning assistant, a receptionist and a team leader as a minimum. A manager and clinical lead were on call when the clinic was open.

The service had low vacancy, turnover and sickness rates and staff described the team as consistent and stable.

Records

Staff kept detailed records of women's care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.

Patient notes were comprehensive and relevant staff could access them easily. Sonographers kept detailed records of scans and referrals to NHS services.

When patients transferred to a new team, there were no delays in staff accessing their records. Women could move between clinics in the provider's network seamlessly and the consent process ensure appropriate staff could access their records where this was necessary for an appointment.

Records were stored securely. Referrals, reports and consent forms were stored in a locked storage room with restricted access.

We observed staff maintaining the confidentiality of women. They locked computer screens when unattended, ensured printed confidential information was not left unattended and ensured conversations were discreet.

All staff were up to date with record keeping, information governance awareness and cyber security awareness mandatory training.

The service had a data protection and retention policy that reflected national guidance. Local records were kept for 12 months and then archived in a secure storage unit for 20 years to meet the provider's requirements for medical indemnity insurance.



Diagnostic and screening services

Incident reporting, learning and improvement

The service managed women's safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team and the wider service. When things went wrong, staff apologised and gave women honest information and suitable support. Managers ensured that actions from patient safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. The service had an incident reporting policy and staff told us how they worked within this. There had been no recent reportable incidents or accidents and staff explained how they would report such an event. Managers demonstrated clear knowledge of reporting, investigating and learning processes.

Staff completed mandatory training on Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) and on the use of the duty of candour.

The service had no never events. Never Events are serious patient safety incidents that should not happen if healthcare providers follow national guidance on how to prevent them. Each Never Event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a Never Event.

Staff understood the duty of candour. They were open and transparent and gave women and families a full explanation if and when things went wrong. Staff who had originally trained outside of the UK and those who also worked for the NHS provided details of how their training was adapted to this specific environment.

The provider had introduced supplemental policy guidance for staff to follow after a missed or incorrect diagnosis. This enhanced the existing process and improved the investigative process with more input from scan assistants and chaperones. This reflected the service's collaborative approach to safety improvement.

Staff received feedback from investigation of incidents, both internal and external to the service. The service shared lessons learned from incidents using the intranet and staff had an opportunity to post responses. Managers also shared such learning through secure messaging groups, in team meetings and during supervisions.

Staff met to discuss the feedback and look at improvements to patient care. We saw evidence of this from speaking with staff and reviewing the minutes of meetings.

Managers investigated incidents thoroughly. There was evidence that changes had been made as a result of incidents. For example, managers had implemented new risk assessments for the use of electrical equipment after an appliance fire at another clinic.

Are Diagnostic and screening services effective?

Inspected but not rated



We do not currently rate effective.



Diagnostic and screening services

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of patients subject to the Mental Health Act 1983.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The provider had a dedicated senior team who monitored policies for compliance with national best practice guidance. Updates were cascaded across all clinic locations simultaneously to ensure all staff delivered care in line with requirements. This system included a record of date changes and reminders of when policies needed to be reviewed.

The clinical lead and director of ultrasound wrote, maintained, and updated scan protocols. These were national documents applied across all clinics.

Sonographers and the clinical leads provided input into clinical policies when new guidance is released. Staff regularly review guidance and alerts from the National Institute for Health and Care Excellence (NICE), the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers (SCoR). This meant care was in line with the latest understanding of best practice. The service subscribed to the BMUS as low as reasonably achievable (ALARA) protocols and displayed this information prominently in the clinic. We saw from looking at scan review documentation sonographers routinely documented adherence to the ALARA protocols. This meant sonographers used the lowest possible output power and shortest scan times possible consistent with achieving the required results.

Staff documented their review and understanding of new policies and guidance in a tracker monitored by the management team.

Staff protected the rights of patients subject to the Mental Health Act and followed the Code of Practice. They completed mental health awareness as part of mandatory training. Sonography staff received additional training on the Deprivation of Liberty safeguards. The service had a process for staff to communicate any psychological and emotional needs of women and their companions at handovers between reception and the scanning team.

Nutrition and hydration

Staff considered women's individual needs where fluids were necessary for the procedure.

Staff gave women appropriate information about drinking water before trans-abdominal ultrasound scans to ensure the sonographer could gain effective ultrasound scan images. Staff provided water during the appointment if necessary.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain during scans.

The service did not undertake pain assessments. However, staff proactively asked women about pain and discomfort and stopped scans if the person reported unusual pain. Sonographers recorded pain in their scan reports and included this in referrals. The service advised women to report pain on the pre-scan consent form and on the website.

Patient outcomes

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for women.



Diagnostic and screening services

The director of ultrasound and the clinical lead used audit and review processes to monitor performance and outcomes.

Sonographers were part of a peer review process to ensure the accuracy and quality of ultrasound scan images, videos, and reports. Sonographers reviewed colleague's scans against internal targets and considered areas for improvement, such as scan times and gender or health inaccuracies. The peer reviews were shared and discussed at monthly review meetings and with the director of ultrasound.

A clinical lead was on call when the clinic was open to provide support to sonographers. The provider's IT system meant the clinical lead could access scans and results digitally and provide real-time input into scan analysis. This ensured women received accurate, timely interpretation of their scans.

In most cases the recommended gap between scans was two weeks. Sonographers assessed this on an individual basis and could reduce the gap to seven days if clinically appropriate, such as if they were unable to obtain a clear 4D scan image.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Sonographers were required to maintain registration with the Health and Care Professions Council (HCPC) in addition to holding a bachelor's degree and a postgraduate diploma.

The clinical lead worked with scan assistants to help them upskill in medical terminology for supporting early pregnancy scans.

Managers gave all new staff a full induction tailored to their role before they started work. Inductions were tailored to people's role and professional circumstances. For example, sonographers who had trained outside the UK undertook qualification conversion training during their induction. Sonographers who worked in the NHS in addition to this role received an induction to ensure they were familiar with differences in procedures.

Managers supported staff to develop through yearly, constructive appraisals of their work. The clinical lead and director of ultrasound supported sonographers in continuing professional development.

The clinical lead carried out a rolling programme of clinical reviews of sonographer work and performance. This included reviews of scan images alongside their written reports and included a sample of gender scans, first scans and high definition live-streamed scans. This process ensured consistent practice. We reviewed a sample of peer review and supervision documents and found them to be detailed, constructive and supported best practice. For example, peer reviews highlighted opportunities for improved scan detail such as asking women to empty their bladder and carrying out the scan more slowly.

Managers made sure staff attended monthly team meetings or had access to full notes when they could not attend.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.



Diagnostic and screening services

Managers identified poor staff performance promptly and supported staff to improve. Clinical leads would manage any performance issues of sonographers or scan assistants although this had not happened to date. The IT system meant clinical leads could securely support sonographers on or off site.

Multidisciplinary working

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

Staff located in different clinics communicated effectively with each other to share information about the service.

We observed active communication and supportive working practices between staff to provide care for women. Staff spoke positively of the integrated IT system that allowed them to meet different levels of demand on the service in different locations.

The clinic had well-established relationships with local NHS services, including early pregnancy units, midwives and labor services. Sonographers used referral pathways to ensure women received timely on-going care, such as when they identified fetal deformities or a miscarriage. Sonographers documented all instances of referrals, including where they made these urgently by telephone.

The clinical lead worked with local NHS services to ensure referral pathways were recognised by their teams and used to improve care and outcomes for women. They were working on a collaborative project to standardise checklists with NHS maternity and gynecology teams to help streamline the referral process.

Seven-day services

Services were planned to support timely patient care.

A central booking team monitored demand and planned opening hours accordingly. The provider's operating model meant staff could work across clinic locations to offer flexible opening times, including evenings and weekends. At the time of our inspection the service operated six days a week.

Patients made appointments online using the providers 24/7 platform or by calling the booking team.

Sonographers provided women and their partners with out of hours contact information of maternity and early pregnancy services at their local NHS hospitals. This meant patients always knew who to contact if they needed urgent care when the clinic was closed.

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

The service had relevant information promoting healthy lifestyles and support in patient areas. This included printed leaflets, signposting by sonographers and on a digital display in the waiting area. Information supported women with needs such as breastfeeding and monitoring their baby's behaviour in the womb.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support women who were experiencing mental ill health.



Diagnostic and screening services

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Consent processes reflected individual requests from women and their chosen scans. For example, staff obtained additional consent for transvaginal scans and to display scan images in the clinic and on social media. Women who had been scanned in the service often contacted staff after the birth of their baby with a photograph they wished to be displayed alongside their first scan. Staff followed a consent process in such cases.

Staff made sure patients consented to treatment based on all the information available. Consent information was provided in multiple languages to help women understand their rights and options.

Staff clearly recorded consent in women's records. Staff undertook training on consent during their induction. Managers updated this when changes in guidance were released or during each person's annual appraisal.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 and the Children Acts 1989 and 2004 and they knew who to contact for advice.

Staff received and kept up to date with mandatory training on the Mental Capacity Act and Deprivation of Liberty Safeguards. They understood how and when to assess whether a woman had the capacity to make decisions about their care.

The provider had a policy to guide staff when managing a woman, or accompanying person, who was experiencing a mental health crisis. Staff discussed an example of how they had acted to get support for a woman who presented for a scan and was unable to meaningfully consent.

Staff worked to a rescan policy that set out a timeframe for repeated scans. Sonographers provided women with assurance that multiple scans were unnecessary in most circumstances.

Are Diagnostic and screening services caring?

Outstanding



Our rating of caring stayed the same. We rated it as outstanding.

Compassionate care

There was a strong, visible, person-centred culture. Staff were highly motivated and inspired to offer care that was kind and promotes people's dignity. Relationships between people who used the service, those close to them and staff were strong, caring, respectful and supportive. These relationships were highly valued by staff and promoted by leaders.

Feedback from women who used the service, those close to them and stakeholders was continually positive about the way staff treated them. Women felt that staff went the extra mile and their care and support exceeded their expectations. Staff were discreet and responsive when caring for patients. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed reception staff welcoming women and those accompanying them warmly and with compassion. Sonographers introduced themselves and the scan assistant by name when they greeted people.



Diagnostic and screening services

Women said staff treated them well and with kindness. Staff kept written compliments they received from women who used the service.

Staff followed policy to keep patient care and treatment confidential. Privacy, dignity and respect training was part of the provider's mandatory requirements for staff and at the time of our inspection, all the team were up to date.

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgmental attitude when caring for or discussing patients with mental health needs. Sonographers and scan assistants completed training in recognising and managing distress in women and their partners.

Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs. This included where women requested a female sonographer to meet religious needs or where they attended with a same-sex partner.

Staff demonstrated attention to detail when ensuring privacy and dignity of women and those accompanying them. For example, staff used privacy curtains in the scan room and ensured the door was closed whilst scans were underway. Scan assistants offered women covers or the use of the privacy curtain whilst undressing. Staff carried out conversations about scan results in private and gave people time to understand information.

Emotional support

Staff provided emotional support to women and those accompanying them to minimise their distress. They understood women's personal, cultural, and religious needs.

Staff treated women with dignity and respect that was well considered and went above and beyond expected levels of care to provide a good service. Consideration of women's privacy and dignity was consistently embedded in everything that staff did, including awareness of any specific needs, which were recorded and communicated. Staff proactively recognised when women might need extra support and offered this discreetly.

Staff found innovative ways to enable women to manage their own health and care and to maintain independence as much as possible. Women described feeling really cared for and that they mattered. Women valued their relationships with the staff team and felt that they often went 'The extra mile' for them when providing care and support.

Staff gave women and those close to them help, emotional support, and advice when they needed it. Sonographers and scan assistants led emotional support in the event they detected foetal abnormalities, or a miscarriage and all staff received training in this area. Staff recognised the trauma of a miscarriage and had identified gaps in emotional support for women who experienced a first miscarriage in the NHS. They worked to address this by providing intensive emotional support and rapid referrals to specialist agencies.

All staff were trained to act as a chaperone when requested by a patient or a sonographer. Women could request a chaperone in advance as well as at the time of their appointment.

Staff supported patients who became distressed in an open environment and helped them maintain their privacy and dignity.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. This was part of communication training that including dealing with loss and bereavement. Staff were trained to signpost women and their partners to specialist support services and to access immediate crisis support.



Diagnostic and screening services

Staff understood the emotional and social impact that a woman's care, treatment or condition had on their wellbeing and on those close to them. They demonstrated the need for sensitivity, individualised communication and good listening skills. For example, staff gave examples of how they provided emotional support to those accompanying women when they were upset or anxious about scan results.

Staff had created a calm, private space separate from the scanning room and waiting area. This room was comfortably furnished and included printed information on specialist emotional support services, which women could access after an unexpected diagnosis. The room was accessible directly from the scan room. This meant women could use the space for personal conversations after receiving bad news. This reflected the significant efforts of staff to anticipate women's needs.

Staff provided emotional support to women who experienced a miscarriage or other traumatic event. For example, sonographers offered keepsake scan images for memory boxes if this was of importance to the woman. The clinical lead used national learning to ensure staff communicated appropriately when discussing bad news. For example, they required unexpected clinical outcomes to be discussed by sonographers and away from the waiting and reception areas and unrelated to discussions of payment and finance.

Understanding and involvement of patients and those close to them

People who use services and those close to them are active partners in their care. Staff are fully committed to working in partnership with people and making this a reality for each person.

Staff empowered women who used the service to have a voice. Women's individual preferences and needs were reflected in how care was delivered. Women consistently noted positive communication as one of the aspects of their visit. The clinical lead had worked with staff to ensure communication was individualised to each person and was carried out with sensitivity.

Staff recognised that women need to have access to, and links with, their advocacy and support networks in the community and they supported people to do this. They ensure that women's communication needs were understood, they sought best practice and learned from it.

Staff made sure patients and those close to them understood their care and treatment. They provided clear information about scanning options available and the appropriate time in a pregnancy for these to take place. The service also provided information on its website, through printed media in the clinic and by referring women to specialist organisations.

Women understood when and how they would receive their scan images and results. They had an opportunity to choose the images, immediately after the scan, to be printed out as part of their presentation photos.

Staff talked with patients, families and carers in a way they could understand. Women consistently noted positive communication as one of the aspects of their visit. The clinical lead had worked with staff to ensure communication was individualised to each person and was carried out with sensitivity.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. Staff encouraged feedback during clinic visits as well as by e-mail, letter, phone call and through contact form submission on the website. Women's feedback was clearly important to staff, who explained how this was a major factor in their understanding of service performance.



Diagnostic and screening services

Staff had developed protocols to help women safely engage with social media for communication and sharing good news. This was in response to a significant, persistent increase in requests from women to share scan images alongside photos of their new-born baby online. While women shared such images out of a sense of pride, staff recognised the risks associated with such online content, including potential for a breach of confidentiality. The information governance director worked closely with care staff to establish safe and secure systems of working that protected personal information whilst empowering women to present images they wished to share. Staff understood women's preferences might change with their personal circumstances.

Staff supported patients to make informed decisions about their care. Sonographers supported women to make decisions about the next stages of their care. This included onward referral to NHS services when scan results indicated abnormalities or other unexpected results. This ensured women did not leave the clinic without fully understanding where they would receive help and support going forward. The clinic worked with multiple local NHS hospitals and provided women with a choice of referral hospital if appropriate. Where women lived out of the area, the sonographer spoke with their local NHS hospital to make a referral.

The clinical lead worked with staff to ensure communication was tailored to the person and scenario. They recognised the importance of effective, caring communication and sought to embed this in all elements of care. They based their work on learning from incidents and complaints publicised nationally and across other providers to embed best practice.

Are Diagnostic and screening services responsive?

Good



Our rating of responsive stayed the same. We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

Staff planned and organised services, so they met the changing needs of the local population. For example, opening times were flexible to meet the needs of women's working patterns and hours.

Facilities and premises were appropriate for the services being delivered.

The service had systems to help care for patients in need of additional support or specialist intervention.

Managers monitored and took action to minimise missed appointments. The booking system sent out automatic reminders ahead of appointments and the service offered a grace period for late attendances caused by unforeseen circumstances. Staff offered flexibility in short notice rebooking in some circumstances, such as if the woman or those close to them had to isolate due to COVID-19.

Managers ensured that patients who did not attend appointments were contacted. This was a rare occurrence due to the reminder system and staff ensured they took account of individual circumstances when rebooking.



Diagnostic and screening services

Meeting people's individual needs

The service was inclusive and took account of women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They directed women to other services and providers where necessary.

Managers made sure women and their loved ones and carers could get help from interpreters or signers when needed. Information on the scans provided and consent process were available in different languages at the reception desk.

All staff completed equality and diversity training that helped them deliver care in line with the provider's diversity policy. This ensured people with protected characteristics defined by the Equality Act (2010) received care free from bias.

Each woman completed a health declaration form on which they could declare any reasonable adjustments they needed to safely and comfortably attend the appointment.

The service offered women a range of baby keepsake and souvenir options, which could be purchased from reception, including photographs and digital video downloads, heartbeat bears, a selection of photo frames and gender reveal confetti cannons. Heartbeat bears contained a recording of the unborn babies' heartbeat. The service had a considerable social media presence and staff received frequent requests to share scan videos online. Staff facilitated this with the completion of additional consent and information governance processes to protect people's data and identity.

The service provided umbrellas if a woman needed to take a walk for baby to move so they did not get wet.

The service maintained links with specialist pregnancy and miscarriage charities. The clinical lead ensured these relationships were used appropriately to meet women's needs and that they could be contacted in urgent situations.

The clinic manager was establishing a user group of women who had experienced care in the clinic. They aimed to convene this monthly and would facilitate the group to help identify areas of good practice and learn where improvements could be made.

The service provided reassurance scans for women if they could not get an early appointment in the NHS. Staff enhanced this service during the COVID-19 pandemic when they received a significant increase in queries and appointment requests caused by reduced NHS availability. The service was able to safely meet demand with increased hours, which helped women to access scans and reduce worry.

The service provided a range of scans to meet the stage of pregnancy and individual preferences.

The clinic had a private, gated car park and all areas were step-free and accessible by wheelchair.

Access and flow

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

Staff facilitated next day appointments and provided direct telephone access to the clinic even when it was not open to the public. Women could also make appointments online 24-hours, seven days a week. Where an appointment slot was not available, or the clinic was not planned to be open, staff offered alternatives at another clinic in their network.



Diagnostic and screening services

The service did not overbook clinics and did not operate a waiting list. Staff ensured there was time between scans for cleaning and rescanning, such as if baby was not in the optimum position for a clear image. This kept delays and waiting times to a minimum.

If a sonographer could not obtain a clear image during a scan due to the position of baby, staff encouraged women to take a walk and have a drink. The appointment structure meant a rescan could take place quickly.

Staff facilitated fast access to scan images and made these available to women immediately.

Learning from complaints and concerns

It was easy for women to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included women in the investigation of their complaint.

Women and those accompanying them knew how to complain or raise concerns. They could speak with staff, including a manager, on request. Staff provided complaint forms and women could also submit a complaint through the service website.

The service clearly displayed information about how to raise a concern in patient areas.

Staff understood the policy on complaints and knew how to handle them. Staff undertook training in complaints handling and resolving minor issues at the time they were raised. They were trained to respond to feedback or concerns raised on social media and online review platforms.

Managers investigated complaints and identified themes.

Staff knew how to acknowledge complaints and patients received feedback from managers after the investigation into their complaint. The provider's policy was to acknowledge receipt of a complaint immediately and then provide a resolution or update by the seventh working day.

Managers shared feedback from complaints with staff and learning was used to improve the service. This was shared through secure staff digital communication, in team meetings and in supervisions.

Staff could give examples of how they used patient feedback to improve daily practice.

The provider's complaints policy included clear escalation for women to follow if they were dissatisfied with the outcome, including contact details for a director. However, the policy directed women to submit unresolved complaints to the Care Quality Commission (CQC). CQC does not mediate complaints and instead the policy should refer to an independent service.

Are Diagnostic and screening services well-led?



Our rating of well-led stayed the same. We rated it as outstanding.



Diagnostic and screening services

Leadership

There was compassionate, inclusive and effective leadership at all levels. Leaders at all levels demonstrate 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, which aims to ensure that the leadership represents the diversity of the workforce.

Comprehensive and successful leadership strategies were in place to ensure and sustain delivery and to develop the desired culture. Leaders had a thorough understanding of issues, challenges and priorities in their service, and beyond.

The leadership team was well defined and had a clear structure that contributed to supporting staff and coordinating excellent care. The registered manager was the franchise owner and operator and held overall responsibility for regulatory compliance, with support from the directors. An area manager was responsible operationally for clinics in the local network and a clinic manager led the individual service on a day to day basis. Staff told us this structure worked well and they felt supported by readily accessible, visible leadership.

A director of ultrasound and a clinical lead worked nationally to support sonographers and scan assistants with clinical care. They provided oversight of policies and compliance with national guidance and best practice.

During our inspection we saw visible leadership and that managers readily engaged with women and those accompanying them.

Vision and Strategy

The strategy and supporting objectives and plans were stretching, challenging and innovative, while remaining achievable. Strategies and plans were fully aligned with plans in the wider health economy, and there was a demonstrated commitment to system-wide collaboration and leadership.

There was a systematic and integrated approach to monitoring, reviewing and providing evidence of progress against the strategy and plans. Plans were consistently implemented and have a positive impact on quality and sustainability of services.

The service had operated continuously during the COVID-19 pandemic and had offered additional capacity for women who could not access NHS services due to reduced availability.

Senior staff were focused on post-pandemic recovery to ensure staffing remained stable with good morale and support. They were developing the service's social media and digital presence and looking at future expansion.

The clinical lead worked with local NHS trusts to build positive working relationships and ensure the clinic was integrated into the range of health services people could access.

Fostering committed staff was a core element of the provider's strategy and was reflected in the development and promotion policy. This meant each new clinical staff member started as a scan assistant to build their clinical knowledge and skills. Following success in this role, managers provided structured training and support for people to progress to team leader roles and beyond.



Diagnostic and screening services

Managers collated requests for services the clinic did not currently provide and monitored these for future planning. For example, a manager said the clinic received a lot of queries about pre-pregnancy fertility testing and were working with the senior team to consider a possible future offer.

Culture

Leaders had a clear shared purpose and strived to deliver and motivate staff to succeed. There were high levels of satisfaction across all staff, including those with protected characteristics under the Equality Act. There was a strong organisational commitment and effective action towards ensuring that there was equality and inclusion across the workforce.

Staff were proud of the organisation as a place to work and speak highly of the culture. Staff at all levels were actively encouraged to speak up and raise concerns, and all policies and procedures positively support this process.

There was strong collaboration, team-working and support across all functions and a common focus on improving the quality and sustainability of care and people's experiences.

Staff we met were friendly, welcoming, and confident. They spoke positively about their roles and demonstrated pride in their work and a deep-seated belief in the quality of the brand.

Marketing in the clinic, on social media and the website displayed a strong emphasis of care for women. This was reflected in the range of personalised displays in the clinic, such as photos of scans alongside the newborn baby. These were submitted voluntarily by women after birth and staff created a display focused on people's happiness and positive experiences. Staff had created another display of scans that showed babies in different positions and labelled them whimsically, such as 'The shy babies' and 'The posy babies'. This was demonstrative of the positive culture staff created.

The professional culture of the provider was one of continuous improvement and innovation. Senior directors and clinical leads empowered and encouraged local leaders and staff to engage with community partners to drive service improvement, such as with research teams in universities. Staff were engaged and passionate as a result and proactively explored new ways of working when this could result in improved care outcomes.

The service had a whistleblowing policy that enabled staff to raise concerns confidentially with any member of the senior team. Managers we spoke with understood their responsibilities in the event they received a whistleblowing complaint and all staff were aware of the procedure to follow. They said they felt confident the senior team would act appropriately.

Governance

Governance arrangements were proactively reviewed and reflected best practice. A systematic approach was taken to working with other organisations to improve care outcomes.

Governance processes were embedded in the operation of the service and managers were clear about their role within them. The governance framework enabled staff to deliver safe and effective care and reflected the nature of the service.



Diagnostic and screening services

The registered manager maintained oversight of safe recruitment processes, regulatory compliance, and maintenance of equipment and premises. They worked closely with the provider senior team to ensure policies and guidance were up to date and to respond quickly to recommended changes made by relevant organisations. Monthly mini audits and an annual audit included all these areas and was the basis for establishing standards of care and planning improvements.

The registered manager reviewed quality and safety performance as part of team meetings. They used these meetings to share learning from incidents, complaints, and other feedback.

Management of risk, issues and performance

There was a demonstrated commitment to best practice performance and risk management systems and processes. The organisation reviewed how they function and ensured that staff at all levels have the skills and knowledge to use those systems and processes effectively. Problems were identified and addressed quickly and openly.

Directors managed risk, issues, and performance at provider level and the registered manager was responsible for these locally. The technical director held responsibility for reviewing, updating, and cascading clinical and operational policies with support from the clinical lead and director of ultrasound.

The senior team had plans in place to cope with unexpected events, such as suspension of the service.

The registered manager operated a policy of no lone working, which meant no member of staff was ever left alone in the clinic. This applied to sonographers carrying out scans and a scan assistant was always present when women were undergoing scans.

Staff understood the procedure to follow if a woman or someone accompanying them were aggressive or threatening. They said this was a rare occurrence and short tempers were usually related to stress during the pandemic.

Staff had access to policies and guidance electronically and in hard copy and knew how and when to refer to them.

Staff completed fire safety and evacuation training as part of the mandatory programme, including annual refreshers and updates. The clinic manager carried out quarterly fire drills, including unannounced evacuations.

Where women noted they were undergoing care or treatment on a defined pathway with another provider, including the NHS, sonographers encouraged them to remain in the care of their main clinical team. The service did not provide second opinions on scan results or pregnancy care and staff ensured women understood this before undergoing scans.

Managers completed appropriate risk assessments to help staff to continue working safely when their circumstances changed. For example, the clinical lead carried out risk assessments for staff who were expectant mothers.

The clinic manager maintained up to date records of the status of local NHS services commonly used for referrals. This meant sonographers knew when to refer patients to alternative hospitals or departments when usual referral pathways were unavailable.



Diagnostic and screening services

Information Management

The service invested in innovative information systems and processes that promoted best practice. The information used in reporting, performance management and delivering quality care was consistently found to be accurate, valid, reliable, timely and relevant.

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.

Information and data management systems were integrated and secure. A director maintained oversight of information management and was the responsible officer for data security and protection. Processes were in place to respond to data requests from the Information Commissioner's Office (ICO) promptly. The senior team maintained a privacy promise policy that detailed how data was used and stored and how women could request more information or data destruction.

Staff completed mandatory training on information governance and cyber security. This included their responsibilities under the UK general data protection regulation (UK-GDPR). The provider approved data access requests on a tiered level depending on the seniority of staff. This meant data was only accessed when necessary and minimised the risk of a data breach.

The service asked women attending gender scans to bring hospital notes confirming they were at least 16 weeks pregnant. The provider implemented this requirement after a series of incidents in which women attended appointments too early for an accurate scan. Sonographers managed this information at the time of the scan and returned documentation to women before they left.

The provider managed the movement of data between the clinic and NHS services for the purpose of clinical referrals. This ensured personal data was shared securely and with consent.

Social media was managed centrally with oversight from the director of franchise and information governance lead. The service had responded to an increase in requests from women to share baby scan images and new-born baby images online by creating governance processes to ensure confidentiality and personal data were protected. This ensured consent processes were followed and women's requests to post their scan images or experiences were published only when information was fully anonymised. Women signed consent for this process and could withdraw this at any time. The team had established innovative ways of using social media for information sharing that empowered women to take more control over their pregnancy care.

The service used overt CCTV for security purposed in non-clinical areas. A permitted users policy was in place, signed and reviewed by the authorised person and was up to date. The policy indicated the need for yellow 'CCTV in use' signs, which we saw in practice. These data were stored only for crime prevention purposes and stored for a maximum of 30 days.

Engagement

There were consistently high levels of constructive engagement with staff and people who used services. Rigorous and constructive challenge from people who used services, the public and stakeholders was welcomed and seen as a vital way of holding services to account.



Diagnostic and screening services

Services are developed with the full participation of those who use them, staff and external partners as equal partners. Innovative approaches are used to gather feedback from people who used services and the public, and there was a demonstrated commitment to acting on feedback.

The service took a leadership role in its health system to identify and proactively address challenges and meet the needs of the population.

Staff told us they felt involved in the running of the service and were able to give feedback and suggestions. Staff worked closely with colleagues in another of the provider's clinics in the region to help support capacity and learning.

Managers reviewed and responded appropriately to feedback from women in real time. The brand had an active social media presence and managers monitored this to ensure feedback was captured and confidentiality maintained.

The service sent out post-scan surveys and encouraged women to leave feedback using any platform with which they felt comfortable. Staff supported women to leave feedback in any way convenient to them and maintained records of all feedback received. They demonstrably used this to improve services available.

Staff told us managers were visible and easy to communicate with through secure messaging, phone or in person. During the pandemic, the senior team maintained regular contact with staff and provided wellbeing support in recognition of the extra pressures on the service from restrictions. This was a part of a strategy to reduce the risk of turnover and to ensure staff had the mental health capacity they needed.

The provider held conferences twice annually for franchise owners and registered managers. This was a structured opportunity to keep up to date with the operation of the business and to share learning, experiences, and challenges with colleagues from clinics across the country.

The clinical lead offered emotional support to staff on demand after they had to deliver bad news to women. The provider offered further support for staff wellbeing where needed.

Learning, continuous improvement and innovation

There was a fully embedded and systematic approach to improvement, which made consistent use of a recognised improvement methodology. Improvement was seen as the way to deal with performance and for the organisation to learn. Improvement methods and skills were available and used across the organisation, and staff were empowered to lead and deliver change.

Safe innovation was celebrated. There was a clear, systematic and proactive approach to seeking out and embedding new and more sustainable models of care. There was a strong record of sharing work locally, nationally and internationally.

The service had launched a high definition (HD) live video streaming service during scans. This meant women's loved ones could view the scan live as it took place remotely. This service helped families who could not travel to scans during the pandemic and meant more of the people important to women could share their experience. The service was digitally secure and protected by layers of electronic protection. The provider had improved the service based on early feedback from women and people who had tried the HD streaming service. This included providing sonographers with microphones so they could narrate the scan as it happened for people watching.



Diagnostic and screening services

Staff outlined potential misconceptions about private healthcare and demonstrated passion and keenness to change this. Managers were in the process of inviting colleagues who worked in NHS early pregnancy and foetal units to visit the clinic and learn more about the services and standards of care. The senior team was also working with specialist non-profit agencies to build understanding of their services and had invited their staff and volunteers to meet women who used the service.

The provider had introduced a new electronic system to manage women's scan pathway whilst in the clinic. This meant the sonographer completed their report and finalised scan images before women attended the reception desk for their prints. This helped reception staff plan for any next steps, such as if the woman needed water and a walk to reposition baby or if the sonographer had found abnormalities and needed to explain these to the woman.

Staff were demonstrably passionate, enthusiastic and committed to the development of women's health care and supporting good health outcomes. They worked with regional universities to support leading edge research on baby scanning services and foetal abnormalities and proactively engaged with artificial intelligence and digital platforms to improve women's experiences. Staff undertook such work within governance frameworks that ensured research was ethical and adhered to each university's ethical committee clearance. Staff were demonstrably invested in such research because of its potential to improve the standard of work and women's outcomes, both in this clinic and across the sector as a whole.

The provider was demonstrably proactive in seeking to test new technology that could improve women's experience. They were working with an artificial intelligence (AI) platform to improve the safety and accuracy of scans and enable issues to be identified much more quickly than at present. The project team had proof of concept of the AI technology and planned to test this in real time with a sample of clinics.

The senior clinical team and directors responded quickly to increased demand during the COVID-19 pandemic. The clinic network experienced a substantial increase in requests for scans from women who had miscarried and knew they carried just an embryonic sac. The NHS was unable to provide support due to service redeployment for COVID-19 and the clinical lead and directors worked to fill this gap. They established new guidelines and protocols, in line with national Royal College of Obstetricians and Gynaecologists (RCOG) best practice, within five days. A senior member of the team said this reflected the ethos of the organisation, "We have to be ready to give women what they need. We can't just say, 'We haven't written a protocol for that' – we need to write it and make sure it's safe."

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation