D.I. Harries Cramlington Limited

Window to the Womb

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?	Outstanding ☆
Are services well-led?	Outstanding ☆

Summary of findings

Overall summary

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 provided good care and treatment. 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.
- Staff were visibly motivated to provide exceptional care and took additional steps to ensure women with treated warmth and kindness. Staff adapted services following requests from women and tailored the care to ensure sensitive compassionate care delivery. The service ensured women understood their care fully, through continues review and ensured women were empowered as partners in their care.
- Women's individual needs and preferences are central to the delivery of tailored services. Facilities and premises are bespoke and innovative and there is a proactive approach to understanding the needs of those women using the services. The service embraced innovation to ensure women received an exceptional experience within an environment with was bespoke to the services provided.

All leaders demonstrated a commitment to provide a high quality service for all women using the service. The provider embraced new technology and sought to harness new advances within the sector, both at research and operational level. Leaders encouraged women to have an active voice when designing services and supported open lines of communication to continually shape and improve the service. Staff fully 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 receiving care. Staff were clear about their roles and accountabilities.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Outstanding ☆	

Summary of findings

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Summary of this inspection

Background to Window to the Womb

The Window to the Womb service at Cramlington, is operated by D I Harries Cramlington Limited. The clinic opened in January 2022 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 offers an early pregnancy clinic (from six to 15 weeks of pregnancy), and a later pregnancy clinic (from 16 weeks of pregnancy).

The service has a registered manager in post since January 2022 and a second registered manager had also recently been appointed in March 2023.

The service is registered with CQC to undertake the regulated activity of diagnostic and screening procedures.

We have not inspected this service before

How we carried out this inspection

The team inspecting the service comprised of a CQC lead inspector and an inspector. The inspection was overseen by Sarah Dronsfield, Deputy Director of Operations.

Our inspection took place on 08 March 2023, using our comprehensive inspection methodology. The inspection was announced with short notice to ensure the service was operational on the day of our visit and enable us to observe routine activity.

During the inspection visit, the inspection team;

• inspected all five key questions and rated four; ('effective' key question is not rated for diagnostic imaging services)

• observed four scanning procedures

• looked at the quality of the environment and observed how staff cared for service users

• spoke with the registered manager

• looked at a range of policies, procedures and other documents relating to the running of the service

• spoke with fourteen service users and their families

We also reviewed performance information about the service, digital applications and information provided to us by the service.

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.

Summary of this inspection

Outstanding practice

We found the following outstanding practice:

- There was a strong visible person-centred culture with staff delivering exceptional and personalised emotional care.
- The service was very conscious of the emotional needs for women attending scans depending on the stage of their pregnancy. It purposely ran the early (6-16 weeks) and later (16+ weeks) pregnancy clinics at different times which ensured no cross over of woman attending. This meant that women who were anxious about their scan or had previous pregnancy losses did not share the same area with women who were much later in their pregnancy and who would be celebrating gender reveals and buying merchandise.
- Staff actively listened to feedback from the women using the services and tailored services to ensure absolute privacy and discretion.
- The provider ensured staff received external training with bereavement and Down's Syndrome charities.
- The service ensured staff received enhanced communication, empathy, loss and bereavement training. This meant staff could provide tailored emotional support for woman depending on different scenarios.
- Staff recognised the emotional needs of partners and carers particularly during loss or the delivery of difficult news.
- The provider recognised and enabled a support structure for women following birth and encouraged training and guidance for women through external agencies.
- The service was involved in the LGBTQ+ community and have rainbow coloured gender reveal balloons and bears in order to be more inclusive.
- The provider ensured the service and facilities were bespoke to the needs of women, ensuring the premises were tailored to provide and exceptional experience.
- The service collaborated with regional university to develop intuitive smartphone technology which was free to women using the service.
- The provider reached out to external specialists within the sector to ensure policies and guidance available was reflective of the latest best practice and research developments.
- The registered manager ensured relationships with NHS colleagues were continually strengthen and both locally and outside of the usual area. This ensured women could be referred quickly and easily following scan showing abnormalities or concern.
- The provider actively took steps to be at the forefront of technology to enable safer services for women requiring ultrasound scanning.
- The service worked closely with local charities raising funds for local services in the area.

Our findings

Overview of ratings

Our ratings for this location are:

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

Outstanding

Diagnostic imaging

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

Is the service safe?

Good

We rated safe as good.

Mandatory training

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

We reviewed the mandatory training policy which included a clear description of what mandatory training was required for each role within the organisation and when it needed to be completed.

The mandatory training was comprehensive and met the needs of women and staff. The clinic manager monitored training compliance through a matrix and records showed compliance with training was consistently above 90%. Staff had protected time to complete this. They completed additional training for patients with mental health needs and the Oliver McGowan training, to support women and those who supported women with a learning disability and autism.

The provider had also developed a training checklist to ensure all training had been completed. This included additional development training needs.

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.

We reviewed safeguard policies for both women and children. Policies included clear definitions of safeguarding, including female genital mutilation (FGM) and domestic violence and we saw contact details of the local authority to enable staff to raise appropriate alerts.

All staff received level 3 child and adult safeguarding training.

No safeguard alerts had been made by the provider in the last twelve months, however staff knew how to make a safeguarding referral and could give examples of how to protect women from harassment and discrimination, including

those with protected characteristics under the Equality Act. Staff were able to articulate areas of particular concern, for example those attending under the age of eighteen. Staff followed safe procedures for children visiting the service and ID checks were sought for all adults accompanying these young women. We saw prompts were also in place on the booking system to ensure these checks were made.

Posters were placed in private communal areas which provided emergency contact information and support for women experiencing harm such as harassment and domestic violence.

All staff had the required Disclosure and Barring (DBS) checks completed.

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.

All areas of the clinic were visibly clean and had new and suitable furnishings which were clean and well-maintained.

We reviewed the infection control policy, which included clear guidance on the cleaning and disinfection of transvaginal probes, cleaning and storage of mops, which were also colour coded, cleaning of the sink, cleaning of the floors, and hand washing.

Staff followed infection control principles including the use of personal protective equipment (PPE). and we saw staff followed this guidance in practice. Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. The service had hand washing facilities and sanitising hand gel in the scan room for sonography staff to decontaminate their hands and equipment following scans.

Managers carried out regular cleaning checks including audits and staff understood their individual daily cleaning responsibilities.

Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. Bookings times were also planned to accommodate cleaning in between scans.

We saw women were asked to notify the clinic prior to attending if they had tested positive for COVID-19 within the last 10 days. Women with a positive test were asked to re book at a later stage when testing negative. We saw policies specific to COVID-19 which were regularly updated in accordance with national guidance.

We saw handwashing guidance posters displayed throughout the clinic area.

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 clinic area was spacious, light and offered a two-storey facility with several rooms across both floors, which were bespoke and individually designed by the provider. All floors were fitted with washable, hygienic materials and we saw anti slip flooring fitted to the stairs.

The service had suitable facilities and had enough suitable equipment to meet the needs of women. The stock room was well organised and adequately equipped.

Diagnostic imaging

Staff completed regular checks of stock, first aid kit and equipment and electrical equipment had undergone safety testing in the previous 12 months in line with the provider's safety policy. Managers ensured the maintenance, service and timely repair of the ultrasound scanning machine.

Fire extinguishers were accessible, stored appropriately and there were clear fire exit signs.

Staff followed a clear process to report faults or low equipment stock to the clinic manager. No ongoing concerns or faults were noted as part of our inspection.

Staff disposed of clinical waste safely. A contract was a place with a third-party provider to ensure safe disposal arrangements were in place.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each woman and removed or minimised risks. Staff knew what to do and acted quickly when there was an emergency.

Staff completed risk assessments for each patient on admission. Women seeking early pregnancy scans were contacted prior to the appointments, to ensure the provider had additional information such as allergies, health conditions, COVID -19 status, previous infections and likely gestation.

Staff understood and responded promptly to any immediate risks to women's health. The provider had a robust process for identifying risk prior to bookings and during the scan, such as the identification of previous ectopic pregnancies. Women were encouraged to bring their NHS records with them to ensure sonographers had a complete medical history.

The service provided clear guidance for sonographers to follow when they identified unexpected results during a scan. Staff were able to provide examples of women referred into their local NHS services and staff knew what to do and acted quickly when there was an emergency. In addition, the provider had carried out emergency scenarios when required to ring for an ambulance. Women requiring referral, were provided with their scan reports to share with their NHS midwives or clinicians to ensure clarity. We reviewed three referral records and saw that they were clear and comprehensive.

Women presenting as less than six weeks pregnant, were advised to rebook when they reached that point. The provider advised women of risks during pregnancy on their website and advised all women to attend their NHS appointments as usual.

Staff completed mandatory training in health and safety, emergency first aid, and fire safety. The provider carried out monthly recorded fire checks and fire evacuation training. This enabled them to monitor staff reaction in the event of an evacuation.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care. Managers regularly reviewed and adjusted staffing levels and skill mix, and gave bank, agency and locum 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.

Diagnostic imaging

The clinic manager had access to the registered manager, area manager and clinical lead at all times, in the event that advice or support was required.

The clinic teamed up with a neighbouring facility which was also part of the business in the event of a staffing shortage or busy bookings period.

The service had low vacancy, turnover, and sickness rates and staff described the team as consistent and stable. At the time of our inspection the service was fully staffed with no vacancies.

Records

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

Patient notes were comprehensive and all staff could access them easily. Records were completed and stored using an electronic database, which was securely protected through encryption and passwords.

Electronic tablets were used in reception to collate COVID-19 status prior to entry into the scanning room.

Clinic staff maintained detailed records and sonographers completed accurate images and descriptions of all scans. Consent was also obtained and stored electronically.

Women using the service were provided with bespoke scan information detailing what images they had been offered and what they would expect to see. The service also offered a smart phone app offering personalised information for each woman, prior to and following their scan appointments. Women choosing not to access the app were provided with the same information in a paper format.

Clinic staff were also able to access records of the women using other clinics within the service. This provided clinic staff with previous medical information and also an indicator of the women exposure to previous scanning sound waves.

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 and personal patient data was destroyed in accordance with this policy.

Medicines

No medicines were prescribed, administered, or stored at this location.

Incidents

The service managed safety incidents well. Staff recognised and reported incidents and near misses. 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 safety alerts were implemented and monitored.

Outstanding ☆

Diagnostic imaging

The service had an incident reporting policy and staff knew what incidents to report and how to report them. Staff were able to articulate what incidents to report and how to report them, although there had been no incidents or never events reported, within the last 12 months.

Managers demonstrated clear knowledge of reporting, investigating and learning processes and all staff had completed mandatory training on Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR) and on the use of the duty of candour.

Managers told us they shared learning about incidents with their staff and across the service and told us that lessons learnt from other Window to the Womb were shared with all staff.

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. All staff we spoke with told us the provider supported an open and honest culture to speak out and raise concerns as they arose.

Is the service effective?

Inspected but not rated

We do not rate effective domain in diagnostic and screening

Evidence-based care and treatment

The service provided care and procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. Staff protected the rights of women 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 team to ensure polices were reviewed and updated in accordance with best practice and national guidance. The provider had also taken additional steps to ensure all policies were sighted and ratified by an independent renowned specialist within the sector, to ensure they were reflective of the latest national guidance and evidence-based practice.

All staff told us they could access policies both online and in paper format and we saw policies and guidance developed by the service, were methodically organised and indexed for clarity and ease. Policy updates applicable to Window to the Womb were cascaded across all clinic locations simultaneously to ensure all staff delivered care in line with requirements. Governance systems ensured records of date changes were maintained and reminders of when policies needed to be reviewed.

Staff regularly reviewed 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 provider ensured (ALARA) protocols were followed and provided guidance to women regarding this prior to and during scanning. We also saw information displayed 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 protected the rights of women subject to the Mental Health Act and followed the Code of Practice. All staff received mantal health training and were aware when and where to signpost women for support.

Nutrition & hydration

The service gave women appropriate information about drinking extra fluids and attend with a full bladder before trans-abdominal ultrasound scans to ensure the sonographer could gain effective ultrasound scan images.

Staff provided additional water during the appointment if necessary.

Pain relief

Staff assessed and monitored patients regularly to see if they were in pain or discomfort during scans. They stopped scans if the woman reported unusual pain.

The website contained information for women who were experiencing pain during pregnancy and signposted them to contact their midwife, GP, or NHS Website.

Patient outcomes

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

The clinic manager carried out clinical and environmental audits to ensure the best outcomes were achieved for women across a number of key performance indicators set by the franchise to monitor performance and benchmark against other Window to the Womb clinics. Areas audited included incidents, inaccuracies, complaints and scan times.

The clinical lead provided focused support for all sonographers across eleven locations. This ensured that sonographers had access to advice including a second opinion regarding imaging, during clinic hours. Digital scan images could be sent securely and quickly for further review. The registered managers also worked in conjunction with the clinical lead to provide on call support during all clinic hours.

Managers and staff carried out a comprehensive programme of repeated audits to check improvement over time. We reviewed a number of audits and saw consistently high compliance across all areas of the audit including peer review completion, scan quality and environmental checks.

Managers used information from the audits to improve care and treatment. We reviewed the clinic audit for February 2023 and saw a comprehensive review of all areas including policies, IPC, equipment, recruitment files and staff training. The auditor also reviewed previous clinic audits to ensure improvements, or any outstanding actions had been addressed. Where areas of improvement were noted, the director of ultrasound for Window to the Womb held additional management meetings to ensure changes were shared across all clinics to drive improvement.

Records were maintained for women referred into NHS services due to concern or possible abnormality detected. We saw seven referrals had been made by the service in the last 12 months. Staff told us they received feedback from the women they had referred and had strong relationships with NHS colleagues to enable swift referral including out of area access.

Outstanding ☆

Diagnostic imaging

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 women. Sonographers were required to maintain registration with the Health and Care Professions Council (HCPC) in addition to holding professional qualifications such as a bachelor's degree and a postgraduate diploma.

All staff were provided with a robust and tailored induction and were supported through this by shadowing peers until mandatory training and clinical competencies were completed. Staff told us they felt valued by the registered manager as they were given time to understand the values of the clinic and the operationally processes fully before commencing their roles. Sonographers who worked in the NHS in addition to this role shared their learning with the other sonographers.

The clinical lead and the registered managers supported sonographers in continuing professional development. Every sonographer received five peer assessments on a monthly basis. The assessment carried out by the clinical lead reviewed scan technique and the appropriateness of the imaging. Sonographers were also supported with a monthly check in process to ensure consistency against national guidance and provider policy.

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. Scenarios were completed for emergency situations or escalation.

Managers identified poor staff performance promptly and supported staff to improve. Clinical leads managed performance issues of sonographers or scan assistants and had developed a handbook to ensure consistency when addressing poor practice.

Multidisciplinary working

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

Staff located across the franchise communicated effectively with each other to share information about the service. We observed positive and effective communication and supportive working practices between staff to provide care for women.

The clinic had well-established relationships with local NHS services across several regions and the registered manager told us of the rapid referral acceptance into the local services due to the strong ongoing relationships held. We saw examples of video conferencing calls held with local NHS trusts to proactively strengthen multidisciplinary working.

Staff held regular and effective multidisciplinary meetings to discuss women and improve their care. We reviewed local and reginal meeting arrangements and saw information regarding women was consistently shared to ensure women received a positive experience.

Seven-day services

Services were available to support timely patient care.

Outstanding ☆

Diagnostic imaging

The provider's electronic booking system was monitored on a daily basis, with bookings reviewed in advance for each week, to ensure all information that was required for a safe scan. Women made appointments online using the providers 24/7 platform or by calling the clinic directly.

The franchise operating model, meant staff could work across other local clinic locations to offer flexible opening times, including evenings and weekends. At the time of our inspection the service operated five to six days a week dependent on bookings requested

Health promotion

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

The service had relevant information promoting healthy lifestyles and support in women's areas. This included printed leaflets, signposting by sonographers and information available through the providers website.

The provider had forged links with the miscarriage association to ensure a varied range of information leaflets were available to all women.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported women to make informed decisions about their care. They followed national guidance to gain women's consent. They knew how to support women who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005, Gillick competency and Fraser guidelines and knew who to contact for advice.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff made sure patients consented to treatment based on all the information available. Consent information was available in multiple languages to help women understand their rights and options. Staff clearly recorded consent in women's records. We reviewed the records of five women and saw consent was completed fully.

Staff took additional steps to ensure women aged between 16-18 were appropriately supported. We saw the provider recorded identification checks including those adults accompanying at the time of the scan.

Staff received mandatory training in the Mental Capacity Act and Deprivation of Liberty Safeguards. Obtaining appropriate consent was included as part of induction training and initial new recruitment shadowing support.

Is the service caring?

Outstanding ☆

We rated caring as outstanding.

Outstanding ☆

Diagnostic imaging

Compassionate care

Staff treated women with compassion and kindness and went the extra mile to ensure their privacy and dignity was respected. Staff were visibly motivated to provide high quality person centred care and feedback from women and families using the service was continually positive.

Staff were discreet and responsive when caring for women. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed women and their families attend the clinic for their scans. Women were greeted with warmth and kindness and we observed staff took individual families to bespoke areas of the clinic to relax with loved ones prior to their scans. Large families told us they were relaxed and were still able to feel private due to the spacious setting of the clinic.

The registered manager had also considered the needs of women attending for scans accompanied with younger children. Sonographers noted the additional level of discretion and privacy needed to enable young children to remain in the scan room with mothers, whilst sensitively providing additional privacy. Women were offered a modestly screen so that all members of the family could participate in the experience.

Women said staff treated them well and with kindness. We spoke with 16 women and their families who told us that staff were 'amazing', 'perfect', 'they can't do enough'. We saw in excess of 50 thankyou cards to staff, praising them for their kindness throughout their pregnancy's. The joy that women expressed was visible during our inspection.

Large groups of families were made to comfortable with ease and the scanning room benefited from an extra-large wall sized mounted monitor, providing clarity and sound quality in high-definition detail. We observed four scans and saw staff explain each step calmly and clearly, taking time to point out baby's individual features and movement, creating an experience which families told us they would 'remember forever'. Staff demonstrated a genuine interest and excitement during every scan that we observed.

We heard how the service was involved in the LGBTQ+ community and we saw rainbow coloured gender reveal balloons and bears in order to be more inclusive.

Emotional support

Staff provided tailored emotional support to women, families, and carers to minimise their distress. They understood women's personal, cultural and religious needs and were active partners in their care. The environment was specifically designed to ensure women's emotional needs were fully supported. Staff ensured women's experiencing previous trauma were recognised and protected.

Staff gave women and those close to them help, emotional support and advice when they needed it. The service proactively ensured women and those supporting these women were emotionally supported throughout their journey. The registered manager who was a midwife specialising in bereavement, ensured communication was tailored to the needs of each woman, scan and outcome scenario. Staff were supported to deliver exceptional communication, empathy and understanding support to the women and families using the service.

Staff undertook training on breaking bad news and demonstrated empathy when having difficult conversations. Staff recognised the trauma of a miscarriage or abnormality detected from a scan and worked to address this by providing intensive emotional support and rapid referrals to specialist agencies. Scan assistants supported women at every scan, providing both chaperone and emotional support.

Diagnostic imaging

The service had a dedicated quiet room for women and families receiving distressing or difficult news, which provided complete privacy and dignity away from the main area of the clinic. We saw staff had received breaking bad news training to ensure upsetting information was delivered in a considerate and supportive way. This training was completed as part of induction so that staff were fully prepared to support women's needs.

The registered manager described the additional support offered to women experiencing trauma or miscarriage, for example discussing and providing keepsake scans or heartbeat recordings.

The service was mindful of supporting women who arrived on their own and had clear guidance for staff to follow, especially if unfortunate news was given. We saw every woman referred into the NHS services received a follow up call, to check on their wellbeing and provided additional support.

Women experiencing a miscarriage prior to their scan were offered a refund.

We reviewed several thankyou cards from women who had experienced this support and praised staff for their kindness and consideration.

The provider had also contacted the miscarriage association to source leaflets and information for the partners of women experiencing miscarriage. This information included dealing with feelings of loss and grief and provided additional signposting to specialist support should it be required.

The providers pre-scan questionnaire enabled women to advise of any previous trauma such as sexual assault or miscarriage. Women refusing a trans vaginal examination were fully supported, as sonographers had the additional understanding, as to reasons why this would not always be appropriate.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. The service also encouraged women to download a smartphone app, which was developed by the provider and a local university and was bespoke to the service. The app offered a function to enable women to monitor their mood and also signposted support and advice prior to, during and after pregnancy. We saw the app in use and found the navigation through the screens to be user friendly and engaging.

Women also had access to 'Instant Midwife' which was a brand new 24/7 service providing instant online pregnancy support.

We saw staff completed equality and diversity mandatory training which covered dignity, privacy and respect. Staff recognised, understood, and respected the personal, cultural and social needs of patients and the diverse group of women who accessed the service.

Understanding and involvement of women 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 to provide detailed support to women and those close to them, to understand their condition.

Staff empowered women who used the service to have a voice in their care and needs. 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.

Outstanding ☆

Diagnostic imaging

Staff made sure women and those close to them understood their care and procedures. We observed staff providing detailed clear information regarding each aspect of the experience, from the process of booking through to what to expect and options available including costs and scan options. Women had an opportunity to choose the scan images immediately after the scan which would be printed out as part of their presentation photos. We observed staff involving younger siblings and family members during this time to ensure everyone felt involved.

Women and their families could give feedback on the service and their treatment and staff supported them to do this. Staff proactively sought out feedback and we saw information for women and families throughout the clinic as to how to do this. Women's feedback was clearly important to staff, who explained how the importance of providing women with the very best experience at every visit.

Feedback was very positive and indicated people's engagement with staff. One woman noted, "Really lovely girls here, who make it really special."

Staff supported patients to make informed decisions about their care. The service 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.

Is the service responsive?

Outstanding ☆

We rated responsive as outstanding.

Service delivery to meet the needs of local people

Services are tailored to meet the needs of individual people and are delivered in a way to ensure flexibility choice and continuity of care.

Staff proactively planned and organised services so they met the changing needs of the local population. For example, opening times were adjusted to reflect women's working pattern and hours.

Facilities and premises were appropriate for the services being delivered. The provider took the decision to purchase the building which enabled the premises to be specifically designed to maximise women's experience of their visit. The clinic was easy to access and was clearly signposted and was bright and welcoming with a range of colourful displays of scan options and personal baby photographs shared by mums who had been supported by the clinic. The clinic provided ample car parking facilities.

Diagnostic imaging

The service offered fetal wellbeing scans, gender scans, growth scans and women's health scans, encompassing 2D, 3D, and 4D scanning technology. 4D scans were more challenging to obtain with clarity and staff provided information in advance to women about what they could do to improve the chances of a clear image. The service offered a re-scan service if 4D images could not be obtained at the planned time.

The booking system sent out automatic reminders ahead of appointments and the service offered flexibility in short notice rebooking in some circumstances, such as work or family commitments. 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 each individual's circumstances when rebooking.

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. Women's individual needs and preferences are central to the delivery of tailored services.

Managers made sure women and their loved ones and carers could get help from interpreters or signers when needed and utilised a third party provision to enable translation.

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. We saw the provider had policies in place to support staff with this.

Each woman completed a pre-scan questionnaire, on which they could declare any reasonable adjustments they needed to safely and comfortably attend the appointment. Those women seeking an early pregnancy scan were contacted in advance of their appointment to ensure staff collated all additional information required to ensure women were safe.

The service offered women a range of baby keepsake and souvenir options, which could be purchased, 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 maintained links with a number of specialist pregnancy and miscarriage charities. The registered manager ensured these relationships were used appropriately to meet women's needs and that they could be contacted in urgent situations.

The clinic had also introduced 'bring back baby days' which encouraged women to revisit the clinic following pregnancy and receive face to face guidance and information from local groups such as paediatric first aid baby and toddler groups. The recent introduction of these groups had received positive feedback, with mums liaising through a group chat forum on a social media platform.

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 could signpost women to a number of specialist pregnancy and miscarriage charities and online pregnancy and support groups. We saw examples of signposting during our inspection.

Outstanding ☆

Diagnostic imaging

Access and flow

People could access the service when they needed it. They received the right care and their results promptly. Technology is used innovatively to ensure people have timely access to treatment, support and care.

Staff facilitated same day appointments and provided direct telephone access to the clinic when it was not open to the public. Women could also make appointments online 24-hours, seven days a week using the providers electronic booking system. Women were also able to view previous booking information through the new smartphone app.

Previous scan information was comprehensive and included images with the supporting narrative and guidance for women so that they could fully understand the imaging.

The service provided reassurance scans for women who could not get an early appointment in the NHS.

The service did not overbook clinics and did not operate a waiting list. There was provision to extend service provision according to the general demand required.

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

The service clearly displayed information about how to raise a concern in patient areas. We saw information available in all areas of the clinic we visited.

Staff understood the policy on complaints and knew how to handle them. All staff we spoke with were able to articulate the complaints process and understood duty of candour processes. Staff spoke passionately about the importance of resolving any concerns quickly for the women who use their services and encouraged feedback at every opportunity. All women we spoke with during the inspection told us they understood how to make a complaint or provide feedback where appropriate.

Managers investigated complaints and identified themes. The provider maintained records of any concerns or complaints that arose. We saw the provider had received one complaint within the last twelve months, which was quickly resolved informally, outside of the formal complaints process.

Managers shared feedback from complaints with staff and learning was used to improve the service. Managers shared lessons learned from complaints across the franchise. We heard positive ways of how these had improved the service.

Women were also offered rescans if they were dissatisfied with the scan image quality.

Outstanding ☆

Diagnostic imaging

Is the service well-led?

Outstanding ☆

We rated well led as outstanding.

Leadership

Leaders demonstrated compassionate, inclusive and effective leadership skills at all levels. The registered managers and clinic lead held significant experience within the sector and displayed the capacity and capability needed to deliver excellent and sustainable care.

There was a deeply embedded system of leadership development with a well-defined leadership team. One of the registered managers was the franchise owner and operator and held overall responsibility for regulatory compliance, with support from director of ultrasound and the clinical lead. As part of strengthening the current management support, a second registered manager had also been appointed.

The clinic manager was responsible operationally for the Cramlington clinic and 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. Senior staff worked to support all clinics nationally and were able to demonstrate flexibility and continuity of support to all locations. One of the registered managers gave a recent example of this when supporting two registrations site visits on the same day, across two geographical areas.

The 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. Leaders demonstrated a deep understanding of issues, challenges, and priorities in their service and beyond.

Leaders ensured managers were equipped with the skills, training, and experience to carry out their roles fully. Additional training was provided to managers by the provider, which was bespoke to the service.

Vision and Strategy

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 service.

The registered managers were able to articulate the franchise strategy and plan for the future and were able to define key objectives for the growth and sustainability of the service, moving forward.

The provider was committed to achieving the very best outcomes for the women and the vision had been developed in collaboration with people who used the service and external partners.

We saw proactive development of the providers electronic booking systems and collaboration with universities across key areas of research affecting women who use the services.

Outstanding ☆

Diagnostic imaging

The provider understood the importance of a digital presence and accessibility for those women seeking services and we saw plans for future expansion and service development. The registered managers 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 and a competent workforce was a core element of the provider's vision and staff told us the personalised training provided from the point of induction ensured they fully understood every woman's needs.

Following induction, managers provided structured training and support for staff to progress including shadowing opportunities and individual skills and training assessment checks.

Culture

Leaders had an inspiring shared purpose and strived to deliver and motivate staff to succeed. 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 in the quality of the experience women received.

Staff morale was positive and the women using the service told us staff were always friendly and helpful. Several women told us they had returned to the service for subsequent pregnancies and 'would not go anywhere else'.

The professional culture of the provider was one of continuous improvement and innovation. Senior clinical leads empowered and encouraged local leaders and staff to engage with community partners to drive service improvement, such as with national 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. 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 new born baby. These were submitted voluntarily by women after birth and staff created a display focused on people's happiness and positive experiences.

The service had a whistleblowing policy and freedom to raise concerns policy which encouraged staff to raise concerns with their manager or the franchises freedom to speak up guardian.

All staff had access to an employee assist programme and free counselling for an external human resources company should they require it.

All staff told us they felt supported by leaders of the organisation and told us they could contact managers at any time if they required it. Staff described the culture as 'a strong family' and spoke passionately about the care they provided.

Governance

Governance arrangements were proactively reviewed and reflected best practice. A systematic approach was taken to working with other organisations to improve care outcomes and the provider took steps to ensure policies not only reflected national guidance but were aligned to emerging best practice within the sector.

The registered manager had overall responsibility for clinical governance with support from the franchise directors. The governance framework enabled staff to deliver safe and effective care and reflected the nature of the service. Senior leaders had allocated roles, such as named safeguarding leads and overall policy review. The registered manager maintained oversight of safe recruitment processes, regulatory compliance, and maintenance of equipment and premises. All sonographers were required to hold HCPC registration alongside professional sector qualifications.

Local managers worked closely with the providers senior team to ensure sonographers worked consistently through a defined audit programme and peer assessment process. Policies were clearly indexed and were comprehensive to the needs of the service. The organisation and layout of information was methodical and easily accessible to all staff.

Managers kept staff personnel and training files in paper format and audited them monthly. A monthly senior management report ensured that sonographers were reviewed individually to ensure consistency of monitoring. These meetings also included a review of each clinic within the franchise. Agenda items were standardised and included scan reviews, abnormalities detected for referral, clinic concerns and medical complaints.

All staff understood their roles and responsibilities. They told us this was due in part to the robust induction they received and understanding of the vision of and values of the organisation. Registered managers ensured peer support discussions aligned to regulatory key lines of enquiry and service objectives.

The clinical lead reviewed quality and performance through individual sonographer assessments and checks in and all staff were included in monthly team meetings which looked at the sharing of 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.

Registered managers addressed risk, issues, and performance at both provider and local clinic level and were able to demonstrate a comprehensive understanding of the service risks in terms of both clinical and operational areas.

The senior team had plans in place to cope with unexpected events, such as suspension of the service due to flood or fire and we saw arrangements to utilise both staff, premises and equipment from a local clinic, also connected to the franchise if needed.

The registered manager operated a policy of no lone working, which meant no member of staff was every 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 completed fire safety and evacuation training as part of the mandatory induction programme, including annual refreshers and updates. Emergency scenarios were also carried out to ensure staff responded quickly to women who required urgent care.

Diagnostic imaging

The clinic manager carried out quarterly fire drills, including unannounced evacuations. The registered manager was responsible for overall risk management in the clinic, such as completion and documentation of Legionella testing.

We saw the service had valid insurance covering both public and employer liability, including professional indemnity insurance for registered professional staff.

The provider ensured women completed additional medical history information prior to early pregnancy scans and 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 and attend all usual NHS appointments and scans.

The service did not provide second opinions on scan results or pregnancy care and staff ensured women understood this before undergoing scans.

The provider ensured that all sonographers received regular auditing to ensure ALARA guidance was adhered to and the appropriateness of scans were monitored. Imagining quality was also reviewed for each sonographer as part of a monthly programme of review and all staff received consistent supervision and appraisal support.

We saw risk was a standardised agenda item on both local and national staff meetings. Shared themes regarding risk were shared to ensure the potential for harm was minimised. For example, women whom may have received several ultrasound scans in quick succession.

Information Management

The service invested in innovative and best practice information systems and processes. The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

Information and data management systems were integrated and secure. A registered manager was the responsible officer for data security and protection.

Staff completed mandatory training regarding information governance and confidentiality and information held about women was managed in accordance with the providers data management policy.

The provider had developed in collaboration with a local university, a smart phone app that was accessible to all women using the service. The provider encouraged women to download the app prior to the scan appointment, so that women could access information ahead of their scans. This included confirmed bookings, scan descriptions and what to expect during the scan. The app also had the ability in which to detect mood changes during users' pregnancy and fertility journeys, in order to support and improve female mental health and wellbeing. This application was exclusively available to women using the provider's service. Women could also track their pregnancy, retrieve the details of any previous appointments, and provide them with access to an online pregnancy support service and information such as the risks associated with ultrasound scanning. The secure smart device application had an appointment booking facility to allow women to securely view their scan images and videos remotely.

The providers social media platform was managed centrally with oversight from one of the registered managers. The service had responded to an increase in requests from women to select additional scan images following their appointments. The introduction of the smartphone app enabled women to share their images and video to social media sites, or other individuals, as they so wished.

Those women choosing not to use the app, were able to select and save images using encrypted memory sticks or paper print outs.

The team had established innovative ways of using social media for information sharing and we saw women using the service had also established a group for ongoing support and information sharing.

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. 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.

Staff told us they felt involved in the running of the service and were able to give feedback and suggestions. Managers reviewed and responded appropriately to feedback from women in real time and leaders made changes to the service in response to this feedback.

The brand had an active social media presence and managers monitored this to ensure feedback was captured and confidentiality maintained. Managers supported and encouraged a monthly user group of women who had used the service to help provide ongoing support and advice. The service sent out post-scan surveys and encouraged women to leave feedback using any platform with which they felt comfortable.

Staff told us managers were visible and easy to communicate with through secure messaging, phone or in person. The provider held monthly meetings for clinic managers, as 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. External providers were encouraged to participate in staff meetings and training.

The clinical lead offered emotional support to sonographers 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

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them.

The service had embraced innovation and sought to design software that incorporated and meet the expectations of women using the service. Women told us extended family members were able to feel involved in the experience as scan recordings can be shared and retained as memories.

The service was digitally secure and protected by layers of electronic protection. The provider had improved the service based on early feedback from women regarding the types and number of images that they wanted to see.

Outstanding ☆

Diagnostic imaging

Referral questionnaires were reviewed as part of an ongoing process of feedback from women. Women were routinely asked how the service could best support them following difficult news and follow care to women was regularly amended to ensure the individual needs of women were met.

The provider acknowledged that not all women wanted to continue with their pregnancy and sought additional information from the miscarriage association to ensure women were adequality supported and understood their options.

It was evident during inspection that women and their families were welcomes at every stage of their pregnancy and beyond. The introductions of 'bring your baby back days' brought women together to share support and advice and provided an opportunity to listen to external speakers.

Staff acknowledged the misconceptions about private healthcare and demonstrated passion and keenness to change this. All staff we spoke with told us of the importance of providing exceptional services for women alongside NHS services. The registered manager described the strong relationships formed with NHS colleagues and some of the future expansion to possibly support some of the NHS services moving forward.

Managers regularly held video conferencing calls with external colleagues and sought to ensure recognised leaders within the sector were involved in policy development and revising.

The senior team was also working with local universities to specifically carry out research aimed at improving current outcomes for women experiencing difficulties becoming pregnant.

The provider had introduced a new electronic system to provide women with the knowledge and understanding of their scans from first visit through to delivery. Women wellbeing and mental health were supported through mood monitoring interactive software which was bespoke to the user.

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. One of the registered managers spoke of concept software which although only in discussion stage, the provider had commenced discussion with university colleagues.

The provider used digital scan simulators as a further aid for training sonographers. All sonographers we spoke with told us of the benefit of using the simulator as part of clinical competency training.

The provider was able to articulate expansion and service development across the franchise with plans to introduce women's health scans such as gynaecological and breast scans and in vitro fertilisation (IVF) scans. The planning for these services included feedback and discussion with the women whom would use them. One of the registered managers described the initial gynaecological scan would count the primary follicles but women requested that all of the follicles be tracked. As a result of this feedback the scan settings were adjusted to ensure this need was met.

They also planned to be sustainable and environmentally conscious and wanted the franchise to move towards electronic data in order to be paper light.

Staff helped fundraise for a local charity to provide heartbeat bears for neonatal families across the North East.