A & J Healthcare Enterprises LTD

Sheffield Private Pregnancy Care

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

Summary of findings

Overall summary

The service had not been inspected previously.

We rated it as good because:

- The service had enough staff to care for women and keep them safe. Staff had training in key skills and understood how to protect women from abuse. Incidents were reported, investigated and shared appropriately. The service-controlled infection risk well and they kept equipment and the premises visibly clean. The service had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm.
- The service provided care and treatment based on national guidance and evidence-based practice and monitored some effectiveness of care and treatment delivered. Staff worked well together for the benefit of the women.
- The service had a strong, visible person-centred culture. Staff were highly motivated and passionate. Women were treated with compassion and kindness and staff respected their privacy and dignity.
- There was no waiting list at the time of inspection and women told us they were able to access the service easily.

However:

- Some governance processes were not embedded such as the oversight of staff records, and the development of service risk registers.
- The provider did not collate or review data regarding booking numbers or women who were referred directly into the NHS central system.
- The provider did not have a formal system in which feedback could be collated, monitored or reviewed.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Good 	Please see summary above.

Summary of findings

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Summary of this inspection

Background to Sheffield Private Pregnancy Care

Sheffield Private Pregnancy Care is an independent pregnancy scan and antenatal support service operated by A&J Healthcare enterprises. The service offers gender, viability, reassurance, wellbeing, fertility, 3D and 4D, harmony (DNA) testing and non-invasive prenatal testing (NIPT) tests. All ultrasound scans are performed at the clinic are in addition to those provided through the NHS as part of a pregnancy care pathway. The service is run by two NHS consultants, one of which is the registered manager. Both consultants specialise in obstetrics and maternal, and fetal medicine at a local NHS trust. The registered manager (RM) had been in post since 2019.

The service, which is registered for diagnostic and screening services, provides services to adults over the age of 18.

The service currently operates from a third party hosted building within Sheffield and provides approximately 547 appointments across a year. At the time of the inspection the service did not directly employ any additional staff, however the service was supported by reception staff, two of which act as chaperones and a governance and compliance manager. This individual was also the independent nominated individual for the service. These staff are managed by the third-party host and the level of support provided, defined through a lease agreement.

Sheffield Private Pregnancy Care was registered in 2019 and had not been previously inspected.

How we carried out this inspection

We carried out a comprehensive unannounced inspection of the service under our regulatory duties on the 14 and 15 September 2022. The inspection team was made up of two CQC inspectors and one offsite inspection manager. We spoke with the registered manager, the independent nominated individual, chaperone support staff and seven patients. We reviewed a range of policies, procedures and other documents relating to the running of the service including consent, patient scanning reports and feedback letters. We reviewed nine patient records and three staff records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

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.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a service SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

- The service must ensure that effective processes are in place to manage patient outcomes including the monitoring of patient numbers, referrals into the NHS due to concern and cancelled appointments. Regulation 17(1)(2)(a)(b)

Summary of this inspection

- The service must ensure that staff records are produced and stored appropriately as per the requirements of the Registered Manager regulations. 17(2)(d)(i)
- The service must ensure there is a robust system in place in which to collect, review and address risk for the service. Including the development of a risk register. Regulation 17(1)(2)(a)(b)
- The service must ensure that the strategy outlines clear measurable objectives in which to drive improvement. Regulation 17(1)(2)(a)

Action the service SHOULD take to improve:

- The service should further develop the testing of all equipment used within the service to ensure it meets The British Medical Ultrasound Society (BMUS) recommendations.
- The service should consider developing its own sepsis and emergency policies.
- The service should ensure that information leaflets are available for all women utilising the service and are readily accessible.

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	Good	Good	Requires Improvement	Good
Overall	Good	Inspected but not rated	Good	Good	Requires Improvement	Good

Good

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

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 to meet the needs of women and staff.

Both consultants received mandatory training through the local NHS trust. We reviewed this training and saw it was comprehensive and appropriate to their role. Mandatory training topics included safeguarding, infection prevention and control, mental capacity act, equality and diversity, fire safety and resuscitation.

We also reviewed the chaperone training, which the two support staff had completed and saw that both staff had signed declarations following this training, to ensure patients privacy and dignity rights were upheld.

Information governance training had also been completed by staff working within or supporting the service.

However, the provider did not have a training policy which outlined the training needs of each staff member depending on their role or have a formal system to review the training and ensure it was up to date. Arrangements both to complete and review mandatory training was dictated by the local NHS trust arrangements and not the providers own policy. The registered manager acknowledged this and told us they would implement a service specific mandatory training policy, which would include how and when training would be reviewed. Following inspection, we saw the provider had developed quality assurance processes and had also introduced a training tracker to ensure compliance was met. We reviewed this tracker and saw all staff had achieved 100% mandatory training compliance.

Staff within the service understood their responsibility to complete training and told us training allocated was relevant to their roles.

Safeguarding

Staff understood how to protect women from abuse and staff had training on how to recognise and report abuse.

All staff received training specific for their role on how to recognise and report abuse.

Good

Diagnostic and screening services

We saw the provider had developed a safeguarding policy for both adults and children, which outlined what levels of safeguarding training staff were required to complete, according to their role. We reviewed the providers safeguard policies and saw that they were recently reviewed and were reflective of current national guidance.

We reviewed the safeguarding training certificates for both consultants and saw that they had completed level 3 adults and children safeguarding training. The registered manager was the nominated safeguarding lead for the service. In addition, we saw within the same building staff had access to lead safeguarding staff who had completed level 4 safeguarding training for both adults and children.

The staff member providing chaperone support had completed level two adults and children safeguarding training.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. All staff we spoke with were able to describe how to identify a safeguarding concern and how it should be reported. Staff were able to describe their understanding of female genital mutilation (FGM) and all staff were aware of the local safeguarding organisations, who to contact and who to escalate concerns to.

Staff understood theadditional checks required and importance of the obtaining the correct consent. No children were seen at this service and bookings were not possible through the third-party central booking system. However, the service had developed a children's safeguard policy due to the potential of children accompanying parents during appointments.

Safety was promoted through recruitment procedures and employment checks. Staff had Disclosure and Barring Service (DBS) checks completed before they could work. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups. A chaperoning policy was in place and all women were entitled to have a chaperone present for scans.

No safeguard alerts had been raised by the provider in the last 12 months.

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. We observed both the waiting and scanning rooms in which treatment was offered and saw they were clean and well maintained. The third-party host was responsible for the overall cleanliness of the rooms, although we saw the provider carried out additional cleaning checks which were fully completed and up to date.

Staff followed infection control principles including the use of personal protective equipment (PPE). All staff wore personal protective equipment where required and we saw access to face masks, alcohol hand gel and appropriate handwashing facilities. We saw staff undertake appropriate handwashing prior to and following each patient appointment and were bare below the elbow.

Staff cleaned equipment after patient contact and labelled equipment to show when it was last cleaned. We observed staff cleaning the equipment in-between each consultation and equipment such as needles, discarded appropriately after each patient use.

We saw all staff had completed level 2 infection control training.

Good

Diagnostic and screening services

All women received treatment in isolation, however women noted to have a potentially infectious condition or disease were identified through the booking process and triaged by the registered manager as appropriate. The provider was able to demonstrate the additional cleaning processes and personal protective equipment which would be used in these scenarios.

In the twelve months before the inspection, there had been no incidences of healthcare acquired infections at the location. Appropriate arrangements were in place to reduce the risk of exposure to blood borne viruses. Appropriate PPE and cleaning arrangements were in place for women undergoing non-invasive prenatal testing (NIPT).

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 to meet the needs of women' and their carers/families. The provider operated from two rooms leased through the third party host. Both rooms were situated on the first floor of the building. We observed both rooms to be bright and airy and we saw clear signage for women and their families attending appointments. A complimentary drinks machine was situated in the waiting area.

Both rooms were accessible only by stairs, however an additional room downstairs was available and used when required, for those women with mobility issues.

The scan room had adequate seating for those attending, including wipeable sofas and chairs. Staff had sufficient space, to move around the ultrasound machine for scans to be carried out safely.

The environment was appropriate for taking blood for women requiring non-invasive prenatal testing. Arrangements were in place to label, collect, store and process bloods and we saw there was an adequate tracking system in place for samples sent to the laboratory.

Staff carried out daily safety checks of specialist equipment which included the mains operating control box and the additional attachments depending on which diagnostic procedure was being undertaken. The ultrasound machine had been checked in accordance with portable appliance testing regimes (PAT). We saw transducers were thoroughly cleaned in between each patient. Calibration of the equipment was not required in accordance with the manufacturers advice that we reviewed. Although the quality assurance of ultrasound equipment was completed in practice, this was not fully documented. The British Medical Ultrasound Society (BMUS) recommend three levels of testing to include infection control and inspections for scanner and probe damage, basic display checks and further tests to assess drop-out, sensitivity and noise. Records we reviewed did not evidence drop out sensitivity and noise testing.

Staff disposed of clinical waste safely using appropriate colour coded bags which were disposed of by the third-party host.

Staff stored substances which met the ‘Control of Substances Hazardous to Health’ (COSHH) regulations in a locked room.

Assessing and responding to patient risk

Staff understood potential and actual clinical risks for each patient and took action to removed or minimised risks. Staff identified and quickly acted upon women at risk of deterioration

Good

Diagnostic and screening services

Women were able to book an appointment through either the third-party central booking system or by ringing the service direct. The provider had developed a standard operating procedure to ensure the booking criteria was followed and when to escalate a concern. The booking process prompted women to highlight any specific risks such as heavy bleeding, pain, mobility issues or specific needs, such as language difficulties. The provider described a clear criterion for acceptance into the service and staff told us that this was strictly adhered to. In addition, we saw clear recorded pathways, signposting women presenting with a medical risk, into the NHS service swiftly. We saw examples of women referred directly into the NHS service by the provider and then seen personally by the consultants at the hospital. We were able to corroborate this at the time of the inspection, although the provider did not formally collate patient numbers.

Women were advised to bring their NHS documents with them and continue with their NHS scans as part of the maternity pathway.

Scans were carried out following 'As Low As Reasonably Achievable' (ALARA) guidance and women were given the information which allowed them to make informed decisions about the risk of scanning. Staff knew about and dealt with any specific risk issues. The website also informed women of potential risks during pregnancy.

Staff knew about and dealt with any specific risk issues and the registered manager was able to describe specific risks which may affect some of the women who were requesting scans. This included women with reduced fetal movement, indications of labour and recent suspected or confirmed active rash.

The provider did not have a separate sepsis policy but followed sepsis management policies as directed by the third party host. The registered manager had also completed training on sepsis management and escalation.

The registered manager outlined clearly defined pathways for women requiring additional escalation or referral to other services. For example, fetal medicine.

Staff responded promptly to any sudden deterioration in a patient's health. The provider had access to a resuscitation equipment in the event if an emergency, which was visible during the inspection. Staff told us that the service did not have a separate emergency policy and followed the Bupa Sheffield Whitehouse Emergency policies including, Resuscitation Policy and Management of Unwell Patient Policy. A major incident grab bag was also available to staff. We reviewed policies relating to these emergency scenarios and saw that they were recently reviewed and were reflective of national guidance.

We saw the third-party host also carried out emergency scenarios to ensue all staff working within the building understood the protocols. We reviewed the last scenario and saw that it was carried out in July 2022 and included all staff.

Staff shared key information to keep women safe when handing over their care to others. The provider told us that all women whom were referred directly back into the NHS were followed up to ensure the referring consultant had received the information and any treatment or ongoing care was in place. We saw examples of this during our inspection.

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 and treatment.

Good

Diagnostic and screening services

The service was led by the registered manager who was also an NHS consultant and supported by a second NHS consultant. Both of which were specialists in obstetrics and fetal medicine at the local NHS trust.

As part of the providers lease arrangements with the third-party host, clerical and chaperone support was provided. We saw chaperone support was available on all operational clinic days. In addition, governance and compliance support was provided by a third-party clinic manager. Bookings to the service were managed through the central third-party bookings system, which was handled by the reception staff for the building.

The team numbers were enough for the number of women referred and kept women safe. There were no vacancies in the service.

No bank or agency staff were used by the provider.

Records

Staff kept 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 specific to the specific scans that were being undertaken. We reviewed the third party booking system and saw that some general medical information was requested and assessed as part of the booking arrangements. These included allergies, risks, previous pregnancies, due dates, language difficulties and the purpose of the referral. In addition, women were asked to complete a medical history prior to each appointment.

The registered manager could also access the full patients' medical records if they were known to the local NHS trust, should there be any areas of further information needed.

Records were stored securely. We saw scan reports were stored on the registered managers laptop and were password protected in accordance with current information governance guidance. We reviewed nine patient reports and saw that they were comprehensive and adhered to Royal College of Radiologists report guidance.

All information was sent through a secure platform and no paper records were kept.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines.

The service did not store or administer any medicines or controlled drugs at the time of our inspection.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. 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 up-to-date incident reporting policy, which detailed staff responsibilities to report, manage and monitor incidents. A paper-based reporting system was available which all of staff within the building had access to. Staff we spoke with knew what incidents to report and how to report them.

Good

Diagnostic and screening services

There had been no incidents including never events or serious incidents at the service from September 2021 to August 2022. 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. The provider had a duty of candour policy which staff could easily access. The duty of candour is a regulatory duty that relates to openness and transparency which requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents and provide reasonable support to that person, under Regulation 20 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. A notifiable safety incident includes any incident that could result in, or appears to have resulted in, the death of the person using the service or severe, moderate or prolonged psychological harm. Staff we spoke with were aware of the importance of being open and honest with women and families when something went wrong, and of the need to offer an appropriate remedy or support to put matters right and explain the effects of what happened.

Learning from incidents was shared through team meetings. We reviewed the most recent governance meeting minutes and saw that incidents were a regular agenda item. Patient safely alerts were shared and discussed through the third party and provider joint governance meetings.

Are Diagnostic and screening services effective?

Inspected but not rated

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 followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. During our inspection we reviewed a selection of policies and found that these were all within their review date and referred to national guidance and best practice. Policies were accessible to staff both electronically and using paper-based systems. Both consultants held significant research experience within obstetrics. This included the role of mitochondrial DNA mutations in the pathogenesis of male factor infertility, the role of cervical electrical impedance spectroscopy in the investigation of term and preterm labour. Both consultants regularly spoke at educational lectures with the UK and overseas and had published over 100 papers across the field of obstetrics and fetal medicine.

All staff we spoke with were able to refer to guidance as defined by the National Institute of Health and Care Excellence (NICE) and best practice we saw the services' policies, procedures and guidance were updated accordingly.

The service followed the 'As Low As Reasonably Achievable' (ALARA) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and British Medical Ultrasound Society, Guidelines for Professional Ultrasound Practice (December 2018). This meant consultants used the lowest possible output power and shortest scan times possible consistent with achieving the required results.

Patient outcomes

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

Good

Diagnostic and screening services

Outcomes for women were positive, consistent and met expectations. The provider completed some audits across the service. For example, waiting times for results, ultrasound scan quality reports and cleanliness.

We reviewed the 'turnaround time' audit for women receiving non-invasive prenatal testing (NIPT) completed in September 2022 and saw that 100% of women received their test results within 10 days. We also reviewed the same audit type for women receiving a harmony test between June 2022 and August 2022 and saw 100% of women received their test within 10 days.

We also reviewed the image quality audits conducted between December 2021 and March 2022 and saw that a comprehensive review of image quality was collated, including reasons as to why image quality was poor. These audits were conducted in line with the Royal College of Radiologists (RCR) advice and guidance.

The registered manager provided examples of women who had been directly and quickly referred into the NHS to be seen by specialist clinicians within the maternity, obstetric and fetal medicine departments.

Competent staff

The service made sure staff were competent for their roles.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. Training records confirmed staff had completed role-specific training. Both Consultant Obstetricians carried out the scans at the service and were registered with the general medical council (GMC) and worked in the NHS which involved mandatory training, appraisal and revalidation. They maintained continuous professional development (CPD) and attended and presented at national conferences to update and share their knowledge and skills. The registered manager was also the lead for postgraduate medical teaching at the local NHS trust and lectured on the annual Sheffield basic ultrasound and biometry course. The registered manager also organised the monthly fetal medicine multi-disciplinary regional team meetings looking at case-based discussions and outcomes. Both consultants held extensive experience within the field and had completed training in areas such as invasive prenatal diagnostics tests, amniocentesis and chorionic villus sampling. The registered manager was also certified by the Fetal Medicine Foundation in 1st trimester screening for chromosomal and structural abnormalities.

The service did not employ any additional staff, however the registered manager held regular meetings with the governance and compliance manager to discuss ongoing operational issues such as training and regulatory compliance.

Peer discussion and patient review was conducted informally. We brought this to the registered managers attention who acknowledged that it was not formally recorded, however dialogue between consultants and attendance through shared professional forums was ongoing. Following inspection, the provider submitted evidence of consultant professional dialogue and patient review processes.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. We reviewed the most recent governance meeting minutes and although they were not detailed, they included regular agenda items such as incidents, safety, patient feedback and clinical updates. Minutes of these meetings were available for all staff to review.

We saw one to one sessions which took place between the registered manager and the compliance manager to review the ongoing operational needs of the service.

Good

Diagnostic and screening services

Multidisciplinary working

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

The service worked well together and communicated effectively for the benefit of the women and their families. Consultants worked across health care disciplines and with other agencies when required to care for women. The service had established links with the local NHS trust to ensure they had effective referral pathways for women when needed and we saw examples of women who was registered directly by the service so that they could be admitted and assessed through specialist teams when needed. All staff spoke positively of team working, effective communication and peer support. We observed staff working well together and saw that governance meetings were well attended by all staff involved in the service.

The provider had developed a list of support groups for women living in the local area and access to mental health support services.

Health promotion

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

The service had limited information promoting healthy lifestyles and support in patient waiting areas.

The provider did not provide information leaflets regarding health promotion, although we saw some information leaflets and information access points in the host waiting areas. We observed the registered manager provide advice and guidance during appointments.

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 appropriate consent.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff received and kept up to date with mandatory training on the Mental Capacity Act and Deprivation of Liberty Safeguards. We reviewed the providers mandatory training tracker and saw 100% of staff had completed mental capacity act training. Although staff gained consent from women for their care and treatment, we found capacity to consent was not clearly captured or considered. We raised this with the registered manager who took immediate action to update their consent form. For example, women booking a scan must now indicate that they have completed the questions themselves or were supported to do this. Women who were not able to consent were signposted to the NHS services.

We were provided with assurances following our inspection that the action had been taken to provide clear consent processes. Staff clearly recorded consent in the women's records. We reviewed ten records and saw appropriately recorded consent.

Good

Diagnostic and screening services

Are Diagnostic and screening services caring?

Good

Compassionate care

Staff treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

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 two women undergoing scans and spoke with an additional five women. We saw and heard that staff were professional and women treated women with kindness. Women were not rushed in any way and appeared relaxed during their appointment.

Staff were very passionate about their roles and were committed to providing personalised care. Women reported feeling well looked after and were happy with the service they received.

Staff followed policy to keep patient care and treatment confidential and we saw information shared in a confidential and respectful manner.

The service operated a chaperone policy, which staff received training on. Women's privacy and dignity was protected by ensuring another member of staff attended the ultrasound scan as a chaperone.

Staff understood and respected the individual needs of each patient. We saw the registered manager explain the scans clearly and took time to answer any questions that women had. Both women were known to the registered manager due to previous pregnancies or historic assessments within the NHS setting.

Staff understood and respected the personal, cultural, social and religious needs of women and how they may relate to care needs. Staff were able to articulate the needs of a potentially diverse group of women who may receive support from the service. We saw family members including young children, accompany women during their appointments.

Emotional support

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

Staff gave women and those close to them help, emotional support and advice when they needed it. Staff worked together within the building and we observed the exchange of information between women and the registered manger during the scans. Time was taken to ensure women understood how the results of the tests or scans were used and where the information would be sent.

The registered manager told us that although they seek feedback from the women who use their services, it is not formally collated currently. Plans to introduce a patient survey had been discussed, but this was not in place at the time of the inspection.

Good

Diagnostic and screening services

Women receiving difficult information were supported by their consultant and could be referred for specialist advice and information, in addition to their usual NHS reviews. Staff recognised the emotional impact on women receiving distressing news and the need for appropriate support in such circumstances. Both consultants held significant experience of counselling women and their families when making difficult decisions regarding their pregnancy and in planning their care and management.

The registered manager had undertaken training on breaking bad news and both consultants provide lectures on breaking bad news to trainee obstetricians and gynaecologists periodically.

Understanding and involvement of women and those close to them

Staff supported women, families and carers to understand their condition and make decisions about their care and treatment.

Staff gave women and those close to them help, emotional support and advice when they needed it.

Staff took time to explain the scan or tests to women and gave them time to understand the information. We observed two scans which corroborated this. Women and their partners felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. Staff supported women to make informed decisions about their care. Staff made sure women were told about the different scans available and the costs associated with them. They were supported to make informed decisions about their care and were guided to choose the right scan depending on the stage of their pregnancy.

Consultants supported onward referrals to NHS services when scan results indicated abnormalities or other unexpected results and the reasons were fully explained. This ensured women did not leave the clinic without fully understanding where they would receive help and support going forward.

Are Diagnostic and screening services responsive?

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.

Information about services offered at the location were accessible through the third-party website and through contacting the provider directly via telephone.

The service offered a range of ultrasound scans for pregnant women; such as wellbeing, viability, growth, presentation, and gender scans and in addition offered antenatal counselling. Harmony testing and NPIT tests were also available.

The provider offered appointments three days each week and worked flexibly to accommodate all women wishing to book an appointment.

Consultants gave women relevant information about their ultrasound scan or test and women were encouraged to contact the provider directly with any additional questions or concerns that they had. We observed this practice at the time of the inspection and saw that consultants replied directly to women whom were seeking additional advice or have specific questions.

Good

Diagnostic and screening services

Facilities and premises were appropriate for the services being delivered and were customer centred.

The service had systems to help care for women in need of additional support or specialist intervention. We saw information provided to women experiencing mental health issues and local support contact information if required. One of the consultants had also completed mental health awareness level 1 training.

Managers monitored and took action to minimise missed appointments by confirming details of the appointments in advance. In addition, the provider had developed a policy for those women who did not attend appointments, which included a follow up call to all women who failed to attend an appointment.

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 coordinated care with other services and providers.

The provider outlined a clear criteria for acceptance to the service and women wishing to book but whom who had additional needs were identified as part of the booking process. Those women presenting with medical conditions such as pain and bleeding were signposted immediately to their NHS services. Women who were not able to consent were also referred to their midwife or NHS service.

Staff understood and applied the policy on meeting the information and communication needs of women with a disability or sensory loss. We saw the provider had access to support with translation and interpretation and hearing and was able to access these services directly.

However, the service did not have information leaflets available in languages spoken by the women and local community. We saw minimal printed information available to women accessing the building, which staff stated was due to document removal and IPC risks during COVID-19. The provider acknowledged the lack of printed information and took steps to reinstate the information.

Access and flow

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

Women were able to book a scan or a test through the third party central booking system or by contacting the service directly. Approximately 547 women were seen annually across three days each week and appointments were managed through the third-party central booking system.

We saw that patent referral information was reviewed by the registered manager at least seven days prior to the appointment date and contact was made with the referring health care professional should any additional information be required. However, the provider did not collate information regarding the types of scans and tests booked or the numbers of women referred into the NHS for specialist support. Therefore, the provider was unable to provide assurance that women were seen quickly and appropriately by specialist professionals.

Managers monitored waiting times and made sure women could access services when needed. We saw there was no waiting list at the time of inspection and women told us they could book an appointment when they needed it.

The provider told us that same day appointments were available, and we were able to corroborate this during our inspection.

Good

Diagnostic and screening services

Due to the size of the service it was not possible to replace each of the consultants during periods of absence, however if an appointment was deemed urgent, women would be prioritised according to risk and need.

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.

Women, relatives and carers knew how to complain or raise concerns. The service had an up-to- date complaints policy, which outlined procedures for accepting and investigating complaints about the service. The policy confirmed that all complaints should be acknowledged and responded to within seven working days. Staff understood the policy on complaints and knew how to handle them.

Managers investigated complaints and identified themes. We saw the provider received two complaints within the last year. One complaint related to a scanning request issue and the other relating to venepuncture concerns. We reviewed both complaints and saw that both complaints were investigated appropriately within the policy timescales.

Staff could give examples of how they used patient feedback to improve daily practice. We also saw that following the venepuncture concern a risk assessment was developed by the service to identify and support women experiencing needle phobia. We reviewed the risk assessment and saw that it was comprehensive and ensured women were provided with additional support, including environmental changes to aid relaxation.

Are Diagnostic and screening services well-led?

Requires Improvement

Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and staff.

There was a clear management structure with defined lines of responsibility and accountability. The registered manager held overall responsibility for the leadership of the clinic and both consultants had significant experience in their area of work, understood the priorities of the service and any issues that may affect it.

Supporting staff told us that there was good leadership within the service and that the manager was well respected, visible, and approachable. We observed positive team working during our inspection.

The registered manager was passionate about the service they led and worked well with the team of staff in their clinic.

They demonstrated an awareness of the service's performance, the clear criteria for the safe and appropriate management of referrals and the pathways into the NHS service to ensure all women were managed and supported safely.

Although at the time of inspection meetings pertaining to the running of the service were managed informally the registered manager took immediate steps to formalise these discussions. Following inspection, we reviewed team meeting minutes which detailed dialogue between staff within the service.

Good

Diagnostic and screening services

Vision and Strategy

The service had a vision for what it wanted to achieve. However, the strategy lacked detail to turn it into action and was not developed with all relevant stakeholders.

We reviewed the providers strategy and mission for the service which outlined the mission and values held by all staff working within the service.

The mission defined by the service was 'To provide expert advice and personalised care before and during pregnancy'. This mission was supported by a series of values, aligned to behaviours and professional standards, which all staff followed.

The provider outlined a strategy based on pricing, marketing, capacity and engagement. However, the strategy was not detailed and did not define measurable objectives for the future development of the service. There were no timescales within the strategy and no overall aim in which the service was aiming towards. External stakeholders were not included within the development of the strategy. It was not clear how the service reviewed outcomes for women against the success of the organisation and therefore we were not assured that the strategy was sufficiently detailed to support overall improvement for the organisation.

Culture

Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service had an open culture where women, their families and staff could raise concerns without fear.

All staff we spoke with were positive and passionate about the quality of the service that they provided. We observed a sense of pride within the team and a warm professional exchange between staff and the women who use the services.

The culture encouraged openness and honesty at all levels. Women were encouraged to give feedback, despite the lack of a formalised patient survey process.

Staff told us there was a culture of openness and honesty and they felt they could raise concerns without fear of blame. All staff said they felt that both consultants were very approachable and felt they could raise any concerns.

Governance

Leaders did not always operate effective governance processes, throughout the service and with partner organisations. However, staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

The provider leased a waiting area and scanning room from the third-party host. We reviewed the lease agreement and saw that some governance support was also provided through this agreement. It was not clear from the documents who had overarching responsibility for some aspects of the governance arrangements, for example, auditing and incident management. We raised this with the registered manager who acknowledged that clarity was required in order to define responsibilities within the service.

The provider did not hold information or data in regard to cancelled appointments or the overall capacity of the service to offer appointments.

Good

Diagnostic and screening services

We reviewed the recruitment records for all staff working within the organisation, however, comprehensive files were not in place to show what recruitment checks had been undertaken or what training had been completed, for the staff employed by the service.

We saw the provider followed safer staffing recruitment checking; however, files had not been maintained for the staff employed and were not subject to any audits or review. We saw electronic records showing that staff had completed disclosure and barring checks and had the appropriate employments checks in place. Following our feedback, the registered manager took immediate steps to improve staff files in accordance with the requirements as registered manager, to show clearly what records were held for each member of staff. The provider sent evidence of this following the inspection.

We requested mandatory training information for all staff and we saw training records were in place but had not been collated and stored in accordance with the requirements of the registered manager role. However, the provider took immediate steps to ensure records were improved to clearly show all training that had been undertaken and reviewed.

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
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • The service must ensure that effective processes are in place to manage patient outcomes including the monitoring of patient numbers, referrals into the NHS due to concern and cancelled appointments. Regulation 17(1)(2)(a)(b) • The service must ensure that staff records are produced and stored appropriately as per the requirements of the Registered Manager regulations. 17(2)(d)(i) • The service must ensure there is a robust system in place in which to collect, review and address risk for the service. Including the development of a risk register. Regulation 17(1)(2)(a)(b) • The service must ensure that the strategy outlines clear measurable objectives in which to drive improvement. Regulation 17(1)(2)(a)