

Baby Ultrasound Clinic Sheffield Limited

Baby Ultrasound Clinic Sheffield

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?

Good



Summary of findings

Overall summary

The service had been inspected but not rated previously. We rated it as good.

This was a comprehensive, short notice announced inspection to follow up on actions taken since our previous focused inspection in June 2022. At this inspection we inspected the key lines of enquiry within all domains.

Following the June 2022 inspection, we served the provider with a Warning Notice under Section 29 of the Health and Social Care Act 2008. The warning notice told the service that they needed to make improvements in their governance processes to ensure the quality and safety of services provided. The provider sent the CQC a report with the actions that they were taking to meet the requirements.

At this inspection, the provider had made improvements.

- 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 provided mandatory training to staff and all staff were up to date with basic life support training. The service had a process that ensured staff were reminded to renew their training when required.
- The service carried out recruitment processes to ensure that staff employed were recruited safely.
- The service managed infection risk well and had implemented more measures to protect service users and staff from infection. The service had implemented processes and systems, and staff had clear responsibilities for cleaning and checking the environment and equipment. The premises and all equipment were visibly clean.
- The design, maintenance and use of facilities, premises and equipment kept people safe.
- Staff identified and acted quickly upon patients at risk of deterioration. They completed risk assessments for women using the service. Staff were confident in how they would respond to unexpected events such as foetal abnormalities which may be identified or if a woman's health was to deteriorate.
- The service kept good care records.
- The service managed safety incidents well and learned lessons from them. The process for reporting incidents was in place and in line with the service's policies. The manager investigated the most recent incident and shared learning with the team, and it was evident that their knowledge of this had improved.
- 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 treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers.
- The service planned care to meet the needs of local people, took account of women's individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait for their results.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. The registered manager had the skills and abilities to run the service and demonstrated a better understanding of the priorities and issues the service faced. They supported their staff to develop and take on responsibilities.
- Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported, and valued. They were focused on the needs of women receiving care. The registered manager understood equality and diversity in daily work and provided opportunities for career development.

Summary of findings

- Leaders operated effective governance processes. Staff were clear about their roles and accountabilities. Leaders and teams used systems to manage performance effectively.

However:

- Although incidents were recorded, there was nowhere in the incident book to complete the severity and rating of the incident and therefore the provider's adverse incident reporting policy was not followed fully.
- The service should consider making some of their documentation more detailed. The risk register would benefit from a review date, a timescale for when actions would be completed, and the location associated with the risk being added. The service should also consider including a severity rating on the incident log, in line with the adverse incident reporting policy.
- The service did not have facilities to meet the needs of people with sight or hearing problems. There was not a hearing loop and no information available in accessible formats.
- The service did not have information leaflets available in different languages, staff understood the needs of their local population and told us information from the website could be translated when necessary.

We rated this service as good because it was safe, effective, caring, responsive, and well led.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	

Summary of findings

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Summary of this inspection

Background to Baby Ultrasound Clinic Sheffield

Baby Ultrasound Clinic Sheffield is privately operated by Baby Ultrasound Clinic Sheffield Limited. The service registered with the Care Quality Commission in 2021 and has had the same registered manager in place since then. It is registered to provide the regulated activity of diagnostic and screening procedures.

The clinic provides private ultrasound services to self-funding women who are over the age of 18 and more than six weeks pregnant. Ultrasound scans are separate from NHS standard care pathways. The service operates from a dedicated clinic with step-free access and car parking.

The service's registered manager is the clinic manager and they employ 2 receptionists and 2 sonographers, one of which was newly recruited and completing their induction prior to beginning clinical duties.

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 13 December 2022, 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.

We reviewed specific documentation including six patient records and two staff files, completed observations, and interviewed key members of staff including the Registered Manager, the receptionist, and sonographer.

We observed ultrasound scans with patients' permission and spoke with 4 patients and their partners using the service.

We looked at complaints received by the service as well as general patient feedback. The provider had recorded one incident and made one safeguarding referral.

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 **SHOULD** take to improve:

- The service should ensure entries in the risk register each have a review date, a timescale for when actions would be completed, and the location associated with the risk being added.

Summary of this inspection

- The service should consider including a severity rating on the incident log, in line with the provider's adverse incident reporting policy.
- The service should consider providing facilities to meet the needs of people with sight or hearing problems. For example, a hearing loop and information available in accessible formats.
- The service should consider providing information in languages spoken by patients and the local community, in writing or via the website.






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	Good	Good	Good	Good
Overall	Good	Inspected but not rated	Good	Good	Good	Good

Diagnostic imaging

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

Are Diagnostic imaging safe?

Good 

This service was not rated before. We rated it as good.

Mandatory training

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

Staff received and kept up-to-date with their mandatory training. All staff completed the full range of mandatory training at induction. The provider had appointed a new sonographer who was part way through their mandatory training which would be completed before commencing working with patients at the clinic.

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

Managers monitored and recorded mandatory training and alerted staff when they needed to update their training. Staff were aware of renewal dates for training, received polite reminders from the registered manager, and were able to set time aside to complete it.

Safeguarding

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

Staff received training specific for their role on how to recognise and report abuse. All staff received online training to level two for safeguarding adults and children which included female genital mutilation (FGM). The registered manager was the safeguarding lead for the organisation and was trained to level 3 and the manager at head office in Bolton was trained to level 4. Staff could access support regarding safeguarding concerns from the registered manager or head office when required.

The clinic displayed relevant posters and guidance around safeguarding and abuse. We spoke with three members of staff including the registered manager and all staff felt confident they could identify any adults or children at risk of abuse or harm.

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Staff reported any safeguarding concerns to the registered manager who completed the safeguarding referrals to the relevant authorities, as per the safeguarding policy. Staff knew they should contact the clinical lead regarding a safeguarding concern if the registered manager was not available.

Staff told us of safeguarding concerns they had discussed as a team and the escalation process they had followed. In one example, the registered manager had made a referral to the local authority. They received feedback on their referral and the registered manager and staff told us they felt confident in reporting any safeguarding concerns in future.

Staff followed safe procedures for children visiting the service. We observed staff communicating with families and staff told us they knew the signs to watch for regarding children's welfare and safeguarding.

The clinic had a "help" box, cards, and pen located in the toilet where patients were encouraged to leave a note if they were experiencing any form of abuse. The receptionist checked the toilet and box after every shift, and tried to check after every patient, to enable staff to act if a request was made. Staff reported there had been no requests for help to date.

At the last inspection we found there was no process in place to assess safeguarding risks during the booking or consent process therefore, staff had no way of identifying whether potentially vulnerable women were safe if they did not attend the service. At this inspection we found improvement. The booking and consent processes and documentation had been amended to enable staff to identify vulnerable women and follow up those where concerns were raised. All women attending were required to provide identification and their GP's name and address. We observed staff explaining to women why this was required before undertaking a scan. Measures to check improvements had been made including regular audits and discussion in team meetings around recognition of warning signs and completing welfare checks.

The service had added extra questions regarding safeguarding to their booking process and consent form. These were noted on the electronic system and patient records for staff to be aware and if a patient failed to attend an appointment and had been highlighted as high risk the necessary referral could take place.

The company had changed their policy to only scan women over 18 years old, whereas it had previously included young women aged 16 and 17 years. This change had been reflected in their terms and conditions on the company website. The clinic required a formal ID check to ensure a patient was over 18.

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. Although the waiting area seating was fabric covered, this was not in a clinical area and was regularly cleaned. There were no spills or marks found during the inspection. All other seating and furniture were suitable for easy cleaning. The service had adequate supplies of appropriate cleaning materials.

The service performed well for cleanliness and cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. At the last inspection we found cleaning records did not demonstrate that all areas were cleaned regularly as these did not include the ultrasound scanning machine. At this inspection we found evidence of

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improvement. We reviewed cleaning records for all areas and equipment. There were no gaps in recording, records were up-to-date and demonstrated that areas were cleaned regularly. Staff in the service, including the receptionists, followed the cleaning schedules and continued to complete infection prevention and control (IPC) cleaning checklists for different parts of the clinic.

Following the previous inspection in June 2022, the provider had implemented some infection prevention control measures. The registered manager was completing infection control audits in which they assessed hand and personal hygiene, personal protective equipment (PPE) and the decontamination and cleaning of equipment and rooms. The registered manager had completed monthly audits since August 2022 and all staff were found to have a good understanding of the policy and appropriate procedures that they must undertake in their roles. We also reviewed newly implemented bed cleaning and probe cleaning audits from in which compliance rates were 100%.

The sonographer cleaned the ultrasound machine daily and completed the checklist. Staff planned appointments so that there were a few minutes between every scan to clean the equipment and change PPE. We observed the sonographer cleaning the plastic cover on the couch between each patient and changing the paper roll. They also cleaned the ultrasound transducer, used non-alcohol wipes for the probe and washed their hands. We saw evidence that the sonographer had completed cleaning records for the scanning machine and the cleaning probes from all sessions we checked in November and December.

The registered manager had implemented a new policy to outline to staff how to clean each area including equipment and how often it should be done. Cleaning schedules were now more in depth to prompt staff how and when to clean the required components. Monthly audits showed 100% compliance.

Staff were aware of current government guidance for COVID-19 and had suspended testing. However, they would be required to complete a test should they experience symptoms. Staff wore face masks in patient areas and provided them for patients and families to use them during their time at the clinic. There was a poster in reception asking all visitors to wear face coverings.

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's families. The service consisted of a large waiting area which had allowed for seating to be socially distanced, was accessible, had an accessible toilet and large sonography room which was fully equipped to meet the needs of women and their families.

The service had facilities in place to dispose of clinical waste safely if required although this was not a routine part of practice. Following the last inspection in June 2022, the registered manager had spoken to the contractor for normal waste collection to ask about the possibility of being provided with a specialist collection such as blood spills. However, at the time of the inspection this had not been confirmed.

Staff carried out daily safety checks of specialist equipment. The sonographer started up the ultrasound scanner 30 minutes before the first appointment to complete a self-test on start up. The sonographer also carried out daily checks of all equipment.

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Equipment was serviced and PAT tested, and all documentation was provided to show full checks had been undertaken. PAT testing was all in date. The ultrasound machine was a year old and had a 5-year warranty with annual service and maintenance included along with management or repair of any faults. If the machine was to become unusable, the company would replace the machine, or the service engineer would come the next scanning day to carry out repairs. Therefore, only one day's list would need rebooking.

At the last inspection, paperwork for staff to evidence that they had visually checked equipment daily did not include what should be checked and had only been completed on a weekly basis. At this inspection staff had full guidance and instructions on daily checks required and documentation showed equipment had been checked every day the clinic was open.

Since the last inspection the service had implemented a policy to outline to staff how to check the ultrasound machine and when to alert the registered manager. There was also a more in depth schedule prompting staff when to check equipment and how it should be done. The registered manager carried out a monthly audit of equipment checklists and compliance was discussed in staff appraisals. The compliance to date was 100%.

Substances that are hazardous to health, for example bleach and toilet cleaner, were stored safely in a locked cupboard.

A Legionella testing policy was in place and testing had been provided when the clinic opened. However, the clinic landlord had advised the premises had no water storage, only supply.

The clinic's hand hygiene policy was provided to all staff members. A monthly audit had recently been implemented in October 2022 and 100% compliance was achieved. Hand hygiene posters were displayed in high visibility areas.

The clinic's shared shopping precinct had a back-up generator in case of loss of power supply.

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.

At the previous inspection we found staff did not assess and manage risks such as allergies, health conditions or concerns or to identify potentially vulnerable women as this information was not collected before scans on either women's booking information or consent forms and staff did not know what to do to act quickly when there was an emergency. At this inspection the service had made significant improvements and added specific questions on the booking form.

Staff were now able to complete a risk assessment for each woman when they contacted the service to book their appointment. The risk assessment requested information from women such as multiple pregnancies, number of weeks pregnant, disabilities and purpose of the scan. We found evidence that the risk assessments were documented in the booking system and the clinical lead completed monthly documentation reviews. We observed the receptionist and sonographer checking booking forms prior to patients entering the scanning room. The 'Did not attend' policy stated, and staff confirmed, women would be contacted following having not attended a scan, we reviewed a patient record that showed staff had referred one case to the local authority safeguarding team.

We also observed 4 ultrasound scans where the sonographer checked patient identification and consent and used a 'pause and check' checklist to ensure that the correct person was receiving the correct scan. They asked each woman about previous pregnancies, whether this was their first, history of multiple births, any health issues, worries, concerns,

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cramps, bleeding, date of last menstrual period (LMP), and if a midwife appointment was booked and the date. The sonographer added notes to the booking forms and updated electronic records to include any further information provided. The sonographer had access to guidance and information on 1st, 2nd and 3rd trimester problems and kept up to date flow charts in a folder with clear guidance and actions to take.

We observed staff asking women to return for another scan a week later if dating showed it was too early in the pregnancy to scan. The sonographer also took care to obtain the best possible images and asked women to turn or reposition to enable a better scanning position, or to go for a short walk.

Staff had a good knowledge of the exclusion criteria and the service's website signposted women to legitimate sources of information about potential risks of the use of ultrasound scanning. Staff were aware that women could have a maximum of three scans per pregnancy and that they were unable to scan women who could not provide consent. We observed the receptionist checking women's identification on arrival to ensure they were over 18 years of age.

At the last inspection, the service had not provided clear guidance to sonographers if unexpected results were identified on the ultrasound scan, this had led to inconsistent action in response to abnormalities seen on scans. At this inspection we found significant improvements and we observed staff explaining to women the service could not provide diagnostic scans. Staff had a good understanding of how they would manage a sudden deterioration in a woman's health whilst on the premises and their process for escalating concerns from scans that required urgent attention. The sonographer provided a detailed description of what they would do if abnormalities were discovered, which was in line with the policy. The sonographer asked the clinical lead to check all images where abnormalities were suspected.

We observed the sonographer explaining to a woman they could not discern a heartbeat and gave advice to go to their nearest early pregnancy unit (EPU). Staff made a telephone call to ensure the EPU were aware the patient would be arriving. They also attempted to request an appointment at the EPU but the EPU staff were not able to do this in the call we observed because the appointment desk was closed. The sonographer printed a report direct from the scanning machine with measurements for the woman to take to her appointment. Staff were able to send an electronic copy of the report to the EPU. We reviewed two more patient notes which showed staff had shared information to keep women safe when finding anomalies on scans and referred the concerns to the NHS or early pregnancy unit.

We observed staff advising women about the importance of attending their NHS scans and appointments.

The service had a general, COVID-19 and fire risk assessments and a fire risk evacuation procedure and environmental risk assessment in place.

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 gave all staff a full induction.

At the last inspection the provider did not ensure that recruitment procedures kept people safe from harm. Disclosure and Barring service checks (DBS), an official record

stating a person's criminal convictions, had been gained from employee's previous roles instead of their current employment. At this inspection we found this had improved. The provider had updated their policy and we found complete DBS checks had been carried out for all new and existing staff.

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The service had employed a new sonographer in August 2022 and had recently recruited another sonographer who was completing their staff induction and training. At the last inspection the manager had accessed sonography staff and locums from another baby scan clinic, and it had not been clear which clinic was responsible for ensuring staff had the right qualifications, skills and training to conduct keepsake scans. At this inspection this had improved, and the registered manager had clear and complete records for all staff which included full details of qualifications and training. Staff from the provider's head office had completed checks of all staff files onsite and the clinical lead visited monthly to undertake audits. The registered manager had plans in place to review all staff DBS and qualification updates every 6 months.

At the last inspection we found the provider did not ensure staff were carrying out their role correctly in line with the provider's registration. At this inspection we spoke with the sonographer and registered manager who confirmed that although the sonographer was fully qualified, the service did not provide diagnostic information to patients in line with professional guidance and the service policy. The service had full job descriptions in place for all staff members including clear roles and responsibilities and the clinic had updated clinical standard operating procedures.

The provider website had been updated to reflect the sonographer's professional qualifications.

The sonographer was fully qualified with several years' experience and carried out non-diagnostic scans only. They were recruited in July 2022 and registered with British Medical Ultrasound Society (BMUS) and planning to gain further registrations.

There were always two members of staff for every clinic; a receptionist and a sonographer. This ensured no lone working at any time.

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. The service offered non-diagnostic scans and patient notes were sufficient for the scans that were being completed. We reviewed 6 records that included women's details and comments regarding their pregnancy which included all relevant data for a non-diagnostic scan. Following the last inspection, the registered manager had introduced new processes which ensured consent was monitored thoroughly. Monthly audits to check that consent forms were being completed correctly were now in place and all records we reviewed showed consent was recorded.

Records were stored securely. The clinic used an electronic system, shared with the provider that ensured bookings and records were kept secure. The electronic system was stored on computers which were password protected. Paper booking and consent forms were stored securely in lockable cabinets to ensure records were only accessed by staff.

Scan images were stored within the machine and if a woman requested a copy the images were loaded onto a USB stick and could be viewed on a dedicated computer near the waiting area but out of sight of other patients and families. Women could then request copies of any images they wanted to keep.

When women were referred to an external service, the service produced an obstetric report to hand over to health care professionals.

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All records were checked and signed by the receptionist. We observed staff explaining to a patient why all details such as their age and GP details were required. The patient provided these before the scan took place. Scan records were fully completed and signed by the sonographer. The scan machine stored records and images for 3 months so these could be viewed up to that time.

The clinic kept paper records onsite for a year before transfer to head office to be kept in secure storage for a further 6 years.

Incidents

The service had an incident reporting policy Most staff recognised what an incident was and had knowledge of how to record and report them appropriately. The manager investigated the most recent incident and shared lessons learned with the team. Staff had knowledge of the duty of candour.

At the last inspection we found staff were unable to differentiate between incidents and complaints, the service had not reported any incidents and staff had not always recognised when safety incidents had occurred and therefore could not share lessons learned with the whole team. At this inspection we found improvements and staff were able to identify incidents and provided an explanation of how they would report them. Staff used a clinical standard operational practice document, which was produced for all sonographers and showed a visual flow chart of the incident reporting process.

We reviewed a recent incident. The incident log included a brief description of the incident and the actions completed. The registered manager told us that the incident recorded was the only one since the last inspection. Although the incident book was completed, the severity and rating of the incident was not included, and the provider's adverse incident reporting policy was not followed fully. Staff provided assurance that they were aware of the incident that had been recorded.

The team discussed any incidents immediately and informally. Staff met every morning prior to a clinic to discuss patient care and any points for action from the previous session. Staff used a communication diary to ensure information was passed on when staff changes occurred. The registered manager kept in touch with staff to ensure all messages were passed on. Staff also discussed incidents during monthly staff meetings and appraisals.

A regular audit was carried out by the clinical lead to look at what changes could be implemented based on the findings.

The service had reported no never events since they opened.

All staff understood what the Duty of Candour was and when it would be used.

Are Diagnostic imaging effective?

Inspected but not rated 

We did not inspect effective at the previous inspection in June 2022. At this inspection it was inspected but not rated. CQC does not provide a rating for effective for diagnostic services.

Diagnostic imaging

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 service provided care and procedures based on national guidance and evidence-based practice. The lead sonographer checked to make sure staff followed guidance. The sonographer was registered with The British Medical Ultrasound Society (BMUS) and followed up to date Guidelines for Professional Ultrasound Practice. All policies and procedures were in date. The clinical lead also provided updates and guidance and the sonographer accessed online updates from the Royal College of Radiologists and BMUS.

Patient safety was checked by the receptionist at the time of booking and by the sonographer when preparing for a scan. The electronic patient record recorded the number of scans patients had and would flag if a patient had 3 scans. Staff told us this had never happened to date but they could ensure safe levels of scanning per patient.

Staff protected the rights of women subject to the Mental Health Act and followed the Code of Practice and completed mental health awareness as part of mandatory training. Sonography staff received additional training on Deprivation of Liberty safeguards.

The service had a process for staff to communicate any psychological and emotional needs of women and their companions at handovers between reception and the scan room.

Staff ensured all women completed the booking form in full. This included details of past medical history and the consent process. Staff were aware of mental health issues for patients, in particular those arising during pregnancy, and would follow their referral processes if they suspected, or a woman discussed, any concerns.

Patient outcomes

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

Managers and staff carried out a comprehensive programme of repeated audits to check improvement over time. The clinical lead carried out regular weekly audits of scans. They checked 3 scans per month and gave feedback to the sonographer and the registered manager. The sonographer could contact the clinical lead any time for advice, a second opinion, or training update on any aspect of a scan. A new cycle of quarterly audits had begun in October 2022 and the manager used the audit findings to make immediate improvements to the service and shared outcomes with staff.

Outcomes for women were positive, consistent and met their expectations. Staff had available information technology to collect patient outcomes. The scanning machine was able to collect sonography data and images could be viewed and copied for patient use and keepsakes.

Managers and staff used the results to improve women's outcomes. Audit outcomes were consistently good, and the sonographer used feedback to make improvements to their practice. Managers shared and made sure staff understood information from the audits and used information from the audits to monitor and improve care and treatment which included improved methods of communication with patients about scan results.

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Staff checked scan times to ensure scans were carried out at the correct gestation. The sonographer recorded accurate gestation dates and measurements.

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. Staff had clear job descriptions detailing the responsibilities and limits of their role. Sonographers were fully qualified and registered with BMUS but were clear they could not provide diagnostic information to patients.

Managers gave all new staff a full induction before they started work. They completed training and shadowed the clinical lead, also completing competency checks as part of a 15 day induction prior to starting clinical practice. An additional, newly recruited sonographer was completing their induction and mandatory training at the time of the inspection. Inductions were tailored to each individual's role and their professional circumstances. For example, sonographers who had trained outside the UK undertook qualification conversion training during their induction.

Managers supported staff to develop and all staff had an annual appraisal, although the receptionist was the only member of the team eligible. Other staff had not yet been in post a full year but were aware they had an appraisal booked.

Managers supported sonographers to develop through regular clinical supervision of their work. The clinical lead provided the sonographer with clinical supervision and which included feedback from scan images and reports.

Managers identified poor staff performance promptly and supported staff to improve. We saw an example of feedback and training given following a measuring error. Follow up audits showed no further concerns regarding measurements.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. Team meetings were scheduled monthly prior to clinics starting so the full team could attend. Two receptionists worked on a rota and notes were shared with staff not on duty on the day of the meeting. The manager kept in regular contact with staff to ensure they received all information discussed and shared.

The registered manager worked with staff and the clinical lead to support and identify any specialist or additional training required, and gave them the time and opportunity to develop their skills and knowledge. The sonographer was qualified and experienced but hoped to complete additional professional registrations once the new sonographer was in post.

Multidisciplinary working

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

Staff held regular and effective multidisciplinary meetings to discuss women and improve their care. Staff met every morning prior to the clinic starting to discuss events and outcomes from the previous session. They also met in between patients when necessary to discuss a woman's needs or if a referral was required. There was sufficient time allowed between appointments to facilitate this. Clinic staff could easily contact the clinical lead or registered manager for a second opinion or advice.

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Staff spoke positively of the electronic record system and portal that enabled information sharing and clinical support for the sonographer. Staff reported they felt part of a team.

Records of team meetings showed the registered manager shared information with staff. We observed staff liaising with other health care professionals to further support the women who used the services. Staff described other scenarios when they had contacted the EPU to make appointments for patients following concerns found during scanning.

When patients had not attended for a scan after 20 weeks, staff had made calls to the EPU to inform them.

Seven-day services

Services were available to support timely patient care.

Scan appointments were available 5 days a week including evenings and weekends and the service did not provide emergency care and treatment.

All clinic bookings were made through a central electronic database which was operated by a third-party provider.

At the previous inspection the clinic had to cancel a full scanning list because the sonographer was unavailable at short notice. Staff had been unsure as to which days they would be operational due to sonographer availability and the clinic had also been closed on a number of occasions due to staff ill health. However, at this inspection there was a dedicated sonographer employed directly by the clinic in August 2022 and a newly appointed sonographer to enable the service to offer further clinic sessions. There had been no further cancelled clinics.

Health promotion

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

The service had relevant information promoting healthy lifestyles and support in patient areas. The reception area displayed posters on smoking cessation and prevention and the sonographer gave women advice about monitoring their baby's movements in the womb.

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.

At the previous inspection we found staff did not understand how and when to assess whether a patient had the capacity to make decisions about their care. Staff were unable to describe how they would apply the principles of the act or describe the legislation in which the act relates to. Staff were unable to describe how they have supported women whom may have lacked capacity.

At this inspection we found improvements. Staff received and kept up to date with training in consent, the Mental Capacity Act, Mental Capacity Act 2005, and Deprivation of Liberty Safeguards. These were included in mandatory training that all staff completed on induction and the clinical lead provided regular updates. They understood how and when to assess whether a woman had the capacity to make decisions about their care and made sure women consented to treatment based on all the information available. The provider had added consent information to the paper record. We observed the receptionist explaining to patients they needed to read the document thoroughly and all patients were allowed sufficient time to do this and signed this form before going through to the scan room.

Diagnostic imaging

We observed the sonographer checking consent with patients before commencing the scan. We reviewed completed consent forms within patient records and found these were all fully completed. We observed staff adding notes to patient records when they attended for appointments.

The service had an up to date consent policy in place. Staff worked to a rescan policy that set out a timeframe for repeated scans. Sonographers provided women with reassurance that multiple scans were unnecessary in most circumstances.

Although the service did not have a process to audit the frequency of women attending for multiple scans, staff would contact the registered manager if they had concerns. The receptionist demonstrated the electronic record that showed how many scans and appointments a patient had attended. This information was available to all clinic staff and the booking team.

Are Diagnostic imaging caring?

Good 

We had not previously inspected caring. We rated it as good.

Compassionate care

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

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

Feedback from women who used the service, those close to them and stakeholders was consistently positive about the way staff treated people. Staff took time to interact with women and those close to them in a respectful and considerate way. We observed reception staff welcome women and those accompanying them warmly and with compassion. We saw positive examples of when staff provided compassionate care to women. They were discreet and responsive and took time to interact with women in a respectful and considerate way. The sonographer introduced themselves when they first greeted people.

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

Staff followed policy to keep patient care and treatment confidential. Privacy, dignity and respect training was part of the provider's mandatory requirements for staff and at the time of our inspection all the team was up to date. Staff completed paper and electronic records at the time of the scan. Images were transferred to a USB stick for women to view on a dedicated computer near the waiting area but out of sight of other patients and families. They could select and request images with privacy if they wished.

Staff demonstrated attention to detail when ensuring privacy and dignity of women and those accompanying them. For example, staff ensured the door was closed whilst scans were underway. Staff carried out conversations about scan results in private and gave people time to understand information.

Diagnostic imaging

Staff took time to understand the individual needs of all patients and respected the personal, cultural, social and religious needs of women and how they may relate to care needs.

Emotional support

Staff provided emotional support to women, 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. We saw positive examples of emotional care from online feedback from women who had used the service. We heard a positive example from a patient following their scan. They had attended another service during previous pregnancies but spoke highly of clinic staff and the time they took to explain the scan images.

Women were able to request a chaperone, who was a member of staff, in advance of the scan appointment. If the patient had not requested a chaperone at the booking stage but wanted one the team could provide a chaperone only if an additional member of staff was available. Receptionists would rebook as soon as possible to accommodate patients' needs. We saw chaperone posters in the waiting area and scan room.

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

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. They demonstrated the need for sensitivity, individualised communication and good listening skills. We observed staff provided emotional support to women who experienced a miscarriage or other traumatic event. We observed staff taking care to contact a woman to offer support when they learned she had been signposted by another provider for a "dating scan" after she had requested a termination of pregnancy.

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 supported and involved women to understand their condition and make decisions about their care and treatment. Sonographers supported women to make decisions about the next stages of their care. Staff made it clear scans were not performed for diagnostic purposes, but we observed staff arrange onward referral to NHS services when scan results indicated concerns such as no identifiable heartbeat. This ensured women did not leave the clinic without fully understanding where they would receive help and support going forward.

The service made sure women understood their treatment by providing clear information about scan packages and costs on the website. They were supported to make informed decisions about their care and were guided to choose the right scan or package for them depending on the stage of their pregnancy.

Women reported staff took their time to explain the scan procedures and answered any questions.

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

Diagnostic imaging

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

Are Diagnostic imaging responsive?

Good 

We had not previously inspected responsive. We rated it as good.

Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of local people and the communities served.

Managers planned and organised services, so they met the changing needs of the local population.

The service offered scan appointments at evening and weekends to accommodate the needs of people who worked Monday to Friday. This had previously been subject to staff availability, but the service had recruited additional staff to ensure sufficient scanning sessions. The service offered one evening scanning session up to 9pm but had found the later appointments were not accessed in the winter months. Staff filled earlier slots first but still aimed to meet all patients' needs.

The clinic was easily accessible by public transport and there was free parking available on nearby streets.

Managers ensured that patients who did not attend appointments were contacted. This was a rare occurrence, but staff ensured they took account of patients' individual circumstances when rebooking.

Managers monitored and took action to minimise missed appointments. Staff offered flexibility in short notice rebooking in some circumstances.

Meeting people's individual needs

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

The service made reasonable adjustments to women's additional needs which were identified from the completion of a health declaration form at the booking stage. For example, the scanning couch could be height adjusted as and when required.

The entrance door to the service was on ground level and wide enough for wheelchair and pushchair access. All areas of the clinic were on the same level and were accessible. There was sufficient space in the scanning room for wheelchairs or buggies. Staff provided positive examples of providing additional support to wheelchair users.

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.

Diagnostic imaging

The service provided a range of scans to meet the stage of pregnancy and individual preferences. They directed women to other services where necessary such as patients' own GPs, midwives or EPU.

Although the service did not have information leaflets available in languages spoken by the women and local community, staff understood the needs of their local population and told us information from the website could be translated when necessary.

Staff had not had any bookings for women with additional needs such as learning disabilities or mental health issues. However, staff completed training and the receptionist was experienced in these areas. Staff would arrange reasonable adjustments for patients such as allowing extra time for an appointment to allow for all their needs to be met.

However, the clinic did not have facilities to meet the needs of people with sight or hearing problems. There was no hearing loop and no information available in accessible formats.

Access and flow

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

Bookings could be made online 24 hours a day, using the provider's website or by telephone. A central booking team checked requests and signposted patients to the Sheffield clinic.

The service did not overbook clinics and did not operate a waiting list. There were no waiting lists at the time of the inspection. 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.

The clinic offered an appointment within 7 days if the patient had to cancel. This was usually possible since the service was open 5 days a week including weekends and some evenings.

The registered manager and clinical lead discussed the scanning timescales policy with staff. Staff could add notes onto the electronic record system if follow up scans were delayed.

If a sonographer could not obtain a clear image during a scan due to the position of the baby, staff encouraged women to take a walk and have a drink. The appointment structure meant a rescan could take place quickly. About 10% of the service's total patients needed to be offered rescans for instance if a patient had attended too early in their pregnancy or attempts at repositioning could not elicit a clear enough image.

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

The service used to telephone patients if they did not attend, but staff felt if a patient had since miscarried this could be insensitive. The registered manager had designed an email template to be sent from the clinic's individual booking mailbox after any DNA which staff felt was less intrusive and meant they could avoid a potentially upsetting exchange. They had also updated their DNA policy accordingly. Patients could not book a scan without an email address.

The registered manager planned, but had not yet started, regular monthly audits of their rescan rates.

Women were guided to a centralised third-party booking system in which to book their scans. The registered manager told us that on occasion, appointments could also be booked in person or by telephone. Staff told us that the appointment booking system worked well.

Diagnostic imaging

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.

Women could provide feedback and raise concerns about care on website browser platforms, social media platforms, complaints form or by email. The registered manager responded to all positive and negative feedback.

Staff received mandatory training on complaints handling, customer service and Duty of Candour.

Complaints and informal concerns raised by patients or their families were managed sensitively.

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

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

We reviewed a complaint from a patient who felt staff had been unable to fulfil her expectations regarding a gender scan and the family had been very disappointed. The registered manager had responded with sensitivity to the complaint and the team discussed lessons learned and managing patient expectations at the next monthly meeting.

The registered manager kept a record of formal complaints and responses. Staff checked the website regularly for patient feedback and shared this with the team. The clinical lead included complaints and their management in their quarterly audit. We saw evidence of feedback to staff regarding complaints. The main lessons learned from patient feedback were around managing patient expectations. There was clear information provided to patients in line with policy and national guidance about limitations of the service, non-diagnostic scanning, and gestational limits and staff spent time explaining these to patients.

Complaints were previously sent to head office via email but at this inspection the provider had begun using a secure portal. No patient information or imaging was shared on social messenger services.

Are Diagnostic imaging well-led?

Good 

We had inspected but not previously rated well led. We rated it as good.

Leadership

Leaders had the skills and abilities to run the service. They demonstrated a better understanding of the priorities and issues the service faced. They were visible and approachable in the service for women and staff. They supported staff to develop their skills.

Diagnostic imaging

At the last inspection the registered manager could not evidence that they had the skills and abilities to run the service and they did not always understand and manage all the priorities and issues the service faced. The registered manager did not understand the challenges to clinical safety and quality and had not always identified actions to address them. There had been no arrangements in place to ensure robust vetting and checking of staff at the point of recruitment and no formal clinical supervision for the sonographer.

At this inspection we found significant improvements. The registered manager had been in place since the service was first registered with the CQC. Although the manager was very experienced in business and management, they had previously had very limited knowledge of how to manage a healthcare service. Following the last report, the registered manager had asked the head office of the franchise to share information, organisational policies and procedures that had not been provided to the franchisee when the service opened. They had also requested support from the provider's clinical lead to oversee the sonographer's clinical supervision and to share audit tools and oversee clinical audits. Using their existing business skills and knowledge and the new tools and support provided, the manager demonstrated a significantly improved oversight of the main priorities and issues of the service.

The registered manager met and communicated regularly with head office and the clinical lead and had introduced policies and procedures to enable and guide staff to carry out their roles and responsibilities. They had also introduced a range of clinical, environmental and administrative audits to ensure compliance.

Staff told us the registered manager regularly attended the clinic and was approachable at any time. Staff told us when the manager was not on site, they were accessible by phone and responded quickly to any requests. They met and communicated with staff regularly to manage and support them and the service. Staff could also access support and guidance from head office and the clinical lead when needed.

Staff explained the registered manager was approachable and supported them in their development.

The registered manager had undertaken appropriate training in lead roles such as safeguarding adults and children to level 3.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services and good customer service. Leaders and staff understood and knew how to apply them.

At the last inspection the service had a vision for what it wanted to achieve although leaders and staff were not aware of the actions required and therefore it was difficult to monitor progress.

However, at this inspection the manager and staff knew of plans for the service, understood new and additional staff had been recruited to extend opening hours, reduce waiting times, and allow staff to support each other and have sufficient time to progress and develop. Staff told us these priorities and values were discussed within meetings and appraisals and were a key focus for the registered manager.

The vision for the service was to build a reputable brand that was recognised, and good customer service was at the centre of what the service wanted to achieve.

Diagnostic imaging

Culture

Staff felt respected, supported and valued. They were focused on providing women with a positive experience of baby scanning. The service promoted equality and diversity in daily work and aimed to provide opportunities for career development. The service had an open culture where women, their families and staff could raise concerns without fear.

The registered manager promoted a positive working culture within the service that supported and valued staff. Staff said they felt supported, respected and valued. The staff reiterated the registered manager was approachable and available for them and felt they would be able to raise concerns if required.

Staff were friendly, welcoming, and confident. They spoke positively about their roles and demonstrated pride in their work. Staff came from different cultures and supported each other. Staff were aware of diversity within their locality and all had completed equality and diversity training. The clinical lead shared information with staff about cultural differences and how this might impact on behaviour. In the standard operational practice document provided to sonographers, the clinical lead referred to cultural differences that staff may face and offered solutions, for example there was advice from the World Health Organisation on avoiding the use of alcohol hand gels in relation to religious considerations.

The service encouraged women and staff to raise any issues. We saw examples of where concerns had been investigated with a view to making improvements.

Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. 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.

At the previous inspection in June 2022 we found the provider did not have processes in place to ensure staff were suitably qualified or safely recruited and for their role.

At this inspection we found improvements. The service had policies in place that were up to date, reviewed and referenced current guidelines. All staff had DBS checks completed and the registered manager had set 6-monthly review dates to ensure checks were routinely updated as required. Two new sonographers had been recruited; one in August 2022 and one just prior to the inspection. Full recruitment checks had been carried out and the registered manager kept staff files up to date with full details of their employment history, qualifications and registrations with professional bodies. No staff were shared from other clinics and all staff had job descriptions that outlined the full responsibilities of their role.

The service had improved the process for monitoring the quality and accuracy of scanning. The provider's clinical lead checked 2 or 3 sonographer reports and images a month for the accuracy and quality of the scans. This was audited and feedback given to staff along with any updates or training.

Since the last inspection, all the provider's policies had been reviewed. We looked at a selection of policies, including the infection and prevention control policy, the waste management policy, the consent policy, and the mandatory training policy and found them to be up to date and version controlled. We saw evidence the policies and procedures were to be updated every two years by an external company and whenever required by the provider's clinical lead. The registered manager distributed all new policies and procedures which the team reviewed during staff meetings.

Diagnostic imaging

The provider's clinical lead had produced a clinical standard operating procedure (SOP) for all the sonographers within the service. The sonographers had easy access to this document and told us they found it helpful that all the key information was in one place.

Clinical audits and patient record audits had been completed to monitor quality assurance and drive improvement in line with the provider's quality assurance policy. A regular quarterly audit schedule had been implemented and was in place from August 2022. The clinical lead from head office completed clinical audits and the registered manager completed environmental and administrative audits. Audits were recorded on paper forms and kept in folders but also emailed to ensure a central overview, better information governance and oversight. Managers provided results and feedback to staff including action plans for improvement which were discussed immediately if necessary, at team meetings and in appraisals and supervision.

Staff from head office had carried out the first quarterly team meeting which included topics of the day resulting from updates, guidance and audit results. The registered manager recorded staff meetings and provided minutes.

The registered manager had a system in place for reporting incidents. Staff knew the process involved in reporting incidents and passing the information on to the registered manager. There had only been one incident recorded since the last inspection which all staff had been made aware of through team meetings and appraisals.

When patients raised concerns, these complaints were investigated and taken seriously by the clinic. The registered manager wrote to patients with an apology and explanation for actions taken.

Children under 18 were not scanned, and patients' ages were checked through formal identification documents. Questions asked at the time of booking ensured vulnerable women were protected when accessing the services at the clinic.

Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

At the previous inspection we found the provider did not recognise risk and did not have any risk identification process or a risk register. Incidents were not recognised separately from complaints, there was insufficient clinical information about patients collected, and opportunities to prevent further incidents were missed.

At this inspection we found significant improvements had been made. The service had systems in place to manage performance effectively. The registered manager held regular staff appraisals; team meetings and audits to ensure that staff understood any operational issues and were completing their tasks appropriately. The sonographers had regular clinical supervision with the provider's clinical lead who also checked three of their scans per month. Their clinical supervision and appraisals also covered their scan images and quality as well as any performance support.

The manager had implemented a regular audit schedule with reminders of when they were due. This included a clinical audit by a third party as well as in house infection control, environmental and complaints audits. Action plans were then set based on the findings of the audits. The registered manager used the monthly team meeting to just discuss any concerns raised by staff so changes could be discussed and implemented based on staff experience.

Diagnostic imaging

The service had implemented a process to monitor and respond to a deterioration in women's health during their appointment in clinic. We observed staff escalated concerns in a timely manner to the registered manager and the patient's local EPU. This reduced the risk of harm that women requiring emergency care were not seen when needed.

Information had been added to the provider's website to help women identify risks and those who may be at additional risk, due to excessive ultrasound exposure. The clinic's electronic record held details of the number of scans undertaken staff told us this was limited to three during a pregnancy.

Information Management

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. The manager was aware to submit data or notifications to external organisations as required.

At the last inspection we found the service did not collect reliable data or analyse it. However, at this inspection we found significant improvements had been made. All electronic recording processes had been moved over to a secure portal and system passwords were updated regularly. Reports and images were uploaded and the service shared patient data, images and reports through the electronic record secure portal. This included outcomes including rescans and DNA's.

The service had developed an audit programme and quarterly audits had been conducted in October 2022 with review dates set for the next audit cycle.

Staff gathered feedback data from patients and families who had attended the clinic as well as outcome data which the provider used across all clinics to drive improvement.

Information that was not provided at the previous inspection had been stored electronically so it was readily available to all staff. This included servicing and maintenance records.

The registered manager shared patient details and scan dates with the lead sonographer to enable them to reference and check any complaints or clinical audit results.

The service shared information for safeguarding purposes with the local authority, but only one case had been referred at the time of the inspection. Other patient information and scan details were given directly to patients to share with their GP or NHS services.

Information on the website had been updated to reflect national clinical guidance and the team's qualifications and registrations with professional bodies.

The service had not had any safety incidents; however, the manager was aware of their statutory duty to make notifications to external organisations as required.

Engagement

Leaders actively and openly engaged with staff and local organisations. Leaders and staff collaborated with partner organisations to help improve services for women.

Diagnostic imaging

Managers sought feedback from women's experiences through email and monitored external reviews. They used this information to plan and manage services such as clinic opening times. They had recruited another sonographer and receptionist to extend the number or times of scan sessions if required.

Staff told us managers were approachable, supportive, and used the phone, emails, and team meetings for engagement. They were involved in the day to day running of the service.

Managers told us they collaborated with another clinic to help improve sonography scans and reports through assurance audits. The registered manager and sonographer discussed learning and benefits implemented from it.

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. Leaders encouraged innovation and participation in research.

All staff told us they were committed to continually learning and improving the service. The registered manager told us they encouraged innovation and feedback from staff and service users. Staff had noted that although evening appointments were offered for working families, fewer patients accessed scan appointments after dark in the winter months. The team had discussed options to reduce evening clinics and offer more appointments in daylight hours.