Starlight Ultrasound Limited

12 Crompton Street

Inspection report

12 Crompton Street
Bury
BL9 0AD
Tel: 07966015245
www.starlightultrasound.co.uk

Date of inspection visit: 02 February 2023
Date of publication: 18/08/2023

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?	Requires Improvement
Are services well-led?	Good

Summary of findings

Overall summary

We rated this location as good overall because:

- The service had enough staff with the right qualifications, skills, training, and experience to keep patients safe and to provide the right care and treatment.
- Staff kept accurate care records.
- The service managed safety incidents well and had a process to learn lessons from them.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work.
- Staff felt respected, supported, and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities.
- The service engaged well with patients and the community to plan and manage services and all staff were committed to continually improving services.
- The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided support for development.

However:

- The privacy and dignity of patients was not always maintained.
- The service did not always control infection risk well and did not always fully comply with infection prevention and control (IPC) measures.
- The service did not provide a clear understanding to patients for registering a complaint.
- The service did not improve assistance measures for patients after an incident which identified concerns regarding patient safety.
- The service did not have a formal quality review process for ultrasound images.

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 overall summary.

Summary of findings

Contents

Summary of this inspection

Background to 12 Crompton Street

12 Crompton Street is operated by Starlight Ultrasound Limited. The service registered with CQC to provide the regulated activities of diagnostic and screening procedures and maternity and midwifery services in 2019. The service provides diagnostic ultrasound scans to fee paying patients. The service encouraged patients to attend NHS scans. However, some patients chose to only have scans with the service. These were overseen by the service's registered manager who is a qualified midwife The service completed 4100 scans during the last 12 months up to the date of our inspection.

In addition to fertility and pregnancy scans, the service offers men's and women's general medical ultrasound scans as well as paediatric ultrasound scans for babies, children, and teenagers. The service completed 541 female general medical scans and 36 male general medical scans during the last 12 months up to the date of our inspection.

The service completed 18 abdominal scans on children during the last 12 months up to the date of our inspection.

At the time of our inspection the service was managed by the registered manager who was one of the sonographers for the service and was also one of the owners. There was also a joint owner who acted as the administrator and receptionist. The service also employed another sonographer. They were not working at the location during our inspection.

The registered manager had been in post since the service was registered in 2019.

This was the first time we inspected the service since it was registered in 2019.

The main regulated activity provided by this service is diagnostic and screening procedures. The service is also registered for maternity and midwifery services. However, we confirmed during our inspection that maternity and midwifery activity at this service were minimal. During our inspection, the registered manager was observed to give folic acid and samples of vitamins to patients. They also gave patients advice about contraception.

It was established that this was in scope for the service's current registration of maternity and midwifery services. Maternity and midwifery services has not been reported on separately for this service.

How we carried out this inspection

We carried out a comprehensive inspection to assess the service's compliance with fundamental standards of safety and quality. We looked at our 5 key questions of safe, effective, caring, responsive and well-led.

Two inspectors carried out the inspection at the service with off-site support from an inspection manager.

We reviewed policies and procedures, interviewed key members of staff, including the registered manager, sonographers and the senior management team who were responsible for leadership and oversight of the service. With their consent, we observed the care of 7 patients during their appointments on site. We also spoke with 5 further patients by phone about their experience of treatment and care as a service user.

Summary of 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 to improve:

- The service must ensure information and guidance about how to make a complaint is available and accessible to everyone who uses the service (Regulation 16).

Action the service SHOULD take to improve:

- The service should ensure they always comply with infection prevention and control measures and best practice (Regulation 15).
- The service should ensure it improves assistance measures for stairs at the location (Regulation 15).
- The service should ensure it has a regular formal process in relation to the quality assurance review of a sample of ultrasound images by external sources (Regulation 17).

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

Good

Diagnostic and screening services

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

Is the service safe?

Good

This is the first time we inspected the service. 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. The service had identified a training matrix for mandatory training in core subjects. Subjects included basic life support, manual handling, infection control, fire safety, and health and safety.

Other subjects included safeguarding, equality and diversity and information and security. At the time of inspection, staff we spoke with were up to date with their mandatory training and we saw evidence of this. We looked at the training matrix and sampled 4 staff files during the inspection. These showed mandatory training compliance was 100% for all staff across the service.

The mandatory training was comprehensive and met the needs of patients and staff. Most of the mandatory training was provided through an electronic learning platform which all staff could access and was updated every 2 to 3 years, depending on the training topic.

Clinical staff completed training on recognising and responding to patients with mental health needs, learning disabilities and autism. The mandatory training included Mental Capacity Act and Deprivation of Liberty Safeguards.

Female Genital Mutilation was referenced within the service's safeguarding policy. The Sonographer we spoke with stated they had training in this subject as part of their NHS employment.

Mandatory training certificates for core and contracted staff were kept in individual staff files and maintained by managers. Managers monitored mandatory training and alerted staff when they needed to update their training. The operations manager monitored staff compliance with mandatory training through an electronic system. Staff we spoke with during our inspection stated they had enough time to complete their mandatory training.

Good

Diagnostic and screening services

Safeguarding

Staff understood how to protect patients from abuse. Staff had training on how to recognise and report abuse and they knew how to apply it.

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

Staff knew how to identify patients at risk of, or suffering, significant harm and how to make a safeguarding referral and who to inform if they had concerns. The registered manager was the safeguarding lead for the service. They had safeguarding level 3 training for adults and children.

The registered manager was responsible for the review, investigation and external referral for any safeguarding concerns that had been raised by staff. However, they told us the service had not made any safeguarding referrals since they registered.

The service had a safeguarding adult and a safeguarding children policy which referenced appropriate national guidance for safeguarding.

The service had a safeguarding flowchart which directed staff to raise any safeguarding concerns to the safeguarding lead and to fill out an incident form on the electronic reporting system. All staff in the service were required to complete safeguarding training. The sonographer we spoke with stated they had completed their safeguarding training through their NHS employment, and it was level 3 for adults and level 2 for children.

The safeguarding training completed by the service included preventing radicalisation training.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. Staff kept equipment and the premises visibly clean. However, they did not always follow all infection prevention and control principles.

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

Cleaning records were up-to-date and demonstrated that all areas within the premises were cleaned regularly. The cleaning record listed each day of the week with “am/pm” and staff initialled the time slots for all areas. The service had a contract with an external company who attended at the premises monthly to complete a deep clean. We did not see any specific schedule for this, or evidence of dates deep cleans were carried out.

Staff did not always follow infection control principles including the use of personal protective equipment (PPE). The registered manager, whilst working as a sonographer, wore PPE whilst in contact with all patients during procedures which included bloods. However, they were observed to be wearing rings whilst carrying out procedures.

We saw staff cleaned equipment after each patient contact, but they did not record this to show it was cleaned. After the inspection, managers told us that they did not think it was necessary to record cleaning of equipment in between each patient.

The service’s cleaning record checklist sheets had equipment listed within the relevant areas they were in as one of the required items to be cleaned and they indicated they were cleaned at set timeframes during the days the service operated at the location.

The service had a decontamination and cleansing policy which contained additional guidance for decontamination of ultrasound probes.

The service conducted transvaginal ultrasound investigations and used individual single use gel probe covers for these procedures.

The service completed periodic hand hygiene audits. The sonographers stated they watched each other scan periodically and stated the hand hygiene audit was part of that process. It was stated in the service's infection control policy that 6 monthly supervised handwashing audits for all staff members would take place. We observed audits were completed within the service for handwashing. However, the dates of the last audits on records we saw during our inspection was July 2022.

Environment and equipment

The design, maintenance and use of facilities and premises did not always keep people safe. Staff managed clinical waste well.

The service had suitable facilities to meet the needs of patients and their families. Appointments were scheduled with sufficient spacing which meant there was enough seating and space for patients and persons accompanying them.

The premises were large enough to accommodate the business with an ultrasound room, reception, waiting area, an office, kitchen, stock room and toilet. The premises also had a retail function as the provider sold baby clothes, nursery items, gifts, and accessories.

Access to the premises was through the front entrance door, which was locked, and access was gained via intercom/ doorbell system controlled from the reception area. There was 1 step into the premises which could limit accessibility for wheelchair users. The service did not have a ramp to assist facilitating access into the premises. However, staff told us this had not been an issue for wheelchair users accessing the service in the past. Following the inspection, staff told us they planned to purchase a ramp to improve accessibility.

The waiting room was upstairs and did not have any disabled access. However, the service did offer patients and persons accompanying them the choice to remain downstairs if they requested. There was no handrail on either side of the stairs which could present challenges for people with mobility issues and heavily pregnant women. There was a glass side panel on one side of the stairs which could be used to assist movement, but it was not a specifically designed aid for movement on the stairs.

There was an incident which occurred in June 2020 where a patient slipped down the stairs. The service reviewed the incident and made enquiries with a contractor to suggest improvements which included fitting a handrail. However, no improvements were made. We observed the joint owner telling all patients to be careful as they went up and down stairs and they did draw attention to there being no specific assistance measures in place on the stairs.

The entrance, scan room, waiting room and toilet had wipeable flooring but the reception shop area along with the stairs were carpeted.

The scan room had frosted glass sliding doors with blinds behind them. It was secure during each appointment. Music was playing in the shop area so no conversations could be heard from the scan room.

The couch in the scan room was electronically adjustable and could be lowered and raised. This meant it was easier and safer for patients to use. The room appeared very clean and well maintained. There was a large television on the wall so that patients and persons accompanying them could see the scan in real time.

The service kept adequate stocks of personal protective equipment (PPE) such as masks and gloves. These were stored in original packaging and were all in date.

The service had enough suitable equipment to help them to safely care for patients. Staff conducted daily safety checks of specialist equipment. The service had an external contract for the maintenance of equipment. The contract was also for an annual inspection of the equipment which was a scanning machine. The service owned the scanning machine. The service had not had any incident of equipment breakdown since it began in 2019. The service had up to date servicing records for relevant equipment.

Staff disposed of clinical waste safely. The service had a contract with an external company for removal and disposal of clinical waste.

Clinical waste was stored outside of the main building across the street in a locked plastic wheeled container. The container was not secured to any fixture so could be removed. The service's joint owner stated the contractor stipulated how the container should be stored and decided on its location.

There was a foot pedalled clinical waste bin in the scanning room and a sharps bin on a desk. Neither were overfilled. The sharps bin was not dated. It was observed to have a temporary closure mechanism which was not in use. Waste from these storage items was disposed of as part of the overall clinical waste collection contract.

Safety testing had been completed on electrical devices. Each device had a label to show when it was last tested and when the next test was due.

Fire equipment was tested and in date, and staff knew what to do in case of a fire.

The service kept a first aid box.

There was a locked cupboard in the waiting area which was used for storing cleaning materials. We saw that they were stored appropriately and access to the cupboard was controlled by staff with no access for patients.

Assessing and responding to patient risk

Staff assessed the risks of patients and identified and acted upon patients at risk of deterioration.

Staff knew about and dealt with any specific risk issues.

Patients were asked to complete a questionnaire specifically relevant to the procedure they were having completed. There were general scan forms for adults and paediatric scan forms for children. Patients were asked to document their medical history on these forms which included any allergies. The service also had forms for patients attending for pregnancy scans. We saw copies of all these forms during our inspection.

Patients who were having pregnancy scans were asked to complete a pre-scan questionnaire about their pregnancy history, for example, previous miscarriages, stillbirths, or abnormalities as part of the appointment booking process. Staff used latex free gloves and had latex free probe covers for use when required.

Good

Diagnostic and screening services

Staff shared key information to keep patients safe when handing over their care to others. For general non pregnancy scans, patients were referred to their local hospital or GP. For pregnancy scans, the service had an adverse outcome procedure in the event that a foetal abnormality or other concerns such as no heartbeat were suspected. If major concerns were found during any type of scans, patients were referred straight to hospital.

In the case of pregnancy scans, the sonographer completed a report for the patient to take to their local hospital gynaecology assessment unit and permission was asked from the patient for the service to contact the local early pregnancy unit or their GP or midwife in order to pass on the concerns at the earliest opportunity. Urgent reports where any concerns were identified were communicated to the patients' GP within 24 hours.

The service stated they had referred 2 patients to their GP during the last 12 months up to the date of our inspection following general ultrasound scans.

The registered manager stated it was made to clear to patients that the scans they completed did not replace NHS scans. During our inspection they were observed to advise patients that they needed to keep their NHS appointments and attend any that were offered. We observed staff advise patients to contact their early pregnancy assessment unit (EPAU) if they were concerned or had any new symptoms. The service had all local EPAU, and pregnancy numbers displayed on the wall in the scan room.

The service stated they did not provide any emergency services and in the event any situation necessitated emergency services intervention, all staff were aware to direct patients to the relevant emergency service provider through their escalation and referral procedure.

Staffing

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

The service had enough staff to keep patients safe. The service was managed by the registered manager who was one of the sonographers for the service. There was also 1 receptionist / administrator. This person was not in work at the time of our inspection and the role was performed by the joint owner of the service's provider company.

The service did not use bank or agency staff in the service.

Leaders made sure staff had a full induction to the service. The induction for staff comprised of a 3-month probation period which entailed job shadowing and monthly appraisals during this period. Once staff had completed their probationary period, they had an annual appraisal thereafter. We did not see this in practice as the non-management staff employed at the time of our inspection had not worked there in excess of 12 months.

Records

Staff kept detailed records of patients' 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 were completed at the time patients attended and all staff could access them easily.

Good

Diagnostic and screening services

The service used an electronic patient record system for most patient contact. During scan appointments, the sonographer made written notes of the scan. After the scan, administrative staff then typed up the written notes into the system. Once the upload was completed, the paper records were shredded and disposed of securely. This same process was used for patients' signed consent forms.

Staff stored records securely on the electronic system. Scan images were saved on to a secure imaging portal once uploaded. Images were stored standalone on the ultrasound machine for a period of 90 days after which they automatically deleted. The scanning machine was encrypted, and password protected for access.

Incidents

Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the whole team. When things went wrong, staff apologised and gave patients honest information and suitable support. Managers did not always ensure actions from incidents were implemented and monitored.

Staff knew what incidents to report and how to report them.

Staff reported serious incidents clearly and in line with the service's policy. They stated they had not had any serious incidents in the last 12 months up to the date of our inspection.

The service had reported 3 incidents between January 2022 and February 2023. All were non-clinical and graded as low risk.

Staff understood the duty of candour. There had been no incidents reported by the service that met the threshold for implementing the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.

The registered manager was aware of their responsibility to report notifiable incidents to the Care Quality Commission (CQC) and other external organisations.

They were open and transparent and gave patients and families a full explanation when things went wrong.

Staff received feedback from investigation of incidents both internal and external to the service and met to discuss the feedback and look at improvements to patient care. The registered manager told us any reported incidents would be reviewed and discussed in team meetings so shared learning could take place. We saw evidence of this in the meeting minutes we looked at.

Managers investigated incidents thoroughly and there was evidence that changes had been made as a result of feedback received. However, this did not happen for all incidents. An example of this was where a patient had slipped on the stairs. Although immediate learning was identified to advise patients with full bladders or unstable footwear to take extra care on the stairs, improvements such as installing a handrail were not implemented.

Is the service effective?

Good

Diagnostic and screening services

Inspected but not rated

We do not rate effective in diagnostic imaging services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The registered manager was an advanced practitioner clinical specialist sonographer and registered midwife with the Nursing & Midwifery Council (NMC) and was also a member of the Royal College of Midwives, British Medical Ultrasound Society (BMUS) and the Society of Radiographers (SoR). The sonographer employed by the service was registered as a radiographer with the Health and Care Professions Council (HCPC).

The service provided care based on national guidance. The registered manager told us they used the National Institute for Health and Care Excellence (NICE) guidelines. They cited an example where guidance from NICE had changed in relation to use of ultrasound gel, moving from large containers to using single-use bottles of gel. The service immediately changed their operating practice because it was recommended in the updated guidance.

The service followed the BMUS guidelines on as low as reasonably achievable (ALARA). This meant that ultrasound exposure was kept as low as reasonably achievable and scans were conducted within minimal timescales and the thermal index or the amount of heat that may be produced, was kept to the minimum level, dependent on the type of scan being conducted.

Foetal measurements were based on BMUS guidelines, and the equipment was calibrated against these guidelines.

When we reviewed policies during our inspection, we saw each had a start date and an identified expiry or review date.

Nutrition and hydration

Staff ensured patients had drunk enough water when needed prior to their appointment. Patients could access drinking water at the location.

Patients told us they received clear instructions about how much to eat or drink before their scans.

Patients were also given instructions as part of the initial booking and this information was followed up by text message and e-mail confirmation.

Patient outcomes

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

Outcomes for patients were positive, consistent, and met expectations. Patient outcomes were measured through patient experience and satisfaction.

Managers and staff conducted a programme of audits to check improvement over time but there was no recent documented evidence of this relating to handwashing and staff peer reviewing colleagues completing scanning appointments for quality assurance purposes. These included early pregnancy scans, follicle scans, fertility scans and gender scans.

The information we saw indicated they were last completed in July 2022. However, we did observe that audit of signed consent forms was up to date. The checks were completed on a monthly basis with the most recent up to the time of our inspection being completed in January 2023.

The service completed audits for scan appointments and had data showing how many scans had been completed in the last 12 months. The data was broken down to indicate the type of scan and sex of the patients.

The service completed 4100 scans in total during the last 12 months up to the date of our inspection. The number of pregnancy related scans completed within this timeframe was 2910 and the data showed a significant majority of scans completed by the service were this type accounting for 71%. The service completed 541 female general medical scans and 36 male general medical scans during the last 12 months up to the date of our inspection accounting for 13% and 1% respectively.

Staff stated they frequently peer reviewed each other's work in a number of competencies and audits were completed relating to these areas. These included hand washing, equipment cleaning and how they communicated to patients during different types of scan appointments. They discussed feedback from the audits at team meetings and if there was anything that was deemed, they needed to do differently to improve care and treatment this was acted upon accordingly.

We checked the most recent peer review audit reports during our inspection which were dated from July 2022 and noted there was 100% compliance in the required competencies. These included obtaining consent, cleaning and infection control measures and obtaining appropriate images for the type of scan being completed which image quality.

Staff told us they completed audits more frequently as part of their quality assurance process, but these weren't documented, and they completed it more "unofficially". The sonographer told us they and the registered manager peer reviewed each other's scan images. The registered manager told us they had an external process to review images if required.

The registered manager stated they completed handwashing audits for their clinic using a national NHS audit as the benchmark.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and provided support and development.

Staff were experienced, qualified, and had the right skills and knowledge to meet the needs of patients. The service's recruitment policy stated references and original qualifications for staff would be verified and records we reviewed confirmed this. Staff were professionally registered with NMC and HCPC where applicable and were up to date with their revalidation.

Good

Diagnostic and screening services

The service offered non-invasive prenatal testing (NIPT) to patients. These were completed by the registered manager who was a qualified midwife and had received specific training for this process. We observed her to complete NIPT on 1 patient during our inspection. They fully explained the process to the patient and discussed the different test options the service offered, explaining the costs with no pressure applied. The service had provided information leaflets detailing the tests to the patient before their appointment, so they had time to read and make an informed choice.

Managers supported staff to develop through reviewing their work and identified any training needs for staff to develop their skills and knowledge. We saw evidence that the sonographers had completed additional training as part of their role. One of the modules completed was training in understanding autism level 2.

Managers gave all new staff a full induction tailored to their role before they started work. Staff completed a 3-month probation period. Once staff had completed their probationary period, they had an annual appraisal.

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

Staff stated they had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge.

The sonographers stated they peer reviewed each other's work monthly. However, we did not see evidence of this during our inspection. The most recent documented evidence in the information provided indicated they were last completed in July 2022.

The registered manager stated they also had contact with a GP and Consultant to whom they could send images for review where required. The registered manager stated they also sent images to the Consultant to review as part of audit review process, but we saw no evidence of this. The GP and Consultant were not employed by the service and the arrangements for reviewing ultrasound images was on an informal basis with no formalised contract process in place.

Multidisciplinary working

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

We saw that staff worked well together and supported each other. Patients and their families were greeted as they arrived at the service.

Staff held regular meetings to discuss patients and improve their care. They met at least every other week to catch up. If something was needed urgently, they were able to contact each other quickly to discuss and take appropriate action.

Staff stated they also followed systems for raising any urgent concerns, whenever this was needed. The process was escalating to the registered manager who would review the information and delegate externally of the provider, escalating to most appropriate organisation where required. We did not see any examples of this during our inspection.

Staff stated they had made 2 GP referrals following general ultrasound scans in the past 12 months up to the date we completed our inspection.

The service did not see patients on behalf of, or instead of, NHS and they did not have any formalised arrangements with any NHS service provider.

Good

Diagnostic and screening services

Seven-day services

Key services were available to support timely patient care.

The service was open 5 days a week. This included weekend days and weekend evenings to meet the needs of as many patients as possible who may have varied working hours or childcare commitments. However, Saturday opening hours were sometimes limited by the sonographer's availability outside of their NHS role.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent.

Staff were clear in their knowledge of consent procedures and gained consent from patients for their care and treatment in line with legislation and guidance. We observed staff taking care to explain their actions to patients in a way they could understand, involving patients in decisions about their treatment and care.

Staff clearly recorded consent in patients' records. They competed consent forms and went through them with the patients and outlined what was going to happen. If English was not their first language, they used a translation app. Staff described, and we observed, how they would involve family members in discussions to support patients in their understanding.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Staff could describe and knew how to access the policy on Mental Capacity Act and Deprivation of Liberty Safeguards.

Staff received and kept up to date with training about the Mental Capacity Act and Deprivation of Liberty Safeguards and had a full awareness and understanding of the Gillick competence and Fraser guidelines relating to obtaining consent from child patients. The registered manager was the only member of staff who saw child patients. They told us they didn't treat child patients under the age of due to low demand for the service.

Is the service caring?

Good

This is the first time we inspected the service. We rated it as good.

Compassionate care

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

We saw that staff consistently had a caring and compassionate approach when looking after patients. They ensured as far as possible that patient's privacy and dignity was maintained during treatment and care. They showed respect and caring towards family members that attended with patients.

We spoke with patients who told us they had an incredibly positive experience, had received compassionate care and the sonographer was always available to answer questions in a way that they could understand and put them at ease. Patients and families could give feedback about their treatment, and we saw how staff supported them to complete this.

Good

Diagnostic and screening services

We reviewed feedback from people who used the service. They were incredibly positive about the service they received. Feedback was received from reviews placed on the service's website and on social media platforms.

Staff followed policy to keep patient care and treatment confidential. We saw staff spoke with patients in private to maintain confidentiality.

The service's website had web links and contact numbers displayed for local and national support groups and charities about pregnancy loss and abnormalities. The service also had information cards in the clinic room, and they were given to patients where appropriate.

We saw during our inspection, there was no privacy screen for patients to change behind within the scanning room.

However, we observed the scanning room had privacy measures, namely frosted glass sliding doors and blinds within the scan room. We observed the registered manager held up a piece of couch roll whilst patients undressed in order to afford them privacy. We noted music was constantly playing in the shop area which meant no conversations could be heard from within the scan room.

Staff adapted their approach when caring for patients according to the situation. Staff were very reassuring and explained things clearly to patients. Appointments were not rushed, and staff provided as much time as needed.

We observed staff to be caring and compassionate with patients and it was evident that they took a very holistic approach.

There was a chaperone policy in place and all staff were authorised to function as a chaperone if required. The joint owner stated that one of the questions on the online booking form was whether the patient wished to have a chaperone present, and this was verified when we checked as part of the inspection process. Staff stated the policy was not frequently implemented as most patients attended with company.

Emotional support

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

We observed staff gave patients and those close to them help, emotional support and advice when they needed it. We observed staff were attentive to individual patient concerns and reassured any patients who were anxious or distressed continually showing kindness.

Staff engaged fully with patients to put them at their ease and supported their families to be involved where appropriate.

Staff understood the emotional and social impact that a person's care, treatment, or condition had on their wellbeing and on those close to them. Patients told us they had been through the best and the worst of their pregnancies with the service. They stated when they wanted short notice reassurance scans the service always accommodated them and saw them the same day.

Understanding and involvement of patients and those close to them

Staff supported patients, families, and carers to make decisions about their care and treatment.

Good

Diagnostic and screening services

Staff made sure patients and those close to them understood their care and treatment.

Staff talked with patients, families, and carers in a way they could understand. Staff took the time to explain what the scan involved and were clear about how to access results following the appointment.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this.

Patients gave positive feedback about the service. They felt staff were friendly and supportive. They also appreciated the emotional support and understanding.

People who used the service were given full information on the cost of their scan, packages available and the cost of added extras, such as confetti cannons or balloons. The clinic website showed the scan packages that were available along with the cost so people who used the service could make a choice about what they wanted.

People who used the service were able to choose the photographs they received from all the available computerised images. People who used the service were able to change their mind about the package they received and pay the balance outstanding.

Is the service responsive?

Requires Improvement

This is the first time we inspected the service. We rated it as requires improvement.

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.

The service offered several types of fertility and pregnancy scans, and also men's and women's general medical ultrasound scans. They also offered paediatric ultrasound scans for babies, children, and teenagers. However, the registered manager told us they did not currently complete paediatric scans citing low demand for this type of service. The registered manager was the only member of staff qualified within the service to see children.

Facilities and premises were appropriate for the services being delivered. Patients booked in at the main reception and were directed to a relevant waiting area for the service. Patients had access to drinking water whilst in the service.

The service had systems to help care for patients in need of additional support or specialist intervention, for example offering non-invasive blood tests that screened for specific chromosome conditions. They used two tests for Down's syndrome and other genetic conditions which were the IONA test and Harmony prenatal tests.

Managers recorded data for appointments where patients who had booked did not attend. The process was designed to ensure patients received a number of reminder notifications for their appointment. The booking system sent confirmation text messages and emails at set intervals which included 48, 24 and 1 hour prior to the appointment.

Good

Diagnostic and screening services

Managers ensured that patients who did not attend appointments were contacted. The booking system sent an email to the patient informing them their appointment had been missed and to make contact if they wished to re-book. The process ensured patients were fully aware that they had an appointment.

The system had a contingency in place for patients who had an early pregnancy scan appointment. These were still recorded as part of the missed appointment data, but the provider did not let the system send a did not attend (DNA) email as it was highly possible the patient had miscarried since booking the appointment and would not have wanted to notify the service to cancel. The service considered it insensitive to send a DNA notification in case that was the reason.

Managers stated there were not many cases of missed appointments and issues surrounding them were minimal. Where there were missed appointments, they were re-booked accordingly if still required. The service did not keep any data for DNA appointments.

Meeting people's individual needs

The service was not fully inclusive and did not always take account of patients' individual needs and preferences. Staff made some reasonable adjustments to help patients access services.

Staff had some awareness of the support needs of patients living with learning disabilities. Managers stated they had considered how they could assist patients with learning difficulties and those who may be non-verbal or struggle to read. An example of this was the sign on the door of the toilet was a picture of the toilets as well as the word.

Following the inspection, we saw the service's website provided a list of the different types of scans available. The website listed their specific details about the procedures and whether any preparation would be required. Information was available to be translated into other languages for patients whose first language was not English.

During our inspection we saw the service had some information leaflets in English but did not provide any for other languages spoken by the patients and local community. Staff told us there had been little demand for leaflets. Patients who accessed the service's website and online booking system had the option to choose their preferred language. Staff stated that interpretation requirements on site was completed using Google translate on the phone. The service did not have a policy for provision of language interpretation requirements.

In cases where patients had suffered miscarriage, staff provided additional support by contacting hospitals to arrange required follow-up appointments on their behalf.

The service did not have full accessibility for patients who were disabled or had reduced mobility. The premises did not have step free entry/exit and there was no ramp to assist wheelchair users. The waiting room was located upstairs and there was no lift access to it. There was no handrail on either side of the stairs which accessed the waiting room.

Access and flow

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

All patients attending the service were self-referred. They could book their appointments at a time and date of their choice in advance. Appointment bookings were made in person, by telephone or online through the service's website which accounted for most bookings.

Good

Diagnostic and screening services

Patients were given appointments based on their preference. There was no waiting list for appointments, and they could be seen promptly including on the same day in some instances. Patients who had to cancel their appointments were offered the option to book an alternative date and time. The service offered a complimentary re-scan if it was too early to confirm viability of a pregnancy at the original appointment.

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed time frames. Patients had a choice of appointments. During our inspection we saw that clinic appointments were kept to time, and they were not rushed.

Managers worked to keep the number of cancelled appointments to a minimum, however acknowledged on occasions that circumstances dictated this, and they were sympathetic to patients accordingly. Managers told us the service had cancelled 2 appointments in 4 years and rescheduled them to the following day.

A copy of the scan report and images was sent to patients via secure encrypted email. If a patient wanted a copy of the material to be forwarded to their GP or midwife this was facilitated accordingly. The service had a separate account from which they would send images and reports to doctors using specific encrypted software.

Consent was obtained from patients to see if they were happy for their GP to receive a copy of the report. Staff checked the consent paperwork to see if patients had ticked to say they didn't want the information shared and if they had, would speak to them before the scan to explain if there were any concerns, information sharing with other medical professionals would be required.

Learning from complaints and concerns

The service did not display information about how to raise a concern in patient areas at the location we inspected. Although, it was easy for people to give feedback and raise concerns about care received once they knew the process for doing so. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint. The service had a process to review any concerns and complaints.

Patients did not know specifically how to complain or raise concerns. All patients we spoke with said they believed they knew how they could give feedback but had not been provided any information about how to raise a concern or make a complaint. All patients we spoke with stated they had no cause to make a complaint. If they did have to, they would contact the service accordingly.

We had full sight of the provider's complaints policy during our inspection. It clearly stated how complaints would be dealt with and listed timeframes for when investigations would conclude. The policy outlined the procedure for various stages of the process.

However, the service did not display information about how to raise a concern in patient areas at the location we inspected. It was also observed the service's website did not have a complaints section for service users to obtain information in order to register a complaint.

The service's website had a link to enable customers to leave a review of the service. Following the inspection, we saw the website link was to a review platform verified by independent review management software. It was here that reviews could be posted, and they were subsequently linked to the provider's website.

Good

Diagnostic and screening services

The service's website listed a sample of reviews the company had received. Patients could give feedback at any time anonymously or with their name attached to it.

The service stated there was an automated follow up text message asking for feedback and it was very generic, and the text could not be amended. They therefore removed these for any patient who had attended and suffered a miscarriage.

Staff understood the policy on complaints and knew how to manage them. Managers investigated complaints and identified themes. The registered manager stated they had received 2 complaints in the last 12 months up to the date we completed our inspection. We reviewed the records for these complaints. These showed they had all been appropriately investigated and responded to within the service's own specified timeframe.

Staff knew how to acknowledge complaints and patients received feedback from managers after the investigation into their complaint.

Managers shared feedback from complaints with staff and learning was used to improve the service. During our inspection we were told that managers used complaint examples in team meetings, to encourage reflection and improve practice.

Managers reported the trend regarding complaints was primarily about the quality of scan images. An example given was of a patient attending for a 5d scan and the image produced was not as expected. The service offered the patient the opportunity to reattend for another scan which was complimentary at no extra cost.

Managers stated that if the occasion arose where a complaint received was complex, they would consider referring it for an independent external review. They had never had to go through that process from when they were registered to the date, we completed our inspection.

Managers stated they recognised that all feedback, especially criticism, was welcome and useful and they afforded the opportunity to make improvements in service in order to deliver the very highest standards of care, treatment, and customer service. Managers stated they were dedicated to remaining open, honest, welcoming, and transparent in dealing with all complaints, concerns, and feedback.

Examples of improvements made from complaints was implementing improved segmentation of mailing lists and updating the system to double opt-in confirmation before any marketing correspondence was sent to patients. This negated inappropriate information such as satisfaction surveys being sent to patients who had suffered upset.

The service was not a member of the Independent Sector Complaints Adjudication Service (ISCAS) or similar. We did not see any evidence of how the service provided information to patients to escalate their concerns to external organisations if they were not happy with the response to their complaint.

Is the service well-led?

Good

This is the first time we inspected the service. We rated it as good.

Good

Diagnostic and screening services

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 patients and staff. They supported staff to develop their skills.

We reviewed the personal files of senior leaders against fit and proper person criteria. We noted that senior leaders underwent a comprehensive and competency-based appointment process. This included validation of professional registrations, qualifications, and DBS checks.

Senior leaders articulated the top challenges the service faced and how to meet them.

Staff involvement was encouraged in developing services within the service's operation. Patients we spoke to were highly complementary of the registered manager and joint owner stating they were compassionate and caring and thoroughly professional. Staff told us the management team were very accessible and visible. They were there to listen and help deal with problems.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. Leaders and staff understood and knew how to apply them and monitor progress.

Leaders told us they had a vision and we saw a copy of this within the quality management policy. They stated they were quite unique as a service in that they offered a combination of private midwifery and ultrasound services. It was the owner's plan to create a calm reassuring clinic where people sought their expertise.

Leaders told us a long-term plan was the service would become a 7-day service offered at both service's locations and they wanted to employ more staff to be able to facilitate this. They told us although there was demand for scanning services, they were limited by the availability of suitably qualified staff.

Leaders said their intention was for the service to appear less clinical whilst acknowledging they were a diagnostic clinic. They stated they had specific objectives in place in order to fulfil their vision and we saw a copy of these documented within the quality management policy. Whilst they were aware of their legal and regulatory obligations, they did not view their operation as simply a task to satisfy these requirements. Leaders stated it was the framework of their business to ensure they delivered high standards of care and exceeded the expectation of patients.

The service's business plan stated their aim was to consistently deliver excellent patient care and maintain the health and well-being of the individual as their priority.

Culture

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

Staff we spoke with felt supported and valued by the management team. There was a positive culture in the service which centred on the needs of patients, with an open and friendly aspect in everyday staff communications. Staff told us they were confident in raising issues with managers and that they were both fair and approachable. If something needed changing staff knew they could speak to management freely without fear.

Staff stated managers regularly met with staff, both in groups and individual meetings. We were told that staff had the opportunity to raise any issues during team meetings.

Staff worked collaboratively and had pride in working for the service.

The service had a complaints policy and specific whistleblowing policy in place at the time of our inspection and it incorporated who to contact if staff felt they could not approach the directors in the first instance. The service had an appointed firm of solicitors to function as independent advisors for staff in the event the concern(s) related to director(s) of the service and staff felt the concerns wouldn't be dealt with appropriately if raised with them directly.

Equality, diversity, and inclusion training was in place for staff as part of annual mandatory training and was reflected in the planning and delivery of services and shaping of culture within the service. We looked at 4 staff files during our inspection and noted there was 100% compliance for completion of this training for all staff within the service. This showed the service was committed to promoting equality, diversity, and inclusion in all areas.

Governance

Leaders operated effective governance processes, throughout the service. Staff were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

We reviewed the structure of the organisation which demonstrated a clear line of management from the directors of the organisation to the staff employed.

We noted that a head of safeguarding was in post.

Governance processes were clear and enabled effective monitoring of key service information.

We looked at 4 staff files during the inspection. They included information such as identification checks, qualifications attained and training certificates. We noted that professional registrations for staff were valid and in date. We also noted there were employment and individual references in

Disclosure and Barring Service (DBS) checks were completed as part of the recruitment process at commencement of employment.

The service held monthly staff and governance meetings. Meeting minutes had no fixed agenda but included discussions of key areas of the service, such as clinic details, feedback from recent complaints, clinical issues, and service updates. Managers told us all staff completed their own notes in advance for what they wished to discuss in the meetings. These included any changes they were proposing and were discussed as a group before any changes were implemented.

Staff in the service were clear about their roles and responsibilities.

Management of risk, issues and performance

Leaders used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact.

We reviewed the service's risk register. We noted it contained information regarding open and closed risks. The description of the risk was listed and was allocated a rating of either high, medium, or low. It also listed potential consequences, action taken and outcome. There were 12 risks listed which had been marked as closed and there was 1 risk listed as open.

One of the risks identified was steep stairs leading to the waiting room and no handrail was fitted. The register showed the risk consequences were identified and listed action to be taken which was informing patients to walk slowly and indicating they could potentially use glass side panel which formed boundary and which they had listed as glass banister on the register.

During the inspection, operational leaders told us the service had a risk register which was reviewed on an annual basis. They told us the register could be updated at any time if new risks were identified. They were aware of the risks to the service and stated it was a reactive process for consulting the register if a review was required prior to the scheduled annual review date.

The service held monthly team meetings for staff during which incidents and risks was discussed.

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 secure.

The service had comprehensive digital systems for managing patient referrals, overall service activities, and staff matters. Data was collected and processed through an electronic system. This included training compliance, staff absence, staffing rotas and feedback from patients. This allowed managers to be able to make real time decisions about operational capability.

The joint owner told us they securely stored information electronically which was password protected. They had a contract with an external company to support their IT systems. We were told images were stored for a maximum period of 90 days after which they were deleted automatically. The ultrasound machine was encrypted, and password protected.

The joint owner sent images and reports to patients securely using encrypted email. They also had a separate account to send images and reports to patient's GP or appointed hospital if required using the secure software.

The service had a system in place where images were securely shared internally between their 2 locations.

Paper documentation completed within the location was processed electronically. They were collated and uploaded on site, then shredded and disposed of as secure waste.

The service had a system in place to monitor appointment times for the two locations it operated. It worked in real time so staff could see a complete up to date schedule whenever they accessed the system, and it provided information for available appointments to patients who booked by phone. Patients who booked through the service's website had access to the booking system and could see what appointments were available.

Good

Diagnostic and screening services

Staff told us they were aware of the service leads who would be responsible for making safeguarding alerts to appropriate authorities and what to do if they were not contactable. This also applied to situations where referral to patients' healthcare provider was required. The service had policies on data protection and confidentiality in place.

The service reported they had not had any data breaches in the past 12 months which were reportable to the Information Commissioners Office.

Engagement

Leaders and staff actively and openly engaged with patients to plan and manage services. They collaborated with partner organisations to help improve services for patients.

The service held monthly staff meetings to review, improve and share service updates. Meeting notes showed discussions had taken place to ensure the service and staff were maintaining good standards. We saw that staff meetings were formally documented with standing agenda items for discussion and staff could contribute their views.

The service worked with a faith-based charity who assisted patients going through In-vitro fertilisation (IVF) treatment who could not afford to pay for the treatment. The charity funded IVF treatment and the service completed follicle tracking scans for patients who had received assistance from the charity. The service completed the scans at a reduced charge for patients referred by the charity, as they wished to assist patients in the local community.

The service promoted feedback on their experience from patients who used the service. Patients were invited to complete feedback after their appointment, and we saw that staff reviewed and discussed any patient feedback received. Most patients we spoke to were aware of how they could provide feedback about the service stating there was the option to leave a review on the service's website. We looked at the service's website and noted there was a specific section titled "Reviews" which linked to a separate page displaying a sample of 30 reviews from a total number listed of 774 reviews.

The service was primarily promoted through their website, social media platforms and through word of mouth from people that had used the service. Patients could give feedback at any time either anonymously or providing their name if they wished to. The registered manager collated comments received via the website and social media pages.

Managers stated they had implemented changes and improvements through earning, discovery, experience, feedback from users, as well as through routine engagement with the Care Quality Commission (CQC).

Learning, continuous improvement and innovation

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

The service had a clear aim to make improvements wherever these were identified and a focused approach to quality improvement and continuous learning.

Staff engaged in regular meetings to discuss discrepancies and any recent complaints or feedback. The service had a focused approach to continuous learning for staff and their business plan stated they would explore new educational opportunities to update practice and ensure continuous professional development throughout all staff levels.

Good

Diagnostic and screening services

The registered manager stated they were awaiting a place on a course to expand their competency to scan lumps and bumps which would expand the services they could offer. If staff wanted to expand their skills the service was open to supporting them.

Leaders stated they believed in striving to continuously improve services and patient experience and would always endeavour to assess performance against benchmarks of high customer satisfaction, excellent values and excellent care tailored to each patient's needs. They reviewed feedback received from patients so that consideration could be given on how to further improve the quality of care offered to patients by the service.

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 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints The service did not display information about how to raise a concern in patient areas at the location we inspected. It was also observed the service's website did not have a complaints section for service users to obtain information in order to register a complaint. Patients did not know specifically how to complain or raise concerns. All patients we spoke with said they believed they knew how they could give feedback but had not been provided any information about how to raise a concern or make a complaint.