

Lucy Jane's

Quality Report


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This report describes our judgement of the quality of care at this location. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations

Ratings

Overall rating for this location

Good 

Are services safe?

Good 

Are services effective?

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Good 

Overall summary

Lucy Jane's is operated by Lucy Jane's Limited. Lucy Jane's provides early pregnancy and keepsake scans to self-paying members of the public. The service carries out trans abdominal ultrasound scans, including 2D, 3D and 4D baby keepsake scans and gender scans. The service does not provide diagnostic scans.

The service is based in Colne Lancashire. Two staff work in the service on a part time basis. Both staff are directors of Lucy Jane's limited and have additional employment outside of the service.

Diagnostic imaging services are provided from the scan studio, from premises situated on the main high street. Public transport services and car parking are available nearby. The studio has a waiting room and reception area, ultrasound scan room, toilet facilities and a staff kitchen area. We inspected diagnostic imaging services.

We inspected this service using our comprehensive inspection methodology. We carried out a short

Summary of findings

announced visit to the service on 7 January 2020. We gave staff two working days' notice that we were coming to inspect to ensure the availability of the registered manager, service users and staff.

To get to the heart of patients' experiences of care and treatment, we ask the same five questions of all services: are they safe, effective, caring, responsive to people's needs, and well-led? Where we have a legal duty to do so we rate services' performance against each key question as outstanding, good, requires improvement or inadequate.

Throughout the inspection, we took account of what people told us and how the provider understood and complied with the Mental Capacity Act 2005.

The main service provided by Lucy Jane's was baby keepsake souvenir scanning.

Services we rate

We rated it as **Good** overall because:

- The service provided mandatory training in key skills for all staff and ensured everyone completed it.
- Staff understood how to protect patients from abuse and had completed safeguarding training in line with national safeguarding guidance.
- Staff identified risks for service users and signposted service users to NHS services, where any concerns were identified.
- The service used appropriate control measures to manage the risk of infection and ensured equipment was correctly maintained.
- The service provided care based on national guidance and evidence-based practice. The service ensured staff were competent for their roles.
- Staff treated service users with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.

- Staff provided emotional support to patients, families and carers to minimise their distress.
- Service users could access the service at a time and in a way that suited their needs. The service took account of service users' individual needs and preferences.
- The service treated concerns and complaints seriously, investigating these and identifying learning.
- Leaders operated effective governance processes throughout the service. Leaders supported each other and there was an open culture in the service, focussed on making improvements.

However:

- There were no handwashing facilities immediately within the scan room or toilet area; staff and people accessing the service used a nearby kitchen sink for handwashing.
- Staff frequently worked alone in the premises, leaving the main front and rear doors unlocked during scan appointments. We were told this was necessary due to Fire Safety Risk Assessment.
- The service did not identify a vision for what it wanted to achieve. Systems to identify and manage risks in the service were not clearly identified.
- The service did not have a system for identifying overall risks in the service, or actions to manage or mitigate any risks arising in the service.

Following this inspection, we told the provider that it should make other improvements, even though a regulation had not been breached, to help the service improve. Details are at the end of the report.

Ann Ford

Deputy Chief Inspector of Hospitals (North region)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Summary of each main service

Good



The service provided at this location was diagnostic and screening procedures. We rated this core service as good overall. We rated safe, caring, responsive and well-led as good. We did not rate effective because we do not have enough information to make a judgment. Overall, we rated the service as good because: Staff had completed mandatory training and had the skills to carry out their roles. The service identified procedures to signpost women to relevant NHS care, wherever any concerns were identified during scans. The service had suitable premises and equipment and looked after them well. The ultrasound machine was serviced and maintained as per manufacturing guidelines. Staff were caring and showed respect for service users. Women could access the service in a timely way. Individual needs were identified and responded to. Leaders were focussed on providing a high-quality service. Leaders had the appropriate skills and experience to manage the service.

Summary of findings

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Good 

Lucy Jane's

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Lucy Jane's

Lucy Jane's is operated by Lucy Jane's Limited. The service opened in 2019. It is a private ultrasound scan studio in Colne, Lancashire. The scan studio offers early pregnancy scans, gender scans, 3D and 4D scans to fee paying members of the public, primarily serving the communities of Colne and the surrounding area. It also accepts service users on a self-referral basis from outside this area.

The service has had a registered manager in post since February 2019.

We have not previously inspected this service.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a second CQC inspector. The inspection team was overseen by Judith Connor, Head of Hospital Inspection.

Information about Lucy Jane's

The clinic had one ultrasound scanning machine and is registered to provide the following regulated activities:

- Diagnostic and Screening services.

During the inspection, we inspected all areas at the clinic and observed an ultrasound scan. We spoke with both staff in the service, one being the registered manager of the service. We reviewed records, including consent forms, and service user feedback.

There were no special reviews or investigations of the clinic ongoing by the CQC at any time during the 12 months before this inspection. This was the clinic's first inspection since registration with CQC.

Activity (March 2019 to December 2019)

In the reporting period March 2019 to December 2019
There were 704 scans

Track record on safety

- Zero Never events (never events are serious patient safety incidents that should not happen if healthcare

providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event), or serious incidents.

- Zero duty of candour notifications (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 people who use the services (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person).
- Zero safeguarding referrals.
- Zero incidences of healthcare acquired infections.
- Zero unplanned urgent transfers of a patient to another health care provider.
- Zero number of cancelled appointments for a non-clinical reason.

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

We rated this service as **Good** because:

- Staff had training in key skills, understood how to protect patients from abuse, and managed safety well.
- The service had enough staff to care for women and keep them safe.
- The service controlled infection risk well.
- Staff assessed risks to patients, acted on them and kept records securely.
- The service followed systems for maintaining and servicing the ultrasound equipment, in accordance with manufacturer's guidelines.

However,

- There were no handwashing facilities immediately within the scan room or toilet area; staff and people accessing the service used a nearby kitchen sink for handwashing.
- Staff frequently worked alone in the premises, leaving the main front and rear doors unlocked during scan appointments.

Good



Are services effective?

We inspected for this key question but did not rate because we do not have enough information to make a judgement. We found:

- Staff provided good care and advised women regarding their fluid intake when they needed it.
- Managers monitored the effectiveness of the service and made sure staff were competent.
- Staff worked well together for the benefit of service users and supported them to make decisions about their care.

Are services caring?

We rated this service as **Good** because:

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood service users' personal needs
- Staff supported and involved service users and their families to understand their condition and make decisions about their care and treatment.

Good



Summary of this inspection

Are services responsive?

We rated this service as **Good** because:

- The service planned and provided care in a way that met the needs of local people and the communities served.
- The service was inclusive and took account of service users' individual needs and preferences. Staff made reasonable adjustments to help patients access services.
- People could access the service in a way and at a time that suited them.
- It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously and identified learning from complaints.

Good



Are services well-led?

We rated this service as **Good** because:

- Leaders had the skills and abilities to run the service. They understood the service and managed the issues the service faced.
- Leaders supported each other and were approachable for service users.
- The service had an open culture where service users could raise concerns without fear.
- Leaders operated effective governance processes, appropriate for the service.
- The service collected reliable data and analysed it, using findings to improve the service.
- Leaders and staff actively engaged with service users to obtain feedback.

However

- The service did not have a vision for what it wanted to achieve or a strategy to turn this into action.
- The service did not have a risk register or use a system to identify risks, and actions to reduce their impact.

Good







Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Good	N/A	Good	Good	Good	Good
Overall	Good	N/A	Good	Good	Good	Good

Diagnostic imaging

Safe	Good 
Effective	
Caring	Good 
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

We rated safe as **good**.

Mandatory training

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

- Staff in the service had completed mandatory training in key skills, including health and safety, infection prevention and control, manual handling and information governance. The registered manager had completed this training as part of their NHS role requirements, and during the inspection we saw evidence of up to date records which confirmed this. The second staff member had completed eLearning programmes in health and safety, fire training and safeguarding training.
- Both sonographers had completed their training in pregnancy ultrasound techniques in October 2018. This was a four-day course, completed with a private ultrasound imaging training company. Staff appeared knowledgeable about ultrasound practice, and supporting documentation identified staff competencies for different scan techniques.
- The service had not identified a local mandatory training policy; although we saw the manager maintained an up-to date record of completed staff training. We saw that training completed was appropriate to staff's roles within the ultrasound scan service, and for the scope of the service provided.

Safeguarding

Staff understood how to protect service users from abuse and the service knew how to work 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. Both staff had completed safeguarding children level three and safeguarding vulnerable adults' level two training. The service provided pregnancy scans for under 18-year olds, also for 17 to 18-year olds, however the manager confirmed there had been less than five scan appointments provided for this age group since the clinic opened.
- Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had a safeguarding children and a safeguarding adult's policy for staff to follow. Both policies were up to date and reflected current national guidance, including Safeguarding Children and Young People: Roles and Competencies for Healthcare Staff (2019). Policies identified a flow chart for actions to take, where any safeguarding concerns were identified. This included contact details for local authority safeguarding teams for advice and referral if needed. The service had not identified any safeguarding concerns or made any referrals to the local authority to date. Staff were aware of potential safeguarding issues which could present in the service and confidently described the scenarios where they would identify possible concerns.
- Both staff files contained current records for Disclosure and Barring Service (DBS) checks.

Diagnostic imaging

Cleanliness, infection control and hygiene

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

- The premises appeared visibly clean and were free from clutter. Staff managed cleaning duties on a daily basis, following a cleaning schedule. The cleaning schedule identified general cleaning tasks including mopping and cleaning surfaces. A weekly schedule was maintained of completed cleaning tasks; we reviewed the latest schedule and saw records were completed for the past month.
- Staff carrying out scans were arms bare below the elbows. Staff did not have access to hand washing facilities in the scan room but we observed the sonographer used hand gel prior to one scan we observed. Aprons were not provided but gloves were available for sonographers to wear during scan procedures.
- The service had an infection prevention and control policy. Staff had completed training in infection prevention and control as part of health and safety training, and were aware of these principles. The service completed spot check audits to monitor compliance with hand hygiene and infection prevention and control.
- A paper towel covered the treatment couch during client scans and was replaced after each client's use. During the scan, women were given a paper towel to help maintain their dignity. Following the scan, paper towels were used to wipe the gel from the ultrasound transducer head.
- Staff wiped down the treatment couch after each appointment, using antiseptic wipes. Staff cleaned the machine and ultrasound transducer head with antiseptic wipes.
- Handwashing signs were displayed in the toilet facilities to prompt service users and staff.
- There had been no incidences of healthcare acquired infections at the service since it opened.

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 was provided from shop premises, located on a main road, accessible with steps from the street. Local free parking was available to service users. The ground floor had a reception area leading to the main scan room. External signage was clear for people accessing the service.
- Next to the scan room a small kitchen area for employees led to toilet facilities for both employees and customers. There were no handwashing facilities in the scan room or immediately within the toilet facilities; staff and customers would use a nearby sink in the kitchen area as needed. From the kitchen area a back door led to the rear of the premises.
- A storage room was available upstairs, with staff files and general stock items stored.
- The service had an ultrasound scan machine, leased from a medical equipment company. Arrangements were in place with the company for routine servicing and maintenance of the ultrasound scan equipment, and for emergency replacement in case of any breakdown. The manager told us they had not had experience of any equipment failure and that the service provided by the company had been satisfactory.
- We saw during inspection that electrical equipment including the ultrasound scan machine had been electrical safety tested, with items displaying labels to indicate the dates last test completed.
- The premises had clearly marked fire exits, smoke alarms and extinguishers which were stored securely. Tackling fires and fires extinguishers was part of the mandatory fire training. The service had a certificate of water treatment for legionella testing.
- Cleaning liquids were stored inside a locked cupboard in the kitchen area. The service had arrangements for collection of waste in routine local council provision.
- During the inspection the manager told us that staff often frequently worked in the premises alone, including when scan appointments were taking place. During these times, the front door would be left

Diagnostic imaging

unlocked; we were told this was necessary due to Fire Safety Risk Assessment. Although there had been no security incidents to date, during the inspection we discussed the potential security concerns which may present from this with the manager, for their consideration.

- We were told that relatives and children often accompanied women to scan appointments, however there were no toys provided at the premises and there was a limited child-friendly aspect to the environment.

Assessing and responding to patient risk

The service had systems in place to assess and manage risks to women and their babies.

- The service did not offer medical diagnostic imaging scans. Information provided to service users clearly stated the service offered non-diagnostic ultrasound scans, from early pregnancy through to full term.
- Staff told us the scans were not intended to be diagnostic and did not replace routine hospital scans. This was reflected on the service's website.
- Women were not routinely asked to bring their NHS maternity records to appointments, although were asked to confirm details of the hospital where they would be having their baby. We were told if any concerns were identified during initial phone enquiries from service users, they would be directed to NHS services and declined any request for scan appointments.
- Service users were asked to complete a booking proforma at the time of their appointment. The contained various information about terms and conditions, including the statement that 'under no circumstances should Lucy Jane's Limited be a substitute for your hospital ultrasound appointments or antenatal care.'
- The booking proforma also provided information about potential risks of ultrasound imaging. This explained in general terms what an ultrasound scan was and the types of images provided. Specific information detailed the possible risks associated with ultrasound scan, including that 'ultrasound waves can cause slight tissue heating, but that unlike x-ray imaging, there is no ionizing radiation exposure associated with ultrasound imaging'. However, the

document did not reference information about the potential risks of repeated exposure to ultrasound or advice from the British Medical Ultrasound Society (BMUS) regarding this issue.

- The service identified a procedure on detecting anomalies document for sonographers to follow, where any concerns were identified during a scan. This also highlighted to staff any general symptoms which might indicate concern prior to the scan, including vaginal bleeding, abdominal cramps or pain; reduced or absent fetal movements; and symptoms of fever, or being generally unwell. If any of these symptoms were identified prior to the scan, staff would direct service users to seek immediate medical attention.
- The procedure on detecting anomalies included flowcharts for scans performed between seven and twenty weeks, and scans performed between 20 weeks and term of pregnancy. Both flowcharts directed service users to seek immediate advice from local maternity services, in cases of absent fetal heart beat or other concern. Staff told us they had referred several women following this pathway, however the service did not keep any records to confirm when they had done this.
- Both sonographers had completed basic life support training, with the manager having completed a higher level of life support and neonatal resuscitation training, in association with their NHS role.
- The service had a first aid kit available and all items within it were within their expiry date.
- The service did not undertake non-invasive prenatal blood tests for service users.

Staffing

There were sufficient staff to meet the needs of the service. Staff had the right skills and experience to keep people safe from avoidable harm and to provide the right care and treatment.

- Both staff in the service worked as sonographers, also working together to cover reception activities and other administrative tasks as needed. The service was provided on a part time basis, with both staff engaged in other employment.

Diagnostic imaging

- There were no vacancies in the service at the time of inspection. Any sickness was covered between staff, as and when it occurred. The service did not employ bank or agency staff.

Records

Staff kept appropriate records of service users' care and treatment, using electronic systems and paper records. Records were clear, up-to-date and available to all staff providing care.

- Women accessing the service completed a client proforma form at the time of their appointment. This stated the basic terms and conditions and identified the service user's consent for the scan procedure. We reviewed 12 proforma records and saw these were completed, with signatures of service users.
- The service had a general data protection policy, referencing the General Data Protection Regulations 2018. The service stored paper records of client booking proformas in a locked filing cabinet. During inspection staff told us the proforma records would be kept for seven years and scan images would be kept for four years. This appeared to conflict with GDPR guidance regarding personal data.

Incidents

The service managed safety incidents well. Staff recognised and knew how to report incidents and near misses. When things went wrong, staff apologised and gave service users honest information and suitable support.

- The service had an accident and incident policy and an incident book. Staff would record any incidents in the incident book located at reception. There had been no incidents recorded since the service was registered.
- Staff described what they would identify and record as an incident, including slips, trips and falls; breakdown of equipment, or failure of service supplies.
- The service had a duty of candour policy and staff were aware of the principles of being open and honest. 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

- We were told us of occasions where staff had communicated openly to share information with service users, after identifying a possible abnormality during their scan. The duty of candour policy had been introduced following learning from a complaint during 2019.
- The registered manager was aware of the requirements for reporting incidents and submitting statutory notifications to CQC (Care Quality Commission). At the time of our inspection there had been no incidents to report to CQC.

Are diagnostic imaging services effective?

We inspected for this key question but did not rate because we do not have enough information to make a judgement

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence of its effectiveness.

- Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance.
- The service identified and completed different audits, including customer satisfaction audits; cleaning audits; data protection audits and business exposure audits. At the time of inspection, the manager had not identified any audits directly relating to clinical quality of the service but was planning to do this.

Nutrition and hydration

Staff advised service users about their need to drink.

- Advice was provided for women having different types of scan regarding the need for hydration. Women were advised to have a full bladder if they were having an early pregnancy scan, to improve the quality of the ultrasound image.

Diagnostic imaging

- We observed one scan during later stage of pregnancy for a service user. In order to gain a clearer image for a 3D scan, the woman was directed to go for a walk and have a drink, to stimulate the baby's movement.
- Drinks were not provided by the service but could be easily accessed from shop premises next door to the scan studio premises.

Patient outcomes

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

- The service asked all women who attended to complete feedback forms on leaving their appointment. Staff reviewed any comments in order to identify improvements to the service and scanning experience.
- Staff had created a 'frequently asked questions' page on the service's website following review of comments. Common questions and themes from service users had been identified from service user feedback. Frequently asked questions included what the earliest time is to have a gender scan, and the best time to have a 4D scan.
- The registered manager was knowledgeable and experienced in maternity care through her continuing experience in NHS midwifery services. We saw that local policies implemented in the service were thorough and reflected national guidance where this was relevant.
- The service had a system in place for women who required a rescan if a clear image of their baby was not achieved due to their stage of pregnancy. The service recorded this and had access to all details of previous appointments through the electronic booking system.

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.

- The provider kept appropriate staff files containing details of qualifications and relevant training. Current

employment details were recorded, including details of job description and role. The service informed us following inspection that photographic identification such as passports and driving licences of both staff members are kept electronically in an individual staff file, although we did not review these during inspection.

- We saw completed enhanced Disclosure and Barring Service (DBS) checks were in place for both members of staff; both had completed a Fit and Proper Persons self-declaration form, as requirement for CQC registration.
- Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women accessing the service.
- Both the sonographers worked closely together to support each other in their ultrasound practice, carrying out informal observations of practice and reviewing these at monthly meetings. Each completed an annual supervision document to identify development needs and improvement in practice.

Multidisciplinary working

Staff in the service worked together as a team to benefit service users. They supported each other to provide good care.

- During our inspection we observed both the sonographers working well together. They maintained a professional working relationship, which promoted a relaxed environment for women and their families using the service.
- The registered manager did not have any immediate contact with external services at the time of inspection; this was on the basis the service provided was a non-medical and non-diagnostic. Where any concern was identified however, women were signposted to medical and NHS services as required. The registered manager had identified the relevant contact details for local authority safeguarding teams, however had not had occasion to be in contact to date.

Seven-day services

Diagnostic imaging

- The provider offered pregnancy ultrasound scan services on a part time basis, with appointments offered during different days of the week and at weekends. Opening times were flexible, dependent upon individual appointment bookings.

Consent and Mental Capacity Act

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

- Staff understood how and when to assess whether a woman had the capacity to make decisions about their care. There were processes to ensure women consented to having an ultrasound scan.
- Both sonographers were aware of the importance for gaining consent from women before conducting any ultrasound scan. All women were given a client proforma containing written information to read and sign before their scan appointment. This information included the terms and conditions; and questions about health and their pregnancy.
- We observed one scan during which the sonographer checked the information details were correct, obtaining verbal consent in the scan room prior to carrying out a scan.
- Both sonographers had completed training in Mental Capacity Act and consent. Both staff confidently explained how they would proceed when assessing capacity to gain consent from a service user aged under 18 years and 16 -17 years old. We were told service users under 18 years would only be seen when accompanied by a parent.

- Staff took time to interact with patients and those close to them in a respectful and considerate way.
- We observed staff during inspection and saw they were very reassuring and interacted with the women and their families in a respectful, professional and supportive manner. During one scan appointment we saw staff treat the woman and their partner with compassion. Staff demonstrated a caring approach in all aspects of their work and general communication.
- Feedback from service users was consistently positive, confirming that staff treated them with kindness and respect.
- Women's privacy and dignity was provided for, with ultrasound scans carried out in a separate room. This allowed for women accessing the service to ask any questions confidentially.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress.

- Staff were aware of the emotional needs of women accessing the service and recognised this could be an anxious time. We saw staff provided emotional support for patients to minimise their distress and concerns around the scanning procedure, by explaining the scanning procedure and answering questions.
- Reception staff supported women and their families appropriately when choosing a scan image. Staff welcomed any children and family members attending with the woman for the scan, providing a comfortable and relaxing environment.
- Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff described how they would share difficult news and provide support for women who were identified with concerning scans. They would refer them to other services for appropriate support.

Are diagnostic imaging services caring?

Good 

We rated caring as **good**.

Compassionate care

Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Staff were discreet and responsive when caring for patients.

Understanding and involvement of women accessing the service and those close to them

Diagnostic imaging

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

- During the inspection we observed the sonographer making sure that women and those close to them, felt able to ask questions about their care and treatment. Staff gave people who use the services time to ask questions.
- The sonographer spoke in a clear manner and used appropriate language to explain the position of the baby and what the baby was doing. They asked women and those close to them if they had any questions during and at the end of the scan.
- Information regarding the different types of scans and packages available for people to purchase was clearly presented on the provider's website. Feedback from service users indicated they were happy with the service they had received and felt supported throughout.

Are diagnostic imaging services responsive?

Good 

We rated responsive as **good**.

Service delivery to meet the needs of local people

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

- The service provided private pregnancy ultrasound scans for individuals wishing to have extra scans outside of their NHS maternity care.
- The scan studio premises were located in the town centre, with access from the main street. There was a reception area, a scanning room, staff kitchen area and toilet facilities for service users and staff.
- In the scan room there was an ultrasound machine, chairs and a clinical treatment couch. A wall mounted

display screen was provided for viewing images during the scan procedure. The service provided a second computer terminal for women to choose their scan pictures.

- Women accessing the service could book appointments directly through the service's website or social media platforms, or through phone contact with the reception. Staff actively monitored and responded to any contacts from women wishing to use the service.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services.

- The premises were not immediately accessible for wheelchair users and toilet facilities were not accessible. However, the service had a disability access plan, with arrangements identified for meeting any disability related needs identified. The registered manager informed us they had arrangements for hiring a height adjustable treatment couch and other equipment, if this was requested. The service could provide a ramp for wheelchair access and had arrangements with the local council, for nearby accessible toilet facilities. Any access or disability needs would be noted at first contact with service users. There had been no requests for this to date from women, or families and others accessing the service.
- The website and other clinic information was only provided in English language format. The manager stated there had not been any service user requests for language translation in the service to date, but staff were aware of internet translation services and other interpreter services which could be accessed.
- Both staff had completed equality and diversity training and had awareness of different individual, cultural and religious needs.

Access and flow

People could access the service when they needed it and at a time which suited them.

Diagnostic imaging

- Women could access the service when they needed it and received the right care in a timely way. Appointments were available on weekends and evenings, flexibly according to the service's opening hours.
- Appointments were booked at a time to suit individuals' preference; appointments and staffing were planned in response to demand.
- The service allocated one hour long appointments for each scan. The manager had introduced this system to ensure there was no overlap in appointment times, and to allow women accessing the service sufficient time to ask questions and not feel rushed. This also allowed extra time to support women in cases where staff needed to share any concerns or if there was need to direct women to NHS services for advice.
- The service had a system in place for service users who required a rescan. Rescans were provided where it had not been possible for the ultrasound assistant to obtain a clear scan image due to the baby's stage of gestation.
- No planned appointments had been cancelled or delayed for a non-clinical reason such as breakdown of equipment.
- The service did not have a waiting list.

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 had a comprehensive complaints policy detailing how complaints would be responded to by the manager. The policy included draft letters for response to potential complainants, indicating timescales for this response.
- The service recorded two complaints in the inspection reporting period, one of which proceeded through a formal response. This complaint was also raised to the Nursing and Midwifery Council (NMC) but did not proceed further through the NMC process. The manager described how this experience had brought a lot of important learning for the service, which had been used to develop improvements.

- Staff in the service informed us any concerns would be responded to if they arose and raised to the manager if these could not be resolved in the first instance.
- The service reviewed feedback comments and social media platforms to continue to identify any changes or improvements needed.

Are diagnostic imaging services well-led?

Good 

We rated well-led as **good**.

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 for women accessing the service.

- Both staff in the service were directors of the company and worked as sonographers; they were also family members. The registered manager was a midwife in NHS services and the other director was employed in another non-clinical role outside the service. Although both directors worked flexibly as staff in the service, we were told the registered manager took a lead for clinical aspects within the service. The other director took the lead for the business and administrative activities relating to the service.
- The registered manager had completed a postgraduate qualification in leadership skills during 2019, in relation to their NHS role. Both directors had an understanding of their service and the context for their work; they were passionate and committed to providing a high-quality service.
- There was close working day-to-day between both the directors; they routinely engaged in ongoing discussions about the service, including any identified issues and plans for future development. During the inspection we saw how both staff supported each other closely in their continued working relationship.

Vision and strategy

The service did not have a vision or current strategy.

Diagnostic imaging

- The registered manager described the service aim was to provide a high quality pregnancy ultrasound baby keepsake scan service, for women wishing to have this. The service did not have a documented strategy or other written plan to identify how this would be achieved, although both directors shared the same general vision and ambition for future services.

Culture

The service had an open culture where women, their families and staff could raise concerns without fear.

- The manager promoted a positive culture across the service that supported and valued staff.
- Both staff spoke proudly about their roles within the service and said they supported each other in their work. They told us they felt valued and supported. Women accessing the service were positive about their experience of the service.
- As co-directors, both staff felt able to raise any concerns they had without any fear of retribution. They shared a close working relationship and were able to communicate openly about all aspects of the service.

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.

- Leaders identified processes to oversee and monitor key aspects of the service.
- The service had systems to ensure that policies and practice were regularly reviewed and were based on current best practice guidelines. We saw that appropriate policies and procedures were in place for the operation of the service and these were available to staff in electronic folders in the clinic.
- The manager and co-director were clear about the running of the service and had a clear understanding about the quality of service to be provided.
- Files stored at the premises contained current certificates of Disclosure and Barring Service (DBS) checks for both staff. Records of training and

employment history were held in staff files, although photographic identification records were absent. Both directors had completed a Fit and Proper Persons self-declaration, as requirement for CQC registration.

Managing risks, issues and performance

Leaders and teams used systems to manage performance effectively, although they did not always identify and escalate relevant risks. They had plans to cope with unexpected events.

The service did not always have effective arrangements in place for identifying and recording risks.

- The service provided details of risk assessment forms and a risk assessment spreadsheet which would be used to be able to identify manage and mitigate risks in the service. However, information we reviewed during inspection appeared limited in consideration of wider risks in the service, with staff describing risk assessments mostly in context of following procedures when identifying an anomaly or concern during the scan.
- The service had a business continuity plan, identifying arrangements for breakdown of equipment or other interruption to services. This had recently been extended to include actions in the event of extended staff sickness absence.
- Staff in the service frequently worked alone on the premises, carrying out booked scan appointments during these times also. Staff described the arrangements they followed for lone working, including ensuring access to a charged mobile phone for raising any alarm. The service also had an electronic diary which could be accessed when staff were not on the premises. This diary could also be used to check the appointments proceeding, or if there had been any delays or cancellations.
- Although we were informed of the fire safety assessment need to have the doors unlocked, during the inspection we discussed the security aspects, when staff were lone working in the premises.

Managing information

Diagnostic imaging

The service managed and used information to support its activities, using secure electronic systems with security safeguards.

- Patient records and scan reports were easily accessible and were kept secure. Paper client records were stored in locked filing cabinets and staff locked computer terminals when not in use. All electronic records and systems were password protected and scan images were deleted from the dedicated computer for service users to use, after they had made their selections.
- We saw during inspection that whilst client records were kept securely, the two staff files were left out on shelves in the store room. The store room was upstairs in private accommodation, however was not locked.

Engagement

Leaders and staff actively and openly engaged with service users and the public to plan and manage services.

- The provider engaged with service users and the public through the service's website and social media accounts, to promote its services.
- Women's views and experiences were gathered and used to improve service provision. Women were asked to comment about their care in feedback forms and provide a rating of their overall experience. The provider monitored feedback from service users via follow up surveys and social media comments.
- The two directors held a monthly meeting to review the service, including service user feedback, and consider any actions to progress.

Learning, continuous improvement and innovation

Staff were committed to continually learning and improving services.

- Although we did not hear of any specific development plans, staff in the service were keen to improve services where they could and were open to opportunities to do this in the future.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

The provider should review appropriate access to handwashing facilities in the scan room and toilet area.

The provider should review lone working arrangements to ensure the safety and security of service users and staff.

The provider should consider keeping a record of when service users have been signposted to access NHS services, if potential concerns are identified.

The provider should review how the General Data Protection Regulations (GDPR) are applied in the service.

The provider should consider developing a vision and strategy for the service.

The provider should ensure appropriate systems are implemented to identify and manage risks in the service.