ScanLinc Early Pregnancy Service

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

ScanLinc Early Pregnancy Service is an early pregnancy private ultrasound service providing care for the women and families of Lincolnshire and surrounding areas. The service has one location - Greetwell Place, which is a City Council owned managed workspace with car parking and reception staff and facilities.

The service provides an ultrasound scan service to pregnant women aged 18 and over for reassurance in early pregnancy, gender opinion and a 3/4D experience. The service also offers screening in the form of non-invasive pre-natal testing (NIPT).

Summary of findings

We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection (staff did not know we were coming) on 14 February 2020 and carried out a further announced visit on 18 February 2020.

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.

Services we rate

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it as **Good** overall.

We found good practice in the ScanLinc service:

- The premises and facilities of the service were appropriate, well maintained and visibly clean.
- Infection prevention control guidance was consistently followed.
- There was good partnership working and communication with other local healthcare providers to manage any unexpected or abnormal findings.
- Women and staff reported that the service was very responsive, and we saw that women were able to be offered appointments quickly.
- There was an overwhelming focus on delivering good quality patient care. Extended appointment slots meant that women received plenty of time. We observed that time was taken to provide information and advice and time was given for women to asks questions. The service demonstrated an extremely caring approach at all times which was commented on by nearly all women who provided feedback.
- There was a very positive culture within the service with both staff demonstrating exceptional enthusiasm and passion in their work.

However, we also found areas of practice that required improvement in the ScanLinc service:

- Complaints information in the form of leaflets or posters was not widely available meaning it may not be easy for women to know how to raise concerns or make a complaint.
- Risk assessment templates lacked detail and risks were not rated or regularly reviewed.
- There was no documented process for investigating incidents, identifying areas for learning and sharing this.
- Not all women had the opportunity to provide feedback as comments cards were issued at random, and not routinely to all women.
- There was no formal appraisal of the staff member working for the service, hence learning and development needs were not identified.
- Staff had not completed any recent training in relation to the Mental Capacity Act in order to be able to assess women's capacity to consent and make decisions about their care.

However, we found that the registered manager was very responsive to the concerns raised and took prompt action to put processes in place to address most of the concerns raised within two weeks of us completing the inspection. These actions are identified within the report.

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

Heidi Smoult

Deputy Chief Inspector of Hospitals (Midlands region)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good	We rated it as good because: • The service had enough staff to provide the service and keep women safe. Staff had training in key skills, understood how to protect women from abuse, and managed safety well. The service controlled infection risk well. Staff assessed risks to women, acted on them and kept good care records. • Staff provided good care and treatment. Managers made sure staff were competent. Staff worked well together for the benefit of women, advised them on how to lead healthier lives, supported them to make decisions about their care, and had access to good information. The service was available five days a week. • Staff treated women with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to women, families and carers. • The service planned care to meet the needs of local people, took account of women's individual needs. People could access the service when they needed it and did not have to wait too long for appointments. • 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 women receiving care. Staff were clear about their roles and accountabilities. All staff were committed to improving services continually. However: • The service had a process to report safety incidents but did not have systems for investigating them and sharing the lessons learned. • There were not established systems for monitoring the effectiveness and responsiveness of the service.

Summary of findings

- The service did not routinely offer the opportunity for all women to provide feedback about their experience.
- The service did not display information about how women could complain.

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Background to ScanLinc Early Pregnancy Service

ScanLinc Early Pregnancy Service provides an ultrasound service and non-invasive prenatal testing (NIPT) for the Women of Lincolnshire, North Lincolnshire and Nottinghamshire. Primarily the service provides care, opinion and reassurance to women and their families in the early weeks of their pregnancies.

The service was set up in October 2018. It is a private ultrasound service for pregnant women, based in a shared building owned by the local authority. Women self-refer themselves to the service and self-pay for all appointments. The service does not see women on behalf of the NHS.

The service offers appointments for ultrasound scans and non-invasive pre-natal testing to pregnant women aged 18 and over.

ScanLinc is staffed by two Midwife Sonographers who are both qualified and registered with the Nursing and Midwifery Council (NMC).

The hospital has had a registered manager in post since October 2018.

The facility operates from a single office and is based in Greetwell Place in the city of Lincoln, which is a City Council owned managed workspace with car parking and reception staff and facilities. There is disabled access and toilets and a lift for access to the first floor. The service has a reception that is manned Monday to Friday. Appointments are offered on Mondays and Tuesday through to Saturday.

We inspected this service on 14 and 18 February 2020 using our comprehensive inspection methodology. The inspection visit on 14 February was unannounced (staff did not know we were coming).

Arrangements for emergency patient care for example, in the event of cardiac arrest, are via a 999 call to the paramedic ambulance service. Staff have basic life support training and the registered manager is trained in first aid. There is a first aid equipment box in the clinic room.

There have been no previous inspections of the service.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector, with the support of an off-site inspection manager. The inspection team was overseen by Fiona Allison, Head of Hospital Inspection.

Information about ScanLinc Early Pregnancy Service

The service provided pregnancy ultrasound scans. This location is registered to provide the following regulated activity:

• Diagnostic and screening procedures.

During the inspection, we visited the only site from which the service operates. We spoke with two members of staff; the registered manager, and the self-employed midwife sonographer. We spoke with one woman who had used the service and observed four episodes of care delivery. We also reviewed women's feedback from thank you cards and social media forums. During our inspection, we reviewed five sets of care records. We reviewed policies, training records and audit results.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. We have not previously inspected this location.

Summary of this inspection

During this inspection we identified that there were no breaches of regulations.

Activity (December 2018 to December 2019):

From December 2018 to December 2019 the service had delivered 2,003 activities which are broken down by type as follows:

- 585 Early Pregnancy Reassurance Scans
- 85 Early Pregnancy Emergency Scans
- 206 3D Scans
- 999 Gender opinion scans
- 82 NIPT
- 46 Endometrial Assessment Scans

All women seen were self-pay private patients.

Track record on safety (December 2018 to December 2019):

- No never events or serious injuries
- There have been no reported incidents since the service has been operating
- There have been no reported complaints since the service has been operating.

There were no services provided at the clinic under a service level agreement except for a room rental agreement between the building owner and the registered manager. The agreement included provision of a reception service shared by all building occupants. The maintenance of the clinic room was the responsibility of the building owner, for example, testing of any electrical equipment such as the room heater and sockets. All furnishing and clinical equipment was the responsibility of the registered manager. The agreement did not include any cleaning services.

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?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it as **Good** because:

- Staff understood how to protect women from abuse and the service worked well with other agencies to do so. Staff had training on how to recognise and report abuse, and they knew how to apply it.
- The service controlled infection risk well. Staff used equipment and control measures to protect women, themselves and others from infection. They kept equipment and the premises visibly clean.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff completed risk assessments for each woman and removed or minimised risks. Staff identified and quickly acted upon women in need of additional support.
- The service had enough staff with the right qualifications, skills, training and experience to keep women safe from avoidable harm and to provide the right care and treatment.
- Staff kept detailed records of women's care and treatment. Records were clear, up-to-date, stored securely and easily available to all staff providing care.
- The service managed safety incidents well. Staff recognised incidents and near misses and knew how to report them appropriately. When things went wrong, staff understood the need to apologise and give women honest information and suitable support.

However, we also found the following issues that the service provider needs to improve:

- The manager did not have a process for investigating incidents and sharing lessons learned with staff.
- The service did not ensure completion of mandatory training by all staff in all key skills.

Are services effective?

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it as **Not rated** because we do not currently rate effective for diagnostic imaging services. We found the following areas of good practice:

Summary of this inspection

- The service provided care and treatment based on national guidance and best practice. The manager checked to make sure staff followed guidance.
- Staff assessed and monitored women regularly to see if they were comfortable.
- The service made sure staff were competent for their roles. Peer supervision sessions were held between staff to provide support and development.
- Sonographers and other healthcare professionals worked together as a team to benefit women. They supported each other to provide good care.
- Services were available five days a week to support timely patient care.
- Staff gave women practical support and advice to lead healthier lives.
- Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain women's consent.
- Staff always had access to up-to-date, accurate and comprehensive information on women's care and treatment. All staff had access to an electronic records system that they could update.

However, we also found the following issues that the service provider needs to improve:

- The manager did not have a documented appraisal process to monitor staff's work performance.
- There was no evidence that staff had completed Mental Capacity Act training, meaning they may not know how to support women who lacked capacity to make their own decisions. Nor had staff received training to recognise women who may be experiencing mental ill health.

Are services caring?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it as **Good** because:

- Staff consistently treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Feedback from families who had used the service was extremely positive and highlighted that staff took extra time to put families at ease.
- Staff provided emotional support to women, families and carers to minimise their distress. They understood women's

Summary of this inspection

anxiety, spent time offering reassurance and demonstrated empathy. If women had suffered a pregnancy loss, staff understood the impact of this and provided appropriate support both during and after appointments.
- Staff supported and involved women, families and carers to understand their condition and make decisions about their care and treatment. Women and families were provided with appropriate information. Staff took additional time to explain scan findings and answer questions.

Are services responsive?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it 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 women's individual needs and preferences. Staff made reasonable adjustments to help women access services. They coordinated care with other services and providers.
- Feedback from women and staff identified that women were seen promptly and could access appointments easily and quickly.
- The service had a complaints policy which demonstrated that it would treat any concerns and complaints seriously, however, no complaints had been received by the service.

However, we also found the following issues that the service provider needs to improve:

- Waiting times for appointments were not routinely monitored. We were not therefore, able to judge if women could access the service when they needed it or if they received the right care promptly.
- It was not always easy for women to give feedback and raise concerns about care received as there was no complaints information displayed by the service.

Are services well-led?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated it as **Good** because:

Summary of this inspection

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for women and staff. They supported staff to develop their skills.
- The service had an aim statement for what it wanted to achieve and objectives to turn it into action.
- Staff felt respected, supported and valued. They were focused on the needs of women receiving care. The service had an open culture where women, their families and staff could raise concerns without fear.
- Leaders operated effective governance processes, throughout the service. Staff were clear about their roles and accountabilities and had regular opportunities to meet. Team meetings were held and were used to discuss any issues of concern.
- The registered manager identified relevant risks and issues and identified actions to reduce their impact.
- The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats. The information systems used were secure.
- Staff actively and openly engaged with women. They collaborated with partner organisations to deliver appropriate services for women.
- Staff were committed to continually learning and improving services. They undertook professional development activities in order to remain up to date and improve their practice. The registered manager encouraged and supported the midwife sonographer in their continuing professional development.

However, we also found the following issues that the service provider needs to improve:

- There were no systematic processes for monitoring service performance.
- Risk assessment templates lacked detail and did not rate risks identified.
- The service did not have plans to cope with unexpected events.

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

Notes

Good

Diagnostic imaging

Safe	Good
Effective	
Caring	Good
Responsive	Good
Well-led	Good

Are diagnostic imaging services safe?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated safe as **good.**

Mandatory training

The service did not ensure completion of mandatory training by all staff in all key skills.

The midwife sonographer received and kept up-to-date with their mandatory training, however the registered manager had not recently completed many mandatory training topics. Records held by the registered manager showed that the midwife sonographer had completed mandatory training in a range of topics as part of their NHS role. The midwife sonographer provided evidence of completion of this to the registered manager. The registered manager had completed mandatory training in some topics but had not recently updated their training in infection prevention control or information governance for example. The manager told us that they had written the policies for infection prevention and information governance. As part of this they had completed reading and research around the topics in order to do this meaning they were up to date with current knowledge and practice. Following our inspection, the registered manager told us they planned to complete some online training in both infection prevention control and information governance.

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

Not all staff completed training on recognising and responding to women with mental health needs, learning disabilities, autism and dementia. The midwife sonographer had completed training in dementia and mental health awareness in their NHS role, but the registered manager had not completed any training in these topics.

The registered manager monitored mandatory training and alerted the staff member when they needed to provide updated information about their training compliance. The manager held a record of evidence of training completion which we saw to be complete and up to date.

Safeguarding

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

All staff received training specific for their role on how to recognise and report abuse. ScanLinc staff were required to complete safeguarding training courses through the Lincolnshire Safeguarding Children's Board (LSCB) which included an 'introduction to safeguarding everyone in Lincolnshire' module and the LSCB 'Pre-birth protocol-policy'. Training was reviewed annually and re training occurred every three years. Both staff in the service were trained to level two in adults safeguarding. The midwife sonographer had completed training to level three in children's safeguarding as part of their NHS role. The registered manager had completed level two training in children's safeguarding and was booked to complete level three training in adults and children's safeguarding in March 2020.

The registered manager and the self-employed midwife sonographer were both named as safeguarding leads for the service.

Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. There was a poster displayed in the screened changing area of the scan room informing women they could talk to staff if they were frightened and provided contact details for the National Domestic Violence helpline. Staff knew how to make a safeguarding referral and who to inform if they had concerns. The registered manager told us how they had previously needed to speak to a lady on their own as they had suspicions that they may be suffering abuse. They described how they would contact the local safeguarding board if they needed advice or to make a safeguarding referral. Staff were required to seek advice from LSCB regarding any serious concerns which could affect an unborn baby's health including alcohol and drug use, domestic violence or other risk taking or dangerous behaviour or neglect that could impact upon the child.

The service had a safeguarding policy statement which outlined types of abuse, signs to watch out for and staff's responsibilities and associated procedures to be followed in the event of any safeguarding concerns.

Staff ensured that they performed the right scan on the right woman by checking women's name and date of birth with them prior to carrying out the scan.

Cleanliness, infection control and hygiene

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

Clinical areas were clean and had suitable furnishings which were clean and well-maintained, although there was carpet throughout the scan room. This is against advice from HBN 00-09, infection control in the built environment, which states in clinical areas where spillages are anticipated (including patient rooms, corridors and entrances) carpets should not be used. It was noted during our inspection, that minimal invasive procedures were carried out in area where carpet was present which minimised the risk of any spillage. The carpet was discussed with the registered manager who showed us that they had completed a risk assessment about the use of carpet in the clinical area in order to mitigate any risks. The risk assessment identified actions such as the use of protective absorbent sheets when taking blood samples or if a lady was bleeding vaginally when she attended for a scan in order to reduce the risk of any spillage on the carpet. In addition, they had a spillage kit to manage any spillages of bodily fluids which may rarely occur. The registered manager had been advised that the kit was suitable for cleaning carpet. On our first visit on 14 February 2020 we noticed there was no expiry date on the spillage kit box although the bottle of antimicrobial cleanser contained within the box was in date until December 2020. We raised this with the registered manager who contacted the supplier of the kit and was advised that the shelf life of all other items, such as the absorbent crystals was three years. When we returned to visit on 18 February 2020, we saw that the manager had placed a sticker on the box indicating a renewal date of January 2023.

The service generally performed well for cleanliness. We saw that staff used disposable paper towel to cover the treatment couch which was disposed of and replaced between patients. In addition, the couch was wiped with an antiseptic wipe between each patient. The ultrasound probe used for internal trans-vaginal scans was cleaned using a chlorine dioxide high level disinfectant at the start of each day and after each use. This cleaning process was recorded daily in a log and we saw that this was up to date. The abdominal probe which was only used externally, was cleaned with disinfectant wipes after each use, which also included wiping down the cable attaching the probe to the machine. We noted that this was routinely completed between each patient.

Cleaning records were up-to-date and demonstrated that all areas were cleaned regularly. Although there was no cleaning contract for the clinic room, the registered manager performed regularly cleaning duties their self. They had a cleaning schedule to follow which included a daily tidy and vacuum and a weekly more in-depth clean of the environment. This involved the cleaning of windows, all furniture and surfaces. The registered manager had started keeping a log of this weekly clean since January 2020 and we saw that this was complete and up to date.

ScanLinc had an infection control policy and a sharps policy that it followed in order to ensure safety to all

women. The infection control policy set out procedures for effective hand washing, the use of personal protective equipment (PPE), cleaning requirements for ultrasound probes, cleaning of spillages and the safe handling and disposal of clinical and soiled waste.

There was no hand wash sink in the clinic room, so staff had to use the facilities in the building's toilets. This was not compliant with HBN 00-09: infection control in the built environment. The registered manager told us that they informed women that they had washed their hands on the way down to collect them for their appointment. They used hand gel in front of women prior to performing invasive procedures such as taking blood and also wore protective gloves during such procedures. There was no audit of hand hygiene at the time of inspection although we saw minutes of a team meeting in June 2019 which showed that staff had completed an observation of hand washing techniques against the recommended technique documented in the Management Policy. After our inspection, the registered manager told us that in future it was planned for hand hygiene observations to form part of the documented peer review observations that happened between staff on a quarterly basis.

The midwife sonographer had completed infection prevention control training as part of their NHS role, but the registered manager had not recently completed any infection prevention control training. However, they had read current relevant guidance and information about infection prevention control practice in order to write the service's infection prevention control policy, which meant they had up to date knowledge.

We saw that staff followed infection control principles including the use of PPE items such as disposable aprons and gloves which were always worn if there was any risk of contact with bodily fluids. We noted that the sonographer wore a glove on the hand used to hold the ultrasound probe when abdominal scans were being completed. In addition, staff followed infection control principles in relation to their dress, and were observed to be bare below the elbow, have hair tied back, and not to be wearing jewellery.

Latex free items and single-use items were used at ScanLinc to protect anyone who may have any allergies and for infection control purposes. We observed that non-invasive pre-natal tests (NIPTs) were completed in line with aseptic techniques. Single use blood giving sets were used which included a disposable tourniquet and we observed that sharps were disposed of safely in a sharps bin. The service had a sharps policy which identified processes for safe sharps management including the use of sharps, managing a sharps injury, and how to report any sharps injuries received.

Blood samples taken were managed appropriately and were clearly labelled with the woman's details and the service identification barcode. Samples were sent for testing to the laboratory by next day tracked delivery and were sent in a protective box which was security sealed.

We saw that all consumables such as ultrasound gel and alcohol wipes were all within their expiry date.

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 design of the environment was appropriate for its purpose. Women waited for their appointments in a reception area which was shared by all the building occupants. Reception staff contacted the ScanLinc staff when women arrived, and they were collected and taken to the scanning room by staff. There was one scan room which included the ultrasound scanning machine, a large TV monitor, a couch, and comfortable seating for women and visitors. In addition, there was an area with a desk and further seating where consultations took place and information about the service was discussed. There was a small screened area where women undergoing an internal scan could go to remove their clothing in private.

Staff carried out daily safety checks of specialist equipment in accordance with British Medical Ultrasound Society (BMUS) guidance .There was a daily visual inspection of the ultrasound probe, cable and scanner controls to ensure they were not damaged. There were also monthly quality assurance checks of the ultrasound machine to ensure it was operating correctly. We saw that logs of all these checks were kept and that they were complete. In addition, there was a six-monthly maintenance check of the ultrasound machine carried out by the manufacturer from whom the registered manager rented the equipment. We saw that this had last been completed in January 2020. As part of the equipment hire contract, staff received regular training

and updates on the ultrasound machine from the equipment manufacturer. Staff also had access to specialist technical assistance if required. In the event of machine breakdown, the contract agreement was that an engineer would come out within 24 hours to fix the system. replacement machine. The registered manager told us that when they had experienced a fault on the machine the part required to fix it had arrived the next day after it being reported, and the engineer had got contact straight away to arrange fitting. If for any reason the machine could not be fixed, a loan machine could be made available by the company within three to five days. The registered manage described the service provided by the company as excellent.

All other electrical equipment (including the treatment couch) was annually safety tested. We saw that most electrical equipment had stickers identifying the last date of testing. All wiring such as to sockets, the heater and lights, had been tested within the last five years by the building owner, in line with their policy.

Staff disposed of clinical waste safely. The service had a business waste duty of care certificate and waste was collected and disposed of in accordance with this.

Assessing and responding to patient risk

Staff completed risk assessments for each woman and removed or minimised risks. Staff identified and quickly acted upon women in need of additional support.

Staff in the service did not provide emergency care but were trained to be able to provide first aid. There was a first aid kit available for staff to use for minor injuries which contained basic dressings which we found to be in date. If a patient experienced any sudden deterioration in health, staff told us they would call 999.

Staff completed risk assessments for each woman on arrival by asking them questions about their past medical and obstetric history, any allergies and their current health status.

Staff knew about and dealt with any specific risk issues. They explained the purpose and scope of the scan being performed and advised that they were not completing a diagnostic scan. Staff were clear with women what they were looking at during the scan procedure and informed them they were not completing a full health check of the baby. Women were encouraged to still attend their NHS scans which were performed with the aim of identifying any anomalies. Staff completed scans in line with ALARA principles (as low as reasonably achievable) to reduce any unnecessary exposure to ultrasound in order to minimise any risk. This meant they would only perform scans to provide the specific information required, such as gender identification, and would not perform extended scans unnecessarily.

Staff explained the limitations of scans and NIPTs to women before carrying them out. We heard staff explain that there may be a need to repeat a NIPT if there was insufficient foetal fragment material in the blood sample taken. In this case, women were offered the retest free of charge. Women were clearly advised that the test would only indicate the statistical risk of foetal abnormality rather than being a definitive result. The sonographer explained to women having a gender scan that they could not give a guaranteed gender decision but could only offer a likely gender decision. If the sonographer was unable to make a gender decision due to the baby's position, they would always offer a re-scan free of charge.

Staff shared key information to keep women safe when handing over their care to others. Women were advised that if the sonographer found anything unexpected or of concern, they would need to be referred to other services such as the early pregnancy assessment unit at the local NHS trust. Staff were unable to make referrals to the unit directly, therefore if staff identified any unexpected findings such as there being no heartbeat, or foetal abnormalities, they would contact the woman's GP, with their consent, in order to request a referral to the early pregnancy assessment unit. If women attended from out of area, staff were sometimes able to make direct referrals to their local early pregnancy assessment services. If any concerns were identified on scans completed after 12 weeks gestation, the midwife sonographers had good working relationships with the screening coordinator at the local NHS trust and could discuss concerns with them. The coordinator would then contact the lady and review them through the NHS antenatal pathway. If NIPT reports indicated a high risk of foetal abnormality, women were contacted by telephone and informed of their test results. With the woman's consent, the results were forwarded to the screening co-ordinators within the NHS for follow up.

Staff would signpost women to the emergency department at the local NHS trust if they felt they required urgent assessment.

The service had access to mental health support if staff were concerned about a woman's mental health. For example, they could refer to counselling services if a woman had received bad news following their scan or NIPT. Access to genetic counselling services was included in the price of NIPTs. The service had information about the miscarriage association to support women who had experienced the loss of a baby.

Staffing

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

The service had enough staff to keep women safe. ScanLinc was staffed by the registered manager and one self-employed midwife sonographer. Both were qualified midwives with post graduate sonography training and were registered with the Nursing and Midwifery Council (NMC). Each staff member had the medical qualifications and clinical experience required to provide the service. The registered manager worked three days a week and the other member of staff worked two days a week. At the time of the inspection this was sufficient to meet the demands of the service. The registered manager told us that if there was any length of staff absence for any reason, they would reduce the number of scans they offered and performed.

The service had no staffing vacancies at the time of inspection.

The service had low turnover rates; no staff had left the service in the 12 months before the inspection.

The service was not using agency staff at the time of inspection and had not needed to use agency staff since it began operating in October 2018.

The registered manager had produced a lone working risk assessment to ensure staff remained safe when working alone. The service sometimes operated outside of the hours when the building reception and security staff were present. At weekends and after 5pm, staff would need to let patients into the building, which would be locked once reception staff had left for the day. As part of the lone working risk assessment, the manager was looking into the option of using an app which would alert an emergency contact if a staff member was in difficulty.

Records

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

Patient notes were comprehensive, and all staff could access them easily. The service used a standard records template for all women which included their personal details, medical and obstetric history, current health information and details of scan findings. We reviewed five sets of records and saw that all sections of the templates were completed in all records reviewed. All records were dated and identified any actions required following the scan findings. However, in three out of the five records reviewed we saw that there was no name documented of the sonographer who had performed the scan. There was no section on the template for the staff name to be recorded. At the time of inspection, the service did not routinely complete audits of patient records. The registered manager stated that staff look at each other's records during the peer review process but there was no documentation of what had been reviewed. However, after our inspection, the manager provided evidence that a records audit process had been developed which involved a biannual audit of a sample of 20 records against a checklist template. A first audit had been completed and learning from the findings had been identified and discussed between the sonographers.

Records were stored securely as electronic care records. All electronic information was stored on centralised password protected facilities. Any consent forms that were signed by women were stored in a locked box kept in the scan room, which only the registered manager and the midwife sonographer had a key for. These forms were kept for a period of one year before being securely destroyed. Ultrasound images were not retained in hard copy as any images that were printed were given straight to the client to take away as their own. The ultrasound machine stored images taken in an archive and deleted them automatically after 183 days.

Good

Diagnostic imaging

When women transferred to a new team, there were no delays in staff accessing their records. Any high-risk results from NIPTs or concerning later scan findings were shared with screening coordinators in the local NHS trust. NIPT test results were forwarded to the coordinator by email. Where there were any scan findings of concern, the lady was given the images and report in a sealed envelope to take to their GP, the screening coordinator or local early pregnancy assessment unit as appropriate.

Medicines

The service did not store, prescribe or administer medicines.

Incidents

The service managed safety incidents well. Staff recognised incidents and near misses and knew how to report them appropriately. However, the manager did not have a process for investigating incidents and sharing lessons learned with staff. When things went wrong, staff understood the need to apologise and give women honest information and suitable support.

Staff knew what incidents to report and how to report them. Staff felt confident to raise concerns and report incidents and near misses in line with the service's incident management policy. There had been no incidents reported since the service began operating in October 2018.

Staff understood how and when to report serious incidents in line with the service's incident management policy which stated that all serious incidents needed to be reported as soon as possible to the Health and Safety Executive (HSE). There had been no serious incidents reported since the service began operating in October 2018. However, the manager told us that if an incident occurred, the details would be discussed in team meetings.

The service had no never events.

Staff understood the Duty of Candour and described the need to be open and transparent and give women and their families a full explanation if and when things went wrong. However, the service had not needed to make any duty of candour notifications since it had been in operation.

The registered manager did not have a process for investigating low risk incidents as part of their incident management policy. There was no process for staff to routinely receive feedback from investigation of incidents. Following our inspection, the manager updated their incident management policy to include a process for identifying and sharing learning from any low risk incidents.

Are diagnostic imaging services effective?

We have not previously rated this service. We do not currently rate effective for diagnostic services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and best practice. The manager 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. We saw that policies provided were in date for review and were referenced to national legislation such as the Health and Safety at Work Act 1974 and the Control of Substances Hazardous to Health Regulations 2002. Policies also referred to care standards guidance from the Department of Health (2010) Essence of Care document and Department of Health (2007) Dignity in Care document. The manager told us that staff remained updated through BMUS (British Medical Ultrasound Service) publications and meetings and attendance at national conferences.

Nutrition and hydration

There were refreshments available at the service. Staff ensured water was available for women during appointments and there was a vending machine with drinks and snacks available in the reception area.

Pain relief

Staff assessed and monitored women regularly to see if they were comfortable. We observed staff making adjustments to a woman's position during scans to ensure they were comfortable throughout.

Patient outcomes

Good

Diagnostic imaging

The registered manager did not have processes in place to routinely monitor the effectiveness of care and treatment. They were therefore unable to use audit findings to make improvements and achieve good outcomes for patients.

The registered manager told us that the quality of the service was demonstrated by the number of re-visits, women's reviews and word of mouth recommendations that made use of the service. The service had recently started collecting patient feedback and was in the process of collating this data at the time of our inspection.

There were no other methods of collecting outcomes for patients at the time of our inspection. The service did not routinely complete any audits of their practice. This meant that managers and staff were unable to use audit results to improve patients' outcomes.

Competent staff

The service made sure staff were competent for their roles. However, managers did not have a documented appraisal process to monitor staff's work performance. Peer supervision sessions were held between staff to provide support and development.

The registered manager had sought input from a senior specialist midwife sonographer and clinical supervisor in the NHS to supervise their practice and provide feedback and suggestions for improved practice.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of women. There were two staff who delivered the service; the registered manager and a self-employed midwife sonographer. Both staff were midwives registered with the Nursing and Midwifery Council (NMC) and had the medical qualifications and clinical experience required to provide the service. They had both completed a post graduate qualification in sonography and the midwife sonographer had also completed additional training at Master's degree level in scans during the third trimester of pregnancy. This enabled them to complete 3D and 4D scans.

Managers gave all new staff a full induction tailored to their role before they started work. ScanLinc had an induction pack for any new members of staff, such as agency staff, although agency staff had not been employed in the service since it started operating. The manager told us that any new staff would not be left to work unsupervised until they had proven their capabilities and any training needs had been identified and addressed. All new members of staff would be offered workshops and training within the area of early pregnancy, for example, attendance at the annual early pregnancy conference. This scientific meeting had been attended by both existing staff in the service in 2018 and 2019.

Regular training and updates on the ultrasound machine were delivered by the manufacturing company who provided the ultrasound machine on hire.

Both staff were members of the British Medical Ultrasound Society (BMUS) and were able to keep up to date with the latest information by reading the monthly BMUS ultrasound publication.

Managers did not support staff to develop through yearly, constructive appraisals of their work. A formal documented staff appraisal system was not in place at the time of inspection. However, staff were supervised in their practice quarterly through a peer review process of each other's practice. The midwife sonographer explained these peer reviews were documented using a set template and these records were kept by the registered manager. Following our inspection, the registered manager planned to complete an appraisal with the midwife sonographer. There was a further opportunity for staff to reflect on their practice through six monthly meetings with a clinical psychologist. At these meetings staff could discuss cases, such as when they had identified a pregnancy loss, so that they could explore their feelings and be supported to manage them.

Staff had the opportunity to discuss training needs with the registered manager and were supported to develop their skills and knowledge. There were informal conversations during peer supervision sessions and on an ad hoc basis when staff could identify any training needs. The midwife sonographer explained that the registered manager supported them to attend the annual early pregnancy conference and funded this.

Managers made sure staff received any specialist training for their role. There were regular training update sessions provided by the ultrasound machine manufacturing company.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. Meetings were held between the registered manager and the midwife sonographer every three months and covered any issues arising rather than following a set agenda. We saw that a documented record of these meetings was kept and that these identified any actions required.

Multidisciplinary working

Sonographers and other healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

Staff worked together with other agencies, when required, to care for women. For example, the service worked with local GPs, the local NHS screening coordinator, and local counselling and support services to provide holistic and coordinated person centred care.

Staff referred women to other services for additional support as appropriate. For example, if NIPT results indicated a high risk, women were offered genetic counselling as part of the test package.

Seven-day services

Services were available five days a week to support timely patient care.

Scan appointments were able to be booked through an online booking system where appointments were available in advance and on the day. Appointments were offered Monday through to Saturday except for on Tuesdays. Clinics were held up to 8pm on some days to accommodate attendance for working couples.

Health promotion

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

The service did not have information leaflets in the clinic promoting healthy lifestyles in pregnancy. However, there were links to health information on the service website, such as NHS choices and government advice on healthy eating during pregnancy, including advice on alcohol consumption and smoking. Following our inspection, the registered manager told us that they had put a poster up in the clinic room about the risks of smoking when pregnant. In addition, they had added smoking and alcohol consumption to the list of questions to ask women who attended, in order that they could provide health promotion advice as appropriate. We observed staff giving contact information to women about local antenatal services such as aqua natal and hypnobirthing classes.

Consent and Mental Capacity Act

Staff supported women to make informed decisions about their care and treatment. They followed national guidance to gain women's consent. However, there was no evidence that staff had completed Mental Capacity Act training, meaning they may not know how to support women who lacked capacity to make their own decisions. Nor had staff received training to recognise women who may be experiencing mental ill health.

Staff gained consent from women for their care and treatment in line with legislation and guidance. There was guidance for staff on obtaining patient consent in the service's management policy. The policy identified that consent could be verbal, in writing or non-verbal but implied, for example offering out an arm for the taking of a blood sample. Staff at ScanLinc recorded obtaining consent in the case notes. There was an assumption that women could make their own decisions unless it could be proved that they were unable to do so. The registered manager told us that staff in the service followed the principles of the Mental Capacity Act 2005 to assess if a person had capacity. After answering any questions and explaining the examination/procedure, if the staff member judged a woman to have the capacity to give consent then the procedure would be carried out. If the staff member believed that the person did not have the capacity to make a decision, they deferred completion of the intervention and sought advice from the team at the Lincolnshire Safeguarding Board.

Staff had not received training in the Mental Capacity Act (MCA) and Deprivation of Liberty Safeguards. There was no record to evidence that either member of staff had completed any training in the Mental Capacity Act. When this was raised as a concern with the registered manager, they told us that they had booked themselves onto an e-learning Mental Capacity Act programme. They

provided evidence that they had completed these sessions in February 2020, shortly after our inspection. However, they were unable to provide evidence that the midwife sonographer had completed MCA training.

Staff clearly recorded consent in the patients' records. Women needed to give specific consent to an internal examination if this was required, for example, when an early pregnancy scan was performed. We saw that this consent was documented in the lady's notes.

Consent to refer to other services such as the GP or local screening coordinator and share information with them was sought appropriately.

Women undergoing a NIPT were given a written information leaflet detailing the purpose of the test to enable them to make an informed decision.

We observed that as part of the consent process, staff gave women an explanation of the procedure they planned to perform and ensured women verbally consented to this before they carried it out. However, consent to the service's terms and conditions was completed after scans had been completed. This included obtaining a signature from women to show they agreed to the terms and conditions and the taking of payment. Fees for the service were not discussed with women prior to scans or blood tests being completed, but the registered manager explained they were clearly displayed on the service website, so women knew the cost before they arrived.

Access to information

Staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment. All staff had access to an electronic records system that they could update.

Are diagnostic imaging services caring?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated caring as **good.**

Compassionate care

Staff consistently treated women with compassion and kindness, respected their privacy and dignity, and took account of their individual needs. Feedback from families who had used the service was extremely positive and highlighted that staff took extra time to put women at ease.

Staff were discreet and responsive when caring for women. We saw that staff took time to interact with women and those close to them in a respectful and considerate way. All appointment slots were 45 minutes long, which gave women enough time to have a discussion about any concerns and to ask questions. There was a large television screen in the scan room which displayed the images so that women and their visitors were able to view them easily. We observed how the sonographer took time to speak with both the women and their visitors to help their understanding of what they were viewing. They made sure they highlighted areas on the screen and took time to explain what they could see. After the scan was completed, the sonographer sat with women and their visitors and showed them the printed images of the scan. They described what they could see and highlighted features to women and their visitors to ensure they could understand them.

Staff were required to adhere to the 10 core principles of the dignity challenge (Department of Health, 2007). We saw that staff embraced this in several ways. For example, they always introduced themselves by name at the beginning of consultations and treated women and their families as individuals, involving them in their care and seeking to offer them a personalised service.

Women whom used the service said staff treated them well and with kindness. There was a lot of positive feedback on the service website and on social media as well as thank you cards displayed at the clinic. We saw that one social media site showed an average recommendation score of five out of five and another site scored the service as 4.8 out of five. Women's comments we saw on thank you cards and on the internet included:

- staff were described as 'lovely' and 'patient'.
- staff made sure we understood everything, answered our questions and always left us feeling cared for and listened to.

- staff made me and my partner feel very comfortable and made the whole experience so special.
- staff were inviting from the start and made us feel at home.
- the sonographer was really lovely, and the scan experience was an amazing experience to have; every detail was clear and explained.
- the sonographer gave us lots of time and clear information that was above and beyond the remit of our appointment.
- on one occasion, the sonographer was described as providing an experience to remember by being kind enough to involve a woman's little sister (aged 7) by letting them have a go at doing a little scan to see the baby's heartbeat.

We saw that staff were friendly and welcoming and took time to put women at their ease. Soft music was played during scan appointments to create a welcoming and calming atmosphere. Noise and light levels were kept to a minimum to help women relax.

Women's privacy and dignity was maintained through a variety of methods. Consultations, treatment or discussions were not interrupted except in an emergency. During appointments, the door was locked to ensure there were no interruptions and to maintain a lady's privacy. Staff warmed the ultrasound gel before use to ensure the experience was as comfortable as possible for women. Paper towel was used to cover women's clothing to keep it clean. When an internal examination was required the woman would be asked to go behind a mobile screen which was used to provide a private changing area within the room for a woman to undress her lower half. A dignity sheet was provided to cover the woman as much as possible during the examination.

Staff followed policy to keep patient care and treatment confidential. Care was taken when accessing the electronic diary to re-book appointments for women. The computer screen was turned away so that another client's information could not be overlooked.

For early pregnancy scans a relative or friend was advised to attend due to the possibility of an internal examination where the relative or friend would act as a chaperone during the ultrasound scan. If a lady did not bring a chaperone to their appointment a second healthcare professional would act as chaperone if they were available. If a second member of staff was not available or the lady declined to have a second healthcare professional present for an internal examination, they would be invited back at another time when two members of staff could be available, or the lady could be accompanied by a family member or friend.

Emotional support

Staff provided emotional support to women, families and carers to minimise their distress. They understood women's anxiety, spent time offering reassurance and demonstrated empathy. If women had suffered a pregnancy loss, staff understood the impact of this and provided appropriate support both during and after appointments.

Staff gave women and those close to them help, emotional support and advice when they needed it. Counselling was available from partner organisations and was offered as part of the NIPT package if high risk results were received. Women were also referred to specialists in the NHS for additional support and advice if required. The service held information and contact numbers for counselling services, for example, Miscarriage Association cards and leaflets were available for any women suffering a loss. This information was available in several different languages.

Staff supported women who became distressed and demonstrated empathy when having difficult conversations. We saw patient feedback on thank you cards stating that staff had been 'kind and sympathetic' and 'compassionate' when women had experienced a pregnancy loss.

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. Staff were aware that women attending for an early pregnancy scan could be very anxious and needed reassurance. The sonographers made sure they were aware of a woman's previous obstetric history by reading any records from previous attendances at the clinic. This meant they were able to provide additional sensitivity and support for women attending for an early scan who had previously suffered a pregnancy loss. Women who had provided feedback regularly commented on how staff had demonstrated understanding of their anxieties by being

patient and allowing time for discussion, questions and reassurance during appointments. We saw that appointments were not rushed, and that staff ensured women had sufficient opportunity to ask questions before they left the appointment. We observed that staff provided reassurance to women during early pregnancy scans and pointed out the heartbeat as soon as it was identified. They advised women that the scan findings looked as expected and that they would have pointed out any concerns had they identified them. This demonstrated that staff understood the anxiety many women felt when attending for early pregnancy scans. Staff told us that the 45-minute appointment slots enabled them to have time to get to know women and their families and to have time to break bad news and offer advice and support if required. The midwife sonographer told us that they would follow up any women who had been referred on to early pregnancy services at the local hospital by taking the time to call them and ensure they had been seen and were being appropriately supported.

Understanding and involvement of patients and those close to them

Staff supported and involved women, families and carers to understand their condition and make decisions about their care and treatment. Women and families were provided with appropriate information. Staff took additional time to explain scan findings and answer questions.

ScanLinc welcomed partners, husbands, relatives and children to be present at scan appointments at a lady's discretion.

Staff made sure women and those close to them understood their care and treatment. We observed that time was taken to explain the scan images and describe the scan findings in detail both during the scan and afterwards when discussing the printed images with families. We saw that staff encouraged women and their visitors to ask questions during and after the scan. Staff were mindful that patients might be anxious and prompted them to ask relevant questions to support their understanding. We observed the sonographer pointing out key features of the image such as the baby's heartbeat, ribs, spine, stomach and bladder. This meant that families were involved in the experience and could understand the scan findings clearly.

Staff talked with women, families and carers in a way they could understand, giving plenty of opportunity for questions to be asked. The service did not have access to interpreters, but the registered manager explained how they had used a translation app on their mobile phone to ensure communication support was provided for a family whose first language was not English. They also explained using gestures to improve understanding and having worked with a sign language interpreter who attended with a woman who was deaf.

Women and their families could give feedback on the service and their treatment. Many women left feedback on the service website or social media sites. We saw that feedback provided was extremely positive with women consistently praising the staff and the scan experience they had received. In addition, some women took time to send thank you cards to the service which described overwhelmingly positive patient experiences. The service did have some comments cards for women to provide feedback, however, these were not provided to all women. The registered manager told us they were issued to women at random, and that two or three cards per day were handed out. Completed cards were placed in a box at reception. The service had only been collecting feedback for three months at the time of inspection. Twenty-three feedback cards had been completed which showed that 100% of women had rated the service as the highest rating of excellent. Following our inspection, the registered manager told us they planned to review the process for patient feedback so that all women had the opportunity to complete a feedback card.

Are diagnostic imaging services responsive?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. We rated responsive as **good.**

Service delivery to meet the needs of local people

Good

Diagnostic imaging

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.

Managers planned and organised services so they met the changing needs of the local population. The service offered appointments at different times of the day and at weekends in order to facilitate the attendance of working couples.

Facilities and premises were appropriate for the services being delivered.

Staff could access mental health support in the form of counselling for women who had experienced bad news, such as a pregnancy loss or high risk NIPT result.

The manager did not routinely monitor missed appointments or 'no shows' and did not have a process to manage these. The registered manager told us that numbers of women not attending for their booked appointment were low and the incidence of no shows was sporadic. They had reviewed numbers last year and identified there were less than 5% of appointments that were no shows. The manager had considered taking payment or a holding deposit at the time of booking appointments but due to the low numbers had decided this was not necessary. They did not feel it appropriate to contact women that did not show for their appointment in case the reason for their attendance was that they had suffered a pregnancy loss.

Meeting people's individual needs

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

Although the service was tailored to women of a child bearing age, they could cater for able bodied women and those with a disability. The treatment couch was electric which made it accessible for women with any mobility problems.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. The manager had facilitated a deaf woman attending for a scan with a sign language interpreter to enable them to be fully involved in the process.

The service did not have access to interpreters, but staff had used the support of relatives and friends attending appointments when needed. The manager gave us an example of how they had used an online translation tool on one occasion to facilitate communication with a family whose first language was not English.

The service had information on some support organisations available in languages spoken by women in the local community.

Access and flow

Waiting times for appointments were not routinely monitored. We were not therefore, able to judge if women could access the service when they needed it or if they received the right care promptly. However, feedback from women and staff identified that women were seen promptly and could access appointments easily and quickly .

The manager did not routinely monitor waiting times for appointments but described a responsive service that was able to offer quick and easy access to appointments. Appointment bookings were mainly made through an online booking system where appointments were available in advance and on the day. The manager told us the service was responsive to any enquires received and encouraged women to contact the service by telephone if they could not find a suitable appointment slot on line. They described being able to offer most women an appointment of their choice. Although some appointments were booked in advance, there were appointment slots routinely kept free at the beginning and end of each day to enable women requesting an emergency scan to be able to access the service promptly. According to social media and booking data, the service had a response rate to any enquiries about appointments of, on average, less than an hour. The responsiveness of the service was consistently referred to in feedback provided by service users.

The service offered structured appointments which followed a pattern to ensure consistency of approach. Each appointment was offered as a 45-minute slot which

allowed for every eventuality including late arrival, poor positioning during gender scans, or providing emotional support to any women found to have suffered a pregnancy loss. Appointments allowed sufficient time for questions and for each family to feel listened to, cared for and supported. Waiting times in the clinic from booked appointment time to time seen were not routinely monitored. However, since appointment slots were 45 minutes and offered adequate time to complete procedures, the clinic did not usually run with delays

There had been no appointments cancelled by the service for any reason in the 12 months before the inspection.

The manager told us that waiting times for receiving the results of NIPTs was minimal and usually within a few days of the test. We saw that women were advised that should take three to five working days but to allow up to seven to ten days. The sonographer advised women of the process for receiving their results, which was first from the sonographer by telephone and then in writing through the post or by email.

Staff supported women when they were referred or transferred between services. The sonographer provided copies of scan reports and scan images when referring women to the local early pregnancy service (via their GP) or on to the screening coordinator at the local NHS trust.

Learning from complaints and concerns

It was not always easy for people to give feedback and raise concerns about care received as there was no complaints information displayed by the service. The service had a complaints policy which demonstrated that it would treat any concerns and complaints seriously, however, no complaints had been received by the service.

Women, relatives and carers may not know how to complain or raise concerns as there were no leaflets or posters providing information about a complaints process. Although there were service contact details on the ScanLinc website, there was no specific information about how to make a complaint. This was raised with the registered manager and following our inspection, they planned to update the patient feedback form to include information on how to complain and to add information to the service website.

Staff understood the policy on complaints and knew how to handle them. There was a complaints procedure which identified that any complaint raised would be responded to by the registered manager. There was a complaints response template letter which invited women to discuss their concerns further with the registered manager but also offered the option to correspond by letter. The letter invited women to advise the service what steps they could take to resolve their concerns and promised a response within 48 hours.

The manager explained that they would investigate any complaints received, apologise to women for any distress caused and seek to identify a satisfactory resolution. The complaints template response letter provided contact details for independent bodies which women could escalate their complaint to if necessary.

The registered manager told us that they would share any feedback or learning from complaints with staff during team meetings. The service's complaints process stated that if any suggestions or complaints were made in regard to staff, premises or care then these suggestions would be implemented, or the member of staff spoken with to avoid any future instances.

Are diagnostic imaging services well-led?

Good

We have not previously rated this service and cannot therefore compare ratings with the last inspection. 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 in the service for women and staff. They supported staff to develop their skills.

The service was led and delivered by the registered manager who was a qualified midwife with additional training in obstetric sonography. In addition, they had previous clinical experience in an early pregnancy unit. This meant they had transferable leadership skills and experience appropriate for the service.

The sonographer employed in the service told us that they had regular contact with the registered manager and that they demonstrated a passion for delivering a first-class service. They felt that the registered manager led the service with integrity and had a priority of providing a personalised service resulting in a positive and valuable experience for women at each appointment.

Vision and strategy

The service had an aim statement for what it wanted to achieve and objectives to turn it into action.

The aim of the service was 'to provide an ultrasound service for the Women of Lincoln, North Lincolnshire and Nottinghamshire which provides care, opinion and reassurance to women and their families in the early weeks of their pregnancies'. There were a set of objectives set out in order to achieve this. The registered manager told us that the aim and objectives had not been reviewed since they were set out in the statement of purpose for the service when it was established. The manager said that they would add a review of the service aims and objectives to the next team meeting.

Culture

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

The service sought to promote a positive culture through the sharing of positive feedback and to put the service user at the heart of all decisions. We observed that women and families were involved in their scan experience and their satisfaction with the service they received was paramount.

The midwife sonographer working for the service described a very positive working culture, stating that they had very good job satisfaction as the service was delivered with high moral and ethical standards. They told us that it was a great place to work as the focus was on the quality of service that women received.

There was a culture of openness and honesty in the service. Staff in the service recognised their professional responsibility to be open and honest with clients, colleagues and regulators in line with Duty of Candour regulations. The incident policy for the service stated the importance of an honest and open environment where incidents were learnt from with a no blame culture.

Governance

Leaders operated effective governance processes, throughout the service. Staff were clear about their roles and accountabilities and had regular opportunities to meet. Team meetings were held and were used to discuss any issues of concern.

The registered manager was the governance lead for the service. They had developed policies and procedures which guided safe practice, and these were easily accessible. There were policies for safeguarding, infection control, sharps management, data protection, incident management, and dignity and privacy. In addition, there were documented processes for complaints and consent. Policies were evidence based, version controlled, dated and identified a review date. Policies we reviewed were in date.

The service had had a defined set of terms and conditions which women were asked to review and sign during their appointment. There were identified care pathways that were followed by staff in the service. The registered manager had indemnity insurance for the service.

Both staff working in the service had valid up to date enhanced Disclosure and Barring Service (DBS) checks.

Team meetings were held between the registered manager and the midwife sonographer quarterly. We saw that minutes of these meetings documented discussion of any issues arising and identified any actions required to be taken.

Managing risks, issues and performance

The registered manager identified relevant risks and issues and identified actions to reduce their impact. However, there were no systematic processes for monitoring service performance. Risk assessment templates lacked detail and did not rate risks identified. The service did not have plans to cope with unexpected events.

Risk assessments were carried out by the registered manager and held electronically. We saw that there were

risk assessments for blood and body fluid spillage, lone working, working environment and ergonomics and musculoskeletal injury and wellbeing. All risk assessments were kept together in one file and were easily accessible. The template was brief and did not consistently identify the date the risk assessment had been completed nor a risk rating or list of mitigating actions in place. There was no mechanism for tracking what actions were planned and whether they had been completed within agreed timescales. This was raised with the registered manager during inspection who took swift action to update the risk assessment template. They provided evidence that all risk assessments were added to the new template which we saw included a description of the risk, control measures taken, and further action required and by whom. The risks were rated using a risk grading matrix and the assessment date and annual review dates were documented. We were reassured that there was a more robust risk assessment process established following our inspection.

There was no major incident plan for the building where the service operated from. The registered manager did not have a business continuity plan for the service. However, the service did have an agreement with the provider of the ultrasound machine to repair or replace it in the event of breakdown.

Although the service collected some patient satisfaction feedback, there were no other routine processes to measure service performance. For example, appointment wait times, no show appointments or record audits were not completed. This was raised with the registered manager who said they felt assured that women could access appointments of their choice based on the feedback given about the responsiveness of the service. However, they planned to complete a review of patient records as a measure of performance. Soon after our inspection, the manager provided evidence that they had completed an initial records audit and planned to compete this biannually going forwards.

Staff completed peer reviews of each other's practice which were documented. This was a process used to monitor their individual clinical performance. These reviews included the scan process, reviewing of scan findings and the recording of this and sonographer attitude.

Managing information

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats. The information systems used were secure.

There were team meetings held between the registered manager and the midwife sonographer to ensure that relevant information was shared.

Patient records were held securely on an electronic system which was password protected and could only be accessed by staff working in the service.

There was a terms and conditions document which was discussed with women during their appointment and then requested to be signed by them. Terms and conditions were clearly displayed on the service website.

There were established systems for sharing information with partner organisations such as local GPs and NHS trusts. Scan images, reports and NIPT results were shared with a woman's consent with services if required.

The incident management policy outlined the process for reporting serious incidents to the Health and Safety Executive (HSE).

Engagement

Staff actively and openly engaged with women. They collaborated with partner organisations to deliver appropriate services for women.

The manager had recently started collecting feedback from women through the use of comments cards. At the time of our inspection, comments cards were not offered to all women, but the manager planned to increase the use of feedback cards so that all women had the opportunity to provide feedback on their experience if they wished. However, the manager reported that feedback was also freely provided by women through social media and email. The service was responsive to feedback in order to make improvements. For example, service users had requested more specific directions and advice to be texted to them prior to the ultrasound scan, which was then implemented, and the service had begun offering extended evening working times in order to accommodate working couples.

Good

Diagnostic imaging

The manager described a good working relationship with the screening coordinator at the local NHS trust. This enabled them to work well together to provide appropriate care pathways to pregnant women.

The service provided information about some local antenatal services such as aquanatal and hypnobirthing classes to promote women's awareness of other opportunities available during their pregnancy.

Learning, continuous improvement and innovation

Staff were committed to continually learning and improving services. They undertook professional development activities in order to remain up to date and improve their practice. The registered manager encouraged and supported the midwife sonographer in their continuing professional development.

As both staff members were midwives, they were required to continue to learn and develop their knowledge in order to maintain their NMC registration. Staff achieved this through regular online learning, reading research and journal papers and attendance at training courses and conferences. Peer supervision and reflection sessions with the clinical psychologist provided a further method for personal professional development. The midwife sonographer told us that they liked to keep up to date and that the registered manager supported and encouraged this. They explained that the registered manager had a focus on quality and continuous improvement for the service.

There was regular communication between the registered manager and the midwife sonographer which gave opportunity for sharing of any ideas for service improvement or suggestions for changes in practice.

The registered manager was continuously looking at ways to further improve the service and information provided on the website. The website was regularly updated with current information, patient feedback and appropriate links to other websites and services. They had identified a need to consider offering merchandise for gender reveal events through patient feedback and knowledge of what other local services offered. At the time of inspection, they were considering offering the sale of heartbeat bears and gender reveal boxes to women.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider SHOULD take to improve

- The registered manager should consider completing additional mandatory training in topics such as infection prevention control and information governance.
- The registered manager should consider discussing with the building owner, making the provision of a clinical handwash sink in the scan room a high priority when any refurbishment of the existing premises is undertaken, in order to be compliant with Health Building Note 00-09: infection control in the built environment.
- The registered manager should consider discussing with the building owner, replacing the carpet for flooring that is compliant with HBN 00-09: infection control in the built environment, when any refurbishment of the existing premises is undertaken.
- The service should ensure that regular hand hygiene audits are completed and that there is documented evidence of this happening. (Regulation 12: Safe care and treatment)
- The registered manager should ensure that a process for identifying and sharing learning from any low risk incidents is embedded within the service. (Regulation 12: Safe care and treatment)
- The service should ensure that there is an embedded process for routinely measuring and monitoring patient outcomes such as appointment and clinic waiting times. (Regulation 17: Good governance)
- The registered manager should ensure that a formal documented annual staff appraisal system is developed. (Regulation 18: Staffing)
- The service should ensure that information about how to complain is easily available to women. (Regulation 16: Receiving and acting on complaints)
- The service should consider further developing their patient feedback process to enable all women the opportunity to provide feedback on their experience.
- The service should ensure that they can access a major incident plan for the building and have their own business continuity plan for the service. (Regulation 12: safe care and treatment)