NW Ultrasound Services Limited

Insta-Scan

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	**Requires Improvement**
Are services effective?	**Inspected but not rated**
Are services caring?	**Good**
Are services responsive to people's needs?	**Requires Improvement**
Are services well-led?	**Requires Improvement**

Summary of findings

Overall summary

We rated this service as requires improvement because:

- Staff did not always collect all the information they needed to ensure they could safeguard service users.
- Staff did not always have enough time to assess risks to service users and manage safety well.
- Staff did not always provide service users with information in a way that supported them to make informed choices around consent.
- The service did not always provide reasonable adjustments to support people to engage with the service.
- The service did not always comply with General Data Protection Regulations
- The service did not always have systems and processes in place to ensure staff could perform their duties in line with policies.
- The service did not have servicing records for the ultrasound machine available at the time of the inspection.

However:

- The service-controlled infection risk well. Staff had training in key skills and understood how to recognise abuse.
- Staff provided evidence-based care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of service users and understood the need to gain consent.
- Staff treated service users with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their pregnancy. They provided emotional support to service users, families and carers.
- The service planned care to meet the needs of local people and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for appointments.
- Leaders developed a vision and values for the service and applied them in their work. They were focused on the needs of service users receiving care. They were clear about their roles and accountabilities. The service engaged well with service users and the community to plan and manage services and were committed to continually improving services.

Summary of findings

Our judgements about each of the main services

Service		Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement		See overall summary.

Summary of findings

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Summary of this inspection

Background to Insta-Scan

Insta-Scan is operated by NW Ultrasound Services Limited. The service first registered with the Care Quality Commission (CQC) since 6 May 2020. The service is registered to provide diagnostic imaging and the registered manager has been in place since registration. The registered manager is the person responsible for the service and is also the director of the provider company. The manager and the sonographer were the only members of staff employed by the service at the time of our inspection.

The service provides private ultrasound services to self-funding service users who are over the age of sixteen and more than six weeks pregnant. The scans offered by the clinic include; early pregnancy scans from six weeks gestation, reassurance and gender scans from 14 weeks and reassurance and 4D scans from 26 weeks. At the time of our inspection the service did not offer transvaginal scans or non-invasive prenatal tests (NIPTs).

How we carried out this inspection

We inspected this service using our comprehensive methodology. We carried out an unannounced inspection on 28 May 2022.

To get to the heart of service users' 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.

During our inspection we spoke with four service users and their families who attended the service on the day of our inspection. With their consent, we observed these service users' ultrasound scans. We spoke with one other service user on the telephone after our inspection.

We interviewed the registered manager and the sonographer, reviewed five service user records and looked at a range of policies, procedures and two staff files.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Outstanding practice

We did not find any outstanding practice.

Areas for improvement

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

Action the service MUST take to improve:

Summary of this inspection

- The service must ensure service user records are stored in line with General Data Protection Regulations (Regulation 17(1)(2)(c)).

Action the service SHOULD take to improve:

- The service should ensure service users are given enough time and information to understand and complete consent forms (Regulation 11 (1)).
- The service should ensure they have sufficient systems in place to support staff to report abuse (Regulation 13 (2)).
- The service should ensure staff have enough time to fully assess risks to service users (Regulation 12(2)(a)(b)).
- The service should ensure systems and processes are in place to support staff to perform their duties in line with policies (Regulation 17(1)).
- The service should make reasonable adjustments to support service users to access the service and understand their care and treatment (Regulation 9(3)(c)).
- The service should consider increasing the time between appointments to ensure staff have time to manage the individual needs of service users and prevent the service from becoming overcrowded.
- The service should consider providing service users with health promotion materials.
- The service should consider implementing training for healthcare staff about breaking bad news to service users.
- The service should ensure they signpost service users who are dissatisfied with the outcome of their complaints to the correct organisation.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Requires Improvement	Inspected but not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic and screening services

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

Are Diagnostic and screening services safe?

Requires Improvement

Mandatory training

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

The registered manager completed mandatory training relevant to their role online. We saw they developed a schedule and checklist to keep track of how often they should repeat the training and when it was next due. The schedule was in line with the NHS Health Education England core skills training framework.

The mandatory training was comprehensive and met the needs of service users and staff. The mandatory training included key topics such as infection prevention control, fire safety, information governance, health and safety and equality and diversity.

The sonographer completed mandatory training as part of their role as a sonographer in NHS pregnancy services. The registered manager collected evidence the sonographer was up to date with all their NHS mandatory training.

Safeguarding

Staff understood how to protect service users and completed training about how to recognise abuse. However, staff did not always collect enough information to report abuse properly.

The registered manager completed adult and child safeguarding training up to level three. This included recognising and reporting abuse as well as recognising other vulnerabilities. The registered manager told us the service had not need to make any safeguarding referrals since the service opened. However, they were able to verbally describe situations where they would need to make a referral and could give examples of how to protect vulnerable people.

The sonographer completed adult and child safeguarding to the level they needed to be compliant with the requirements of their employment in NHS pregnancy services, level two. In their role at this service, we saw the sonographer was often alone with service users and their families during their scans. This meant the sonographer had the most opportunity to identify any potential safeguarding concerns. During our inspection, we discussed the potential risk the sonographer would not identify concerns due to not completing further safeguarding training. As a result, the sonographer completed level three safeguarding training shortly after our inspection.

Requires Improvement

Diagnostic and screening services

Staff knew how to make a safeguarding referral and who to inform if they had concerns. However, they did not always collect enough details from service users to make a referral properly. The service had a safeguarding policy in place. The policy included details of the nearest local authorities' safeguarding teams and how to contact them. However, we saw the service did not always ask for service user's addresses to support them to identify the correct local authority for each service user or include their address as part of any safeguarding referrals. We saw service users often booked their appointments using social media. At the point of booking, the registered manager asked for the service users' names, phone number and how many weeks pregnant they were. The forms staff asked service users to complete during their appointments did not ask for service users' addresses.

The service required all staff to have a Disclosure and Barring Service (DBS) check as part of their recruitment. Managers told us they would repeat DBS checks for all staff every three years in line with national guidance. The service had a recruitment policy to support this. We saw all staff had a DBS check completed within the three years before our inspection.

Cleanliness, infection control and hygiene

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

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. We saw the chairs, ultrasound couch and surfaces in the scanning room were wipeable and staff used disinfectant wipes to clean them between service users.

Cleaning records were up-to-date and demonstrated staff cleaned all areas regularly. The service had a cleaning schedule which identified what areas or equipment staff should clean between service users, daily or weekly. Staff completed the schedule each day the clinic opened. The registered manager showed us they recently introduced an audit to check staff completed the cleaning schedule properly.

Staff followed infection control principles including the use of personal protective equipment (PPE). The service provided service users with face masks and hand sanitiser at the entrance. Staff wore face masks when service users visited the service.

We saw managers used British Medical Ultrasound Society (BMUS) guidance to inform the service's infection control policy and cleaning specialist equipment.

The service provided service users and visitors with face masks and hand sanitiser when they entered the clinic. Service user consent forms asked service users if they had experienced symptoms of Covid-19 in the days leading up to their visit. However, service users were already inside the clinic when they completed the form and therefore presented a risk of infection to others.

Environment and equipment

The design and use of facilities and premises kept people safe and staff managed clinical waste well. Staff were trained to use specialist equipment however the service did not always ensure equipment was maintained.

The service had appropriate environmental, health and safety risk assessments. We saw the service was up to date with fire safety checks and managers regularly reviewed the fire risk assessment.

Requires Improvement

Diagnostic and screening services

The clinic was located on a main high street where service users could access on street parking nearby. The clinic was all ground floor level and made up of a small reception area, small waiting area, one scan room, a toilet and one storage cupboard. Although the clinic was small, staff tried to maintain social distancing by preventing too many service users and their families from being in reception or waiting areas at the same time.

The scan room contained an adjustable ultrasound couch for service users which was wipe clean and well maintained. The sonographer covered the couch in disposable paper towel roll for each service user and disinfected the couch between service users. As the service did not provide internal scans, the sonographer disposed of paper towels in a general waste bin and the service had a trade waste contract in place for waste removal.

There was a hand wash station in the scan room with appropriate hand gel and lockable cupboards where staff stored cleaning products in line with control of substances hazardous to health (CoSHH) guidance.

We saw all electrical equipment, including the ultrasound scanning machine, had up to date portable appliance testing (PAT). However, on the day of our inspection, staff were not able to describe whether the machine had any specific servicing and maintenance requirements. This meant there was a lack of assurance around the performance of the scanning machine. They told us they checked the machine probes, cables and connectors daily and the machine was under warranty. Following our inspection, the service provided evidence to show they had enquired about recommended servicing for the machine and they had purchased a new servicing contract.

Assessing and responding to service user risk

Staff identified and quickly acted upon service users at risk of deterioration. However, staff did not always assess service user risks prior to their scan.

The sonographer knew about specific risk issues and how to deal with them as they arose during scans. They had produced a clinical risk pathway which identified what action the sonographer should take depending on the severity of the risk. The clinical pathway referenced compliance with relevant national institute for health and care excellence (NICE) guidelines. The pathway identified scenarios where it would not be appropriate to continue a scan as well as which types of fetal issues required urgent intervention, urgent referrals or non-urgent referrals to NHS services. For urgent referrals, the service would send scan reports directly to a service user’s midwife, hospital or early pregnancy unit wherever possible. In all cases, service users received a copy of the scan report to show to their NHS care providers.

The clinical pathway also stated staff should telephone emergency services immediately if they suspected a service user was experiencing a medical emergency. The sonographer had completed adult and child advanced life support training. The registered manager told us they would not have service users in the clinic unless both them and the sonographer were there. This meant the sonographer would always be there if a service user suffered a medical emergency.

The service told service users they should not treat their scan as an alternative to their NHS scans. Service users signed to say they understood this as part of the consent process.

The service collected service user risk information such as physical health conditions and pregnancy history on the service user consent form. However, service users did not complete the form until after they had arrived at the clinic, immediately before their scan. We saw the registered manager would handover this information to the sonographer as the service user entered the scan room and lay on the ultrasound couch. This meant there was very little time for the

sonographer to consider relevant risk information before the scan began. During one scan we observed, we saw the sonographer did not find out about a service user's relevant health condition until their scan was in progress. We saw the registered manager and sonographer discussed this issue at a recent board meeting and agreed to look into implementing a system for service users to provide risk information before the day of their appointment.

Staff explained local NHS pregnancy services had recently introduced new digital systems which meant many service users were not able to bring their NHS pregnancy notes to their scan appointments with them. This was another factor that influenced the sonographer's ability to fully consider service user risk, however this was outside the service's control. Service users provided the service with the date of their last NHS scan on their consent forms. The service advised service users they should not have frequent scans outside of their planned NHS scans.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep service users safe from avoidable harm. However, staff were under pressure to perform their duties quickly.

The registered manager and the sonographer were the only staff employed by the service.

We saw the registered manager often needed to juggle tasks for different service users at the same time. Their duties included meeting and greeting service users, providing their consent forms, introducing them to the sonographer, transferring and printing scan reports and images and taking payments. We saw this was difficult for them to manage when there were multiple service users and their families in the clinic at the same time.

Managers told us they were conscious they wanted service users to know in advance their sonographer was male. They ensured this was clear on their website and social media platforms. We saw the registered manager offered to act as a chaperone for service users if they wanted one. However, in order to chaperone service users, the registered manager would have to either lock the clinic entrance during the scan or leave other service users alone in the reception or waiting areas.

After each service user's scan, the sonographer wrote the wellbeing report whilst the service users waited at reception. During some of the scans we observed, we saw the sonographer needed to produce scan reports quickly because other service users were waiting, and the registered manager needed to show them in before taking payment from the previous service user.

This increased the risk of either staff member making a mistake or not having time to properly considering the risks of individual service users.

Records

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

Staff stored service user notes securely and could access them easily. During each scan the sonographer stored the scan images and wellbeing report on the ultrasound scanning machine. At the end of the scan, they would copy the images and wellbeing report to a blank memory stick and give it to the registered manager. The registered manager would use the computer at reception to upload the images and report from the memory stick to a secure online cloud storage service and print copies for the service users. The registered manager would also scan the service user's signed consent form and store it with the images and report. This meant there were copies of each service user's scan and report stored both in the online cloud and on the ultrasound scanning machine.

Diagnostic and screening services

When making a referral to NHS services, staff would send service user records to secure NHS email addresses with service users' consent. Service users also received copies of their records to share with services if they wanted to.

Medicines

The service did not store or administer any medicines. Staff ensured they asked service users if they had any allergies before applying ultrasound gel.

Incidents

The service managed service user safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers ensured that actions from service user safety alerts were implemented and monitored.

Staff knew what incidents to report and how to report them. The service had a clinical incident reporting policy and a template for recording incidents, actions and outcomes from incidents. Staff told us the service had not had any incidents since they began recording them, but they were able to verbally describe situations where they would report, investigate and learn from them. The service recently introduced board meetings where staff would discuss incidents or reviews of the policy.

Staff understood the duty of candour. They were open and transparent and gave service users and families a full explanation if things went wrong.

The service received service user safety alerts from the medicines and healthcare products regulatory agency (MHRA). We saw evidence that the registered manager had reviewed an alert about the safe use of ultrasound gel to reduce infection risk and had implemented changes as a result.

Are Diagnostic and screening services effective?

We do not rate effective in diagnostic imaging services.

Evidence-based care and treatment

The service provided care and treatment based on national guidance and evidence-based practice.

Staff followed up-to-date policies to plan and deliver good quality care according to best practice and national guidance. The service had a suite of policies and copies of relevant national guidance to refer to at any time. Managers stored paper copies of policies in a folder in the clinic for staff to access. We saw the service had a policy review schedule to ensure they regularly reviewed and updated policies.

During scans we observed sonographers following British Medical Ultrasound Society (BMUS) and Society of Radiographers (SoR) guidelines using alternative techniques to obtain better images such as scanning service users on their sides. The sonographer explained they received training and updates on best practice in their role in NHS and they used this knowledge to inform their practice at the service. For example, they told us how they adhere to the standards of the NHS fetal anomaly screening programme.

Requires Improvement

Diagnostic and screening services

Pain relief

Staff assessed and monitored service users regularly to see if they were in pain.

During scans we observed the sonographer asked women if they were comfortable or experiencing any pain at regular intervals.

Service user outcomes

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

A lot of baby scan services audit rescan rate as an outcome measure. This service had developed a unique service user outcome measure based on the radiological principle 'as low as reasonably achievable'. This is a principle recommended by the British Medical Ultrasound Society (BMUS) who also recommend safe ranges of thermal index dependent on gestation. Thermal index relates to the potential for the ultrasound beam to heat tissue around the fetus. Rather than auditing rescan rates the sonographer audited the thermal index of scans and lowered acoustic power ranges accordingly. This, alongside keeping scan times as short as possible, ensured the thermal index, and therefore any potential effects of this on the fetus, were well below the thresholds recommended by BMUS.

Competent staff

The service made sure staff were competent for their roles.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of service users. The sonographer was health and care professional council (HCPC) registered and worked in NHS services. They sonographer explained clinical leads audit their work in the NHS. The registered manager relied on the sonographer to provide proof of their competence through training, appraisal and feedback they received in their NHS role.

The registered manager and sonographer ran the service together and told us they did not have plans to recruit more staff. However, they had developed a recruitment policy for the service which included information about how they would screen, induct and train new staff if they recruited any.

The registered manager and sonographer did not supervise or appraise each other but they told us they worked together to improve the service and had recently begun to record discussions about the service as board meetings.

Multidisciplinary working

Staff worked together as a team to benefit service users and to provide good care.

The registered manager and sonographer held board meetings to discuss how they could improve the service and service user care.

We saw the registered manager handover service user information to the sonographer before each service user's scan.

The service had processes in place for sharing information when they referred service users to NHS services.

Seven-day services

Key services were available to support timely service user care.

The service was open part-time due to the sonographer working within NHS services two to three days each week. At the time of our inspection, the service opened on two weekday evenings and one weekend day. However, service users could contact the service by phone or via the service's website and social media platforms at any time. The registered manager told us they monitored the phone and online activity every day and offered service users flexibility with appointments. Service users we spoke with told us they found it easy to book an appointment.

Health promotion

Staff gave service users practical information relevant to their pregnancy. However, the service did not offer all service users additional information about how to improve their health.

The service included a link to NHS pregnancy and antenatal care information on each scan report. We saw the sonographer talk to service users about the types of care their NHS midwives would offer them. The service also offered service users information about complementary therapies such as pregnancy massage. However, the service did not provide service users with generic information about their health or healthy lifestyle choices.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

The service followed national guidance to gain service user's consent. However, they did not always support service users to make informed decisions about their care and treatment.

Staff understood how and when to assess whether a service user had the capacity to make decisions. The registered manager completed level three safeguarding training which included mental capacity. The sonographer completed level three safeguarding training shortly after our inspection.

Staff gained consent from service users for their care and treatment in line with legislation and guidance. We saw the service had a three-stage consent process. Service users implied consent when they booked their appointment. When service users arrived for their appointment they completed and signed a consent form. Finally, we saw the sonographer asked service users if they were still happy to consent immediately before their scan.

However, some of the information on the consent form was not explicit about what the service users were agreeing to. For example, the form included some points about which aspects of the babies' wellbeing and anatomy the sonographer would examine during the scan. The service called this the wellbeing checklist. The consent form asked service users to sign to say they understood the checklist was not as comprehensive in NHS services and that the sonographer may not always complete the checklist due to the position of the baby. However, the form did not include details of what was on the checklist.

The service provided service users with an ultrasound safety statement which contained links to British Medical Ultrasound Society information about ultrasound safety. The statement said the purpose of the document was to provide service users with information to help them decide if they were comfortable to go ahead with their scan. However, we saw staff gave service users the statement alongside the consent form shortly before their scan. This meant service users had little time to read the statement or follow the website links to read the information.

The service accepted service users aged 16 and 17 years old. We saw managers were in the process of producing a separate consent process for this age group which took account of gillick competence and fraser guidelines. Gillick competence is concerned with determining a child's capacity to consent. Fraser guidelines are used specifically to decide if a child can consent to contraceptive or sexual health advice and treatment.

Requires Improvement

Diagnostic and screening services

Are Diagnostic and screening services caring?

Good

Compassionate care

Staff treated service users with compassion and kindness, respected their privacy and dignity, and understood service users' personal, cultural and religious needs.

Staff were discreet and responsive when caring for service users. Staff took time to interact with service users and those close to them in a respectful and considerate way. All service users we spoke with told us staff treated them kindly and respectfully. On the day of our inspection, we saw many of the service users had visited the clinic before and staff were familiar with them and their families.

The sonographer protected the privacy and dignity of service users during scans. The service only provided abdominal scans. However, we saw the sonographer ensured service users felt comfortable and encouraged them to lower their waistbands, apply paper towels and wipe off ultrasound gel themselves to minimise unnecessary contact.

Staff followed policy to keep service user care and treatment confidential. The scan room had a large monitor that mirrored the screen of the ultrasound scan machine so service users could see their scans in progress. We saw the sonographer turned the service users' screen off at the end of each scan so nobody who went into the room could see the last service user's details on the screen. As the waiting area was directly outside the scan room, managers installed a radio to ensure service users waiting for their scan could not overhear other service users' scans.

Staff understood and respected the personal, cultural, social and religious needs of service users and how they may relate to care needs. Staff told us they were careful not to assume the gender of service users' partners and used gender neutral terms to talk with service users about their partners if they were not with them at the clinic.

Emotional support

Staff provided emotional support to service users, families and carers to minimise their distress and took account of their individual needs.

Staff supported service users who became distressed in an open environment. We spoke with one service user whose scan showed there were serious concerns for their baby. The service user told us the way staff told them about the problems, supported them to understand what to do next and the emotional support they provided them was "amazing".

Staff gave service users and those close to them help, emotional support and advice when they needed it. On the day of our inspection, one service user who visited the service was very anxious. We saw the registered manager took time to reassure them whilst they waited for the scan and ensured they discussed how anxious the service user was with the sonographer before the appointment.

Staff did not complete training for healthcare staff about breaking bad news and having difficult conversations. The sonographer told us the training formed part of their professional qualification.

Requires Improvement

Diagnostic and screening services

Understanding and involvement of service users and those close to them

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

Staff made sure service users and those close to them understood their care and treatment. We saw the registered manager took the names of service users' family, friends and carers who attended the scan with them. The registered manager introduced each person to the sonographer by name when they went into the scan room and the sonographer took time to involve everyone in the scan where appropriate. One service user we spoke with told us they attended their scan with their three-year-old child. They told us the sonographer took the time to explain parts of the scan to the child in a way that was fun, and they understood.

We saw the registered manager would ask service users and families before they went into the scan if they would prefer the sonographer to tell them the babies' gender in private or share it with everyone there. Managers did this to ensure they did not accidentally ruin service user's plans for revealing the babies' gender to family and friends.

Are Diagnostic and screening services responsive?

Requires Improvement

Service delivery to meet the needs of local people

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

Managers planned and organised services, so they met the changing needs of the local population. They planned the days the service opened in line with the availability of the sonographer. However, they considered the needs of service users in deciding to open at flexible times on weekday afternoons and evenings and one day at the weekend. We saw the service extended opening times or opened ad-hoc if an anxious service user contacted them for a reassurance scan.

Managers had considered the impact of missed appointments and how they could minimise them. However, they decided not to take deposits from service users when they booked their scan. They explained they did this because they felt it would not be nice for service users to have to ring to arrange a refund if they lost their pregnancy before the scan. For the same reason, managers explained they did not routinely contact service users who missed appointments. However, they explained they considered doing this when they knew the service user well.

Meeting people's individual needs

The service was took account of service users' individual needs and preferences. However, the service did not always make reasonable adjustments to help service users engage with the service.

The service purchased a ramp to ensure the entrance to the clinic was accessible to wheelchair users. The rest of the service was on one floor and all rooms were accessible.

The ultrasound couch was adjustable to support service users with mobility issues to get on and off the couch safely. The couch was able to accommodate bariatric service users.

Requires Improvement

Diagnostic and screening services

The service did not always have provisions in place to help some service users to book or understand their scan. For example, the service did not have access to interpreter services for service users whose first language was not English. However, we saw evidence that managers had researched which languages were most prevalent in the local area and started planning to have service information translated into these languages.

The service was aware of the needs of deaf service users and explained they would remove their masks, at a safe distance, to support service users who needed to lip read. However, they did not have specialist systems to support service users with hearing aids, such as a hearing loop.

Access and flow

People could access the service when they needed it and received the right care promptly. However, the service did not always manage flow through the clinic well.

Service users could book appointments by phone or online at a time that suited them. Service users we spoke with told us they found it easy to book an appointment and did not have to wait too long.

Facilities and premises were appropriate for the services delivered. However, we saw that the clinic sometimes became overcrowded when some service users arrived slightly before their appointment time or the sonographer had asked a service user to come back because the position of the baby wasn't appropriate for the scan at the time of their appointment.

Staff told us they would only cancel appointments if the sonographer or registered manager were not able to attend the clinic due to sickness or other extenuating circumstances.

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.

Service users, relatives and carers knew how to complain or raise concerns. The service had a copy of its complaints policy available for service users to read in the waiting area. They also provided surveys and paper with a box for service users to leave anonymous feedback if they wanted to.

Staff understood the policy on complaints and knew how to handle them. Staff told us they had not received any complaints in the time the service had been open. They were able to verbally explain how they would receive, investigate and respond to complaints. However, the complaints information directed service users to contact the Care Quality Commission if they were dissatisfied with the outcome of their complaint. The Care Quality Commission do not investigate individual complaints.

Are Diagnostic and screening services well-led?

Requires Improvement

Leadership

Leaders understood the priorities and issues the service faced and were visible and approachable to service users. However, they did not always have the awareness required to manage regulated activities.

Requires Improvement

Diagnostic and screening services

The registered manager and sonographer ran the service jointly and worked together for the benefit of service users. The sonographer was appropriately skilled and experienced to perform scans. However, both staff recognised they needed time and support to develop systems and processes to ensure the service met regulatory requirements and they welcomed feedback to support them to do this.

Vision and Strategy

The service had a vision for what it wanted to achieve and had some strategies in place to achieve this, however these were not always robust.

The registered manager's main goal was to ensure the service fully complied with regulatory requirements. They understood, and had identified, many of the priorities required to achieve this. We saw evidence staff had started to develop plans for improvement. However, we identified some areas where the service's existing systems and processes were not robust enough to fully satisfy compliance with some regulations, such as consent processes.

Managers had broader plans for the service which included adding non-invasive prenatal testing (NIPT) to the service offer. NIPT is a prenatal screening that looks at DNA from babies' placenta blood to identify whether a baby is at increased risk of having a genetic disorder.

Culture

Staff focused on the needs of service users who received care. The service promoted equality and diversity in daily work.

Staff valued the importance of working together to achieve the best possible outcomes for service users. They demonstrated commitment to ensuring service users experienced a good service. We saw the service promoted equality and diversity in the way they interacted with service users and were keen to be flexible to meet their needs. Staff completed equality and diversity training as part of their mandatory training.

Governance

Leaders did not always operate effective governance processes.

At the time of our inspection, not all governance processes were robust. However, staff had started to implement better governance processes for the service. We saw the registered manager developed some policies, based on relevant national guidance, to provide a framework for how the service operated. However, they had not fully developed systems and processes to ensure staff practice consistently reflected all policies. For example, the safeguarding policy described how and why staff would make safeguarding referrals. However, the service did not have a process to ensure they always collected the information required to do this properly.

The registered manager recently developed a range of paper-based audits to monitor the safety and effectiveness of the service. We saw they produced an audit schedule which showed a list of monthly, quarterly and annual audits they had begun to carry out. We saw they recently completed monthly audits of cleaning schedules and fire risk assessments.

Staff were clear about their roles and accountabilities and were keen to work together to continue to improve how they governed the service.

Management of risk, issues and performance

Leaders had recently developed systems to monitor and mitigate risks.

Requires Improvement

Diagnostic and screening services

The service had a newly developed risk register. The risk register identified some of the risks we identified during our inspection and the progress the service had already made to mitigate against them. The register also included the risk of service users being unable to access their NHS pregnancy notes and midwife details through new digital systems introduced by local NHS services. We saw that the service had taken some actions to try to mitigate this. For example, the sonographer included a link to NHS pregnancy advice services on all scan reports and staff provided service users with the telephone numbers for local early pregnancy units if they needed them.

The service had liability insurance in place.

Information Management

The service collected data and analysed it. Staff could find the data they needed, in easily accessible formats. The information systems were secure. However, the service did not always store data in line with regulations.

The registered manager kept up to date folders for polices, audits and personnel files. Staff stored service user records in secure online storage services and on the ultrasound machine. However, the service did not have a timeframe for how long they kept service user records. The sonographer explained they would delete files from the ultrasound scanning machine when the machine indicated that it was close to its storage limit. The registered manager told us they would delete them from the online storage service every few months, but they were not sure how long they needed to keep them and did not have set timeframes for deleting them. The service's information governance policy stated that the service may keep service user records for up to six years, but the service did not share this information with service users through a privacy statement or on their consent forms.

Engagement

Leaders and staff actively and openly engaged with service users and the public to plan and manage services. The service had an open culture where service users, their families and staff could raise concerns without fear.

The service had a public website which provided the public with information about what the service offered. Managers told us they proactively used social media to engage with new, existing and potential service users. Service users we spoke to used social media platforms to book their appointments.

Service users and their families could give feedback on the service and staff supported them to do this. Managers left service user feedback surveys in the service user waiting area for service users to complete if they wanted to. They also provided a sealed box for service users to put the surveys into if they wanted their feedback to be anonymous. The registered manager told us not many service users completed the surveys, so they encouraged them to complete reviews online and on social media.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

We saw evidence staff had started to implement changes based on feedback they received during monitoring activities we undertook shortly before our inspection. On the day of our inspection, staff were keen to understand any potential shortfalls in their ability to meet regulatory requirements and use the inspection feedback as a catalyst for further improvements.