Clinical Diagnostic Services LLP

Clinical Diagnostic Services

Inspection report

104 Harley Street
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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?	Insufficient evidence to rate
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this location stayed the same. We rated it as requires improvement because:

The service did not always control infection risk well. The service did not conduct infection prevention control (IPC) audits such as hand hygiene audits. Sonographers did not always follow the service's policy on personal protective equipment (PPE), for example they did not always wear aprons for scans.

There was no formal policy for the management of patients who suddenly became unwell. The provider relied on a co-located service's emergency equipment.

The service did not manage medicines well. The service could not provide assurance that the staff that offered pain relief were trained and competent to make the decision to treat and administer the medicines safely. They did not record the administration of pain relief in the patient records. The service did not store a contrast agent used for some scanning procedures in a temperature-controlled environment, which was not in accordance with manufacturer guidelines. Patient biopsies that required refrigeration were stored in a fridge with no lock which was used by staff to keep their lunch in. and was accessible to other services who used the premises.

Leaders did not operate effective governance processes. The management of risk process was not fit for purpose. There was no practising privileges agreement in place for the gynaecologist who worked for the service. The service's policies did not include the author or source guidance. Leaders of the service did not exhibit an understanding of the Duty of Candour.

However:

The service had enough staff to care for patients and keep them safe. Staff had training in key skills.

Staff provided good care to patients. Staff worked well together for the benefit of patients, supported them to make decisions about their care, and had access to good information. Key services were available with flexible times throughout the week.

Staff treated patients 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 patients. Feedback from patients was overwhelmingly positive.

The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait for a diagnostic procedure.

Staff felt respected, supported and valued. They were focused on the needs of patients.

The service and its director were recognised by the sector for their involvement and pioneering work in developing key technical advances in ultrasound imaging.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires Improvement 	Our rating of this service stayed the same. We rated it as requires improvement because: See the summary above for details.

Summary of findings

Contents

Summary of this inspection

Background to Clinical Diagnostic Services

Clinical Diagnostic Services at Harley Street is operated by Clinical Diagnostic Services (CDS) LLP. CDS operates ultrasound services across two locations Harley Street and BMI Hendon Hospital.

The service at Harley Street consists of one scanning and consultation room with an ultrasound machine, an office and shared reception area and waiting room. The service is co-located with other independent healthcare providers. The service offers advanced ultrasound scanning and transvaginal scanning covering several specialties including general gynaecology and women's healthcare, fertility managements and scanning related to In Vitro Fertilisation (IVF), early pregnancy assessments and prenatal screening. They also offer general medical ultrasound scans.

We inspected diagnostic imaging services at Clinical Diagnostic Service at Harley Street using our comprehensive inspection methodology. We carried out an unannounced visit to the service on 21 September 2021.

We previously inspected this service on 29 October 2018. We found the provider had now met all requirement notices except for two: the provider must take prompt action to ensure audit and monitoring systems are in place to monitor performance and compliance with local and national guidelines; and the provider must take prompt action to ensure that all risks related to patient safety are recorded with actions to mitigate them.

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.

How we carried out this inspection

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

Outstanding practice

We found the following outstanding practice:

The service was recognised within their sector for pioneering work in developing key technical advances in ultrasound imaging including transvaginal scanning, 3D and 4D volumetric ultrasound amongst others. Senior staff had published papers for journals including technical papers for ultrasound machine manufacturers.

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust 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 that the contrast agent is stored in a temperature-controlled environment in accordance with the manufacturer's guidelines (Regulation 12(1),(2)(d)).

The service must ensure that biopsy samples are stored appropriately and securely to ensure patient data is protected and the biopsy cannot be tampered with (Regulation 12(1), (2d)).

The service must ensure that adequate infection control measures are in place and PPE measures are adhered to (Regulation 12 (1), (2)(h).

The service must ensure they have oversight of safety checks including portable appliance testing of electrical appliances (Regulation 12 (2)(e)).

The service must ensure medicines are managed appropriately, administered by competent personnel. (Regulation 12 (2)(g)).

The service must ensure that written consent is obtained for interventional scanning procedures including those where a biopsy is taken, in line with national guidance (Regulation 11 (1)).

The service must ensure medications are recorded in patient records (Regulation 17(2c)).

The service must ensure there are systems in place to assess and monitor risk (Regulation 17 (2)(b)).

The service must ensure that appropriate practising privileges are in place for the gynaecologist working for the service (Regulation 17(2)(d)(i)).

Action the service SHOULD take to improve:

The service should ensure that appropriate IPC audits are undertaken such as hand hygiene.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Requires Improvement	Insufficient evidence to rate	Good	Good	Inadequate	Requires Improvement
Overall	Requires Improvement	Insufficient evidence to rate	Good	Good	Inadequate	Requires Improvement

Requires Improvement

Diagnostic imaging

Safe	Requires Improvement
Effective	Insufficient evidence to rate
Caring	Good
Responsive	Good
Well-led	Inadequate

Are Diagnostic imaging safe?

Requires Improvement

Our rating of safe stayed the same. We rated it as requires improvement.

Mandatory Training

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

The service now had a mandatory training program and monitored staff mandatory training compliance. Staff received and kept up to date with their mandatory training. The registered manager monitored mandatory training and alerted staff when they needed to update their training.

We saw mandatory training records which showed which modules staff had completed and when they were next due. This included basic life support for the sonographers.

Safeguarding

Most staff understood how to protect patients from abuse and had training on how to recognise and report abuse.

Staff now received safeguarding training, including safeguarding children, and this was specific for their role. The director was now trained to Level 3 and knew how to make a safeguarding referral and who to inform if they had concerns. However, the registered manager had limited understanding of safeguarding and when asked about safeguarding they told us they did not have that “level” of patient at the clinic.

The service had not reported any safeguarding concerns in the last 12 months.

The service mainly saw adults. They saw some under 18’s, but only with a parent or guardian present.

The service now had a safeguarding policy, however, it did not include any information or guidance on female genital mutilation (FGM). However, we were assured that sonographers had an understanding of FGM and had a process in place to escalate concerns.

Cleanliness, infection control and hygiene

The service did not always control infection risk well including through the use of personal protective equipment (PPE). They did not conduct any infection control audits. However, staff used other equipment to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

The service still did not complete any hand hygiene audits. Hand hygiene audits are carried out when trained members of staff observe staff and patient interactions to ensure all best practice guidelines are followed. Hand hygiene audits provide assurances that good practice is consistently upheld throughout the service. The registered manager told us they knew the sonographer washed their hands and that they saw no need for a hand hygiene audit. Therefore, there was still no oversight or assurance that hygiene procedures were being followed by sonographers.

Staff did not always follow infection control principles including the use of personal protective equipment (PPE). The policy stated that sonographers should wear aprons for all scans, however, the director/lead sonographer did not use an apron for scans except for those scanning procedures where a biopsy was obtained.

Staff used sterile packs for scanning procedures where biopsies were taken. We saw that these were stored appropriately and were in date.

The environment was visually clean and uncluttered. There was a regular cleaning schedule and we saw a cleaning checklist. We observed appropriate handwashing and cleaning of equipment before and after patients were seen in the scanning room. Staff demonstrated how they cleaned ultrasound equipment, including ultrasound probes.

Environment and equipment

There was inadequate storage for biopsies and the contrast agent used for scanning was not stored in a temperature-controlled environment in line with the manufacturer's guidelines. However, the design, maintenance and use of facilities, premises and equipment kept people safe. Staff managed clinical waste well.

The contrast agent used for advanced scanning procedures should be stored at a controlled room temperature between 20 to 25 degrees Celsius in line with the manufacturer's guidelines, however the cupboard where it was stored had no temperature gauge.

The fridge used to store biopsy samples that required refrigeration was not fit for purpose. The fridge had no lock and could be accessed by people outside of CDS who used the premises. The fridge had no mechanism for monitoring or controlling the temperature. Food items were also stored in the fridge. However, the service had bought a new fridge and were waiting for the landlord of the property to agree to it being installed at the time of our inspection.

The provider had no oversight of whether the electrical appliances had been portable appliance tested (PAT) within the required time limit.

Requires Improvement

Diagnostic imaging

The two scanning machines were well maintained and were serviced regularly. If there was an issue with one of the machines, the other could be used as back up. The provider also told us that the manufacturer was quick to respond to any issues.

We checked equipment including speculums and scissors and saw all were packaged and stored appropriately and were in date. We saw appropriate processes and equipment for managing clinical waste.

Assessing and responding to patient risk

Staff did not always complete full risk assessments for each patient and there were no checks to ensure the correct resuscitation equipment was available and in order. However, staff shared key information to keep patients safe when handing over their care to others.

The patient risk assessments did not include a process to check contraindications for the contrast agent used in advanced scanning procedures, for example the contrast agent is contraindicated for use in patients with known or suspected genital tract inflammation or infections. There was no record in patient notes on how much contrast was used or what type.

There was no formal policy for the management of patients who suddenly became unwell whilst on the unit. Staff informed us patients attended the unit for routine pre-planned ultrasound scans and they rarely had to deal with patients who were unwell, although they had told us they had a patient who had a vasovagal episode around three years ago, which was reported as an incident. The provider told us they would call 999 in case of a medical emergency.

The service did not have oversight of the resuscitation equipment which would be required in the rare case of an adverse reaction to contrast agents, such as anaphylactic shock. It belonged to another service on the same premises and there were no checks undertaken by CDS and they sought no assurance from the other service.

The provider told us after the inspection that they were placing a resuscitation pack on the other side of the door adjacent to the scanning couch, thereby giving immediate access. The director/lead sonographer would take responsibility for checking it once a week and for signing and dating the checks. The provider also told us that after the inspection a defibrillator had been placed on the stairway within 15-30 seconds from the scan room. They said it was checked by another provider on the same premises monthly and that the director/lead sonographer would check it once a week too.

Staff shared key information about patients with referring clinicians and scan reports were usually sent within 24 hours.

Sonographers had up to date basic life support training.

If there were unexpected or significant findings in a scan, the service would escalate this to the referring clinician or the patient's GP. They also made follow up calls to ensure patients were well following their scans. If an abnormality was detected, the service would refer the patient to their obstetric unit. They said they did not talk in detail about genetic abnormalities.

Women were still advised to attend their NHS scans as part of maternity pathway. Scan reports were given to patients and could be sent on to GP. Scan reports were also sent to referring clinicians.

Requires Improvement

Diagnostic imaging

When asked about whether there was a limit to the number or frequency of scans a woman could have, the provider told us the service only undertook clinically necessary scans.

Staffing

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

The director and lead sonographer led ultrasound services across two locations. There were also two part time sonographers. The practice manager and two administrative staff provided administrative support. The administrative staff had completed chaperone training and acted as chaperones where required. A gynaecology consultant worked with the lead sonographer on Fridays for specialist ultrasound procedures. The registered manager ensured there were sufficient staff on each shift for the number of patients being seen.

Records

Staff kept detailed records of patients' 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. Records were stored securely. Patient records were stored on an electronic record system. We looked at a random sample of eight electronic patient records. All records included details of the patient and the clinician referring them. The records also included a registration form signed by the patient, referral from clinicians and a consultation letter providing feedback on the ultrasound findings. However, we found that when the lead sonographer worked alone, records were not always fully completed.

Ultrasound reports were sent to the patient and referring clinician via encrypted email systems and by secured post. All scan reports were completed within 24 hours.

The director/lead sonographer did not make any record of conversations with patients that they had out of hours using the emergency contact phone. This meant we could not ascertain whether the advice given was within the remit of the sonographer.

Medicines

The service did not use systems and processes to safely prescribe, administer, record and store medicines.

Sonographers offered paracetamol and ibuprofen to patients before scanning procedures that might cause pain or discomfort. The service could not provide assurance that the staff that offered pain relief were trained and competent to make the decision to treat and administer the medicines safely and there was no agreed formulary. There was no prescription process and no patient group directive. They did not record the administration of pain relief in the patient record and when we spoke with the lead sonographer (the director) they said they did not see any problem with them administering the medicines and did not see the need to record it in the patient record. There was no evidence that they asked patients what their normal pain relief was or if they had taken any in the last 24 hours. There was no evidence of them asking if the patient had allergies or intolerances, or if they were asthmatic.

Requires Improvement

Diagnostic imaging

Following our inspection, the provider sent a document about medicines management which stated that medicines administered would be recorded in a register. However, it did not stipulate that is would be recorded in patient records and did not provide assurance that medicines would be administered by trained and competent staff.

Incidents

There was limited evidence available regarding the service's management of patient safety incidents.

The service had an incident logbook, however there was only one incident recorded in the last 12 months, which was a patient complaint about being unable to get through to the clinic on the phone on a Friday afternoon. The registered manager told us they had made changes as a result of the complaint by making the recorded answerphone message clearer regarding opening times.

The service had an incident reporting policy which included sharing learning from incidents. Staff understood their responsibilities to record safety incidents, concerns and near misses.

Are Diagnostic imaging effective?

Insufficient evidence to rate

We do not rate effective for diagnostic imaging services.

Evidence-based care and treatment

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

The service based its policies and procedures on guidance from professional bodies such as the British Medical Ultrasound Society. However, we noted most of the policies we saw did not include an author, and none had a date to indicate when the next review was due. The registered manager told us they reviewed policies every August, however there was no evidence to show they had input from sonographers for example to include updates to national guidelines. However, the provider told us that the lead sonographer had oversight of the policies.

The service had a checklist for scanning procedures which included "pause and check" which is best practice in accordance with BMUS guidance.

Pain relief

The service was not monitoring and auditing the effectiveness of pain relief.

Paracetamol and ibuprofen were offered to patients for advanced scanning procedures, however, the service did not record or monitor the effectiveness of pain relief.

Patient outcomes

Requires Improvement

Diagnostic imaging

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

Although the unit did not carry out audits to monitor patient outcomes, the service requested feedback from referring clinicians.

We reviewed four recent feedback letters from referring clinicians, which addressed areas including the quality of diagnostic ultrasound and reporting, and patient feedback. All feedback confirmed the reports were accurate, detailed and prompt. Referring clinicians indicated the images were clear and enabled them to diagnose and treat patients effectively. Suspicious or clinically relevant findings were promptly relayed to the referring clinician.

Routine scan reports were usually sent to both the referring clinician and the patient within 24 hours. Urgent reports were made available sooner.

Competent staff

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

All appraisals were up to date at the time of our inspection. The director did the appraisal for the registered manager, and a consultant gynaecologist who worked with the service did the appraisal for the director/lead sonographer. Administrative staff also had appraisals.

The service supported staff to develop through regular educational sessions in monthly staff meetings with input from a consultant gynaecologist. The service also supported staff to develop by attending professional conferences, for example with the Royal College of Radiologists.

Sonographers were registered with the Health and Care Professional Council (HCPC) and had qualifications as ultrasound specialists.

We saw certificates showing that staff were trained to chaperone.

Multidisciplinary working

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

Sonographers and other staff in the service including the practice manager worked together to deliver care in a coordinated way.

The director informed us they and other sonographers could contact referring clinicians to discuss relevant issues in relation to patient scans.

Seven-day services

Services were available to support timely care.

Requires Improvement

Diagnostic imaging

The unit operated an appointment-based service, which opened from 9am to 5pm on Tuesdays and Thursdays, and from 9am to midday on Fridays. The service also offered early morning, evening and weekend appointments on an ad hoc basis.

The lead sonographer had a mobile phone which patients could use to contact him on out of hours.

Consent

Staff supported patients to make informed decisions about their care and treatment, however, they did not always obtain written consent for interventional scanning procedures which was not in line with national guidance.

Guidance published by the Society and College of Radiographers and British Medical Ultrasound Society states that written consent is required for interventional ultrasound procedures and those where a biopsy is taken. The service did not always obtain written consent for these procedures and the service's consent policy did not include the need for written consent for these procedures.

The service gained written consent for women when they had their first scan, but subsequent scans were done with verbal consent. We saw that women were informed about their care and treatment and that verbal consent was given.

Following our inspection the provider sent a copy of their new consent form for hysterosalpingo contrast sonography (often referred to as HyCoSy or HSS, an investigation of the fallopian tubes) and saline infusion sonography (SIS) which included a list of potential risks and side effects.

Are Diagnostic imaging caring?

Good

Our rating of caring stayed the same. We rated it as good.

Compassionate care

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

Patient feedback was overwhelmingly positive. Patients we spoke with said they found the service caring and compassionate, and that the sonographer explained things thoroughly and gave time for questions. One patient said they felt the service goes "above and beyond".

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way.

Patients said staff treated them well and with kindness.

Requires Improvement

Diagnostic imaging

Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs.

Patients were offered a chaperone for all ultrasound examinations.

Emotional support

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

Staff gave patients and those close to them help, emotional support and advice when they needed it.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them.

Patients we spoke with said they were treated with care and compassion and staff minimised their distress.

If there were issues detected in the scan, the service would advise the patients to go back to their GP or referring consultant as they would have their own counselling services. For bad news relating to fertility and pregnancy the provider told us they could refer patients to a counsellor.

Understanding and involvement of patients and those close to them

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

Staff made sure patients and those close to them understood their care and treatment. Patients we spoke with told us they were well informed about their scan procedure. They said staff spoke with them in way they could understand.

Staff supported patients to make informed decisions about their care.

Patients could give feedback on the service and their treatment and we saw that patient feedback was overwhelmingly positive.

Are Diagnostic imaging responsive?

Good

Our rating of responsive stayed the same. We rated it as good.

Service planning and delivery to meet the needs of the local people

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

Requires Improvement

Diagnostic imaging

Facilities and premises were appropriate for the services being delivered.

The service responded to patients' and referring clinicians' requests for urgent scans and accommodated them whenever possible. Staff contacted patients if they missed an appointment.

The clinic's regular opening hours were 9am to 5 pm on Tuesdays and Thursdays and 9am to 12 noon on Fridays. The service also operated weekend clinics to fit in with the needs of their local population including Orthodox Jewish patients.

Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. They coordinated care with other services and providers.

Staff were aware of the cultural needs of individual patients and were sensitive to their treatment needs. Staff were sensitive to the religious and cultural needs of individual patients.

The unit was on the ground floor and there was a ramp for patients to access the building from the main entrance. Patients waited in a shared waiting area which was spacious with adequate sitting arrangements.

Where a patient did not speak English, instructions were given to the person arranging the appointment to ensure a suitable interpreter accompanied the patient. If patients had communication needs, for example those with hearing or visual impairment, the service asked them to come to the clinic accompanied by a family member, friend or carer.

Access and flow

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

The service received referrals from GPs, consultants and other clinicians. Referrals were completed by the referring clinicians and sent to the service.

There was no waiting list and patients could usually book a scan as soon as it was required. Patients had timely access to scan results with most scans being reported and sent to the patient and referring clinician within 24 hours.

Appointments were very rarely cancelled, and in the case of one of the sonographers being unwell the service told us that one of the other sonographers were usually able to provide cover. Services ran on time and there were rarely any delays.

Learning from complaints and concerns

The service had systems in place to investigate complaints.

The service had only received one complaint in the last 12 months. They demonstrated that this had been investigated and changes had been made as a result.

Requires Improvement

Diagnostic imaging

Feedback forms were sent to patients to ensure they were able to make any comments, suggestions or complaints. Patients we spoke with told us they had never had a need to make a complaint, however, they would know how to contact the service if they did.

Are Diagnostic imaging well-led?

Inadequate

Our rating of well-led went down. We rated it as inadequate.

Leadership

Leaders had most of the skills and abilities to run the service. They were visible and approachable in the service for patients and staff.

A director led Clinical Diagnostic Services (CDS) across two locations. The director was also the lead sonographer. The director was a specialist ultrasound practitioner with skills in the area of gynaecology, reproductive medicine and pregnancy. The practice manager supported the director and managed administrative staff. The practice manager also acted as the registered manager of the service.

Leaders did not demonstrate a full understanding of the challenges to quality and sustainability. There were two requirement notices from the previous inspection that still had not been met. Leaders did not show an understanding of the risks to safety detailed in this report.

Vision and Strategy

The service had a short-term vision for what it wanted to achieve and a strategy to turn it into action.

The service aimed to provide high quality, advanced ultrasound scanning with ready access to appropriate clinical care for patients. The service had a clear commitment to meeting the needs of their patients and ensuring the service's continuity and sustainability. Staff shared a goal of providing excellent care and support to patients. They were in the process of getting a new premises instead of the Hendon location and this was their main strategic focus at the time of inspection.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

There was a positive culture in the service and staff were very patient focussed. Staff worked well together as a team and most had worked for the service for a significant number of years.

Governance

Leaders did not operate effective governance processes. There was no formal practising privileges agreement in place for the gynaecologist who worked for the service.

Requires Improvement

Diagnostic imaging

A consultant gynaecologist worked alongside the director/lead sonographer on Friday morning clinics for ultrasound procedures involving the use of a contrast agent and obtaining biopsies. There was no practising privileges arrangement in place with the gynaecologist and no contract of any other kind.

Leaders were not always clear about their role and had limited understanding of governance processes. There was no process in place for identifying and recording contraindications and there were no IPC auditing processes in place, and leaders did not recognise the importance of these. The registered manager told us they did not see any need for IPC audits such as hand hygiene.

Neither the registered manager nor the director/lead sonographer appeared to know what the Duty of Candour regulations were, however, they understood the principle of being open and transparent with patients if things went wrong, and had not had any incidents requiring the Duty of Candour. Following our inspection, the provider sent us a Duty of Candour policy and stated that they consider Duty of Candour part of safeguarding. This further illustrated the lack of understanding of the regulation.

The provider had completed Disclosure and Barring Service (DBS) checks for all staff except the gynaecologist. However, there was no policy in place for the renewal of DBS checks and some were several years old, for example the lead sonographer's was dated 2010. They did not know if the DBS for the lead sonographer was enhanced or not. Further checks on staff depend on whether the registered person judges that this is necessary or advisable after a certain period. When making their decision they should undertake a risk assessment taking into account the work staff do, the potential scope for abuse, and the stability of the workforce. However, the registered manager had not undertaken a risk assessment.

Management of risk, issues and performance

Leaders did not use systems to manage performance effectively. They did not identify and escalate relevant risks and issues. However, they had plans to cope with unexpected events.

The risk assessment and recording process was not fit for purpose. Risks listed were generic and not specific to the service. There were no actions or dates completed on the risk register. Risks identified on inspection, and known to the provider, such as the use of a fridge with no temperature control or lock, were not on the risk register.

However, the service held regular leadership and staff meetings which were minuted.

Information Management

Staff 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 all update.

We saw that patient records were stored on an electronic system and staff had access to this. The service was aware of the requirements of managing patient's personal information in accordance with relevant legislation and regulations. The service had systems in place to ensure they were compliant with provisions of the General Data Protection Regulations (GDPR). At the time of our inspection, the service held a current registration with the Information Commissioner's Office for data protection.

Patient records were stored on secured electronic systems with password access and ultrasound reports were transferred using secure systems.

Requires Improvement

Diagnostic imaging

Engagement

The service engaged with patients, staff, and partner organisations to plan and manage appropriate services.

The service held regular staff meetings and we reviewed the minutes of recent meetings which showed staff discussed the quality of scans and had regular opportunities for learning. The service engaged with referrers and obtained annual feedback from several of their regular referrers. They also liaised with referring clinicians when required to discuss patients' needs. The service obtained feedback from patients.

Learning, continuous improvement and innovation

The service promoted research and innovation.

The service and its director were recognised within their sector for their involvement and pioneering work in developing key technical advances in ultrasound imaging including transvaginal scanning, 3D and 4D volumetric ultrasound amongst others. The director had presented his research at international conferences, such as the International Society of Ultrasound in Obstetrics and Gynaecology.

The director had been involved in clinical research and had published papers for journals including technical papers for ultrasound machine manufacturers. They were about to publish a new paper at the time of our inspection. The service was also recognised for its educational and training programmes and the service director had spoken at several ultrasound clinical meetings.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 11 HSCA (RA) Regulations 2014 Need for consent • The service must ensure that written consent is obtained for interventional scanning procedures including those where a biopsy is taken, in line with national guidance (Regulation 11 (1)).

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • The service must ensure that the contrast agent is stored in a temperature-controlled environment in accordance with the manufacturer's guidelines (Regulation 12(1),(2)(d)). • The service must ensure that biopsy samples are stored appropriately and securely to ensure patient data is protected and the biopsy cannot be tampered with (Regulation 12(1), (2d)). • The service must ensure that adequate infection control measures are in place and PPE measures are adhered to (Regulation 12 (1), (2)(h). • The service must ensure they have oversight of safety checks including portable appliance testing of electrical appliances (Regulation 12 (2)(e)). • The service must ensure medicines are managed appropriately, administered by competent personnel. (Regulation 12 (2)(g)).

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Diagnostic and screening procedures

Regulation 17 HSCA (RA) Regulations 2014 Good governance

- The service must ensure medications are recorded in patient records (Regulation 17(2c)).
- The service must ensure there are systems in place to assess and monitor risk (Regulation 17 (2)(b)).
- The service must ensure that appropriate practising privileges are in place for the gynaecologist working for the service (Regulation 17(2)(d)(i)).