

JJPT Ultrasound Services Limited Ultrasound Direct Milton Keynes 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?	Good	
Are services well-led?	Requires Improvement	

Summary of findings

Overall summary

This was our first inspection for Ultrasound Direct Milton Keynes. We rated it as requires improvement because:

- Staff had not always ensured that cleaning, equipment checks and first aid kit checks had been carried out and recorded as required.
- Staff had not carried out risk assessments for substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations.
- Staff did not complete any training on recognising and responding to patients with learning disabilities or autism. This became a requirement in July 2022.
- Staff did not have access to contact details for the local authority so that they could make a referral when they identified safeguarding concerns.
- Staff did not always report incidents and near misses in line with the service's policy.
- Data or notifications were not consistently submitted to external organisations as required.
- The registered manager was not always able to demonstrate that they had appropriate knowledge of applicable legislation and regulations.
- There were inconsistencies in the effectiveness of governance, information management and the management of risk, issues and performance.

However:

- The service had enough staff to keep patients safe. Staff understood how to protect patients from abuse. Staff assessed risks to patients, acted on them and kept good care records.
- Staff provided good care and treatment. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and supported them to make decisions about their care.
- 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, families and carers.
- People did not have to wait too long for treatment. The service made it easy for people to give feedback.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and staff were committed to improving services continually.

Summary of findings

Our judgements about each of the main services

Service

Rating

g Summary of each main service

Diagnostic and screening services Requires Improvement

This is the first time we have rated this service. We rated it as requires improvement overall. We rated this service as requires improvement for safety and leadership. We rated caring and responsive as good. We do not rate the effective domain in diagnostic and screening services. See the summary above for details.

Summary of findings

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Background to Ultrasound Direct Milton Keynes

Ultrasound Direct Milton Keynes is owned by the provider JJPT Ultrasound Services Limited and operates under a franchise agreement with Ultrasound Direct.

Ultrasound Direct Milton Keynes provides ultrasound scans for self-funding men and women and limited phlebotomy services, including non-invasive pregnancy tests (NIPTs) and fertility services. The core business is early pregnancy scanning and NIPTs. The service is provided to those aged 16 and over and is provided on a self-referral basis.

Ultrasound Direct Milton Keynes is provided from the main location in Stony Stratford and 2 satellite locations in Bedford and Hertford. Each of these locations has 1 scanning room.

Ultrasound Direct Milton Keynes was registered in 2020 and had not been previously inspected as part of this registration. However, Ultrasound Direct Milton Keynes, and the satellite locations in Bedford and Hertford, had been operating under a different registration prior to 2020.

Ultrasound Direct were acquired by The Fertility Partnership (TFP) in 2017. The provider was supported by TFP for HR advice, policies, clinical support, audit and review and other operational support. Staff and sonographers are employed by JJPT.

At the time of our inspection, the clinic employed 1 registered manager, 1 lead sonographer, 5 sessional sonographers and 4 administrative assistants. The service did not employ any medical staff. The clinic did not store or administer any medicines or controlled drugs.

The service had a registered manager in post and was registered to carry out the following regulated activities:

• Diagnostic and screening procedures

How we carried out this inspection

We carried out a comprehensive inspection of the service. The inspection team comprised of a lead CQC inspector and a specialist advisor. We carried out a short notice announced inspection on 30 August 2022. We made a short notice announcement to make sure the service was open and that staff would be available at the time we planned to visit. No clinics were running at the service on 30 August 2022, so we returned on 2 September 2022 to observe patient care and to visit the satellite clinic in Bedford.

We spoke with the registered manager, lead sonographer and the clinical and quality manager for Ultrasound Direct. We also spoke with 6 other members of staff, including 3 sonographers and 3 administrative assistants. We observed 3 appointments. We observed the environment and spoke with 4 patients and 4 relatives. We reviewed 10 patient records. We also looked at a range of policies, procedures and other documents relating to the running of the service.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

Summary of this inspection

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

Areas for improvement

Action the service MUST take 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:

- The service must ensure that systems and processes to maintain cleanliness and control infection are consistently implemented and documented. (Regulation 12(2)(h), Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service must ensure that systems and processes in place to ensure that equipment is properly maintained are consistently implemented and documented (Regulation 12(2)(e), Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service must ensure that effective processes are in place for governance, information management, and management of risk, issues and performance. (Regulation 17, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)

Action the service SHOULD take to improve:

- The service should ensure that leaders are aware of and up to date with all the requirements placed upon the service by regulations. (Regulation 7, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014)
- The service should ensure that notifications are submitted to the Care Quality Commission as required. (Regulation 18, Care Quality Commission (Registration) Regulations 2009.
- The service should consider the introduction of training for staff responsible for carrying out incident investigations.
- The service should consider reviewing the information about clinic accessibility that is available to patients on the website prior to booking an appointment.
- The service should consider reviewing the arrangements in place for the independent external review of complaints.
- The service should consider broadening the data used to understand performance within the service. For example, data relating to access and flow, and staffing data.
- The provider should consider the on-going risk of having carpeted flooring in some clinical locations and the risk this presents to patients.

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

Requires Improvement

Diagnostic and screening services

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

This is the first time we have rated this service. We rated safe at this service as requires improvement.

Mandatory training

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

Staff received and kept up-to-date with their mandatory training. On the first day of our inspection, the overall mandatory training completion rate was 91.6%. This equated to 1 member of staff who was not fully up to date with mandatory training. However, information provided shortly after our inspection showed that mandatory training compliance had improved to 100%.

The mandatory training was mostly comprehensive and met the needs of patients and staff. Staff completed mandatory training on fire safety, equality and diversity, lone worker, conflict resolution, complaints handling, communication skills, health and safety, moving and handling, safeguarding and basic life support. Staff received training in an e-learning format. Face-to-face training sessions were not being provided at the time of our inspection due to the COVID-19 pandemic. However, the service had plans to reintroduce face-to-face mandatory training when staff were next due to complete their mandatory training. Some staff had already had face-to-face training reintroduced as part of their role in the NHS.

Staff did not complete any training on recognising and responding to patients with learning disabilities or autism at the time of our inspection. From 1 July 2022, all health and social care providers registered with the CQC were required to ensure that their staff received training in how to interact appropriately with people who have a learning disability and autistic people, at a level appropriate to their role. We raised this concern with managers during our inspection. The registered manager identified training courses in learning disabilities and autism following our inspection, which were added to the mandatory training schedule for staff. This therefore addressed our concerns.

Managers monitored mandatory training and alerted staff when they needed to update their training.

Safeguarding

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

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Staff received training specific for their role on how to recognise and report abuse. The registered manager and 2 other sonographers were trained to level 3 in both adult and children's safeguarding. All other sonographers and administrative assistants were trained to level 2 in both adult and children's safeguarding. Staff completed an additional training course on female genital mutilation.

Staff had access to a safeguarding lead within Ultrasound Direct who was trained to level 4 for additional support and advice.

Staff could give examples of how to protect patients from harassment and discrimination, including those with protected characteristics under the Equality Act. Staff knew how to identify adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff knew who to inform if they had safeguarding concerns.

Staff had not made any safeguarding referrals in the 12 months prior to our inspection.

Staff followed safe procedures for children visiting the service. Staff would make a safeguarding referral if a patient had become pregnant when they were under the age of 16. Staff completed an extra written consent form for 16 to 18-year olds. The service did not image children under the age of 16, but patients were permitted to bring younger children with them for appointments. Staff told us they did not allow children to be left alone in the waiting room and we observed staff enforcing this during our inspection.

Staff had electronic access to safeguarding adults and children policies. However, the safeguarding policies did not contain contact details for the local authority so that staff could make a referral when safeguarding concerns were identified. Instead, staff followed a process of passing any safeguarding related concerns to their manager. We were concerned that this could result in delays to referrals being made, for example if a concern was identified during a weekend or evening clinic. The line manager and other managerial staff may not be available to make the referral during this time. We raised these concerns during the first day of our inspection on 30 August 2022. When we returned on 2 September 2022, the manager had put the contact details for the local authority in the clinic folder which was kept in the scanning room. This ensured that staff would be able to make a referral directly with the local authority if necessary and therefore our concerns had been addressed.

Cleanliness, infection control and hygiene

The service did not always control infection risk well. Staff did not always use control measures to protect patients, themselves and others from infection.

Clinical areas were generally clean and had suitable furnishings which were clean and well-maintained. We did note some areas of dust in the scanning rooms at Milton Keynes and Bedford, including on the ultrasound scanning unit. However, no clinics were running at the time that the dust was noted. When we returned on 2 September 2022 to observe patient care at the Milton Keynes clinic, no dust was found in the scanning room.

Sonographers and clinic assistants carried out cleaning of the premises and equipment. Cleaning equipment was available but there was limited storage space in the cleaning cupboard at the Milton Keynes location. This meant that cleaning supplies could be difficult for staff to access.

Cleaning schedules were in place. However, we identified gaps in the completion of cleaning records. We could therefore not be assured that all areas were being cleaned as required. Staff at the Milton Keynes clinic had not completed the cleaning schedule for the kitchen area on 7 days that clinics were running in August and 5 in July. Staff at

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the Milton Keynes clinic had not completed the cleaning schedule for the staff toilet on 5 days that clinics were running in August and 7 in July. Staff at the Bedford clinic had not completed the daily ultrasound machine checklist (which involved cleaning the equipment) on 6 days that clinics were running in August and 3 in July. Staff at the Bedford clinic had not completed the weekly machine checklist during 2 weeks in August and 1 week in July. This meant that we could not be assured that cleaning was being carried as required.

Staff did not label equipment to show when it was last cleaned. For example, through the use of 'I am clean' stickers. However, information about when equipment had last been cleaned was available separately on cleaning and equipment schedule documentation.

Staff cleaned and decontaminated ultrasound probes in line with the service's policy and national guidance.

Staff followed infection control principles including the use of personal protective equipment (PPE). Staff had access to appropriate hand washing facilities and sanitising hand gel was available. Staff adhered to 'bare below the elbows' principles. Personal protective equipment was readily available for staff to use.

The service generally performed well for cleanliness. Managers carried out regular audits of infection control and prevention standards, including ultrasound probe cleaning logs and hand hygiene. We reviewed the most recent audit results as part of our inspection and these showed a high level of compliance. Managers did not complete a formal audit to review the cleanliness of the environment or equipment. However, the registered manager stated that they reviewed this informally on a regular basis.

Appropriate arrangements were in place to reduce risk of exposure to blood-borne viruses (BBV). All scan rooms had blood spill kits, for the safe cleaning of blood spills.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always people safe. Staff were trained to use equipment. Staff mostly managed clinical waste well.

The design of the environment mostly followed national guidance. For example, the scanning room at Milton Keynes had laminate flooring which meant that it could be easily cleaned if there were any spillages. Staff had access to portable sinks in the scanning rooms. However, the scanning room at the Bedford location had carpeted flooring. This is not in line with national guidance. However, staff used a wipeable plastic covering on the floor, and bloods would only be taken over this, therefore minimising the risk of blood being spilt on the carpet.

The registered manager carried out 6 monthly risk assessments of the environment and took action to address any risks identified by the risk assessments.

We identified some concerns about the condition of the environment at the Milton Keynes location. This included a crack on an internal wall, a plug socket in the scanning room which had been taped up after coming away from the wall and leaking hot water taps. All these concerns had been identified on the most recent clinic risk assessment (completed August 2022) and actions had been identified to address the concerns.

Staff did not always carry out and document regular safety checks of specialist equipment. Managers ensured that ultrasound equipment was serviced annually and a process was in place for daily and weekly quality checks to be

carried out. However, staff at the Bedford clinic had not carried out daily checks as required on 6 days that clinics were running in August and 3 in July. Staff at the Bedford clinic had not carried out weekly machine quality checks during 2 weeks in August and 1 week in July. This meant that there may be delays in identifying any quality issues with the ultrasound machine.

Managers had ensured that all electrical equipment had been safety tested within the 12 months before our inspection to ensure it was safe.

Staff completed competency assessments to show they had the knowledge and skills to use the equipment safely.

The service had enough suitable equipment to help them to safely care for patients. The service had an ultrasound machine at each of the 3 locations and they had access to a spare machine if needed. Sonographers received training on the use of the ultrasound machines as part of their induction.

First aid equipment was readily available. A process was in place for weekly checks to be carried out. However, staff at the Milton Keynes clinic had not carried out checks as required for 2 weeks in August 2022.

Staff disposed of and stored clinical waste safely. Staff ensured that sharps bins were correctly assembled, labelled appropriately and below the fill line. Staff used the correct bins to dispose of clinic waste and domestic waste. Clinical waste was collected by an external contractor. Clinical waste was being stored safely at the time of our inspection. However, the Milton Keynes location had very limited space to securely store clinical waste whilst awaiting collection. The service had experienced delays in the collection of clinical waste and this had previously led to staff having to temporarily store clinical waste in the staff toilets. Managers had implemented a change in procedure whereby staff now requested the collection of clinical waste when bins were only half full. The registered manager confirmed that this had ensured that clinical waste was now stored safely.

The service's clinical waste policy had not been updated to include details of the local waste management procedures. This meant that staff would not have access to written guidance about these procedures if necessary. However, staff spoken to during our inspection were aware of the local waste management procedures.

There was mostly adequate storage for consumables. However, due to a lack of space in the Milton Keynes clinic, consumables were stored within the scanning room. However, patients would not have unsupervised access to this area. The vast majority of consumables checked during our inspection were within their expiry date. However, a set of blood test vials were found to be past their expiry date in the Milton Keynes location and 1 pack of disposable tourniquets in Bedford. This was escalated to the registered manager during our inspection, who noted that the blood vials were no longer in use. Processes for ordering and replenishing consumable equipment meant there was enough equipment available.

Appropriately trained staff followed set processes for labelling, storing and processing blood samples.

The scanning environment was set up to avoid work related musculoskeletal disorders.

Staff had not carried out specific risk assessments for substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations. This meant that staff had not gone through a process of identifying all the hazardous

substances being used, of reviewing potential risks to health, and of identifying and implementing appropriate control measures. We highlighted our concerns about this during the first day of our inspection on 30 August 2022. When we returned on 2 September 2022, the manager provided evidence of the completion of COSHH risk assessments and this therefore addressed our concerns.

Assessing and responding to patient risk

Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration.

Staff responded promptly to any sudden deterioration in a patient's health. The service had a first aid kit available. All staff working for the service were required to complete basic life support (BLS) training. In case of a medical emergency, staff called the emergency services via a 999 call.

Staff completed risk assessments for each patient prior to arrival. A health screening questionnaire was completed on the day of the appointment.

We observed that sonographers checked 3 points of ID and used the Society of Radiographers "pause and check" system to ensure the right person received the right ultrasound investigation at the right time.

Staff knew about and dealt with any specific risk issues. Women attending for pregnancy scans were advised to still attend their NHS scans as part of their maternity pathway. Women attending for pregnancy scans were provided with information about the risks of frequent scanning. Staff would not scan a woman within two weeks of a previous scan and there were limits on the number of scans an individual woman could have. Re-scanning rates were monitored. There were clear processes to escalate unexpected or significant findings at the examination. Any concerns identified were dealt with in accordance with localised protocols. This included advising the patient to contact their GP, referring patients on to the local NHS early pregnancy unit and advising the patient to contact their midwife.

Staff shared key information to keep patients safe when handing over their care to others. All patients received an electronic copy of their scan and report to share with other health care professionals. Staff could also share scans and reports with health care professionals directly, with explicit patient consent to do so. If necessary, staff contacted relevant health care professionals by telephone to escalate concerns and arrange any appointments for follow-up.

Staffing

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm. Managers calculated and reviewed staffing levels, and gave new staff a full induction.

The service had enough staff to keep patients safe. The service employed 5 sessional sonographers on zero-hour contracts. The majority of sonographers worked regular shifts on set days and times each week. The service also employed 4 administrative assistants. The administrative assistant manned the reception desk, supported the sonographer as required and worked as a chaperone.

Managers calculated and reviewed the number and grade of staff needed. Managers scheduled 1 sessional sonographer and 1 administrative assistant for each clinic. Managers would only make appointments available on the appointment booking system once staff had confirmed their availability through the electronic rota system.

Managers adjusted staffing levels according to the needs of patients. Sessional sonographers told the service their availability at least 6 weeks in advance. This meant that managers could open extra clinics, based on patient demand, dependent on sonographer availability.

The number of staff matched the planned numbers. If members of staff were unable to work at short notice, for example due to sickness, other members of staff across all ultrasound direct locations would receive an electronic notification to inform them that a shift had become available. They would then be able to log onto the rota system and accept the shift if they were available to work. The clinic would be cancelled if managers were not able to meet the planned staffing numbers of 1 sonographer and 1 administrative assistant.

The service did not provide vacancy rates when this was requested as part of our inspection. However, managers said that shortages in sonographer staffing numbers were impacting on the number of clinics and appointments that were available for patients to book onto. Shortages in sonographer staffing levels was a national issue at the time of our inspection. Managers were actively recruiting and had identified a range of actions to attempt to increase sonographer staffing numbers.

The service was not able to provide staff turnover rates when this was asked for as part of our inspection.

The service had low sickness rates. Overall sickness rates between January and August 2022 were 4.8%

The service did not use bank or agency staff as they had a pool of sessional staff which they could draw upon when required. This meant that all staff were familiar with the service and had received all relevant training and induction.

Managers made sure all new staff had a full induction tailored to their role. This included at least one shift working alongside a more experienced member of staff.

Managers assessed the risks associated with lone working as part of their 6 monthly clinic risk assessment and identified measures in place to control the risk. Administrative staff carried out lone worker training and a lone working policy was in place.

All staff had an up to date Disclosure and Barring Service (DBS) check. We reviewed 3 personnel files during our inspection and all staff had proof of identification, evidence of qualifications and professional registration, references and a curriculum vitae with full employment history. This gave the service the assurances they were employing suitable staff.

Records

Staff kept detailed records of patients' care and treatment. Records were clear, up-to-date, and stored securely.

Patient notes were comprehensive and all staff could access them electronically. However, booking information, reports and scanned consent forms were saved on separate systems and this meant that staff did not have easy access to all relevant information on one system. At the time of our inspection the service was preparing to transfer to a new electronic records system which would link up these electronic records.

We reviewed 10 records and reports as part of our inspection and these were mostly completed appropriately. However, we identified 1 record where a consent form had not been signed.

Sonographers could access previous reports or images when a patient attended multiple times.

When patients transferred to a new team, there were no delays in staff accessing their records. Patient images and reports were uploaded to a 'cloud based' record keeping system. This meant patient images and reports were always available to sonographers, even if patients had previously been scanned at a different satellite location. Patients received copies of their reports and scans electronically before leaving the premises. Staff could share reports and scans with other health professionals, such as the patient's GP or midwife, if the patient asked for this.

Staff stored records securely. Staff stored all patient records, ultrasound scan images and sonographers' reports on a secure electronic system. Electronic records were stored using passwords and access was only given to authorised members of staff. We observed that all computers and ultrasound machines were left locked when not in use. This ensured that patients' confidentiality was protected.

Staff obtained sufficient information from patients prior to their scan. This included allergies and number of weeks pregnant.

The lead sonographer carried out a regular image audit which included a review of report quality. We reviewed the most recent audit results as part of our inspection. The audit findings included that sonographers were not consistently using the pre-set report templates. The lead sonographer fed audit findings back to staff on an individual basis and re-audits were carried out every 6 months.

Medicines

The service did not store or administer any medicines or controlled drugs.

Incidents

The service did not always manage patient safety incidents well. Staff did not always recognise incidents and near misses and report them appropriately. Incidents had not always been reported externally as required. However, managers investigated incidents and shared lessons learned. Managers ensured that actions from patient safety alerts were implemented and monitored.

Staff mostly knew what incidents to report and how to report them. The majority of staff spoken with on inspection had limited or no experience of reporting an incident as part of their role at Ultrasound Direct. Staff provided some examples of what incidents they would report, although there was a tendency to provide examples which related to safeguarding concerns rather than incidents. Staff mainly said that they would contact their manager to make an incident report.

Staff had reported 2 incidents across the service (the location and satellite units) in the 12 months prior to our inspection. These related to an abusive patient and a data protection breach. Staff had reported no never events or serious incidents during the same period.

Staff did not always report incidents and near misses in line with the service's policy. The service's incident policy defined an incident as "An event or circumstance which could have resulted, or did result in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public." We identified some incidents which fit with this definition but had not been reported as incidents. For example, a non-invasive pregnancy test (NIPT) sample box had been received for testing without the contents, which should have included a blood vial. The service had identified that a person could have come to harm because of this as they stated that it was a 'potential hazard to anyone had the vial broken'. In addition, staff at the Milton Keynes clinic told us that there had been occasions where clinical waste had to be stored in staff toilets due to delays in the collection of this waste. This could have

resulted in harm to a member of staff. In the Hertford clinic, there had been a leak into the clinic from above which could have led to damage. However, managers had identified and monitored these concerns as risks on their risk register and/ or as part of their governance reports. In all cases, managers had put actions in place to address the concerns. The impact on safety had therefore mostly been addressed. However, incident reports go through a more detailed and standardised investigation process than risks, which would include a review of the need to inform external agencies and a consideration of duty of candour requirements. In addition, we remained concerned about the impact on the validity of the data that leaders used to monitor the service. This has been reported on further in the well-led domain.

Managers had not always reported incidents externally as required. As part of our inspection we reviewed an incident where the police had been called after a patient became abusive to staff. Managers had not reported this to the Care Quality Commission as required. The service's incident reporting policy did not include the Care Quality Commission in the list of external agencies that incidents may need to be reported to.

Staff understood the principles of the duty of candour but had not had experience of putting this into practice. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person. Staff were aware of the importance of being open and honest with patients and families when something went wrong.

Managers of the service were responsible for conducting investigations into all incidents. Managers had not received any specific incident investigation training.

Administrative staff met on a regular basis and this provided an opportunity to discuss learning from incidents and look at improvements to patient care. Managers did not hold regular meetings for sonographers. Instead, managers said that learning would be shared through the electronic workspace, by email, in staff newsletters and on a 1 to 1 basis. However, we found no reference to incidents in the last 3 sets of meeting minutes or newsletters that we reviewed as part of our inspection.

There was evidence that actions had been identified as a result of incident investigation findings. For example, managers had taken action to ensure that staff knew where personal alarms were located after an incident involving a verbally abusive customer.



We do not currently rate effective for diagnostic and screening services.

Evidence-based care and treatment

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

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. The service based its policies and procedures on the National Institute for Health and Care Excellence (NICE) guidelines and on the British Medical Ultrasound Society (BMUS) guidance.

Most policies and procedures were developed by the organisation that Ultrasound Direct Milton Keynes was a franchise of. Staff said that they were then reviewed at a local level to ensure that they reflected the premises and local procedures.

Staff had access to policies and guidelines electronically. There were processes for regularly reviewing and updating policies. All staff had to log onto their electronic profiles to actively confirm they had read policies and protocols applicable for their role.

All scan rooms had Society of Radiographers 'pause and check' posters on the walls to remind staff of the checks that needed to be completed before starting a scan. We observed that this guidance was always followed and sonographers routinely confirmed patient ID, contact details and which scan they had booked in for and why before starting the scan.

Nutrition and hydration

Staff did not routinely offer food and drink to patients due to the nature of the service and due to the Covid pandemic. However, staff had access to a selection of refreshments if necessary.

Pain relief

Patients undergoing an ultrasound scan or blood test do not routinely require pain relief. However, we observed that sonographers checked to ensure patients remained comfortable throughout their scans and tests, and made changes where required.

Patient outcomes

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

Managers and staff carried out a programme of repeated audits to check improvement over time. Audits included a sonographer compliance audit, a pre-screening audit, a hand washing audit, a probe cleaning log audit, and an image audit.

Outcomes for patients were positive, consistent and met expectations. We reviewed the most recent audit results as part of our inspection. These showed a high level of compliance. Leaders at Ultrasound Direct carried out a national audit of image quality at all franchises every 6 months. Ultrasound Direct Milton Keynes had come out as the top performing location for image quality in the November 2021 audit.

The lead sonographer carried out peer reviews on 5% of the sonographer's ultrasound reports. This was to provide assurance about the quality, accuracy and consistency of reporting across the service. This met the guidance by the British Medical Ultrasound Society about the number of peer reviews that should be carried out.

Managers also carried out a bi-annual quality review. This included a review of a range of data, including relating to incidents, complaints, audits, training, and compliance with CQC key questions. We reviewed the most recent quality review as part of our inspection and this showed a high level of compliance.

Managers used information from the audits to improve care and treatment.Improvement was checked and monitored. Managers spoke to staff if any concerns were identified about their practice. Managers identified actions to address any concerns identified as a result of audits.

Managers shared and made sure staff understood information from the audits. Managers shared information through team meetings and on an individual basis.

The service's scanning and non-invasive pregnancy test (NIPT) protocols did not include steps for sonographers to confirm their findings after they identified a suspected anomaly on a scan or a woman received a higher chance result for NIPTs. For example, by carrying out follow up calls after a patient had been seen by fetal medicine or an early pregnancy unit. This meant that a process was not in place to ensure that staff would routinely review their findings and apply learning to practice. The service stated that health care providers would provide feedback regarding findings where necessary. In addition, staff said that follow up calls may be carried out with patients, if appropriate, and this would provide them with some information about patient outcomes.

Competent staff

The service made sure staff were competent for their roles. Managers appraised staff's work performance and held meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. All Sonographers were registered with either the Health and Care Professional Council (HCPC), the Nursing and Midwifery Council (NMC) or Society of Radiographers (SOR). Managers kept records which showed when staff needed to renew their registration. This ensured the service only employed professionally registered staff to carry out ultrasound examinations.

Managers carried out an annual audit of sonographer compliance. The audit included a review of up to date professional registration, appraisal, mandatory training, satisfactory image audit results, and confirmation that policies had been reviewed. Managers had carried out an audit of sonographer compliance in January 2022 and this showed that there were no areas of non-compliance.

Managers gave all new staff a full induction tailored to their role before they started work. Sonographers completed clinical and equipment competencies as part of their induction. The competencies included the process to follow when carrying out transvaginal scans, and ensuring that sonographers could explain and discuss the associated benefits and limitations of the NIPTs screening with women. New sonographers worked on a supernumerary basis with the lead sonographer for at least 1 clinic. The lead sonographer would also review images after each list when a new sonographer started.

Managers supported staff to develop through yearly, constructive appraisals of their work. All staff had completed an appraisal in the 12 months prior to our inspection.

Managers supported staff to develop through regular, constructive clinical supervision of their work. The lead sonographer conducted a regular image audit and reported findings back to the operator.

The clinical educators supported the learning and development needs of staff. The lead sonographer was available for professional support and was able to access and view images remotely to offer advice and guidance. Staff provided examples of being able to access additional training. For example, some sonographers had completed 4d scanning training as this was not a part of their NHS role.

Managers mostly made sure staff attended team meetings or had access to full notes when they could not attend. Managers held regular team meetings for administrative staff. Managers ensured that meeting minutes were completed and available. Managers did not hold regular team meetings for sonographers. However, the lead sonographer met with sonographers every 6 months to discuss the findings of image audits.

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Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Staff had the opportunity to do this at annual appraisals.

A sonographer had developed a magazine for sonographer staff focused on continuous professional development (CPD), to share information about interesting cases and any learning. Staff had access to training through an Ultrasound School at Ultrasound Direct and we spoke with 1 member of staff who had trained to become a sonographer in this way.

Managers made sure staff received any specialist training for their role. Managers held equipment training records for staff who operated the ultrasound equipment. Managers reviewed evidence of training for staff involved in phlebotomy on an annual basis. Phlebotomy training had been completed by 3 out of 5 sonographers.

Managers identified poor staff performance promptly and supported staff to improve. For example, if the lead sonographer identified concerns about performance through the service's image audit, they would provide extra support and training for the relevant member of staff.

Multidisciplinary working

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

Staff at Ultrasound Direct Milton Keynes worked well together and communicated effectively. We observed positive interactions between team members during our inspection and staff provided positive feedback about team working.

Staff worked across health care disciplines and with other agencies when required to care for patients. Staff communicated with GPs or other healthcare professionals if required. Staff told us they had good relationships with local NHS trusts. Managers had liaised with maternity services to ensure their referral pathways were appropriate.

Staff said that they would contact midwifery staff to confirm that a woman had been appropriately referred to fetal medicine services if necessary. However, the service's scanning and NIPT protocols did not include steps on follow up with other healthcare professionals after an initial referral had been made.

The service had a contractual agreement at a national level with a pathology service for NIPT testing. This included plans for tracking of the sample and receipt of result.

Staff held regular team meetings but they were not multidisciplinary. However, staff used an electronic workspace to discuss and share information and learning.

Seven-day services

Services were available to support timely care but they were not available 7 days a week.

The service was not able to offer 7-day service provision at the time our inspection due to sonographer staffing shortages. However, appointments were made available at weekends and in the evening. This offered flexible service provision to allow patients to attend around work and family commitments.

Patients were able to book appointments 7 days a week, 24 hours a day, using the booking system on the provider's website. Patients could also book appointments by telephone between 9am and 5pm.

Health promotion

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

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The service shared relevant information promoting healthy lifestyles and support. The service used their social media channels to share information about topics such as healthy pregnancy and breastfeeding.

The service offered health scans which could help with the detection or exclusion of common health issues.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

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

Staff understood the relevant consent and decision-making requirements of legislation and guidance, including the Mental Health Act, Mental Capacity Act 2005 and the Children Acts 1989 and 2004 and they knew who to contact for advice. Staff understood how and when to assess whether a patient had the capacity to make decisions about their care.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. We observed staff gaining consent from patients prior to starting their ultrasound scan or blood test.

Staff obtained consent to share information and results with other healthcare staff if necessary. Staff documented this and explained why this might be necessary.

Staff made sure patients consented to treatment based on all the information available. Patients were asked to review written information before their scan which included the limitations and risks associated with the scan. This meant that patients could make an informed decision on proceeding with the scan.

Staff mostly recorded consent clearly in the patients' records. We confirmed this through a review of 10 records during our inspection. However, staff had not ensured that a consent form had been signed appropriately in 1 of the 10 records that we reviewed.

Staff understood Gillick Competence and Fraser Guidelines and supported children who wished to make decisions about their treatment. Sonographers understood their responsibilities in assessing whether a young adult was able to consent for a scan. Staff completed an extra consent form for patients between the ages of 16 and 18. Patients under the age of 16 were not seen by the service.

Training in the Mental Capacity Act and Deprivation of Liberty Safeguards was included in mandatory training for staff.

Staff could describe and knew how to access policy on Mental Capacity Act and Deprivation of Liberty Safeguards. Staff had electronic access to these policies.

Managers did not formally monitor how well the service followed the Mental Capacity Act. For example, through an audit. However, the registered manager said that they carried out a regular check to ensure that consent forms had been scanned into the computer system for all transvaginal scans. This was an informal way of ensuring that staff were completing consent forms as required.

The service did not have a referral pathway for women experiencing acute anxiety or mental health crises during pregnancy. This meant that there was not a set process for staff to follow to ensure that women were provided with the

right support when concerns were raised about their mental health. Instead, staff said that they would respond on a case by case basis. The registered manager provided a recent example where staff had become concerned about a woman's mental health and they had liaised with the local NHS trust at which the patient was already being seen to ensure that appropriate support was being provided.

Are Diagnostic and screening services caring? Good

Compassionate care

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

Patients said staff treated them well and with kindness. Feedback received from patients and relatives during our inspection was continually positive about the way staff treated people. We spoke with 4 patients and 4 relatives who told us staff were "lovely", "kind" and "they make you feel comfortable and welcome".

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. Staff welcomed patients and those joining them warmly and with compassion. We observed a friendly and jovial environment.

Staff followed policy to keep patient care and treatment confidential. For example, staff kept the door to the scanning room shut during the scan to ensure patients' privacy was maintained. Patients were not always able to speak to the staff at reception without being overheard due to space limitations. However, staff adjusted their approach to address this, such as providing information about the scans in a written format for patients to read and holding telephone calls with the patient prior to their arrival to gather relevant information.

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

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. If a potential concern was detected during the scan, staff described how they would allow extra time to help the patient understand the concern and to make support available to them. Staff had access to leaflets from a well-known charity to hand to patients to provide advice if they were going through a miscarriage. If a woman received a higher chance result for non-invasive pregnancy tests (NIPTs), staff would inform them of this by telephone to ensure that emotional support could be provided.

Staff undertook training on breaking bad news and showed empathy when having difficult conversations. Staff also had access to written guidance on delivering bad news.

Patients provided positive feedback about the support provided by staff and said that they felt able to discuss any concerns or worries with staff. We observed staff providing appropriate support to patients. For example, we observed a patient discussing their anxieties about the viability of their pregnancy with the sonographer. The sonographer took the time to reassure the patient through an explanation of the scan findings. The sonographer also signposted the patient to other healthcare professionals for further support. The patient described feeling "relieved" and "reassured" after their discussion with the sonographer.

Staff supported patients who became distressed in an open environment, and helped them maintain their privacy and dignity. Staff could provide support to patients and their relatives in a quiet room which was available at the Bedford clinic. Staff did not have access to a quiet room in Milton Keynes due to the size of the building. Patients who became distressed would therefore be provided with support in the scanning room and the appointment time would be extended if necessary.

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 members were observed displaying understanding and empathy when speaking with patients.

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 and relatives felt they were fully involved in their care and had been given the opportunity to ask questions throughout their appointment. Patients said that they felt listened to by staff and that their views were considered. Patients understood how and when they would receive test results and who to contact if they were worried about their condition or treatment after they left the service. Patients said that staff introduced themselves and we observed this in practice.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. The service asked patients to provide feedback via a review website 48 hours after their appointment. A QR code was also available in the reception area to allow patients to provide feedback.

Patients gave mostly positive feedback about the service. Managers sent us a report of feedback provided by patients in August 2022. The report showed that 100% of patients in Bedford, 93.5% of patients in Hertford, and 90.7% of patients in Milton Keynes had provided 4- or 5-star feedback. Managers received a notification to prompt them to review and respond to any feedback which was between 1 and 3 stars. This provided the opportunity to address any concerns raised.

Staff supported patients to make informed decisions about their care. Staff were observed providing clear explanations about what the NIPTS and scans involved, providing after care advice, and answering patient questions. Staff gave patients an electronic copy of their scans and the report to allow them to decide who to consult for any further treatment or advice. Staff provided patients with written information to explain the scan or test. Staff held appropriate discussions about cost.

Are Diagnostic and screening services responsive?

Good

This is the first time we have rated this service. We rated responsive as good.

Service delivery to meet the needs of local people

The service mostly planned and provided care in a way that met the needs of local people and the communities served. However, facilities and premises were not always appropriate for patients with mobility issues.

Managers mostly planned and organised services so they met the changing needs of the local population. Ultrasound Direct Milton Keynes was not commissioned to provide any NHS services. Therefore service provision was driven by patient demand. Managers said that sonographer staffing numbers were limiting the days and times that appointments were available for patients to book at each of their locations. For example, the service was no longer able to offer 7-day services at the time of our inspection. Managers were taking action to attempt to improve staffing numbers but sonographer staffing levels were a national issue at the time of our inspection.

People could access services and appointments in a way and at a time that suited them. The service had 3 locations to cover Buckinghamshire, Bedfordshire and Hertfordshire which meant that there was normally a clinic local to where patients lived. The service operated clinics on evenings and at weekends to fit with the needs of the patients they served. Patients could book an appointment to suit them either through the website or calling the clinic directly.

Facilities and premises were not always appropriate for the services being delivered. There was mostly sufficient seating in waiting areas. Patients had access to toilets at all clinics. Managers had removed children's toys and books from waiting areas due to the COVID-19 pandemic. Parking was not available at the Milton Keynes and Hertford clinics. These clinics were town centre locations where patients had access to public car parks nearby. The clinics in Milton Keynes and Hertford did not have step free access. The scanning room at the Milton Keynes clinic was up a flight of stairs and the Hertford clinic had a step down into the scanning room. This may therefore not have been accessible for patients with mobility problems. The service did not have plans to make these locations more accessible. We were told that staff would ensure people were informed of this prior to their appointment and staff would attempt to book them into a clinic which would be accessible.

Managers were not able to monitor the number of missed appointments. Managers said that there was a low rate of non-attendance because the service carried out pre-screening calls on the morning of the appointment to ensure that patients would still be attending. Managers were not able to formally monitor non-attendance rates as there was no reporting tool available. However, this would be possible once the service moved onto a new website in October 2022.

Meeting people's individual needs

The service mostly took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services on a case by case basis. However, clinics were not always accessible for patients with mobility issues.

Staff were aware of the individual needs of patients living with mental health problems, learning disabilities and dementia. Staff or patients were able to add notes to a booking through the service's booking system if there were any specific needs that needed to be met. Staff said that they would then work to accommodate these on a case by case basis.

Staff did not have access to any specific communication aids to help patients who may have difficulty with their speech or understanding. However, staff said that they rarely had patients attend their clinics who had complex needs.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. Staff could use the booking system to record any information and communication needs. Staff provided examples of adjustments that had been made to support patients with a disability or sensory loss. For example, staff had used a clear visor instead of a face mask for a deaf patient so that they could lip read during the appointment. Staff had worked with the patient to understand how best to meet their needs.

Staff were not always aware of information leaflets or other documentation available in languages other than English. During our inspection, staff said that the service did not have any information leaflets in languages other than English and said that they would use online translation services to translate leaflets if necessary. However, information provided after our inspection showed that the service did have scan information sheets available in a range of languages, which described what each scan included and any requirements.

Managers made sure staff, and patients, loved ones and carers could get help from interpreters or signers when needed. Staff used online translation services to support patients whose first language was not English. Staff also had access to a telephone interpretation and translation service if necessary. A poster was available in reception areas to make patients aware of the translation services that were available and this provided information in 21 different languages.

Clinics were not always accessible for patients with mobility issues. This was due to a lack of step-free access at the Milton Keynes and Hertford locations. This was not made clear on the Ultrasound Direct website. This meant that patients may book an appointment at a clinic which would not be accessible to them. However, we were told that staff would ensure people were informed of this prior to their appointment and staff would attempt to book them into a clinic which would be accessible.

Access and flow

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

Managers monitored waiting times and made sure patients could access services when needed. The service did not have a waiting list. The service used an online booking system which allowed patients to view appointment availability and choose an appointment date and time that suited them. At the time of our inspection, patients would normally be able to book an appointment on the same week that they were requesting one. However, appointment availability was being impacted by sonographer staffing levels.

Patients received their ultrasound reports and images before they left the clinic. Waiting times for blood test results were not formally monitored at the time of our inspection but managers said that they were 'within the timescales predicted by the providers'. Managers planned to monitor waiting times for blood test results after our inspection.

Managers said that waiting times once patients arrived for their appointment were minimal. They were not able to formally monitor this as there was no reporting tool available. However, this would be possible once the service moved onto a new website in October 2022. Reception staff monitored waiting times informally during each clinic and would provide updates to patients waiting for their appointment. Reception staff would also contact patients by telephone prior to their arrival if appointments were running behind.

Managers worked to keep the number of cancelled appointments to a minimum. Cancellation rates for appointments cancelled by Ultrasound Direct staff between 1 September 2021 and 31 August 2022 were 1.7%. If members of staff were unable to work at short notice, for example due to sickness, staff across all ultrasound direct locations would be contacted electronically before the clinic was cancelled to ensure all had been done to try and keep the clinic running.

When patients had their appointments cancelled at the last minute, managers made sure they were rearranged as soon as possible. The service would offer an appointment at a different clinic or as soon as possible at the same clinic, if that was the patient's preference.

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 staff. However, the service did not have arrangements in place for the independent external review of complaints.

Patients, relatives and carers knew how to complain or raise concerns. The service clearly displayed information about how to raise a concern in patient areas.

Staff understood the policy on complaints and knew how to handle them. Staff told us that they would attempt to resolve any complaints or concerns informally in the first instance and would then escalate to a more senior member of staff.

Managers investigated complaints and identified themes. The service aimed to acknowledge a complaint within 2 working days of receiving it and to send a response within 7 working days. The registered manager also responded to any patient feedback between 1 and 3 stars on the online review website used by the service. The registered manager kept a complaints log to assist with the monitoring of complaints and concerns raised through online patient feedback. There had been 7 complaints between 1 September 2021 and 31 August 2022 relating to the clinics in Milton Keynes, Bedford, and Hertford. During the same period there had been a further 12 reviews between 1 and 3 stars on the review website used by the service. The registered manager was able to tell us themes that they had identified as part of complaint investigations.

Patients received feedback from managers after the investigation into their complaint. We reviewed 2 recent complaint responses as part of our inspection. Managers had investigated complaints in a timely manner in line with the complaints policy. Patients were given a full explanation of what had happened and how this aligned with Ultrasound Direct policies and procedures. Complaint responses included details of what investigation had happened. The responses were detailed, factual and sympathetic.

Managers shared feedback from complaints with staff and learning was used to improve the service. Staff were able to provide information about recent complaints, as well as themes and trends. Staff said that feedback was shared through team meetings, the staff newsletter, and through the electronic workspace used by the service. Managers said that information was also shared by email and on a 1 to 1 basis. However, we found limited direct reference to complaints in the last 3 sets of meeting minutes and newsletters that we reviewed as part of our inspection.

Staff could give examples of how they used patient feedback to improve daily practice. For example, by adapting the information that was provided to patients prior to scans to ensure that all relevant information was included.

The service did not have arrangements in place for the independent external review of complaints, such as the Independent Services Complaint Advisory Services. Patients would be advised to contact the Care Quality Commission (CQC) to review their concerns if they remained unhappy after the internal complaints process had been exhausted. However, the CQC does not have responsibility for reviewing individual complaints.

Are Diagnostic and screening services well-led?

Requires Improvement

This is the first time we have rated this service. We rated well-led as requires improvement.

Leadership

Leaders did not always have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced. However, they were visible and approachable in the service for patients and staff. They supported staff to develop their skills.

There was a clear management structure with defined lines of responsibility and accountability. The service had a registered manager who held overall responsibility for the leadership of the clinic with support from a lead sonographer for clinical management, peer review and training.

Leaders had the experience that they needed. Both the registered manager and the lead sonographer had worked for Ultrasound Direct for over a decade and they were therefore experienced in their roles. The registered manager did not have a clinical background but was supported in these areas by the lead sonographer.

Leaders could not always demonstrate that they had appropriate knowledge of applicable legislation and regulations. For example, risk assessments had not been carried out in line with the 'Control of Substances Hazardous to Health' (COSHH) regulations. In addition, leaders were unaware of new requirements which had come into force in July 2022 which meant that all staff were required to receive training in how to interact appropriately with people who had a learning disability and autistic people. Furthermore, managers said that they would advise patients to contact the Care Quality Commission (CQC) for an external review of their complaint if they remained unhappy after the service's internal complaints process had been exhausted. The CQC does not have responsibility for reviewing individual complaints. In addition, leaders were not always clear about the notifications that had to be sent to external organisations. For example, a notification had not been made to the Care Quality Commission (CQC) about police involvement in an incident, as required by Care Quality Commission (Registration) Regulations 2009. However, prompt action was taken to address these concerns when they were raised as part of our inspection. In addition, some of these concerns were linked to Ultrasound Direct policies at a national level, which did not clearly set out the requirements of regulations. For example, the national incident reporting policy did not include the Care Quality Commission in the list of external agencies that incidents may need to be reported to. In addition, the Ultrasound Direct national complaints policy and patient information about complaints stated that patients should contact the Care Quality Commission for an external review of their concerns if they remained unhappy after the internal complaints process had been exhausted.

Leaders mostly understood the challenges to quality and sustainability, and could identify the actions needed to address them. For example, the registered manager identified sonographer staffing as the biggest challenge for their service and identified some actions that had been taken to address this concern.

Leaders were highly responsive to concerns identified during our inspection and took prompt action to address concerns raised.

Staff told us that leaders were well respected, visible, and approachable. Staff felt confident to discuss any concerns with managers. The registered manager was available by telephone when they were not on site. The registered manager told us that the provider level team were available for support if needed.

There was no specific leadership development programme at the service. The lead sonographer had plans to retire but had continued in their role because the service was not able to find a replacement lead sonographer. There was no clear succession planning but the registered manager said that head office staff could provide support on an interim basis with the clinical management of the service once the lead sonographer retired.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services. Leaders and staff understood and knew how to apply them.

There was a provider level vision and this was underpinned by provider values, with quality and sustainability as the top priorities. The Ultrasound Direct values were care, expertise, passion, trust and innovation.

There was a robust, realistic strategy for achieving the priorities and delivering good quality sustainable care. Ultrasound Direct had a 3-year plan which was developed in 2021 and was focused on workforce planning, acquisitions, financial growth, and innovation. Managers from each region had been asked to present a localised strategy at the annual meeting in 2021.

The service also had a clear statement of purpose and this set out the aims of the service. These aims included providing services "of the highest quality", with "convenient access", "delivered flexibly" and "offering comfort within a relaxed environment alongside the most advanced ultrasound equipment, and highly qualified practitioners".

Managers knew and understood what the provider vision, values and strategy were, and their role in achieving them. During our inspection we saw that staff worked in line with the service's values. Staff we spoke to were committed to providing a high-quality service to all patients who used it.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where patients, their families and staff could raise concerns without fear.

Staff felt supported, respected and valued. Staff felt positive and proud to work in the organisation.

The culture was centred on the needs and experience of people who use services. Staff described being proud of the emotional support provided to patients and relatives, particularly when bad news had to be delivered.

There were cooperative, supportive and appreciative relationships among staff. We observed positive working relationships between managers, administrative assistants and sonographers throughout our inspection. Staff spoke positively about the working relationships with their colleagues.

The culture encouraged openness and honesty. The provider had processes and procedures in place to ensure they met the duty of candour, although this had not needed to be put into practice in the 12 months prior to our inspection.

Leaders and staff understood the importance of staff being able to raise concerns without fear of retribution. A whistleblowing policy and process was in place, but this had not been used in the 12 months prior to our inspection. Staff said that they felt able to raise concerns if necessary.

There were mechanisms for providing staff with the development they needed, including high-quality appraisal and career development conversations. Staff provided a range of examples of the additional training and development that they were offered through Ultrasound Direct.

There was a strong emphasis on the safety and well-being of staff. For example, staff had access to counselling and a dedicated virtual library for information to manage physical and mental health.

Governance

Leaders did not always operate effective governance processes. Staff did not always have regular opportunities to meet, discuss and learn from the performance of the service. However, staff at all levels were clear about their roles and accountabilities.

The service's manager held monthly governance meetings with leaders from Ultrasound Direct head office and other regional leaders. Governance reports were produced for each meeting, which provided the opportunity to escalate up any areas of concern.

There were some inconsistencies in the effectiveness of governance processes. We found limited evidence in the last 3 sets of management meeting minutes that the data within clinical governance reports was used to generate discussion amongst attendees and to identify any areas where actions should be implemented to drive improvement. For example, during one of the meetings, a complaint theme was identified around staff attitude and patients feeling rushed but no actions had been identified to address this. We found no evidence of discussion of the contents of governance reports in the other management meeting minutes we reviewed. Managers did not complete an action log to monitor the completion of any actions identified as part of these meetings.

Managers held regular team meetings for administrative staff at a local level and this provided an opportunity for relevant information to be fed back down from management meetings. We reviewed the last 3 sets of meeting minutes as part of our inspection and this showed discussion about clinic processes and procedures including any changes, as well as audit outcomes. However, there was no direct reference to any complaints or incidents.

Managers did not hold team meetings for sonographers. Instead, managers said that they would share relevant information through the electronic workspace, by email, through newsletters and on a 1 to 1 basis. We reviewed the last 3 newsletters as part of our inspection and they did not contain reference to any complaints or incidents.

Staff were clear about their roles and they understood what they are responsible for, and to whom. The service had an overarching escalation policy which defined who was responsible for what and when to escalate issues and concerns to the next layer of management. This policy included customer complaints and concerns, whistleblowing, performance management framework and critical incidences and operation failures.

Arrangements with third-party providers were governed and managed at a national level.

Management of risk, issues and performance

Leaders and teams did not always use systems to manage performance effectively. They had not always identified and escalated relevant risks and issues and identified actions to reduce their impact.

Assurance systems were in place and performance issues were escalated appropriately through clear structures and processes. Managers produced monthly Clinical Governance reports for leaders at the Ultrasound Direct head office. This gave leaders an oversight of quality and performance. Reports included data on complaints, audits, incidents, safeguarding, infection control, health and safety, professional development, service delivery and workforce planning.

There were processes to manage current and future performance, but these were not always effective in identifying all areas of concern. Managers completed a quality review twice a year which included a review of data such as risks, incidents, complaints, training completion, audit results, numbers of scans completed and rescan rates. The most recent quality review had shown a high level of compliance. However, these processes had not always identified the areas of concern that were identified as part of our inspection. For example, gaps in the completion of equipment checks and cleaning records.

There was a programme of clinical and internal audit to monitor quality and operational processes, and systems to identify where action should be taken.

There were some inconsistencies in the arrangements for identifying, recording and managing risks, issues and mitigating actions. The manager carried out biannual clinic risk assessments to identify and review a range of risks within the service. The risk assessments identified the hazards, who or what was at risk, existing control measures in place, the risk rating, whether the risk was adequately controlled, and additional control measures needed. If the manager identified that additional control measures were needed then these were added to a risk register document to ensure that actions were taken in response. However, staff had not carried out specific risk assessments for substances which met the 'Control of Substances Hazardous to Health' (COSHH) regulations. This meant that staff had not gone through a process of identifying all the hazardous substances being used, of reviewing potential risks to health, and of identifying and implementing appropriate control measures. However, the registered manager took prompt action to complete COSHH risk assessments when this was raised as a concern during our inspection.

There was not always an alignment between the recorded risks and what staff said was 'on their worry list'. For example, the registered manager identified sonographer staffing as the top challenge to quality and sustainability but this was not included as a risk on the risk register. However, the manager had identified this as an area of concern on the most recent clinical governance report and was therefore being monitored by the service in this way.

Information Management

The service mostly collected reliable data and analysed it. However, staff did not always have access to the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. Data or notifications were not consistently submitted to external organisations as required.

There was mostly a holistic understanding of performance within the service, although there was scope to broaden the types of data being monitored by service. The service's monthly governance report included data on people's views with a range of information on quality and operations. However, managers did not always have access to or monitor data relating to access and flow, such as the time taken to receive blood test results, any delays once patients arrived for their appointment, cancellation rates, or did-not-attend rates. In addition, managers did not monitor staffing related data such as sickness rates, vacancy rates or turnover rates as part of the governance reports.

Staff mostly had sufficient access to information. For example, staff had electronic access to policies and processes, and could access information relating to a patient's previous scans even if these had been carried out at a different Ultrasound Direct location. However, the safeguarding policies did not contain contact details for the local authority so that staff could make a referral when safeguarding concerns were identified. However, the registered manager took prompt action to ensure that staff had access to this information when concerns were raised during our inspection.

Arrangements to ensure that the information used to monitor and report on quality and performance was accurate and reliable were not always effective. Staff had not always reported incidents in line with the service's incident reporting policy. Instead, managers had been identified, actioned and monitored them as risks. However, this meant that the data being used by the service to monitor incident numbers, grades, themes and trends may not always be accurate or reliable.

Information technology systems were mostly used effectively to monitor and improve the quality of care. For example, the lead sonographer was able to use the electronic records system to review images and reports remotely to provide advice and guidance if necessary. However, the records system being used by the service at the time of our inspection did not always allow leaders to monitor all relevant data, such as did-not-attend rates and waiting times once patients arrived for their appointment. However, a new system was due to be introduced in October 2022 which would address these concerns.

There were not always effective arrangements to ensure that data or notifications were submitted to external bodies as required. As part of our inspection we reviewed an incident where the police had been called after a patient became abusive to staff. This had not been reported to the Care Quality Commission as required. The service's incident reporting policy did not include the Care Quality Commission in the list of external agencies that incidents may need to be reported to.

There were robust arrangements to ensure the availability, integrity and confidentiality of identifiable data, records and data management systems. Lessons were learned when there were data security breaches. The service stored electronic records securely and these were password protected. There was a policy in place for the storage of images and reports and how these were securely maintained.

A system was in place to ensure that patients were provided with a statement that included terms and conditions of the services being provided to them and the amount and method of payment of fees.

Engagement

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

People's views and experiences were gathered and acted on to shape and improve the services and culture. The service asked for feedback from all patients 48 hours after their appointment and used this to improve the service. Patients could leave feedback on online review sites and social media pages.

Staff were actively engaged so that their views were reflected in the planning and delivery of services and in shaping the culture. Managers regularly held team meetings for administrative staff and these provided an opportunity for staff engagement. Managers were no longer holding team meetings on a regular basis for sonographers. However, managers said that they engaged with sonographers through their electronic workspace. Ultrasound Direct leaders carried out a national staff survey in November 2021. The survey results identified some areas of concern. However, the results were

on a national level and it was not possible for managers to review the findings of the survey at a local level. We asked for information about any action that had been taken in response to survey findings but this was not provided. There was therefore scope for the service to increase their understanding of staff views at a local level, particularly for sonographers, and to ensure that action was taken in response to concerns identified.

There were positive and collaborative relationships with external partners. The service had established good links with local NHS trusts. Staff told us they liaised with NHS trusts when patients needed a referral after an unexpected scan result.

There was transparency and openness with the provider about performance. The registered manager submitted performance data to Ultrasound Direct on a monthly basis.

Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services.

Mangers were responsive to any concerns raised and sought to learn from them and improve services. Staff took time together in team meetings and franchise meetings to review the service's performance and objectives.

The service continuously sought feedback from patients to improve services. The service used patient feedback, complaints, and audit results to help identify any necessary improvements and ensure they provided an effective service.

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

Diagnostic and screening procedures

Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment

Staff had not always ensured that cleaning, equipment checks and first aid kit checks had been carried out and recorded as required.

Regulated activity

Diagnostic and screening procedures

Regulation

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

There were inconsistencies in the effectiveness of governance, information management and the management of risk, issues and performance.