

Private Ultrasound Limited

Quality Report

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Date of inspection visit: 9 December 2019

Date of publication: 04/02/2020

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

Ratings

Overall rating for this location

Good



Are services safe?

Good



Are services effective?

Are services caring?

Are services responsive?

Good



Are services well-led?

Good



Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

Private Ultrasound Limited is operated by Private Ultrasound Limited. The service provides pregnancy ultrasound, gynaecological and fertility scans for women, as well as liver, upper abdominal, kidney, bladder and prostate scans for patients. The service took referrals from self-paying patients from a wide geographical area, although they were mainly located in London.

The service provides diagnostic imaging for patients aged 18 years and over. It is registered with the Care Quality Commission (CQC) to provide the regulated activity of diagnostic and screening procedures. It has one ultrasound machine in one clinic room.

We inspected this service using our comprehensive inspection methodology. We carried out the announced part of the inspection on 9 December 2019. We gave staff 48 working hours' notice we were coming to inspect to ensure the availability of the registered manager and patients.

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

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

Services we rate

This is the first time we inspected this service. We rated it as **Good** overall because:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills and managed safety well. The service-controlled infection risk well. Staff assessed risks to patients, acted on them and kept care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care and treatment, gave patients enough to drink, and checked if they were comfortable during their scans. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients. Consent processes were followed and patients were advised on how to prepare for scans. The service was available six days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their scan results. They provided emotional support to patients where necessary.
- The service planned care to meet the needs of their patient population and took account of most patients' individual needs. People could access the service when they needed it and did not have to wait too long for treatment.
- Leaders ran services well using reliable information systems. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and all staff were committed to improving services.

However:

- Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, safeguarding policy did not reference female genital mutilation (FGM). We were not assured staff had training on how to recognise and report all types of abuse, and how to apply it. Not all policies referenced up-to-date national guidance.
- Although the service did not perform any blood tests or wound care, they did not have spill kits to clean blood or other bodily fluid spillages.

Summary of findings

- There was no formal written evidence of risk assessment or consent in patient records.
- The sonographer did not receive a formal appraisal, although the quality of their work was reviewed twice a year. Staff did not have regular opportunities to meet, discuss and learn from the performance of the service.
- At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received.

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

Dr Nigel Acheson

Deputy Chief Inspector of Hospitals (London and South)

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating

Good



Summary of each main service

Diagnostic imaging is the sole core service provided at this location. We rated this service as good because it was safe, responsive and well-led. We do not rate effective for this type of service. We did not rate caring on this occasion as we were unable to observe any scans on the day of inspection.

Summary of findings

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Good



Private Ultrasound Limited

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Private Ultrasound Limited

Private Ultrasound Limited is operated by Private Ultrasound Limited. The service opened at this location in 2019, but previously operated at another address since 2013. The service provides pregnancy ultrasound, gynaecological and fertility scans for women, as well as liver, upper abdominal, kidney, bladder and prostate scans for all patients. All patients are self-funding, and pregnancy ultrasound scans performed at the service are in addition to those provided through the NHS.

The service has had a registered manager in post since opening at this location in 2019.

We have not previously inspected this service.

The service did not use or store any medications.

Our inspection team

The team that inspected the service comprised a CQC lead inspector and one other CQC inspector. The inspection team was overseen by Nicola Wise, Head of Hospital Inspection.

Information about Private Ultrasound Limited

The service provides diagnostic imaging (ultrasound scans). The service is situated on the third floor of a building containing other separately registered healthcare providers. The service leases one clinic room. There is a shared reception/waiting area on the ground floor and a bathroom on the third floor. The service is easily accessible by public transport as it is in central London.

The service is registered to provide the following regulated activities:

- Diagnostic and Screening Procedures

All patients accessing the service self-refer to the clinic and are all seen as private (self-funding) patients. Private Ultrasound Limited offers many different scans including:

- Early pregnancy scan (six to 12 weeks gestation) – including measurement of embryo, viability and dating with estimated due date. Usually performed transabdominally (using an external scan probe on the abdomen), but may need to be transvaginal if earlier in the pregnancy.
- Pregnancy nuchal fold thickness scan (11 to 14 weeks gestation) – to calculate risk of major chromosomal

abnormalities. The service did not perform any non-invasive prenatal testing (NIPTS) but could signpost women to other nearby providers for bloods to be taken.

- Pregnancy dating scan - to establish exact duration of pregnancy and estimated due date.
- Gender baby scan (ideally performed after 16 weeks of pregnancy but could be performed after 14 weeks) - the baby and fluid are measured as part of the scan as well as the gender being revealed.
- Anatomy pregnancy scan (18 to 24 weeks gestation) - used to look for possible anomalies within the foetus, as well as the placenta and fluid.
- Pregnancy growth scans (28 weeks gestation plus) – measuring baby and checking wellbeing and placental position. This scan is also offered in 4D.
- Gynaecological scans predominantly related to in vitro fertilisation treatment or ovarian scans.
- Breast scans - primarily used to help diagnose breast lumps or other abnormalities.
- Various other scans of areas/organs such as the pelvis, upper abdomen, kidneys, bladder, prostate and testicles.

Summary of this inspection

- Deep vein thrombosis screenings to check for blood clots in veins.

The service was open up to six days a week, with evening clinics operating on Mondays and Thursdays, as well as opening 10am to 2pm Saturdays. The service was closed on Sundays.

At the time of our inspection, Private Ultrasound Limited employed a practice manager who was also the CQC's registered manager. A registered manager is a person who has registered with the CQC to manage a service. Like registered providers, they are registered persons. Registered persons have a legal responsibility for meeting the requirements of the Health and Social Care Act 2008 and associated regulations about how a service is managed. The service was staffed by the non-clinical practice manager and one lead sonographer. In addition, the service worked with two consultant radiologists who provided specialist scans (such as breast scanning) on set days and provided advice to the sonographer where required.

During the inspection, we visited the registered location in London. We spoke with two staff, who were the registered manager and the lead sonographer. We spoke with one patient but were not able to observe any scans as patients did not consent to us being present. During our inspection, we reviewed five sets of patient records.

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

Activity (December 2018 to November 2019)

- In the reporting period, a total of 1,372 scans took place at the service. Of these, 678 were pregnancy growth scans, 346 were anatomy pregnancy scans, 72 were early pregnancy scans, 114 were gender baby scans, 121 were pelvic/gynaecological scans, 20 were pregnancy nuchal fold thickness scans, 17 were testicular scans and four were breast scans.

Track record on safety for the period December 2018 to November 2019:

- Zero never events. Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event.
- Zero clinical incidents.
- Zero serious injuries.
- Zero incidences of hospital acquired Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (C. diff) or Escherichia coli (E. coli).
- Zero complaints.

Services provided at the service under service level agreement:

- Provision of the clinic room, including cleaning
- Waste removal
- Maintenance of ultrasound equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

This is the first time we inspected this service. We rated safe as **Good** because:

Good



- The service required staff to have mandatory training in key skills and made sure everyone had completed it.
- The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. Clinic staff kept equipment and the premises visibly clean.
- The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well.
- Staff removed or minimised risks where possible. Staff identified and quickly acted upon patients at risk of deterioration.
- 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.
- Staff kept records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care.
- The service knew how to manage patient safety incidents, but none had been reported in the 12 months prior to inspection. Staff recognised incidents and near misses and described how to report them appropriately. Managers told us they would investigate incidents and share lessons learned with the whole team.

However:

- Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, safeguarding policy did not reference female genital mutilation (FGM). We were not assured staff had training on how to recognise and report all types of abuse, and how to apply it.
- Although the service did not perform any blood tests or wound care, they did not have spill kits to clean blood or other bodily fluid spillages.
- There was no emergency evacuation chair for the service in the event of a fire on the day of inspection. The service purchased an emergency stretcher immediately following inspection feedback.

Summary of this inspection

- There was no formal written evidence of risk assessment in patient records.
- Staff we spoke with were not fully aware of the duty of candour.

Are services effective?

This is the first time we inspected this service. We do not rate effective for this type of service.

- The service provided some care and treatment based on national guidance and evidence-based practice.
- Staff gave patients enough to drink to meet their needs.
- Staff checked to ensure patients were comfortable during their scans.
- Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients.
- The service made sure staff were competent for their roles. The service checked medical staff received appraisals.
- Staff worked together as a team to benefit patients. They supported each other to provide good care.
- Key services were available six days a week to support timely patient care.
- Staff gave patients advice in relation to their procedure.

However:

- Not all policies referenced up-to-date national guidance.
- The sonographer did not receive a formal appraisal, although the quality of their work was reviewed twice a year.
- The service did not record formal written consent for any type of scan at the time of our inspection.

Are services caring?

This is the first time we inspected this service. We did not rate caring on this occasion as we were unable to observe any scans on the day of inspection.

- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal, cultural and religious needs.
- Staff supported and involved patients, families and carers to understand their scan results.

Summary of this inspection

Are services responsive?

Good



This is the first time we inspected this service. We rated responsive as **Good** because:

- The service planned and provided care in a way that met the needs of the patient population.
- The service was not fully inclusive and only took account of some patients' individual needs and preferences. Staff made some reasonable adjustments to help patients access services.
- People could access the service when they needed it and received the right care promptly.
- The service had not received any complaints in the last year, but there were policies and procedures in place to ensure concerns and complaints were treated seriously, investigated and lessons learned would be shared.

However:

- At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received.

Are services well-led?

Good



This is the first time we inspected this service. We rated well-led as **Good** because:

- Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action.
- 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. The service had an open culture where patients, their families and staff could raise concerns without fear.
- Leaders operated effective governance processes throughout the service. Staff were clear about their roles and accountabilities.
- Staff used systems to manage performance effectively. They identified and managed relevant risks and issues and identified actions to reduce their impact. The service had plans to cope with unexpected events.
- The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats. The information systems were secure.

Summary of this inspection

- The service engaged with patients and staff but there were limited opportunities for them to plan and manage services due to the nature of the business.
- Staff were committed to continually learning and improving services.

However:

- Staff did not have regular opportunities to meet, discuss and learn from the performance of the service.




Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Diagnostic imaging

Safe	Good 
Effective	
Caring	
Responsive	Good 
Well-led	Good 

Are diagnostic imaging services safe?

Good 

This is the first time we inspected this service. We rated safe as **good**.

Mandatory training

The service required staff to have mandatory training in key skills and made sure everyone had completed it.

Mandatory training subjects included: infection prevention and control, fire safety, equality and diversity, safeguarding adults and children, lone working, basic life support, moving and handling, information governance and complaints handling. We saw evidence that staff had completed all of this training.

The two consultant radiologists completed their training with their substantive NHS trust employers. We saw evidence they had completed and were up to date with all required mandatory training. The registered manager kept a record of their training and asked for annual updates to add to their files.

Safeguarding

Although staff understood how to protect patients from abuse and the service worked well with other agencies to do so, safeguarding policy did not reference female genital mutilation (FGM). We were not assured staff had training on how to recognise and report all types of abuse, and how to apply it.

There were clear safeguarding processes and procedures for safeguarding adults and children. A policy was available for staff in a paper format. The service did not see any patients under the age of 18.

At the time of our inspection, 100% of staff were compliant with safeguarding training. All staff had received training in level two of vulnerable adult's safeguarding, and level two for children's safeguarding. The registered manager could access advice from the local council safeguarding teams if needed. This met the intercollegiate guidance 'Safeguarding children and young people: roles and competences for health care staff' (January 2019).

The safeguarding policy did not reference female genital mutilation (FGM). However, these topics were covered in the safeguarding level two course staff completed. The sonographer told us they would not often see patients at risk of FGM as these tended to be younger patients. However, historic FGM can cause difficulty during childbirth and can the babies of any women seen at the service could at risk in the future. We were not assured the service was knowledgeable in this regard.

Staff were able to describe the correct pathways as per the providers safeguarding policy to take in the event a safeguarding concern was identified. Staff knew how to make a safeguarding referral and who to inform if they had concerns. The safeguarding lead was the registered manager.

Cleanliness, infection control and hygiene

The service controlled infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection.

Diagnostic imaging

Clinic staff kept equipment and the premises visibly clean. Although the service did not perform any blood tests or wound care, they did not have spill kits to clean blood or other bodily fluid spillages.

The clinic room was clean and had suitable furnishings which were clean and well-maintained. The clinic room had washable flooring and wipe-clean furnishings. The service used fresh paper towelling on the couch for each patient.

We saw a hand sanitiser placed in a prominent position in the scanning room. Staff informed us they followed infection control principles including the use of personal protective equipment (PPE) when performing intimate examinations. All staff involved in clinical work were bare below the elbows.

There was a handwash basin in the ultrasound room and access to hand disinfectant. Handwashing guidance was posted above the basin to remind staff of best handwashing techniques. However, the service did not complete any hand hygiene audits to ensure staff were following the World Health Organisation's 'five moments for hand hygiene' recommendations, in line with best practice.

Staff correctly cleaned and stored equipment such as probes used for intimate ultrasound investigations (for example, transvaginal investigations). Staff covered the probes with an appropriate sheath during investigations and cleaned them with the recommended sporicidal wipes after each ultrasound scan. This eliminated the risk of cross-infection between patients.

The clinic had recently started records that demonstrated staff cleaned the equipment and immediate environment before seeing any patients in the clinic room. This included the ultrasound unit, the patient couch and surfaces. The overall deep cleaning of the clinic room was completed by the premises provider's contractor and we saw evidence to demonstrate cleaning had taken place. Staff knew how to report and escalate any concerns with cleanliness appropriately.

Although the service did not perform any blood tests or wound care, they did not have the spill kits to clean blood or other bodily fluid spillages.

There had been no incidences of healthcare acquired infections at the service in the 12 months prior to inspection.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use them. Staff managed clinical waste well. However, there was no emergency evacuation chair for the service in the event of a fire on the day of inspection. The service purchased an emergency stretcher immediately following inspection feedback.

The ultrasound machine's manufacturer maintained and serviced it annually. We reviewed service records for the equipment, which detailed the maintenance history and service due dates. The service had systems to ensure machines or equipment were repaired on time, when needed.

Staff disposed of clinical waste safely. Clinical waste bags were collected under contract with an external company. The service did not use sharps, as they directed patients to other separately registered services for any blood tests.

Due to the nature of the service they did not require a resuscitation trolley. However, they did have access to a first aid box.

Fire extinguishers were available on each floor and were checked by the premises' provider. The registered manager was aware of the evacuation procedure in the event of a fire. Fire alarm tests took place weekly. However, on the day of inspection, there was no emergency evacuation chair for the service in the event of a fire. Following our inspection, the service purchased an escape stretcher in case of collapse or fire emergency, which was kept in a secure cupboard on the same floor as the service.

Assessing and responding to patient risk

Staff removed or minimised risks where possible. Staff identified and quickly acted upon patients at risk of deterioration.

Staff told us what action they would take if a patient became unwell or distressed while waiting for, or during, an ultrasound scan. All clinical staff were basic life

Diagnostic imaging

support (BLS) trained. In the case of emergency, the patient would be transferred to the most appropriate neighbouring NHS hospital, using the standard 999 system.

Staff described what actions they would take if they found unusual findings on an ultrasound scan. Once the sonographer identified an abnormal scan, they created a report which clearly outlined their concerns. In the case of an acute abnormality, the patient was instructed to attend their nearest emergency department with a copy of the report. Staff gave an example of a scan where they found the patient had deep vein thrombosis (a blood clot in a vein). They explained the report, gave the patient a copy and booked them a taxi directly to the neighbouring emergency department. In the case of any other abnormal result, a copy of the scan report would be given to the patient for their NHS notes and the sonographer would ring and speak directly to the patient's GP or appropriate healthcare professional. This was documented in a policy which was reviewed annually.

The service ensured the right person got the right scan at the right time, by asking patients to confirm their identity and date of birth. This evidenced staff followed best practice and used the British Medical Ultrasound Society's (BMUS) 'pause and check' checklist.

Following our inspection, the service drafted a document which outlined what type of patients they would accept for scans. The service accepted patients between 18 and 80 years of age. Any patients suffering from severe heart disease, epilepsy, dementia, unstable diabetes or unstable blood pressure, or pregnant patients with broken waters or heavy bleeding would be directed to NHS services.

The sonographer reported they had not had patients who requested frequent scans. They advised any patients who wanted longer appointments that their scanning time was restricted to 10 -15 minutes as per the BMUS guidance and followed the as low as reasonably achievable (ALARA) principles, outlined in the 'guidelines for professional ultrasound practice 2017' by the Society and College of Radiographers (SCOR) and BMUS.

The service included information on their website from Public Health England about the potential risks associated with ultrasound 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 lead sonographer completed the majority of scans. The sonographer had completed a medical ultrasound degree level course. There were two consultant radiologists employed on a locum basis who conducted specialist clinics on Wednesdays and Thursdays as patient demand required. If at any point the consultant radiologist's opinion or follow up was needed, they could be contacted at any time or asked to rescan a patient. The registered manager checked the appraisals and training records for these medical staff were updated annually. We were told there was usually a second member of staff present, who was normally the registered manager.

Both staff we spoke with felt the staffing levels were sufficient to cover the work required.

Clinics were usually planned around the sonographer's availability and to date the service had not cancelled any appointments. The service's sickness rate from November 2018 to October 2019 was 0%.

If there was need for an agency sonographer (in the case of planned annual leave or sickness, for example), the service used the same members of staff, who had been instructed in the local procedures such as safeguarding and fire safety. The registered manager informed us they always spent a full three sessions with any agency staff to ensure they were the right match for their clients.

Records

Staff kept records of patients' care and treatment. Records were clear, up to date, stored securely and easily available to all staff providing care. However, there was no formal written evidence of risk assessment in patient records.

Patients having all types of scans would receive a report written by the sonographer at the time of the scan in hard copy, or by email, to add to their NHS notes. Where appropriate, and with consent, the sonographer could also send a copy of the scan report to the patient's GP or another relevant healthcare professionals. All electronic reports were emailed directly from the ultrasound machine through a secure and encrypted mail platform.

Diagnostic imaging

The ultrasound machine was password-protected and kept in the locked clinic room at all times. Staff downloaded the images and reports regularly from the ultrasound machine onto an external hard drive and stored this securely in a locked cupboard.

We reviewed five ultrasound reports. Staff recorded information in a clear and correct way. This included the reason for the scan, the findings, conclusions and recommendations. However, there was no formal record of any pre-existing medical conditions in the patient records, although staff told us they took a verbal history. Following our inspection, the provider informed us they would document any risks and provided evidence they had added a potential risk information request to all their email signatures on communications sent to patients.

The service did not routinely keep any paper records. Some referral letters were received and were kept in a locked cupboard within the clinic room, which the service had sole use of.

There was a data protection policy and all staff received information governance training.

Medicines

The service did not store or administer any medicines.

Incidents

The service knew how to manage patient safety incidents, but none had been reported in the 12 months prior to inspection. Staff recognised incidents and near misses and described how to report them appropriately. Managers told us they would investigate incidents and share lessons learned with the whole team. However, staff we spoke with were not fully aware of the duty of candour.

The service used a paper-based reporting system, with forms available in the clinic for staff to access. The registered manager would be responsible for handling investigations into all incidents.

From December 2018 to November 2019, no incidents were reported at the clinic. Staff we spoke with knew how to report incidents and could give examples of when they would do this. The managers told us they would

investigate any incidents and share lessons learned with the whole team in person, or would arrange a meeting if necessary. There was an incident reporting policy which described how incidents should be reported and graded.

Never events are serious patient safety incidents which should not happen if healthcare providers follow national guidance on how to prevent them. Each never event type has the potential to cause serious patient harm or death but neither need have happened for an incident to be a never event. From December 2018 to November 2019, the service did not report any incidents classified as a never event.

In accordance with the Serious Incident Framework, the service reported no serious incidents (SIs) from December 2018 to November 2019.

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 we spoke with were not fully aware of the duty of candour. The registered manager told us there had been no incidents when statutory duty of candour had to be used since the service had opened.

The registered manager was aware of the requirements for reporting incidents and sending notifications to the CQC. However, at the time of inspection the registered manager had not been required to submit any notifications.

Are diagnostic imaging services effective?

This is the first time we inspected this service. We do not rate effective for this type of service.

Evidence-based care and treatment

The service provided some care and treatment based on national guidance and evidence-based practice. However, not all policies referenced up-to-date national guidance.

We reviewed nine policies which were version controlled and current. The majority of policies did not reference national guidance from the Royal College and Society of

Diagnostic imaging

Radiographers, the foetal abnormality screening programme (FASP) standards or the British Medical Ultrasound Society (BMUS). The safeguarding adults did not include a definition of female genital mutilation (FGM). This meant staff might not have been following relevant up-to-date national guidance.

The service followed as low as reasonably achievable (ALARA) principles outlined by the Society and College of Radiographers. The registered manager told us frequent scans did not occur and scans were time limited.

Nutrition and hydration

Staff gave patients enough to drink to meet their needs.

Staff gave women information on drinking water before a fertility or pregnancy scan to ensure they attended with a full bladder which enabled the sonographer to gain a better view of the womb. In the case of fasting (for four hours) before a liver scan, diabetic patients were instructed they could have a sugary supplement to maintain their blood sugar levels.

Patients had access to drinking water in the reception area. The service offered water to patients who were required to have a fuller bladder at the time of the scan.

Pain relief

Staff checked to ensure patients were comfortable during their scans.

Staff did not formally assess pain levels of patients as the procedure was pain-free. However, staff told us they would check frequently with patients that they remained comfortable during the course of their scans.

Patient outcomes

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

The provider told us they performed twice yearly audits of ultrasound images and reports. The consultant radiologist randomly selected 20 records from the external hard drive and reviewed the images and reports

for quality, feeding back directly to the lead sonographer. We saw the most recent audit, which showed that the quality of the scans and reports written by the sonographer were good.

When staff identified any unusual or abnormal images needing further referral to specialists, they told us could follow up the outcomes to assess the accuracy of the diagnoses through a telephone call or email communication. The service told us they often got feedback directly from patients confirming their scan results, as they let them know what further procedures they underwent following their appointments.

Competent staff

The service made sure staff were competent for their roles. The service checked medical staff received appraisals. Although the sonographer did not receive a formal appraisal, the quality of their work was reviewed twice a year.

There were arrangements for supporting new staff at the service, although there was no formal induction record. The registered manager told us they would be informed of the service's safeguarding policy and fire safety rules. Staff would be supervised and guided for at least three sessions before being allowed to work independently.

The lead sonographer did not receive an annual appraisal, but a sample of their scans were reviewed by the consultant radiologist to ensure the quality of their scans and reports. They gave us multiple examples of conferences they had attended in the last year to keep up to date with best practice in ultrasound scanning.

Both consultant radiologists had an annual competency assessment and appraisal within their substantive posts in their NHS trusts. The consultant radiologists did not complete any continuing professional development (CPD) or training relating specifically to their work at the service, but they provided evidence they did so as part of their NHS practice.

We saw confirmation of the lead sonographer's registration with the public voluntary register of sonographers. This was kept in the staff recruitment folder as well as displayed on the wall in the reception and scanning room.

Multidisciplinary working

Diagnostic imaging

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

Staff told us there were positive working relationships between all individuals as the service as it was a small team.

The service had worked for a number of years with a range of separately registered services locally, such as private GPs and obstetricians. They reported good working relationships with these providers and told us they received positive feedback from them regarding patient satisfaction with their scanning experience.

The service told us that where the patient had consented for their information to be shared, GPs could receive a copy of the ultrasound report electronically. Patients were given a hard copy of their report to do with as they wished.

Seven-day services

Key services were available six days a week to support timely patient care.

The service operated up to six days a week, dependent on patient demand. The service was operational from 9am to 6.30pm each Monday, 9am to 2.30pm each Tuesday, 9am to 3pm each Wednesday, 9am to 5.40pm each Thursday and 12pm to 4.30pm each Friday. In addition, the service offered appointments between 10am and 2pm on Saturdays.

Health promotion

Staff gave patients advice in relation to their procedure.

There was patient information on diagnostic imaging procedures available on the service's website. Patients were provided with information on what actions they needed to take prior to their scan. For example, whether to drink anything in order to have a full bladder to improve the image quality for fertility or pregnancy scans. Following our inspection, the service improved the range of information available on their website and added information to the emails sent to patients.

Consent and Mental Capacity Act

Staff supported patients to make informed decisions about their care and treatment. However, the service did not record formal written consent for any types of scans at the time of our inspection.

There was no separate written policy relating to the Mental Capacity Act (2005), although capacity to consent was covered in the clinic's consent policy. Staff were able to verbalise the process to take when they had concerns around a patient's capacity to provide consent, which was in line with the service's consent policy. However, staff reported they had never had an incident of a patient lacking capacity to consent.

All patients were directed to read the provider's website for information about their scan. All staff were aware of the importance of gaining consent from patients before conducting an ultrasound scan. The sonographer confirmed names and dates of birth prior to the scan and obtained verbal consent to begin, but did not document these in all records. The service did not record formal written consent for scans at the time of our inspection, even nuchal fold thickness scans.

Are diagnostic imaging services caring?

This is the first time we inspected this service. We did not rate caring on this occasion as we were unable to observe any scans on the day of inspection.

Compassionate care

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

We were not able to directly observe interactions between staff and patients as on the day of inspection, none of the patients consented to us observing their scans. The sonographer told us they introduced themselves before a patient's scan, explained their role and what would happen next. The patient we spoke with told us staff were "professional" and they explained everything once they were in the room. The patient confirmed they would recommend the service to their family and friends.

The registered manager told us they directed people to leave feedback on their website, or through an internet

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search engine review function. The majority of the 42 reviews on this platform were positive, with the clinic scoring 4.5 out of five overall. Patients praised the compassionate and kind attitude of staff.

All conversations during and after an appointment took place in the private clinic room. Patients were greeted at the reception by the building's receptionist and collected from the waiting room and taken up to the clinic room by staff.

The female registered manager acted as a chaperone during intimate examinations. A chaperone is a person who serves as a witness for both patient and clinical staff as a safeguard for both parties during an examination or procedure. The clinic always ensured two staff were on a shift together and the registered manager told us any gynaecological or pregnancy scans would be rescheduled if a second member of staff was not available.

Emotional support

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

Patients were given 30-minute appointments, though scans often took much less time than this, so as not to rush them. Staff explained how they would provide reassurance and support for nervous and anxious patients.

The patient we spoke with during the inspection told us they would have liked more information before attending the service for their scan, but they felt reassured by the information given by the sonographer once they were at the service. They told us the sonographer's explanation of their scan results helped to alleviate the anxiety they felt before attending the appointment.

The sonographer described how they would explain distressing findings to the patient following a scan, with sensitivity and the appropriate level of detail. They explained they would flag any abnormal results and would refer the patient to NHS care or ongoing specialist care. The GP or health professional would then make further investigations based on the findings of shared report, with the patient's consent. Staff told us there was a small private coffee room patients could sit in if

distressed, and they would ensure any patients receiving bad news were given the opportunity to call someone to accompany them when leaving the service. They described how they would support and comfort any patients in distress.

Understanding and involvement of patients and those close to them

Staff supported and involved patients, families and carers to understand their scan results.

Patients were directed to the service's website and given verbal information where necessary to prepare for their scan. Essential information was sent by email if preferred by the patient. The patient we spoke with told us they would have liked more information on the procedure and what to expect before attending the service. However, once at the service, the patient told us they were given enough time to ask questions and staff answered all questions in a calm, friendly and respectful manner. Following our inspection, the provider improved the range of patient information available on the website and added more information to the emails sent out to patients upon booking.

The sonographer explained the findings of the scan to the patient during the appointment and gave them a copy of the full written report. Patients were able to ring the service at any time to discuss or clarify any issues. If patients called during hours the service was closed, they were able to leave a message and staff would call them back to discuss any concerns or issues.

The service allowed partners and relatives to be present in the scanning room, and described how they sometimes had a number of family members present to observe baby scans.

All costs were clearly stated on the provider's website and confirmed with the client before a scan being booked.

Are diagnostic imaging services responsive?

Good 

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

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Service delivery to meet the needs of local people

The service planned and provided care in a way that met the needs of the patient population.

The clinic's location was close to public transport links. The service provided information on travelling to the clinic on their website.

Patients rang a buzzer to access the reception area on the ground floor, where they were greeted by the building's receptionist and instructed to wait in the waiting area on the ground floor. This area had adequate seating for patients and relatives whilst they waited to be called for their scan. There was fresh drinking water and magazines available.

The service was on the third floor and was accessible by lift and stairs. The toilet was visibly clean and accessible. The scanning room could comfortably accommodate two members of staff, the patient and any relatives who wished to be present. It included a scan couch and some chairs. There was one large screen to view the images.

The service had a range of packages with different price options which it clearly displayed on the website. Patients could book appointments online through a secure portal. The service offered out of hours appointment times, in the evenings and on Saturdays.

Meeting people's individual needs

The service was not fully inclusive and only took account of some patients' individual needs and preferences. Staff made some reasonable adjustments to help patients access services.

Staff had completed the equality and diversity course as part of their mandatory training.

The ultrasound scan room provided a calm and relaxing atmosphere. The room had dimmed lighting to enable the patient to view the images. There was appropriate space within the building for staff to have private conversations with patients.

The staff at the clinic had knowledge of patients living with dementia and patients with learning disabilities. However, there was no written policy at the service regarding patients with enhanced needs and no

admission criteria that specified whether these patients would be seen at the service. The provider told us they would signpost patients to other services where they were unable to accommodate them.

The service was not accessible to individuals who used wheelchairs, as it was on third floor and the lift was small. The couch was adjustable in height to allow easier transfer for patients with limited mobility. The couch in the scan room could accommodate patients with a weight of up to 180kg.

The service did not have access to formal translation services, but had arranged for an Arabic interpreter to attend the service in the past. Staff said they encouraged patients to bring friends or relatives with them if English was not their first language, or arrange for their own interpreter. Although the clinic recognised there was a risk with this approach to translation services and it was not in line with best practice, the registered manager considered this was proportionate for this type of service.

Access and flow

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

Between December 2018 and November 2019, a total of 1,372 scans took place at the service. Of these, 678 were pregnancy growth scans, 346 were anatomy pregnancy scans, 72 were early pregnancy scans, 114 were gender baby scans, 121 were pelvic/gynaecological scans, 20 were pregnancy nuchal fold thickness scans, 17 were testicular scans and four were breast scans.

The service did not have a waiting list for ultrasound appointments. Patients could self-refer to the service on the same day. Where this was not possible, the scan would be booked the following day, or whenever was most convenient for the patient. The registered manager explained the booking system was flexible and allowed changes to packages to meet patient choice. Patients paid a small deposit upon booking the scan and could change the package when they attended for their scan appointment if they wished.

Patients could book their scans through the website, through a secure portal. They could ring to speak to staff

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for instructions or advice. Outside of the opening hours of the clinic, patients could leave a voicemail and the call would be returned the next day. This meant staff responded to most calls within 24 hours.

The sonographer gave the results of the ultrasound scans to patients immediately after their scans, along with a copy of the written report. The report contained images of the scanned areas and any further recommendations.

On the day of inspection, we saw patients arrive in the reception and wait no longer than five minutes for their scan. However, the service did not formally audit the patient waiting times in clinic.

From December 2018 to November 2019 the service had not cancelled any scans.

Learning from complaints and concerns

At the time of inspection, the service did not provide information to people on how to give feedback and raise concerns about care they received. The service had not received any complaints in the last year, but there were policies and procedures in place to ensure concerns and complaints were treated seriously, investigated and lessons learned would be shared.

Staff told us they would deal with informal complaints in the first instance, with attempts made to resolve the complaint locally. In the case of a formal complaint, the service had a policy for handling complaints and concerns, which was in date. The policy stated complaints would be acknowledged within two working days, and the service would provide a full response within 10 working days. Where the investigation was still in progress, a letter explaining the reason for the delay would be sent to the complainant and a full response made within five working days of a conclusion being reached. The policy referred patients who were not happy with the service's response to escalate their complaint to the CQC, but noted that we do not investigate complaints, but welcome and monitor feedback about services.

Staff received mandatory training in complaint handling. The registered manager told us she would share learning from complaints informally in person or by email, with a team meeting organised if required. The registered manager informed us the only negative feedback they

had received recently was through their online reviews. Following one review, the service had reflected on communication with patients regarding sickness absence of the building's receptionist and resolved to be more transparent if this happened again in future.

The service received no formal complaints between December 2018 and November 2019.

There was no information for patients within the clinic room on how to make a complaint. We also could not find this information on the provider's website.

Are diagnostic imaging services well-led?

Good 

This is the first time we inspected this service. We rated well-led as **good**.

Leadership

Leaders had the integrity, skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff.

The registered manager and lead sonographer worked closely together to run the service. At the time of the inspection, the service employed two consultant radiologists on a locum basis. They conducted specialist clinics on Wednesdays and Thursdays in line with patient demand and provided advice and guidance where required. Due to the limited nature of the service, there was no role extension planned for staff within the service.

The sonographer and registered manager felt well supported by one another. They told us were approachable and open to new ideas and suggestions for improvement to the service. This was demonstrated by changes made following our inspection feedback.

Vision and strategy

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

The clinic had a mission statement, which stated the clinic strived to exceed patient expectations by providing an experience that was consistently professional,

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personalised, caring and friendly. The service aimed to provide an affordable and accessible service and adopt evidence-based practice, acting with integrity and understanding at all times.

The service's strategy stressed their priority was to offer the best quality care at the most affordable prices, in order to ensure a wide section of the population had access to their scanning service. The service had recently expanded to provide breast scanning services through recruitment of a consultant radiologist who worked in this specialty. They hoped to add further specialist scanning services in the future and offer these on a more frequent basis.

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

Staff told us they enjoyed working at the service, and there was a friendly, supportive culture where people were happy to raise concerns or make suggestions. We observed good team working amongst staff on the day of inspection. Staff told us there was a 'no blame' culture.

There was an emphasis on patient centred care. Staff promoted openness and honesty, but were not aware of what the term 'duty of candour' meant.

Throughout our inspection, the registered manager responded positively to feedback. They assured us improvements would be made at once following our feedback, and demonstrated this by making changes immediately following inspection. This showed a culture of openness and willingness to learn and improve.

Governance

Leaders operated effective governance processes throughout the service. Staff were clear about their roles and accountabilities but did not have regular opportunities to meet, discuss and learn from the performance of the service.

The service had systems and processes to support the delivery of a safe and caring service. All staff had regular criminal safety checks (Disclosure and Barring Service checks) and completed mandatory training appropriate to their role.

There were policies and procedures for the operation of the service and these were available to staff in a folder in the clinic. All policies were up to date and reviewed annually by the registered manager or sonographer. However, not all policies referenced current national guidance, as the safeguarding policy did not reference female genital mutilation (FGM).

Staff understood their roles and only carried out scans in line with their competencies.

The service did not have regular formal team meetings but relied on informal sharing of information as they were a small team, who worked restricted hours. There was no forum to share potential learning from incidents or complaints, although there had not been any recently.

The service had indemnity and medical liability insurance which covered all staff working within the service for the case of a legal claim.

Managing risks, issues and performance

Staff used systems to manage performance effectively. They identified and managed relevant risks and issues and identified actions to reduce their impact. The service had plans to cope with unexpected events.

The registered manager and sonographer understood the risks relating to the premises, service delivery and business. There was evidence the registered manager and sonographer had identified and mitigated the risks and documented these risks within a risk management framework. This was reviewed annually.

There were some audits to review current practice and drive improvement. For example, the quality of ultrasound scans performed by the sonographer were regularly reviewed by a consultant radiologist.

The service had a contingency plan, focusing on staff absence, premises and equipment failure. There were weekly fire alarm tests and emergency lighting. The ultrasound machine did not have a back-up battery in the case of a power cut. It saved all information as it was

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inputted. However, this did not assure us the sonographer could finish and report on a scan in the case of a power cut. In the event of a power cut, any scans would be terminated and rebooked. In addition, if any scans were perceived as urgent (which was unlikely due to the nature of the caseload), the patient would be advised to attend the nearest NHS centre.

Managing information

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

There was an information governance policy that staff followed. Patients consented for their information to be used and shared in line with the General Data Protection Regulation (GDPR) 2018 by using the service.

The sonographer could access reported ultrasound scans easily. The ultrasound machine was password protected. Ultimately, all patient images and reports were recorded on an external hard drive that was locked away and password protected. The registered manager stored printed referral letters in a locked filing cupboard in the locked clinic room. All staff had access to the key.

Engagement

The service engaged with patients and staff but there were limited opportunities for them to plan and manage services due to the nature of the business.

The service had an easily accessible website where patients were able to leave feedback and contact the service. This showed patients were able to engage with the service online and verbally.

There was no formal mechanism for staff feedback as there were no team meetings or staff survey due to the small size of the service. Staff told us they would be comfortable suggesting improvements to the service.

Learning, continuous improvement and innovation

Staff were committed to continually learning and improving services.

Staff attended conferences appropriate to their roles and regularly reviewed and updated policies and guidance accordingly. The provider was responsive to the feedback from our inspection and made some improvements following immediate feedback, such as the purchasing of an emergency stretcher and improvements to patient information on the website.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **SHOULD** take to improve

- The provider should review their existing policies and add in references to national guidance where appropriate.
- The provider should ensure sonographers have sufficient training and awareness in relation to female genital mutilation (FGM).
- The provider should consider acquiring equipment to clean blood spillages and bodily fluids.
- The provider should consider how to familiarise all staff with the requirements of the duty of candour.
- The provider should consider introducing a formal record of induction for any new staff working at the service.
- The provider should consider introducing a formal appraisal process for staff.
- The provider should consider introducing a written record of patient consent and risk assessment for all scans.
- The service should consider how to improve access to formal translation and interpretation services.
- The provider should display clear information in the clinic environment about how to raise a complaint.
- The provider should consider holding regular meetings with staff in order to improve governance and strengthen engagement.