R.B Imaging Limited

Quality Report

<10 Station Road
Ashford
Middlesex
TW15 >
Tel: 01784244975
Website: www.ultrasound-direct.

Date of inspection visit: 10 September 2019 and 24 September 2019
Date of publication: 14/11/2019

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	Inadequate
Are services safe?	Inadequate
Are services effective?	Not sufficient evidence to rate
Are services caring?	Good
Are services responsive?	Requires improvement
Are services well-led?	Inadequate

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

Overall summary

R. B Imaging Ltd (Ultrasound Direct Heathrow) is operated by R. B Imaging Ltd. The main location is Ultrasound Direct Heathrow. The service operates under a franchise agreement with Ultra Sound Direct (Franchise) Ltd. A franchise business is a business in which the owners, or franchisors, sell the rights to their business logo, name, and model to third party retail outlets, owned by independent, third party operators, called franchisees. The service provides a general ultra sound service for men and women and a baby scanning service which includes early pregnancy scans and gender confirmation scans.

We inspected diagnostic imaging services as this was the only regulated activity the service provided. We inspected this service using our comprehensive inspection methodology. Prior to our inspection we send out a provider information request to gain information about the service and its performance. We asked provider for this document on three occasions over the 12 months prior to our inspection and did not receive one. It is a requirement to provide information to the CQC when requested and the lack of response prompted us to undertake the inspection, as we saw it as a risk.

We carried out an announced inspection at Ultrasound Direct Heathrow on 10 September 2019. We had concerns about what we found at this location, so we carried out two further unannounced inspections at the satellite sites Ultrasound Direct Brighton and Ultrasound Direct Bourne End on the 24th September 2019.

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

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

Services we rate

We have not previously rated this service. At this inspection we rated the service as **Inadequate** overall because;

The service did not control infection risk well. We saw varied use of infection control policies, some of which put patients at very high risk of avoidable harm.

The service did not routinely provide mandatory training in key skills to all staff or monitor this to ensure training was regularly completed.

Not all of the clinic sites were safe and suitable for their purpose.

Although most staff understood how to protect patients from abuse, not all staff had undertaken adequate levels of safeguarding training.

Equipment was not consistently well maintained or regularly serviced.

We did not find lessons learned from incidents were always shared with the wider team. There was no formal log of incidents and these were not regularly reviewed for trends and themes.

The service did not regularly review staff records to ensure staff were competent for their roles. Managers did not hold regular appraisals to monitor staff's work performance. We saw no evidence of supervision meetings with staff to provide support and monitor the effectiveness of the service.

Managers did not monitor the effectiveness of care and treatment and therefore could not use the findings to improve this.

Staff were not following guidance and policy in regard to some aspects of infection control and safeguarding. Managers were not effective in ensuring staff understood local policies and guidance.

The service did not always consider patient's individual needs regarding communication.

The service reviewed concerns and complaints and investigated them, however, these were not monitored for trends and themes and we saw little evidence of complaints being shared with all staff members.

Summary of findings

The service had a vision for what it wanted to achieve but no strategy to turn it into action. We did not see that the leaders and staff understood the vision and strategy or how to apply them and monitor progress or had support from the franchise to deliver them.

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

Leaders and teams had poor systems to manage performance effectively. Risks were not identified and escalated to reduce their impact.

There were no plans to cope with unexpected events. There was no evidence that staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

There was no evidence that the service collected reliable data and analysed it. Therefore, the was little understanding of performance, which could be used to make decisions and improvements.

However, we also saw some good practice;

Staff completed and updated risk assessments for each patient and removed or minimised risks.

The service provided a flexible service taking into account the needs of patients. People could access the service when they needed it.

Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.

Staff provided emotional support to patients to minimise their distress and involved patients and those close to them in decisions about their care and treatment.

Information systems were integrated and secure.

Following this inspection, we followed CQC process regarding the significant safety concerns and told the provider to suspend the regulated activities at the satellite sites of Ultrasound direct Heathrow, Ultrasound Direct Banstead, Ultrasound Direct Bourne End, Ultrasound Direct Kingston, Ultrasound Direct Brighton, Ultrasound Direct Hayes for a period of six weeks. After this time, they will be re-inspected to ensure that they have met all the required regulations to deliver safe care and treatment. We also issued the provider with five requirement notices. Details of these are at the end of the report.

Nigel Acheson

Deputy Chief Inspector of Hospitals (South-East)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	**Diagnostic imaging was the only activity the service provided. We rated this service as inadequate overall. This was because it was inadequate in the safe and well led domains and requires improvement in responsive. We rated the domain of caring as good and we do not rate the key question of effective.**

Summary of findings

Contents

Summary of this inspection

Page

Background to R.B Imaging Limited (Ultrasound Direct Heathrow). 7

Our inspection team 7

Information about R.B Imaging Limited (Ultrasound Direct Heathrow). 7

The five questions we ask about services and what we found 8

Detailed findings from this inspection

Outstanding practice 23

Areas for improvement 23

Action we have told the provider to take 24

Inadequate

R.B Imaging Limited (Ultrasound Direct Heathrow).

Services we looked at
Diagnostic imaging.

Summary of this inspection

Background to R.B Imaging Limited (Ultrasound Direct Heathrow).

R. B Imaging Ltd (Ultrasound Direct Heathrow) is operated by R. B Imaging Ltd. The service opened in 2015. It operates under a franchise agreement with Ultra Sound Direct (Franchise) Ltd. The service is an independent healthcare provider offering ultrasound imaging and diagnostic services to self-funding or private patients aged over 16 years of age. The hospital primarily serves the communities of Surrey, Buckinghamshire, Middlesex and East Sussex It also accepts patient referrals from outside this area.

The service has had a registered manager in post since 2015.

We inspected this service using our comprehensive inspection methodology. We carried out an announced inspection at Ultrasound Direct Heathrow on 10 September 2019. We had concerns about what we found at this site, so we carried out two further unannounced inspections at Ultrasound Direct Brighton and Bourne End on the 24th September 2019.

Our inspection team

The team that inspected the service comprised of a CQC lead inspector and a further three inspectors and an inspection manager. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection.

Information about R.B Imaging Limited (Ultrasound Direct Heathrow).

The service operated a hub and spoke model. It had a central hub, Ultrasound Direct Heathrow, which was the central location for patients to make appointments. It also ran clinics out of the following sites as satellite services. Ultrasound Direct Banstead, Ultrasound Direct Bourne End, Ultrasound Direct Kingston, Ultrasound Direct Brighton, Ultrasound Direct Hayes. During the inspection, we visited three of the six sites where services were provided, Brighton, Bourne End and the hub site in Heathrow.

We spoke with eight staff across three sites including sonographers, the registered manager, assistant manager, receptionists and clinical assistants. We spoke with seven patients and relatives. During our inspection, we reviewed eight staff files and reviewed 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. The service has not been inspected previously, this was the services first inspection since registration with CQC.

Track record on safety

There were no never events, clinical incidents, or deaths reported.

There was no reported incidences of Meticillin-resistant Staphylococcus aureus (MRSA), Meticillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (c.diff), or E-Coli.

We were not provided with the number of complaints that the service had received.

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?

Inadequate

We have not previously rated this service. We rated it as **Inadequate** because:

We found the following issues that the service provider needs to improve:

The service did not control infection risk well. We saw varied use of infection control policies, some of which put patients at very high risk of avoidable harm.

The service did not routinely provide mandatory training in key skills to all staff or monitor this to ensure necessary training was regularly completed.

Although some staff understood how to protect patients from abuse, not all staff had adequate training on how to recognise and report abuse.

Not all of the clinic sites were safe and suitable for their purpose.

Equipment was not consistently well maintained or regularly serviced.

We did not find lessons learned from incidents were always shared with the wider team. There was no formal log of incidents and these were not regularly reviewed for trends and themes.

Are services effective?

Not sufficient evidence to rate

We have not previously rated this service. We rated it as **Not rated** because:

The service did not regularly review staff files to ensure staff were competent for their roles. Managers did not hold regular appraisals to monitor staff's work performance. We saw no evidence of supervision meetings with staff to provide support and monitor the effectiveness of the service.

Managers did not monitor the effectiveness of care and treatment and therefore could not use the findings to improve this.

Staff were not following guidance and policy in regard to some aspects of infection control and safeguarding. Managers were not effective in ensuring staff understood local policies and guidance.

However:

Staff understood the importance of obtaining informed consent, and when to assess whether a patient had the capacity to make decisions about their care.

Summary of this inspection

The service provided a flexible service taking into account the needs of patients.

Are services caring?

Good

We have not previously rated this service. We rated it as **Good** because:

Staff cared for patients with compassion. Feedback from patients confirmed that staff treated them well and with kindness.

Staff provided emotional support to patients to minimise their distress.

Staff involved patients and those close to them in decisions about their care and treatment.

Are services responsive?

Requires improvement

We have not previously rated this service. We rated it as **Requires improvement** because:

The service did not always consider patient's individual needs regarding communication.

The service reviewed concerns and complaints and investigated them, however, these were not monitored for trends and themes and we saw little evidence of complaints being shared with all staff members.

However:

People could access the service when they needed it.

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

Are services well-led?

Inadequate

We have not previously rated this service. We rated it as **Inadequate** because:

The service had a vision for what it wanted to achieve but no strategy to turn it into action. We did not see that the leaders and staff understood the vision and strategy or how to apply them and monitor progress or had support from the franchise to deliver them.

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

Leaders and teams had poor systems to manage performance effectively. Risks were not identified and escalated to reduce their impact.

Summary of this inspection

There were no plans to cope with unexpected events. There was no evidence that staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

There was no evidence that the service collected reliable data and analysed it. Therefore, the was little understanding of performance, which could be used to make decisions and improvements.

There was no evidence that the leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services.

However:

Information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required.

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, however there were limited opportunities for career development.

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Not sufficient evidence to rate
Caring	Good
Responsive	Requires improvement
Well-led	Inadequate

Are diagnostic imaging services safe?

Inadequate

We have not previously rated this service. We rated it as **inadequate.**

Mandatory training

The service did not routinely provide mandatory training in key skills to all staff and record this to ensure it was regularly completed.

We saw a recent training schedule in relation to the administration staff across all locations. This included subjects like disposing of clinical waste and dealing with complicated questions from service users. However, there was no regular training programme and there was no formal record of which staff had received training. This meant there was no assurance by the leadership that staff could deliver safe care and had up to date training.

The two staff we spoke with at the Bourne End satellite site told us that they had not been supported with any mandatory training. The sonographer told us they had completed some mandatory training but that this was not provided by the service and the service had not checked its completion.

Since our inspection we saw email evidence that an external company had been approached to deliver training, however this was not in place at the time of inspection.

Safeguarding

Staff had an understanding of how to protect patients from abuse. However, not all staff had appropriate levels of safeguarding training and showed poor awareness of how to access the safeguarding policy.

The registered manager did not have recent safeguarding training and some staff did not have adequate safeguarding training. This was not in line with national guidance set out by the intercollegiate document on safeguarding children. For example, although staff at the Bourne End site could describe safeguarding and knew what they would do if they had concerns, one member of staff had not had any safeguarding training while the other had completed level 1 safeguarding adults but no safeguarding children training.

Staff who could come in contact with children had not completed safeguarding training. This was not offered to all staff as there was an assumption that staff who were employed at local NHS trusts would have training as part of their employment there. This was not monitored or checked by the provider, so no assurances could be gained. There was no training log and the manager could not easily see who had what level of training, or when it needed to be updated to gain any assurance around this.

Staff we spoke with reported that reception and management staff had meetings where they discussed examples of safeguarding incidents. However, these were not documented so we could not review them during our inspection.

There had been one safeguarding alert in the past 12 months. The staff followed the guidance from the

safeguarding policy and contacted the safeguarding lead for the franchise. However, they did not notify the CQC which is a statutory requirement and showed a lack of understanding of their legal obligations.

The service provided chaperones. At the Brighton site there were always two members of staff during clinics. This ensured that staff could provide a chaperone if needed. If this was the case the clinic door was locked and a notice informing patients was placed on the door for customers arriving that explained where they were and when they would return.

Posters informing patients about the service chaperone policy were displayed in the waiting area and in the scanning room at the Bourne End site. We also saw on the consent form for internal scans patients were asked if they wanted a chaperone present. Staff we spoke with could describe the chaperone process to us, however staff did not undertake formal training on this.

There was a safeguarding policy for young people aged 16-18 which included information on what to do if child Sexual Exploitation (CSE) was suspected. The safeguarding policy was reviewed by the franchisor annually and was within the review period. It gave instruction on Female Genital Mutilation (FGM) as well as a safeguarding flow chart and contact numbers. Staff appeared to be knowledgeable in the areas of CSE and FGM.

We saw emails from staff to record that they had read and understood the safeguarding policy. However, we spoke with a sonographer who was not aware of any safeguarding policy or procedures in relation to the location or franchise.

We saw that the service had a poster in the toilet at the Bourne End and Brighton sites to inform patients about the signs of domestic abuse support and a helpline number.

Cleanliness, infection control and hygiene

The service did not control infection risk well. We found there were poor standards of cleanliness and hygiene with no reliable systems to prevent and protect people from a healthcare-associated infection. We witnessed staff not using the correct control measures to protect patients, themselves and others from infection.

The service was not using the correct cleaning process for transvaginal probes. National guidance states the probes should be decontaminated and cleaned with the use of high-level disinfectant products. Decontamination products we saw did not have these properties and stated on the packaging they were not for use on internal devices.

The products used at the time of inspection were not an effective way to decontaminate and clean the probes. This exposed service users to the risk of harm. There was a risk that ineffective disinfection of internal probes could lead to transfer of human fluids, including blood, to another patient. If body fluids had been transferred between patients this could lead to infectious diseases, some of which could be fatal.Following this inspection we notified Public Health England to notify them.

The registered manager told us that fresh sheaths were used with every new service user when asked about infection control practice. Guidelines for cleaning transvaginal ultrasound transducers between patients, say these sheaths fail 8% to 80% of the time and therefore relying on them alone does not protect service users from the risk of harm.

We highlighted the dangers to the registered manager and asked the provider not to undertake further internal probes until the correct cleaning processes were in place.

To ensure the provider had stopped undertaking scans using internal probes we carried out two further unannounced inspections at Ultrasound Direct Bourne End and Ultrasound Direct Brighton on the 24 September 2019. We found that, despite assurances from the provider, the same inappropriate cleaning products were still being used. There was a service user in the diary for a transvaginal scan later that day. Inspectors told the service again to cancel this and any other scans using internal probes until the correct decontamination process was in place.

At all sites there was a cleaning checklist which was completed and dated. However, this was not further reviewed or audited to ensure completion. Despite completed cleaning logs we saw evidence of poor cleaning. For example, we saw thick dust on surfaces at lower levels and floors that appeared dirty.

Handwashing facilities were not available in the scan rooms at any of the sites we inspected. Sonographers had

to leave the room and use the toilet facilities between patients. This meant opening two doors with contaminated hands and then reopening them once staff had washed their hands. This could spread germs and lead to cross contamination. We found no hot water available at the Brighton site, we were told hot water had never been available at this satellite site. The sink in the toilet had taps were not lever handle and needed to be twisted on and off. Also, the plug hole was directly underneath the tap, this meant the water could splash up causing contamination. This does not comply with the recommended Health Building Note 00-09:03 Infection control in the built environment recommendations to minimise contamination.

At the Ultrasound direct Heathrow a paper roll was stored at the end of patient couch which was changed between patients. However, there was a risk of contamination at some sites as the roll was stored on the floor. This is not in-line with national guidance. We did not see consistent cleaning of the couch between patients which was not in-line with the provider's policy or national guidance. At the Brighton and Bourne End sites we saw the use of using fresh paper roll covering for the couch for each patient and this was stored on the couch. Staff told us that they cleaned the couch between each patient.

Staff at the Bourne end site reported they had not had hand washing training and that managers did not check or audit hand washing practices. However, there were posters in the kitchen and the toilet showing the correct procedure for washing hands.

During our inspection, we saw clinical staff at Heathrow and Bourne End were bare below the elbows and personal protective equipment was available and used correctly. However, staff at Brighton were seen with long sleeves which posed an infection control risk and was not in line with the providers policy.

The service had no procedures to identify or support patients that had communicable diseases. Staff we spoke with at Bourne End said that if patients did not appear well they would advise them they could return another day when they felt better. Staff had no awareness of additional precautions or cleaning that would be required.

Staff followed best practice guidelines in-line with the European Society of Radiology ultrasound working group in regard to appropriate cleaning procedures for ultrasound probes (external probes used on the abdomen). They cleaned the probe with antibacterial wipes between patients.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not always ensure people were safe.

During our inspection of the Brighton site we found a window that could be opened wide enough for an adult or child to fit through that was at least three meters high. It posed an immediate health and safety risk as there was no lock or window restrictor. The registered manager has since sent us photographic evidence that a lock is in place, with an accessible key in the event of a fire.

We had concerns regarding fire evacuation and staff understanding on how to manage a fire. The fire door to the rear of the property at the Heathrow site was locked. This is against national fire safety recommendations. We highlighted this the registered manager who unlocked it, but when we checked again during the afternoon, it was locked again.

At the Brighton site there was a fire alarm button which was inactive, but staff believed it worked. In the event of a fire, staff would not be able to raise the alarm. Although risk assessments and a health and safety review had been undertaken in December 2018 neither had identified the above risks. At the Bourne End site there were no fire doors and only one entrance and exit to the building. There were no other means of exit from the building and as it had bars on all the windows which would make escape if the door was blocked very difficult. There was no risk assessment to address this.

During our inspections, we saw fire extinguishers were accessible and stored appropriately; however, there were no records of them having been inspected and no monitoring of when they were next due to be inspected or serviced. This could mean they were ineffective if needed in an emergency.

Waste in all clinical areas was separated and in different coloured bags to identify the different categories of waste. This was in accordance with HTM 07-01, Control of

Substances Hazardous to Health and the Health and Safety at work regulations. We saw evidence of a contract with a specialist waste disposal company ensuring waste was removed appropriately.

The first aid kit at the Heathrow site was out of date and should have been replaced in April 2017. There was no monitoring of the expiry dates on the first aid kits. We highlighted this the registered manager who immediately removed it and ordered another to be delivered the next day.

An incident book was available to record any instances where someone accessing the service may require first aid. In the event of an emergency, staff told us that they would call 999 for assistance. There had been no incidents where staff needed to contact emergency services since the service's registration.

Staff we spoke with felt competent to use ultra sound scanning equipment. However, training for this was undertaken in their NHS role. The provider did not provide any training or have any way of assessing or monitoring staff competence to use equipment.

There was no regular testing of portable and other electrical equipment to ensure it was safe for use. This had been identified as a risk in a completed risk assessment at the Brighton site (December 2018) it stated "laptop and kettle to be tested," however, staff confirmed neither had been tested.

An external organisation provided the maintenance and servicing of the ultrasound equipment in accordance with manufactures guidance. We saw records of the last service occurring in October 2018, and another service was booked for the week following our inspection.

Staff told us that should there be a technical problem with the scanning machine there was a 24-hour telephone support service available. This aimed to resolve issues within 24-48 hours of reporting any technical problems. The service had not had a technical issue with the machines in the previous nine months.

Assessing and responding to patient risk

Staff completed a basic risk assessment for each patient on initial contact and removed or minimised risks. Further risk assessments were carried out by sonographers prior to scans.

The baby scanning service was clearly marketed as an "additional baby scan service that worked in parallel with the NHS." Patients were made aware that the service did not provide any clinical diagnostics. We saw written information provided by the service strongly advised women to attend scans as part of their NHS maternity pathway and we saw staff advising patients to continue with their NHS scans.

The service ensured there would be follow up if an abnormality detected. As part of consent taking processes at the service, women agreed to the service contacting NHS healthcare providers (such as GPs or NHS antenatal services) should staff identify a potential anomaly or concern.

We saw accompanying written reports and scan images were provided to NHS healthcare providers, as appropriate.

The service only provided ultrasound scans to women over 16 years of age. Women aged 16 or 17 years of age, were required to attend with a responsible adult (for example, someone with parental responsibility). Most women attended with hospital notes, so their date of birth could be verified; if they arrived without notes they would be asked to prove their age if the staff were in doubt.

Prior to the scan staff asked the patient if they had been feeling unwell or experienced any pain or bleeding. If the patient said they had experienced any symptoms, then they were referred to their midwife or hospital for further investigation and the scan did not go ahead.

At the Bourne End site we saw that staff completed checklists. There was a separate checklist for the receptionist and the sonographer. These included areas that needed to be cleaned and information that should be checked with patients. The sonographer's checklist included patient allergies and spelling of their name. These also had reminders to clean the couch between each patient. However, both staff told us that these checklists were not reviewed by managers so if they missed anything on the checklist this would not be brought to their attention. The registered manager had no assurance the actions on the checklist were being carried out. However, we checked two checklists and they were completed.

Inadequate

Diagnostic imaging

Guidance documents contained contact numbers for local hospital and antenatal care providers. If the sonographer suspected higher-risk conditions or concerns (such as, placental abruption or an ectopic pregnancy) they were instructed to immediately dial 999 for emergency assistance. If the patient had suspected tumour the sonographer advised the patient to contact their GP and sent a full report which could be accessed instantly.

Staffing

The service had enough staff to meet the needs of patients.

The service had 20 sonographers and 15 clinical assistants that worked across the five sites. There were always two members of staff attending to each clinic.

Managers reviewed and adjusted staffing levels depending on demand and skill mix.

We reviewed eight staff files and saw that they were not all completed and up to date. We were told they were not regularly reviewed by management and there were no checks completed annually to keep them up to date. This included registration with any professional bodies, training needs and DBS checks.

The service did not use casual staff or agency staff.

Records

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

The service uploaded all patient information results and scan images onto a computer system which was secure and could be accessed by other professionals instantly.

Hard copy records were not always kept confidential. If the computer system could not be accessed, a hard copy of the scan was be printed off for the patient to give to the appropriate healthcare professional. We saw these hard copies were not always being handled securely at the Brighton site. Inspectors saw scan images with confidential patient details on within view of patients and visitors at the reception desk.

The service did not always have appropriate equipment available to dispose of confidential records securely. We were told the hard copy records at the Brighton site needed to be shredded. However, we were also told the shredder was broken and that the registered manager had been made aware of this previously.

Medicines

The service did not prescribe, administer, record or store medicines.

Incidents

There was a limited use of systems to record and report safety concerns incidents and near misses.

There was no incident log and staff did not attend regular meetings to receive updates on incidents. This meant it was difficult for all staff to be aware of incidents that had occurred, or for managers and professionals to identify themes and trends which could be addressed to improve safety.

Managers investigated incidents and there were some shared lessons with the whole team, although managers did not record these. This meant that safety incidents could be repeated as staff were not aware of any learning and changes to processes or policy from previous incidents.

We saw no evidence that managers ensured actions from patient safety alerts were implemented and monitored.

We heard examples of when things had gone wrong staff apologised and gave patients honest information and suitable support.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We did not rate the effectiveness of this service however:

Evidence-based care and treatment

Care and treatment did not always reflect current evidence-based guidance, standards and best practice. Managers did not check to make sure staff followed guidance and we saw some practices which were against national guidance.

Diagnostic imaging

The franchise was governed by Ultra Sound Direct who provided all policies and procedures. Local policies and procedures were in line with current legislation and national evidence-based guidance from professional organisations such as the National Institute for Health and Care Excellence (NICE) and the British Medical Ultrasound Society (BMUS).

We reviewed seven of these policies and they were all regularly reviewed within the review period and linked to national and recommended guidance. However, staff we spoke to at all three sites were not aware of these policies and were not following the guidance provided by the policies and procedures. An example was the decontamination of transvaginal probes.

We saw emails where staff reported to have read updates to policies and confirmed with the registered manager that they understood the changes. However, the registered manager did not check to gain assurance this had happened or gain assurance that changes had been understood and changes to practice made.

We requested but were not provided with any evidence of regular audits being undertaken to provide assurance about the quality and safety of the service. The staff we spoke to at the Bourne End and Brighton site were not aware of any audits being carried out by the service.

We were told there was a scan discrepancy audit programme. The registered manager told us that approximately 20% of all the scans completed were reviewed and that new staff had their findings reviewed more frequently. We requested these audits during both site visits but were not provided with these.

Staff worked to "As Low as Reasonably Achievable" (ALARA) guidelines. As Low as Reasonably Achievable is defined as a fundamental approach to the safe use of diagnostic ultrasound using the lowest output power and the shortest scan time possible. During our inspection staff were witnessed to be working within these guidelines when undertaking an ultrasound scan.

Nutrition and hydration

Tea, coffee and water was available for patients.

To improve the quality of the ultrasound image, women were asked to drink extra fluids on the lead up to their appointment. Women who were having a gender scan were encouraged to attend their appointment with a full bladder. This information was given to women when they contacted the clinic to book their appointment. It was also included in the 'frequently asked questions' on the service's website.

Pain relief

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

Staff asked women if they were experiencing pain and apologised for the pressure of the ultrasound on the women's abdomen. Staff regularly checked during the scan that patients were comfortable.

Patient outcomes

Outcomes for people who use the service were not monitored. The effectiveness of care and treatment was not audited or used to make improvements.

The registered manager had overall responsibility for governance and quality monitoring. The service did not use key performance indicators to monitor performance. There was a basic feedback to the franchisor which included, number of complaints, number of scans and financial details.

We saw evidence of peer review of scans, including for second opinions.

Although requested, we did not receive information about the number of patients that were seen in the last 12 months. We also requested the number of referrals to other healthcare providers, but again we did not receive these figures.

Competent staff

The service had limited input to ensure staff were competent for their roles. There were gaps in the management and support arrangements for staff such as appraisal, supervision and professional development.

A member of reception staff told us that they had completed an induction that included shadowing for two days. A sonographer that has been with the service for several years told us that the manager asked them to work with new sonographers to assess that they have the skills required for the role. There was no formal checklist for this process and no record of this in staff files that we reviewed.

Staff told us that if they needed support there were management and a sonographer that they could contact via telephone. The sonographer was not within the service but was employed by the franchisor, Ultra Sound Direct.

There was no formal peer to peer feedback or clinical supervision. Staff reported that sometimes the manager came and sat with them to observe them but that this was not clinical supervision or peer to peer support as the manager was not a sonographer and no formal feedback was provided or development plans made. Sonographers had access to a lead sonographer for advice.

The service did not maintain staff records that met current legislative requirements. Current regulations stipulate the information they must include such as full work history, records of recruitment, interview and selection processes, evidence of good conduct in previous regulated activity, health declaration and Disclosure and Barring Service (DBS) checks. We reviewed eight staff files. In all staff files we reviewed none contained all these elements and some contained none. The registered manager told us this was being addressed and we have since seen email evidence that the process to complete staff files was underway. However, at the time of inspection this was not in place.

Staff did not receive regular appraisals there were no appraisal records in the staff files we reviewed. Appraisal is important to ensure staff receive appropriate support, training, professional development to carry out their duties well.

We heard from staff that there was an induction and that a period of shadowing was in place. We did not see evidence of a formal induction programme documented.

Multidisciplinary working

Healthcare professionals worked together as a team to benefit patients.

Staff told us the service had good relationships with local hospitals and maternity services and local GP surgeries. They contacted the services by telephone and make appointments on behalf of the patients who needed them.

During our inspection, we observed positive examples of the registered manager, sonographer and clinical assistants working well together. The registered manager often acted as chaperone and we saw all staff engaging with patients in a friendly and caring manner.

Seven-day services

Services were supplied according to patient demand. This meant the location was not necessarily open seven days a week. Services at the location were typically provided on weekday evenings, and daytimes on Saturday. This offered flexible service provision for women and their companions to attend around work and family commitments.

Consent and Mental Capacity Act

Staff supported patients to make informed decisions about their care and treatment.

There was a Mental Capacity Act (2005) policy for staff to follow, which clearly outlined the service's expectations and processes. We did not see any evidence that staff had carried out training in respect of this.

Staff told us that if they were unsure if a patient using the service had capacity to consent to their scan, then they would speak to the registered manager and the scan would not be carried out. Sonographers we spoke with could give examples of when and how they might assess mental capacity.

We witness staff explaining the procedure including the dangers, so patients could make informed decisions around the care they received. Sonographers took the time to allow for any questions.

The service had a consent form used when patients were to have internal scans. We reviewed 15 of these that had been fully completed. They included recording allergies, if patients wanted a chaperone present and if they had any concerns about female genital mutilation.

Are diagnostic imaging services caring?

Good

We have not previously rated this service. We rated it as **good.**

Diagnostic imaging

Compassionate care

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

Staff were observed treating patients with dignity, kindness, compassion, courtesy and respect before during and after their scans. During our inspection we observed four scans, one consent and payment procedure. Staff treated the patients well, were courteous and friendly throughout and ensured that women understood the next steps.

The service gave 15 to 30 minute timeslots for most appointments. Staff told us this was done to ensure privacy and dignity was maintained and to allow patients more time if bad news was delivered. We were given examples where this time had been extended when needed to minimise patients' distress.

All conversations took place in a private room. There was not a quiet room available at two sites we visited but we were told that patients were able to stay in the scan room as long as they needed.

A general ultrasound sonographer(who did not undertake baby scans), told us that they did not deliver bad news to patients as results would not be discussed with patients at scans. The patient would be advised to see their GP or consultant and the results would be sent to the health professional.

During our inspection, we spoke to nine patients and their companions. All patients and companions we spoke with during our inspection described the service positively. For example, one lady reported her experience was "Great, very professional and nice"

Patients and their companions were also able to leave feedback on open online website service platforms, which the registered manager said were frequently monitored. We reviewed a selection of reviews (from the several hundred available) and found the service was highly rated, and feedback was positive.

Emotional support

Staff provided emotional support to patients, families and carers to minimise their distress.

Staff were understanding to the needs of patients and listened to any concerns that they had. Patients and their families had of time to ask questions. These were answered appropriately, and reassurance given when needed. Patients were encouraged to contact their GP, consultant or midwife if they had any concerns.

Patients were given information on counselling services should they need it.

Clinical assistants acted as chaperones, to ensure women felt comfortable and received optimum emotional support. We saw information about this service displayed on posters in the waiting areas.

Staff told us they gave patients as much time as they required if they became distressed were supported. They were given time to ask questions and arrange follow up appointments with their midwife or hospital if needed.

Staff told us they ensure patients privacy was maintained by keeping them in the scan room and completing all documentation before leaving the room or at the Heathrow site utilising the second scan room as a quiet room.

Understanding and involvement of patients and those close to them

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

During our inspection, staff were seen interacting with patients in a respectful way and acknowledged family members when they were there. Patients and their partners or relatives were welcomed by staff and there was enough room to accommodate up to five people in the clinic.

The service displayed their scans and packages with pricing on their website in clinic windows and these were also confirmed at the time of booking. They took payment in the reception areas after the appointment. We saw this process being carried out sensitively at the time of inspection.

We observed staff took time explaining procedures to women before and during ultrasound scans and left adequate time for patients and their companions to ask questions and have these satisfactorily answered. Patients described having time to ask questions.

Inadequate

Diagnostic imaging

Patients we spoke with at inspection said that they had received detailed explanations of scan procedures and accompanying written feedback.

Staff told us that patients were always told when they needed to seek further advice and support. They said always ensured patients knew how to access other agencies for support before leaving the clinic.

Are diagnostic imaging services responsive?

Requires improvement

We have not previously rated this service. We rated it as **requires improvement.**

Service delivery to meet the needs of local people

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

All appointments could be pre-booked by the user via an online booking system several months in advance. Patients could also book over the phone which enabled staff to advise on which service best suited their needs.

There was a comfortable seated waiting area in the main reception of the Heathrow and Bourne end site.

There was play equipment available for children at some sites but no changing facilities for babies as the toilets were small. We were told that patients can arrive with children who may need to make use of changing facilities.

The service had varied parking around each site with some sites having disabled parking available. There was a car park on site at the Bourne End site for patient use. At the other sites we inspected there are paid car parks nearby.

The service offered flexible appointments across all six sites that incorporated evenings and weekends.

Brighton site was very small and loud music could be heard from the occupied flat above the service, this was not a pleasant or appropriate environment for patients some of who may have been anxious or were to receive worrying results.

Meeting people's individual needs

The service did not always take account a of patients' individual needs and preferences. Staff made some adjustments to help patients access services.

Patients additional needs were not formally identified prior to them attending clinics. We heard the reception asking patients over the phone if additional needs were required. This could potentially lead to a person arriving with mobility needs and not being able to access the service, or a person with translation needs not being able to communicate with staff.

Not all sites were accessible to patients who required the use of a wheelchair. We were told patients were directed to alternative sites if this had been highlighted to staff at booking. However, the assessment process may not always identify this.

We saw at the Bourne End site they had level access to the building and no steps inside the unit. Staff reported that this allowed wheelchair users to access the scanning room although they said they had not had any patients that were wheelchair users, but had had some relatives that came with the patients were wheelchair users.

At the Bourne End site staff told us that they had supported a deaf patient via the use of basic sign language as a member of staff knew some sign language. The service did not have any training or support the assist staff care of patients with additional needs.

The service did not have an interpreting service and did not have any resources to support communication with people whose first language was not English. Staff we spoke with at Bourne End told us that they would try to manage as best they could but said that normally people brought a relative that could interpret for them which is not recognised as best practice or national guidance as there can be no assurance that the interpretation is correct.

There were no information leaflets available in different languages.

There was an equality and diversity policy in place. We saw evidence of the administration staff recently undertaking training on additional needs. The service was inclusive to all patients' and we saw no evidence of

any discrimination, including on the grounds of age, disability, pregnancy and maternity status, race, religion or belief and sexual orientation when making care and treatment decisions.

Access and flow

People could access the service when they needed it and received the right care promptly. There were minimal waiting times and a flexible service was offered.

All women self-referred to the service and scans were arranged by appointment only. The service offered several different booking methods. Women could book their scan appointments in person, by phone, or through the service's website.

During our inspection, patients were seen on time. Staff told us if there was to be a delay staff kept the other patients informed in the waiting room, advised them of any delays and apologised.

At the time of our inspection, there was no waiting list or backlog for appointments.

Patients we spoke with at the inspection were positive about the availability of scans and said that they had received suitable appointments in a timely fashion. We also saw this reflected in written feedback we reviewed. During our inspection we observed that clinics ran on time.

Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received.

Service users could make complaints in person, via an online website service and via email. Staff also asked customers post scan if they were happy with the service and aimed to identify any potential dissatisfaction whilst patients were still on site.

We heard evidence that the service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff**.** However, there was no documented evidence that this was the case.

The service did not have formal records of all complaints and any actions that resulted in the complaints. We were given examples of complaints, for example, a staff member attitude was repeatedly complained about. We were told that this was addressed with the staff member and that after further complaints the staff member was dismissed and was no longer working for the provider.

Staff told us that the service used an online website service to monitor for complaints. They told us that if a complaint was raised that related to them then the registered manager would contact them to talk about resolution.

Are diagnostic imaging services well-led?

Inadequate

We have not previously rated this service. We rated it as **inadequate.**

Leadership

Leaders did not have the capacity, skills and abilities to run the service. Leaders failed to understand and manage the priorities and issues the service faced.

Although the registered manager was open and honest about their performance, there was a lack of knowledge about the responsibilities their role entailed. Prior to our inspection we send out a provider information request to gain information about the service and its performance. We asked provider for this document on three occasions over the 12 months prior to our inspection and did not receive one. It is a requirement to provide information to the CQC when requested and the lack of response prompted us to undertake the inspection, as we saw it as a risk.

Leaders were out of touch with what was happening at the front line and could not identify or understand the immediate risks. Examples of this risk include the incorrect decontamination of probes and the cleaning processes not being monitored throughout the service.

The service had recently taken on another member of staff to act as assistant manager; however, we did not see any records, such as references or employment history to ensure that this member of staff had the skills, experience and ability to run the service.

Staff also reported they enjoyed and felt proud to work for the service and felt managers looked after them.

The registered manager had a period of ill health over the past 12 months and reported this had prevented them from running the service as they would like. They felt the franchisor had not provided enough support to them during this time and that this was part of the reason that the service was not governed as they would like.

Vision and strategy

The service had a vision for what it wanted to achieve but no strategy to turn it into action. We did not see that the leaders and staff understood the vision and strategy or how to apply them and monitor progress or had support from the franchise to deliver them.

R.B Imaging' Vision was**:**

- To provide an ultrasound service accessible to all irrespective of gender, for the wellbeing and general health of women and men during all times of life.
- To focus on pregnancy and health crisis where the service isn't accessible, in a timely sensitive manner within the NHS or by complimenting the NHS.

The service also had a mission to be the service of choice for patients in the local area where NHS services cannot provide a timely service. They aimed to "provide the best specialist environment ensuring a sensitive and caring experience for all patients, respecting confidentiality and individuality and the needs and wishes of the client".

Staff were not clear on the vision and values of the service and could not discuss how these affected their daily work to us. One member of staff reported that they thought they were to support the wellbeing of patients and make sure they were safe.

Culture

Staff felt respected. They were focused on the needs of patients receiving care.

Staff we spoke to felt able to raise concerns with the leadership and were proud to work for the service.

Staff were seen to take the well-being of their colleagues in to account by offering drinks to each other. Staff said they were happy to support each other when required.

Although there was an open-door policy and staff reported feeling supported, there were no formal support systems in place, such as appraisals. Staff may not have felt empowered to raise concerns or speak up about some of the practices that we saw, and were not given the opportunity through regular staff meetings.

Governance

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

We found that governance processes were not embedded within the service and we were not assured there was a systematic approach to continually improving the quality of the service. There was no overall responsibility for ensuring staff followed the provider's policies and procedures and no audits were undertaken to ensure compliance with these.

Staff mostly worked in isolation and ran clinics separately with little reporting back to the leadership. Staff told us that if there were any issues they would contact the registered manager for advice, but there was no protocol, policy or regular reporting tool used.

Some staff reported there were no regular meetings held while others told us that there were staff meetings but that these are only for reception staff and management staff. At these meetings they discussed incidents, safeguarding and complaints. We saw no evidence of these meeting having taken place and were told by the registered manager that they were not minuted and were informal. This meant there was no formal record that staff could reference if they were absent, or to check decisions that were made or information given

Changes in practice were communicated via email. Staff told us about the recent introduction of a new cleansing product and an email came from the manager to advise them of this. They then completed online training relating to this product. We also saw emails relating to staff reading new policies. However, we also spoke to staff who had very little knowledge of the policies and procedures and we saw several examples where the policies were not being followed. Including the wrong decontamination of internal probes and staff not following basic hand hygiene and being bare below elbows to minimise the spread of germs.

Inadequate

Diagnostic imaging

Managing risks, issues and performance

Leaders and teams had poor systems to manage performance effectively. Risks were not identified and escalated to reduce their impact. There were no plans to cope with unexpected events. We saw no evidence that staff contributed to decision-making to help avoid financial pressures compromising the quality of care.

There were no measures to manage current and future performance. We saw no systematic programme of clinical and internal audit to monitor quality, operational processes and no action plan for improvement.

At all sites we saw no evidence of audits and staff told us they were not involved in or aware of any audits.

We were told that twenty percent of scan images were audited, but despite requests for this information we did not receive it. However, we saw evidence of peer reviews of scan images that sonographers needed advice or a second opinion on.

The service had carried out some health and safety risk assessments. We saw there were recommendations made after these for example to test the electrical equipment. However, this had not been actioned since 2018. We also saw that the health and safety risks we highlighted at the Brighton site were not on the health and safety risk assessment despite being a risk. Since our inspection the registered manager had been responsive to these risks and we saw evidence of these being addressed.

There was no clear plan for service interruptions or other business continuity plans. We asked staff if they had a power cut what would they do, and we were told that this had never happened, but they would have to try and rebook patients at another site or on another day.

Managing information

We saw no evidence that the service collected reliable data and analysed it. Therefore, the was little understanding of performance, which could be used to make decisions and improvements. However, we did see that the information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required with the exception of statutory notifications relating to safeguarding.

The service had an online secure system in place to upload scan images instantly and this was accessible by local GPs and hospitals. Paper copies were used if the local practices were not integrated. We saw these were managed securely in most sites however, at the Brighton site we saw confidential and patient identifiable information with in view of other patients.

Appointments were booked using an electronic booking system. The computer used was password secured and to maintain confidentiality was positioned in the reception area in way that wasn't seen by others.

Engagement

We saw no evidence that leaders and staff actively and openly engaged with patients, staff, equality groups, the public and local organisations to plan and manage services.

Feedback from service users and partner organisations was welcomed and used to improve the service. However, there was no proactive strategy for involving patients in service design or improvement. There service did not approach equality groups to ensure its service were non-discriminatory and met the needs of those with protected characteristics. There was no dialogue with local commissioners.

The service encouraged patients to provide feedback; and patients could provide verbal feedback and leave written reviews on open social media platforms.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

Action the provider MUST take to meet the regulations:

On the basis of this inspection, the Chief Inspector of Hospitals has recommended that the provider has an urgent suspension for the period of six weeks. At the end of this time, they will be re-inspected to ensure that they have potential to meet all the required regulations to deliver safe care and treatment.

- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to correct cleaning processes are in place for the decontamination of internal probes and ensuring and monitoring good infection control practices. Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment (1)(2)(h).
- The provider must ensure that hand washing sinks are available in scanning rooms and that there is hot water available. Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment (1)(2)(h).
- The provider must ensure staff have the correct level of safeguarding training and awareness. The provider must review safeguarding systems and processes and operate these effectively to prevent abuse of service users. Regulation 13 HSCA (RA) Regulations 2014 Safeguarding 13 (1)(2).
- The provider must ensure staff are adequately assessed as competent for their roles and that these are monitored for compliance regularly. The provider must undertake regular staff appraisals and mandatory training. Regulation 18 HSCA (RA) Regulations 2014 Staffing (1)(2)(a)(b).
- The provider must provide adequate interpreting services and aids for those who do not speak English or have communication needs. Regulation 9 HSCA (RA) Regulations 2014 Person centred care 9 (c)(d).
- The provider must ensure that fire safety and clinic environments are suitable and safe for patients and staff. The provider must demonstrate they had maintained electrical equipment in accordance with national guidance. Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment. 15 (1)(b)(d)(e)(f).
- The provider must assess, monitor and improve the quality and safety of the services provided, and implement systems to evaluate and improve their practice. Regulation 17 HSCA (RA) Regulations 2014 Good governance 1, 2 (a), (b), (d (I), (ii), (f).
- The provider must establish effective systems to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk from the carrying on of the regulated activity. Regulation 17 HSCA (RA) Regulations 2014 Good governance 1, 2 (a), (b), (d (I), (ii), (f).

Action the provider SHOULD take to improve

- The provider should check all staff are working in-line with policies and procedures.
- The provider should engage with staff and hold and minute regular meetings to discuss the risks within the service and how these will be addressed.
- The provider should consider the impact of using incorrectly decontaminated internal probes on patients and apply the duty of candour if they think that patients may have been put at un-necessary risk.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 15 HSCA (RA) Regulations 2014 Premises and equipment How the regulation was not being met: • The provider must ensure that fire safety and clinic environments are suitable and safe for patients and staff. • The provider could not demonstrate they had maintained electrical equipment in accordance with national guidance.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment How the regulation was not being met: • Staff did not have the correct level of safeguarding training in-line with the Safeguarding Intercollegiate document guidance (2018). • Staff did not demonstrate good awareness of policies and procedures in regard to reporting safeguarding. • The provider had no oversight of staff training in regard to safeguarding.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 9 HSCA (RA) Regulations 2014 Person-centred care How the regulation was not being met:

This section is primarily information for the provider

Requirement notices

- The provider did not have translation services or any communication aids to enable patients who may have communication needs to effectively participate and understand the care or treatment to the maximum extent possible.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment How the regulation was not being met: • The provider did not decontaminate internal probes in accordance with national guidance. • Staff did not demonstrate consistent and safe cleaning techniques to ensure safe infection prevention and control. • The provider did not have adequate measures in place to monitor and assess the risk of, and preventing, detecting and controlling the spread of, healthcare associated infections. • The provider could not demonstrate they operated a safe premises environment.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met: • The provider could not demonstrate that all staff had the skills, knowledge and experience to carry out their roles. • The provider did not carry out appraisals or competency checks on staff. • Staff did not receive any mandatory training including safeguarding and this was not regularly reviewed if they had received this training elsewhere.

Regulated activity	Regulation

This section is primarily information for the provider

Enforcement actions

Diagnostic and screening procedures

Regulation 17 HSCA (RA) Regulations 2014 Good governance

How the regulation was not being met:

- The provider did not have systems in place to monitor and improve quality and safety and the welfare of service users and others who may be at risk.
- The provider did not assess, monitor and mitigate risk relating to health, safety and welfare of service users.
- The provider did not keep complete and up to date records of staff to demonstrate competency, and these were not regularly reviewed.