Watford Clinic

Quality Report

45 – 47 Victoria House
Vicarage road
Watford
WD18 0DE
Tel: 0203 95607960
Website: www.ultrasoundplus.co.uk

Date of inspection visit: 25 April 2019 and 08 May 2019
Date of publication: 09/07/2019

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

Summary of findings

Letter from the Chief Inspector of Hospitals

Watford Clinic is operated by Ultrasound Plus Ltd. The service provides diagnostic imaging through ultrasound scanning only. The service provides diagnostic pregnancy, gynaecological, musculoskeletal and general ultrasound scans for private patients aged 18 and above in the Hertfordshire, Essex, London and surrounding areas. The service also provides diagnostic ultrasounds from their two satellite clinics in the following locations:

- Brentwood, Essex.
- Docklands, London.

Watford Clinic was registered with the CQC in April 2018 under the company name Ultrasound Plus. The service has not previously been inspected by the CQC.

We inspected this service under our independent single speciality diagnostic framework and using our comprehensive inspection methodology. We carried out a short notice announced inspection on 24 April and 07 May 2019. We gave the service 48 hours' notice, to ensure the availability of the registered manager.

To get to the heart of patients' experiences of care and treatment, we asked 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 in April 2019, we rated the service as requires improvement overall.

We found areas of practice that the service needed to improve:

- The service did not provide mandatory training in key skills to all staff. Staff were not compliant with mandatory training targets. There was limited managerial oversight of staff training completion rates.
- Systems, processes and standard operating procedures were not always reliable or appropriate to keep people safe. Policies did not support staff to safeguard patients from abuse and harm. However, staff understood how to protect patients from abuse and most staff had training on how to recognise and report abuse and they knew how to apply it.
- The service did not have effective processes for reporting, investigating and learning from incidents. Staff understood their roles and responsibilities to raise concerns and report safety incidents. There was a variable understanding of the duty of candour regulation.
- We did not see evidence of the service working with other providers to improve the pathway for patients to local services.
- There was not an effective system for recording, handling, responding to, and learning from complaints.
- Managers at all levels in the service did not have all the right skills and knowledge to run a service providing high-quality sustainable care.
- The service did not have a systematic approach to improving service quality and safeguarding high standards of care. There was a lack of there was a lack of overarching governance.

Summary of findings

- There were not effective systems in place for managing risks, and there was no evidence risks and their mitigating actions were discussed with the team.

  However, we found the following areas of good practice:

- The service had sufficient staff of an appropriate skill mix, to enable the effective delivery of safe care and treatment.
- Staff cared for patients with compassion. Feedback from patients confirmed 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.
- The service planned and provided services in a way that met the needs of local people.
- The service was generally accessible to all who needed it and took account of patients' individual needs.
- Managers supported staff across the service, however they did not create a sense of common purpose.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, even though a regulation had not been breached, to help the service improve. We also issued the provider with four requirement notices. Details are at the end of the report. As a result of the inspection findings, the service has been placed into special measures. We will reinspect in six months to check that improvements have been made.

Edward Baker
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	The provision of ultrasound scanning, which is classified under the diagnostic imaging core service, was the only service provided at this service. We rated the service as inadequate overall. We rated safe and well led as inadequate, responsive as requires improvement, and caring as good. We do not currently collect sufficient evidence to enable us to rate the effective key question.

Summary of findings

Contents

Inadequate

Watford Clinic

Services we looked at

Diagnostic imaging

Summary of this inspection

Background to Watford Clinic

Watford Clinic is operated by a private diagnostic ultrasound service based in Watford, Hertfordshire and serves the Hertfordshire, Essex, London and Kent areas. It has two satellite clinics in Brentwood, Essex and Docklands in London. Watford Clinic is owned by Ultrasound Plus Ltd who were registered with the CQC in April 2018.

The service provides diagnostic ultrasound services to self-funded adults aged 18 and above.

The service has two registered managers and has not been previously inspected by the CQC.

Our inspection team

The inspection team was comprised of a CQC lead inspector and a CQC inspector. The inspection team was overseen by Phil Terry, Inspection Manager, and Bernadette Hanney, Head of Hospital inspection.

Information about Watford Clinic

Watford Clinic provides diagnostic imaging through ultrasound scanning only. It was registered to provide the following regulated activity:

- Diagnostic and screening procedures.

The service provides the following diagnostic ultrasound scans to adults aged from 18 to 65:

- Pregnancy ultrasound scans.
- Gynaecology ultrasound scans.
- General ultrasound scans.
- Musculoskeletal scans.

All pregnancy ultrasound scans performed are in addition to those provided through the NHS as part of a pregnancy care pathway.

All patients are private paying customers. All new patients are on a self-referral basis. Patients could book an ultrasound scan on the service website or by telephone.

The main service in Watford, is located on the first floor of a shared community building. Facilities include one scanning room, a clinical/consultation room, a waiting area and a staff office. Toilets are situated on the ground floor of the building and were accessible to staff and patients. The satellite clinics had a waiting area, a scanning room and a consultation room. Toilet facilities were provided at both sites.

At the time of our inspection, the service employed 11 members of staff, including two registered managers, six sonographers, and three clinic administrators.

Standard opening hours are:

- Monday: 6pm to 9pm.
- Wednesday: 6.30pm to 9pm.
- Thursday: 6pm to 9pm.
- Saturday: 10am to 2pm.

Patients can book an appointment at the main clinic or either of the two satellite clinics.

At our initial inspection on 25 April 2019, we spoke with two staff members, including the registered manager and one sonographer. We also spoke with five patients and reviewed five patient records. We undertook a follow up inspection on 08 May 2018 at the Brentwood satellite clinic. We spoke to three staff members including the registered manager, a sonographer and a clinic administrator.

Summary of this inspection

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

Activity (April 2018 to March 2019)

- Watford Clinic performed a total of 4,958 ultrasound scans from April 2018 to March 2019. All scans performed were for adults over the age of 18.
- Of all scans performed, 97% were pregnancy scans, 2% were gynaecological scans and 1% general ultrasound scans. The service did not undertake any musculoskeletal scans in this reporting period.
- All patients were privately funded.
- The service did not collect data to monitor cancelled appointments. However, the registered manager reported that some appointments had been cancelled due to small numbers in clinics and being unable to arrange a sonographer.

Track record on safety

- The service reported zero never events from April 2018 to March 2019.
- The service reported zero incidents from April 2018 to March 2019.
- The service reported zero serious injuries from April 2018 to March 2019.
- The service received 15 complaints from April 2018 to March 2019.
- Watford Clinic reported zero incidents of health associated MRSA, Methicillin-sensitive staphylococcus aureus (MSSA), Clostridium difficile (C.diff), and Escherichia coli (E-Coli).

Services provided at the service under service level agreement:

- Specimen analysis service
- Waste disposal
- Equipment maintenance

Services accredited by a national body:

- The service had no accreditation by a national body.

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 inspected this service. At this inspection, we rated safe as **inadequate.**

Mandatory training

- **The service did not provide mandatory training in key skills to all staff. Staff were not compliance with mandatory training targets. There was limited managerial oversight of staff training completion rates.**
- During the inspection, we found the service did not have an effective system in place for managing and monitoring staff compliance with mandatory training. Prior to the inspection, the service told us all staff were compliant with mandatory training; however, during the inspection we found this was not the case.
- Sonographers employed by the service were required to complete the following mandatory training modules: basic life support, safeguarding adults level two, safeguarding children level two, manual handling, equality and diversity, fire safety and information governance. They were responsible for arranging their own training and were required to provide copies of their training certificates to the registered managers.
- We reviewed six sonographer personal files and did not find evidence of certificates for all modules to demonstrate they had completed mandatory training in key skills. The service set a 100% compliance target, however at the time of the inspection, this was not achieved for all seven mandatory training subjects:
  - Basic Life Support (BLS) 33%.
  - Safeguarding adults 50%.
  - Safeguarding children 50%.
  - Manual handling 17%.
  - Equality and diversity 17%.
  - Fire safety 17%.
  - Information governance 17%.
- Managers had not completed any mandatory training modules. Therefore, we were not assured they had the skills and knowledge necessary to lead the service.
- The service provided mandatory training to the clinic receptionists through e-learning in safeguarding level one and basic life support. At the time of the inspection, all three clinic administrative staff were 100% compliant with these mandatory training modules.
- There was no evidence that a training needs assessment had been completed to ensure that all staff at different levels had completed training relevant and necessary to their roles. For example, we found no evidence of staff completing Mental Capacity Act (MCA) awareness or infection control training. Furthermore, clinic reception staff were not expected to complete key modules such as safeguarding level two, fire safety, information governance, manual handling and equality and diversity.

- Not all staff were up to date with training relevant to their roles. For example, staff responsible for taking blood samples, had not completed any venepuncture refresher courses since 2014. Furthermore, reception staff undertaking a chaperone role, had not completed chaperone training. We raised this as a concern to the manager during our inspection on 25 April 2019.During our follow up inspection on 08 May 2019, we were provided with evidence that relevant staff had booked venepuncture training on 11 May 2019. We also found that the manager had purchased an online mandatory training course for all staff. The course covered the following areas:
  - Basic life support.
  - Safeguarding adults and children level one to three.
  - Chaperone training.
  - Preventing radicalisation.
  - Mental Capacity Act (MCA), mental health and mental capacity awareness.
  - Dementia awareness.
  - Health and safety.
  - Fire safety.
  - Infection, prevention and control.
  - Record keeping.
  - Information governance.
  - Conflict resolution.
  - Lone working.
  - Moving and handling.
  - Bribery and corruption.
  - Equality and diversity.
- However, we were still not assured that managers had implemented a system for ongoing monitoring of mandatory training or that there was an effective plan in place for staff to complete it in a timely manner.

Safeguarding

- **Systems, processes and standard operating procedures were not always reliable or appropriate to keep people safe. Policies did not support staff to safeguard patients from abuse and harm. However, staff understood how to protect patients from abuse and most staff had training on how to recognise and report abuse and they knew how to apply it.**
- The provider had a safeguarding adult policy and safeguarding children policy in place. We reviewed both policies and found they lacked detail and did not support staff in taking the actions required where safeguarding concerns were raised. We found the policies had not been adapted to reflect local processes, for example, including contact details for the local authorities within the Hertfordshire and Essex area.
- The safeguarding adult policy had not been reviewed since 2011 and had limited explanations of the types of abuse. For example, the safeguarding adults' policy did not reference different types of abuse such as female genital mutilation (FGM), wilful neglect, domestic abuse, human trafficking and modern slavery. Furthermore, the policy did not provide any guidance to staff on dealing with suspected FGM or modern slavery situations.
- The service had a designated person who was the safeguarding adult and children lead. However, they had not completed any safeguarding adult or children training since 2011. This was not in line with the recommendations from the Intercollegiate Document adult safeguarding: roles and competencies for health care staff (August 2018) or the Intercollegiate Document safeguarding children and young people: roles and competencies for healthcare staff (January 2019).
- The service did not demonstrate all sonographers were trained to level two safeguarding adults and children. We reviewed sonographer personal records and found 50% of sonographers had completed level two adults and children safeguarding training.
- All three clinic administrators had received safeguarding children level one and safeguarding adult level one training within 12 months. However, we were not assured that clinic administrators had received an appropriate level of safeguarding training based on their role. For example, administrators had

contact with children that accompanied parents to appointments and acted as chaperones for some scan procedures. The level of safeguarding training received is not in line with the recommendations from the Intercollegiate Document adult safeguarding: roles and competencies for health care staff (August 2018) or the Intercollegiate Document safeguarding children and young people: roles and competencies for healthcare staff (January 2019).

- Scan records showed chaperones were not always present during transvaginal scans, as outlined in the service procedures. We reviewed two scan records where a chaperone was indicated, and there was no evidence a chaperone was present for either of the internal scans. Similarly, we did not see evidence clinic administrators had received chaperone training to ensure they were competent to undertake a chaperone role. During our follow up inspection on 08 May 2019, online chaperone training had been purchased for all staff.
- Whilst staff had not made any safeguarding referrals, staff were able to tell us how they would identify a safeguarding issue and refer to local safeguarding services. Staff told us they would refer the concerns to the safeguarding lead for the service who would respond to all concerns.
- Safety was promoted through recruitment procedures and employment checks. Staff had Disclosure and Barring Service (DBS) checks undertaken at the level appropriate to their role. DBS checks help employers make safer recruitment decisions and prevent unsuitable people from working with vulnerable groups.

Cleanliness, infection control and hygiene

- **Systems and policies to prevent and protect people from healthcare-associated infections were not always reliable. Whilst staff had not received any training, staff understood how to protect patients from healthcare associated infections and facilities were clean and well maintained.**
- The service had an infection, prevention and control (IPC) policy in place. We reviewed the policy and found it lacked detail and did not support staff in taking the actions required to prevent and protect people from healthcare-associated infections. For example, there was no reference to waste disposal, cleaning of ultrasound equipment and probes and use of hand sanitising gel. In addition, the process for managing bodily spillages was not clear how staff should effectively and safely manage a spillage.
- While the IPC policy did not outline the process for cleaning clinical equipment, staff could explain how they would clean the ultrasound machine and probes. The service also had a daily cleaning schedule at both sites we visited. Staff were aware of the schedule and completed it at the end of the day to demonstrate the equipment and environment had been cleaned and stocks replenished.
- Staff followed best practice guidance for the routine disinfection of ultrasound equipment (European Society of Radiology Ultrasound Working Group, Infection prevention and control in ultrasound – best practice recommendations from the European Society of Radiology Ultrasound Working Group (2017)). The ultrasound transducer was decontaminated with disinfectant wipes between each patient and at the end of each day. The transducer was the only part of the ultrasound equipment that was in contact with patients.
- Handwashing facilities were not available within the clinical environment at Watford Clinic. This meant staff were unable to wash their hands between patient contacts. There were sinks in public toilets situated at the entrance to the service and hand sanitising gel was provided at the point of care. We observed staff using hand sanitising gel during our inspection. The World Health Organisation's (WHO) 'How to hand rub' posters were also displayed throughout the service and hand sanitiser was visible and readily available. However, whilst most scans undertaken were non-invasive, the service did undertake transvaginal scans and blood tests. Therefore, we were not assured staff completing these procedures at the Watford site, had immediate access to facilities to effectively decontaminate their hands before and after invasive procedures. There was also no risk assessment in place to help identify mitigating actions.

Inadequate

Diagnostic imaging

- Handwashing facilities were available in the scanning room at the Brentwood satellite clinic. Hand sanitiser gel was also available in the reception area for staff, patients and visitors to use at both sites.
- Both clinical rooms in Watford Clinic had carpeted flooring which is not in line with infection, prevention and control best practice. This had not been risk assessed and therefore, there were no mitigations in place to reduce any potential risk.
- Spillage kits were not available within the service for staff to use to safely clean bodily fluid spillages. However, at our follow up inspection on 08 May 2019, we found evidence that following our feedback, spillage kits had been ordered for all three sites and the infection control policy had been amended to reflect spill kits being in place. The policy did not detail how bodily fluids spillages should be cleaned and precautions to be undertaken.
- The service had not undertaken any infection control audits to demonstrate compliance with infection control policies and practices.
- The service had a designated infection control lead however, they had not completed any infection control training.
- During our inspection, clinical staff complied with having their arms 'bare below the elbows' and not wearing watches or rings.
- A supply of personal protective equipment (PPE), which included latex-free gloves and aprons, were available and accessible.
- The environment was visibly clean throughout, including waiting areas and treatment rooms.
- A service level agreement was in place for the cleaning of all areas, except clinical equipment, including floors, toilets and waiting rooms.
- The examination couch was protected with a paper towel cover. We observed the examination couch being cleaned between patients and the paper towelling being replaced.
- Cleaning equipment was available and stored securely.
- There had been no instances of healthcare acquired infections from April 2018 to March 2019.

Environment and equipment

- **The environment was generally well maintained but it was not always suitable for all types of care and procedures being provided.**
- The service was situated on the ground floor of a shared building and was accessible to all. Facilities included a waiting area with reception, an ultrasound scanning room, and a clinical room where staff could take blood tests and counsel patients whom received bad news. At the Watford site, there was a staff office used for storage of confidential data and toilets were accessible to patients on the ground floor of the building.
- Waiting areas at both sites were clear of clutter and contained a suitable number of chairs to meet patient needs.
- A system was in place to log and monitor consumable items so that expiry dates could be tracked. However, whilst most consumable items we checked were in date, we found a box of out of date needles used for taking blood, in the clinical room dated March 2019. The manager removed these immediately.
- The service had a pharmacy fridge for storage of blood samples awaiting collection at the Watford site. Blood samples taken at satellite clinics were transported on the day to Watford site where samples were stored in the fridge awaiting collection the following day. There were no storage guidelines in place or documented temperature checks to ensure the fridge temperature did not go out of recommended temperature range.
- Emergency equipment was not required on site due to the nature of the service. A first aid kit was available at both sites and were in-date.
- Sharp bins were clean, dated, not overfilled, and had temporary closures in place to prevent accidental spillage of sharps.
- The scanning equipment used was appropriate for the ultrasound procedures provided. An external company

completed the servicing of the ultrasound scanning equipment. Service records confirmed the scanner had been serviced, the last completed in February 2019.

- Electrical equipment was regularly serviced, and safety tested to ensure it was safe for patient use. All the equipment we reviewed had been serviced within the date indicated.
- Waste was handled and disposed of in a way that kept people safe. Staff used the correct system to handle and sort clinical and non-clinical waste. A service level agreement was in place with an external company who collected and disposed of clinical waste.
- The service did not use substances covered by the Control of Substances Hazardous to Health (COSHH) Regulations. All cleaning agents were managed by a third-party company under a service level agreement (SLA).
- Fire safety equipment was fit for purpose. The alarm system, and heat and smoke detectors were serviced annually. Fire extinguishers were accessible, stored correctly and had been serviced within the last 12 months.
- There was adequate storage for consumables such as ultrasound gel, probe disinfection wipes and baby keepsake and souvenir products, such as photo frames.

Assessing and responding to patient risk

- **The service did not have appropriate arrangements in place to manage risks to patients and visitors.**
- The service did not have a policy for managing emergencies or patient risk. Not all staff were trained in Basic Life Support (BLS). Sonographers were 33% complaint with mandatory BLS training. However, staff could explain the procedures to follow in the event of an emergency. Staff told us they would telephone 999 for urgent support if an emergency arose on the premises.
- The service did not have written referral pathways for patients to local hospitals, emergency services and other healthcare professionals. We were concerned any potential problems such as foetal anomalies or abnormal growths, detected during a scan would not be escalated and reviewed in a timely manner by an appropriate healthcare service. Sonographers told us that if the patient requested, they would call the patients' GP or midwife to verbally share scan results. We raised our concerns with the service during our inspection. The service feedback that pathways would be included in scanning protocols that were being reviewed.
- The service did not have an effective process for documenting allergy status on the patient medical questionnaire to alert sonographers to patients with allergies. For example, there was nowhere to record latex allergies for patients undergoing transvaginal scans. However, during the inspection, the sonographer asked all patients about allergies. The service had both latex and non-latex covers for the transvaginal ultrasound probes and would select the cover according to the response from the patient.
- There were no risk assessments or procedures in place to mitigate the risk of staff working alone or in isolation. For example, administrative staff sometimes locked up the building on their own at night and there was no process in place to mitigate any potential risks.
- Staff used the 'paused and checked' checklist devised by the British Medical Ultrasound Society (BMUS) and the Society and College of Radiographers. These checks ensured the right patient received the right scan of the right anatomical area. We observed staff completing these checks during our inspection. We observed five scans and saw the patient identification was verified prior to the start of the procedure.
- The service accepted patients who were physically well and could transfer themselves to the couch with little support. The service did not offer emergency tests or treatment.

Staffing

- **The service had sufficient staff of an appropriate skill mix, to enable the effective delivery of safe care and treatment.**
- Usual daily staffing consisted of a manager, one sonographer and one receptionist. However, due to staff sickness, the unit manager had sometimes needed to complete administrative duties. During the

inspection, a clinic receptionist was on sick leave and the manager was covering. The staffing structure for the satellite sites was one sonographer and one clinic receptionist, supported by a manager.

- The service employed four clinic administrators on part time contracts. They were responsible for managing enquiries, appointment bookings, supporting the sonographers during ultrasound scan procedures and printing scan images.
- The service employed six sonographers on zero-hour contracts. They were all experienced sonographers and one doctor who had ultrasound experience and worked substantively within the NHS. The service completed appropriate employment checks and recorded qualifications of sonographers in personal files.

Records

- **Staff kept records of patients' care and treatment. Records were clear, up-to-date, and easily available to all staff providing care.**
- Patients completed a medical questionnaire upon arrival. Sufficient information was obtained from the patient prior to their scan appointment, such as medical history, investigation required, general practitioner details and details of pregnancy for obstetric scans. Staff ensured this was present and matched the expectations of the patient before continuing.
- The service had an electronic patient record system for storing images. The electronic system was encrypted and only staff requiring access to images had access to the system.
- Staff securely stored and updated individual patient care records in a way that maintained their confidentiality.
- During pregnancy scans, the sonographer completed a wellbeing report and paper scan report during the appointment. This was given to the patient immediately after the scan appointment. A copy of the scan report was also stored at the service, in case they needed to refer to it at any time. For non-pregnancy scans, reports and images were given to patients following the scan appointment. Patients were advised to share the reports with their GP or hospital.
- Sonographers were required to complete training on information governance as part of their mandatory training programme. At the time of our inspection, we found 17% of sonographers were compliant with this training. Clinic administrators and registered managers had not completed information governance training.

Medicines

- The service did not store, prescribe or administer any medicines.

Incidents

- **The service did not have effective processes for reporting, investigating and learning from incidents. Staff understood their roles and responsibilities to raise concerns and report safety incidents. There was a variable understanding of the duty of candour regulation.**
- The service had an incident reporting policy in place. We reviewed the policy, which was issued in November 2018, and found it contained version control, date for review and authors. However, we found the policy to be brief and lacked some detail. The policy did not provide sufficient detail on how to report an incident, or the information that should be included within the incident report. The policy did not outline the timescales for investigating incidents, process for learning lessons or applying Duty of Candour (DoC). We raised this with the registered manager who acknowledged our feedback and told us they would look at the policy and any improvements that could be made.
- The service did not have a formal log for incidents; however, during the inspection we observed a daily clinic sheet with a section to record any incidents that may have occurred on the day. These forms were regularly reviewed by the registered manager.
- From 01 April 2018 to 31 March 2019, the service reported zero incidents (Source: Provider Information Request).
- The service did not report any never events in the twelve months prior to our inspection (Source: Provider Information Request). A never event is a serious incident that is wholly preventable as

guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all providers.

- In accordance with the Serious Incident Framework 2015, the service did not report any serious incidents in the twelve months prior to our inspection (Source: Provider Information Request).
- Staff could describe the process for reporting incidents. Staff told us they would report all incidents to the registered manager. Staff told us they did not receive any feedback about incidents. The service did not undertake team meetings to discuss any lessons learnt.
- Not all staff we asked, were aware of the DoC regulation. The DoC 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 individuals. Clinical staff we spoke with understood the DoC process and the need for being open and honest with patients when errors occurred. However, managers had limited understanding of the DoC requirements. At the time of our inspection, they had not reported any incidents that met the threshold for the duty of candour regulation.
- The registered manager understood their responsibility to report any notifiable incidents to the CQC.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We do not rate effective for diagnostic services.

Evidence-based care and treatment

- **The service did not always provide care and treatment based on national guidance or provide evidence of its effectiveness.**
- The service did not have an effective system in place for reviewing the content of policies and procedures.
- Policies and guidelines were not always reviewed in a timely manner or reflected the most up-to-date national guidance. For example, both the medical records policy and the safeguarding adults' policy were ratified in 2010 and were not due for review until 2020. The medical records policy also referenced the Data Protection Act 1998 which had been superseded by the Data Protection Act 2018. There was also no reference to the General Data Protection Requirement (GDPR).
- Ultrasound scanning protocols did not have review dates or references to national guidance. For example, we saw protocols were in place for gynaecological, abdominal, renal tract and kidney ultrasounds, however, they did not reference national guidance. We also did not see evidence of an obstetric scanning protocol. Guidance found in the scanning room regarding obstetric measurements (for example, femur length and head circumference) was printed in 2012. This folder also contained guidance from the British Medical Ultrasound Society (BMUS) issued in 2000 and 2003 and had not been updated with the most up to date guidance.
- The service did not have a clinical audit programme in place to review practice against national guidance. For example, an early pregnancy scan audit. Furthermore, there were no audits in place to provide assurance of the safety and quality of the service.
- Paper copies of policies were stored in a policy folder and staff knew how to access them. However, we did not find evidence that staff were informed when policies were updated by the service.
- Sonography staff demonstrated a good understanding of national legislation affecting their practice.
- Sonographers followed the 'As Low as Reasonably Achievable' (ALARA) principles. This was in line with national guidance (Society and College of Radiographers (SCoR) and BMUS, Guidelines for Professional Ultrasound Practice (December 2018)). Sonographers aimed to complete all ultrasound scans within 10 minutes to help reduce ultrasound patient dose, where possible.
- Staff adhered to the 'Paused and Checked' checklist, which is designed as a ready reminder of the checks that need to be made when any ultrasound scan is

undertaken. This was in line with national standards outlined by BMUS and the SCoR. We observed this practice being followed during all five scans we observed.

- We saw no evidence of any discrimination, including on the grounds of age, disability, gender, gender reassignment, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.

Nutrition and hydration

- **Patients had access to enough hydration services to meet their needs.**
- Food and drink was not routinely provided due to the nature of the service and the limited amount of time patients spent there. However, a water cooler was available to patients and visitors in the waiting area. Confectionary machines were also available in the waiting area for patients and visitors to access.
- Patients were provided with information and guidance regarding nutrition and hydration prior to the ultrasound scan.

Pain relief

- Staff asked patients if they were comfortable during their ultrasound scans, however no formal pain level monitoring was undertaken as the procedures were pain free. We observed sonographers advising patients experiencing pain and discomfort to contact their GP or hospital.

Patient outcomes

- **The service did not have effective processes in place to monitor the effectiveness of care or use the findings to improve them.**
- There were limited peer review audits completed to review the quality of ultrasound scan images. A sample of random scans were reviewed quarterly by the registered manager and a sonographer. However, audits were not formally recorded, therefore we could not be assured they had been undertaken in accordance with recommendations by BMUS. Staff reported they received feedback about their scan images in an appraisal meeting, however, these meetings were not documented.
- The service did not have any key performance indicators (KPIs) to monitor performance.
- The service did not collect data to monitor the service activity or effectiveness. For example, the service did not collect data to demonstrate the accuracy rate for gender scans.

Competent staff

- **The service did not always make sure staff were competent for their roles.**
- There were limited systems or arrangements in place to support and manage staff to deliver effective care and treatment. For example, there were no processes in place to enable staff to undergo clinical supervision, and staff reported not having the opportunity to complete continuous professional development (CPD).
- The registered manager told us they appraised staff work performance to provide them with support and to monitor the effectiveness of the service. However, since staff were appraised annually, we were not assured this was effective.
- Whilst we were told staff appraisals had been completed within the last 12 months, we did not see evidence of this. Appraisals and clinical competencies provide evidence individuals hold the necessary skills and capabilities to undertake their role safely and effectively. Therefore, we could not be assured staff were competent for their role.
- All staff underwent a local induction upon commencement of employment. We were told that an established sonographer would observe a new sonographer before they commenced a clinic on their own. This ensured the new sonographer was competent at using the ultrasound machine and completing the scans. However, this was not documented. The sonographers we spoke to reported that they had not undergone any other observation of their practice since their employment with Ultrasound Plus.
- Clinic administrators completed an induction with the registered manager. Induction checklists were in place and new administrators told us they received a thorough induction to the role.

Diagnostic imaging

- We were not assured the service had formal competency assessments in place to ensure staff were working in line with national guidance. However, there was evidence of staff continuous professional development (CPD) certificates in personal files for some staff. For example, we saw a sonographer had completed obstetric scanning training modules in January 2019 with their substantive employer.
- The manager was responsible for completing blood tests within the service, however, they had not undertaken any venepuncture training or refresher course since 2014.
- We were not assured staff undertaking lead roles within the service were adequately trained or competent to provide effective advice and guidance to staff. For example, the safeguarding lead had not completed safeguarding level three training that is appropriate for a safeguarding lead role. The infection, prevention and control lead had not completed any recent infection control training. Our concerns were fed back to the service and observed at our follow up inspection on 08 May 2019, that managers had arranged training for service leads. However, there were no timescale for completion.
- The registered manager was responsible for ensuring staff had the right qualifications and experience to do their job when they started their employment. We reviewed the staff personnel records for the sonographers. They all contained evidence of a recruitment and selection interview, employment history, identification, disclosure and barring service (DBS) checks and one employment reference.
- Five out of six sonographers performed ultrasound scans at local NHS hospitals where they were substantively employed. Five of the sonographers were radiographers and were all registered with the Health and Care Professionals Council (HCPC). One sonographer was a doctor, specialising in In Vitro Fertilisation (IVF) and was registered with the General Medical Council (GMC).
- Each staff member completed a local induction, which included role-specific training provided by the registered manager. All staff completed a disclaimer to confirm they had read the service policies and procedures.

Multidisciplinary working

- **Staff with different roles worked together as a team to benefit patients. However, we did not see evidence of the service working with other providers to improve the pathway for patients to local services.**
- The management team, sonographers and reception staff worked together for the benefit of patients and their families. We observed their positive working relationships promoted a relaxed environment and helped put women and their families at ease. All staff commented on how well they worked as a team.
- Sonographers working within the service rarely had contact with each other and did not contact each other for advice and support. Staff told us they would seek clinical advice from the service manager, however, the manager was not a trained radiographer or sonographer.
- The service did not have established pathways in place to refer patients to their GP, midwife or local NHS hospital if any concerns were detected. At our follow up inspection on 08 May 2019, we were assured that sonographers would contact health professionals with consent from the patient. We were also advised that pathways would be written into the scanning protocols.

Seven-day services

- The service did not operate seven-days a week. The service was available four days a week for pre-booked appointments.

Consent and Mental Capacity Act

- **Staff generally understood how and when to assess whether a patient had capacity to make decisions about their care. However, the service did not have Mental Capacity Act policies or procedures in place.**
- Policies did not support staff to assess whether a patient had capacity to make decisions and consent to ultrasound procedures. The provider did not have a Mental Capacity Act 2005 (MCA) policy in place. Therefore, we were not assured the service had effective procedures in place for assessing a patients' capacity and making decisions about their care.

Inadequate

Diagnostic imaging

- The service did not expect staff to complete MCA training as part of the mandatory training requirements. Managers and clinic administrators had not completed any MCA training. Two sonographers had completed MCA training through their substantive employer. Following the inspection, the service provided assurance that they had arranged an online training module that covered MCA and have asked all staff to complete it.
- Patients' relatives or friends were sometimes used as interpreters by staff when English was not the patient's first language. We were concerned these patients may not fully understand what the scan would involve or their scan results, and as a result, informed consent could not be appropriately sought by the sonographers.
- All staff were aware of the importance for gaining consent from patients before conducting any procedures. Consent to care and treatment was sought in line with legislation and guidance. Staff checked patients had read, understood and signed the terms and conditions of the service before any ultrasound scan was performed. The terms and conditions included the recommendation that scans provided are not a replacement for NHS scans and obstetric scans are complimentary to those made available to them by the NHS. The sonographers would also verbally check the patient was still happy to go ahead with the scan. Staff told us if they suspected a patient could not consent due to lacking capacity, they would not continue with the scan.
- The service did not offer ultrasound scanning to patients under 18. However, there were some discrepancies with what the service advertised. This was brought to the attention of the registered manager who said they would review their marketing on social media websites. Staff told us they checked date of birth prior to the scan and would ask further questions if they felt the patient was under the age of 18.
- Patients were provided with information prior to their appointments and were given opportunities to ask questions when they arrived. This ensured their consent was informed.

Are diagnostic imaging services caring?

Good

We have not previously inspected this service. At this inspection, we rated caring as **good.**

Compassionate care

- **Staff cared for patients with compassion. Feedback from patients confirmed staff treated them well and with kindness.**
- All staff we spoke with were very passionate about their roles and were dedicated to making sure patients received patient-centred care. We observed staff treating and assisting patients in a compassionate manner.
- We spoke with five patients about various aspects of their care. Feedback was consistently positive about the kindness and care they received from staff. One patient described staff as "polite and friendly". Another patient told us their experience was a "great experience" and they were "very happy with the service – it was a lovely and memorable experience".
- We saw staff introducing themselves to patients at the start of the appointments; they also explained their role, and fully described what would happen during the scan. They made sure patients were comfortable and were reassured if they felt nervous. All five patients commented the sonographer explained everything clearly.
- Staff maintained patients' privacy and dignity during and ensured they were covered as much as possible during their scan.
- The service obtained patient feedback through an online provider feedback platform. All patients were sent an email within a week of their appointment asking for feedback about the service. The feedback invited patients to rate the service and provide more detailed feedback. The registered manager reviewed the comments monthly.
- From April 2018 to March 2019, 86 reviews had been posted on the online review site, of which 70% rated the service as five stars (excellent) and 14% rated the

service as four stars (great). Examples of comments included, "Lovely staff, sonographer was nice and polite and made me reassured on the gender of my baby", "Fantastic service!" and "brilliant service, private and special experience. I would highly recommend and have booked our next scan".

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
  - Staff supported patients through their scans, ensuring they were well informed and knew what to expect. We observed staff explaining the procedures and all patients we spoke to fed back the sonographer explained everything clearly.
  - Staff were aware patients attending the service often felt nervous and anxious so provided additional reassurance and support to these patients. We observed staff providing ongoing reassurance to a nervous patient that was experiencing discomfort.
  - Staff told us how providing emotional support to patients was an important aspect of the work they did. There was a quiet room to discuss difficult matters when the need arose. Patients could stay with a sonographer or manager after receiving bad news. Staff felt comfortable delivering bad news and supporting patients afterwards.
  - At the end of all procedures, patients were always given advice of what to do if they had concerns around their health and wellbeing. This included advice to contact their general practitioner, midwife or hospital if they had concerns following the scan.

Understanding and involvement of patients and those close to them

- **Staff involved patients and those close to them in decisions about their care and treatment.**
  - Staff took the time to explain the procedure and the precautions to patients and their relatives. Patients were encouraged to ask questions, which staff ensured they answered before commencing the scan.
  - Staff communicated with patients to ensure they understood the reasons for attending the service. All patients were welcomed into the reception area and accompanied to the clinical room by a staff member.
  - Staff told us they encouraged patients to ask questions about their scan. Patients and family members fed back they were given an opportunity to ask questions.
  - Staff allowed for family, including children to be present during the scan and involved them throughout the appointment. The service provided toys for children in the waiting area and a large screen in the scanning room for the family to see the scans in progress.
  - Patients could access information on different types of scans and packages from the Ultrasound Plus website. There were price lists and information about different scans advertised throughout the service.
  - Whilst staff recognised when patients needed additional support to help them understand and be involved in their care and treatment, the service did not have any information accessible in different languages.

Are diagnostic imaging services responsive?

Requires improvement

We have not previously inspected this service. At this inspection, we rated responsive as **requires improvement.**

Service delivery to meet the needs of local people

- **The service planned and provided services in a way that met the needs of local people.**
  - The service specialised in providing pregnancy scans for women from five to 40 weeks of pregnancy. A variety of packages were available to patients to complement their NHS pregnancy scans.
  - The service also offered a range of general ultrasounds including gynaecological, musculoskeletal, abdominal and urinary tract.
  - The service was open to patients four days a week during the evening and one weekend. Patients could choose which site they wanted their ultrasound scan.

Inadequate

Diagnostic imaging

- The facilities and premises were suitable for the services delivered. There was a comfortable waiting area, scan room and toilet. A separate toilet was provided, which was suitable for people living with a disability. There was ramp access to the building, and clinic rooms at both sites we visited had an adjustable couch, which staff used to support patients with limited mobility.
- The environment in which the scans were performed was spacious and well arranged. There was adequate seating available for those accompanying the woman during the scan. Lights were dimmed when undertaking a scan to darken the room. This meant scan images could be observed more clearly.
- Scanning rooms at both sites had one large wall-mounted screen which projected the scan images from the ultrasound machine. These screens enabled patients and their families to view their baby scan more easily. This was in line with recommendations (Royal College of Radiologists, Standards for the provision of an ultrasound service (December 2014)).
- Children were able to accompany their parent throughout the appointment. We saw staff ensured the children felt involved in the scan and explained the images of their baby brother or sister. The waiting area also contained a selection of children's toys.
- Staff gave patients relevant information about their ultrasound scan when they booked their appointment, with instructions about what to do and nutritional intake prior to the scan.
- The service provided patients with information about pricing and scan options before their appointment. The service offered several scan packages. This information was clearly outlined on the service's website and pricing lists were on display in various locations within the service.
- The service website provided useful information about the service, the range of scans offered, an explanation about the scan and pricing information.
- The service was located near established routes, with a bus stop a short distance away. However, there was limited free parking on site. Patients we spoke to fed back finding parking was difficult.

Meeting people's individual needs

- **The service was generally accessible to all who needed it and took account of patients' individual needs.**
- Both clinics were located on the ground floor of the building they operated from, with ramp access.
- Waiting areas had adequate seating for patients and those accompanying them. The seating was suitable for patients with raised body mass index, as was the examination couch.
- All ultrasound scans were undertaken in a private clinic room with space for additional relatives, friends or carers to accompany the patient.
- The service was inclusive to all patients and we saw no evidence of any discrimination, including on the grounds of disability, pregnancy and maternity status, race, religion or belief, and sexual orientation when making care and treatment decisions.
- The service offered pregnant patients a range of baby keepsake and souvenir options which could be purchased. This included heartbeat bears, a selection of photo frames, fridge magnets and gender reveal products. Heartbeat bears contained a recording of the unborn babies' heartbeat.
- Patients' relatives or friends were sometimes used as interpreters by staff when English was not the patient's first language. We were concerned these patients may not fully understand what the scan would involve or their scan results, and as a result, informed consent could not be appropriately sought by the sonographers.
- The terms and conditions, disclaimer and other key information was not available in other languages. Furthermore, patient information leaflets were not available in larger font size or braille for patients with a visual impairment. We fed back our concerns to the manager following our inspection on 25 April 2019. At our follow up inspection on 08 May 2019, the patient disclaimer was available in different languages and staff were aware of this.

Access and flow

- **People could generally access the service when they needed it. However, it was usual for appointments to overrun, which meant patients waited long periods for their appointment.**
- The service did not have a waiting list. The average time from point of booking to scan appointment was 24 to 48 hours. Patients could access the service at a time to suit them. Patients were offered a choice of location and appointment day and time to suit their needs. We spoke to five patient who all commented they attended the appointment within a few days of booking. Two patients booked the day before the appointment.
- From 01 April 2018 to 31 March 2019, no ultrasound scans were delayed or cancelled for non-clinical reasons (Source: Provider Information Request). However, during the inspection, the manager told us that appointments had been cancelled when a sonographer was not available. The service did not formally record cancellations; therefore, we were unable to assess the impact on care provided. Complaints and feedback from online platforms suggested cancellations happened due to the service double booking appointments.
- During the inspection, the clinic ran over which meant four out of five patients had to wait longer than expected before they went in for their appointment. It was unclear the length of wait as the service did not formally monitor this. Patient feedback confirmed patients were kept informed about appointment delays and received an apology from staff for their delay. Feedback from online feedback websites and complaints suggested appointment delays were a common occurrence. We raised this with the registered manager who told us they would be reviewing their appointment duration to ensure sonographers had enough time with patients.
- Patients could book appointments on a live online booking system, call the service or walk in to book when the service was open. All five patients we spoke to told us that the booking system was easy to use.
- There was no waiting time for scan results. Patients attending for a pregnancy scan were provided with a wellbeing report, an image and report on the day of the appointment. Furthermore, patients attending for non-pregnancy related scans were provided with the image and report immediately after the scan appointment. Patients who underwent a blood test were contacted by telephone within 48 to 72 hours following the blood test with the results.

Learning from complaints and concerns

- **There was not an effective system for recording, handling, responding to, and learning from complaints.**
  - The service had a complaints' policy in place; however, the policy did not outline the process and timescales for investigating and closing complaints. Furthermore, there was no distinction between formal and informal complaint management, management of complaints against registered persons or reference to lessons learnt. Therefore, we were not assured staff were aware about how to respond to a complaint, or that complaints received were responded to within appropriate timescales.
  - The service did not have an effective system in place for recording and tracking complaints. We reviewed 14 complaints received from July 2018 to March 2019. The service had a complaints' log document; however, none of the complaints had been fully recorded on the service complaints' log. Therefore, it was unclear how many complaints had been received and what stage they were in the investigation process. There was no evidence of lessons learnt or shared learning from the complaints.
  - The registered manager was responsible for investigating and responding to complaints. The manager told us all complaints were dealt with; however, there was no evidence they were investigated and closed.
  - There were no posters or leaflets in waiting areas at Watford Clinic telling patients how to make a complaint. A complaint poster was displayed in the scanning room at both sites which directed patients to contact the service to make a complaint. There was a suggestion box in Watford Clinic reception, however there were no feedback forms or instructions about how to provide feedback.
  - Complaints and their outcomes were not discussed and shared with staff across the service.

Diagnostic imaging

- We raised our concerns about complaint procedures and management of complaints during our inspection on 25 April 2019. At our follow up inspection on 08 May 2019, the complaints' log had been updated and we saw that all complaints had been resolved. However, the complaints' log did not record a resolution date. Therefore, we could not be assured that complaints had been dealt with within reasonable timescales. We were also not assured that there was an effective plan to review the complaints' policy.

Are diagnostic imaging services well-led?

Inadequate

We have not previously inspected this service. At this inspection, we rated well-led as **inadequate.**

Leadership

- **The managers of the service did not have all the right skills and knowledge to run a service providing high-quality sustainable care.**
- The service had a registered manager who provided day to day management of the service and was also the nominated individual. The service had a second registered manager, however, the second registered manager did not have any managerial oversight of the service or the carrying on of the regulated activity. Staff told us they did not have contact with the second registered manager. At our follow up inspection, we were advised that the second registered manager would be deregistering.
- We were not assured that managers had all the appropriate knowledge or skills to provide leadership of the governance within the service. For example, managers did not have a system to identify risks or review and implement policies and procedures. We were also not assured that managers understood what policies and procedures were needed for the safe and effective delivery of the regulated activity. For example, following our post inspection feedback on 25 April 2019, the manager contacted an external provider to write the service policies and procedures. However, the requirements from the service did not include key subjects such as mental capacity or lone working.
- Managers did not always have comprehensive systems to evidence that appropriate governance processes were in place. For example, we were told that peer review audits were completed; however, there was no system to document the audits or use the findings to drive service improvements. Furthermore, following our feedback of concerns to the provider, the service did not have an action plan which fully responded to our concerns, included timescales and responsible persons.
- Managers within the service had not completed any mandatory training. We were therefore not assured they have the right knowledge and skills to lead the service.
- Lead roles within the service such as safeguarding, and infection control leads, had not completed the necessary training to fulfil these roles. For example, the safeguarding lead had not completed any safeguarding training since 2011 and the infection control lead had not completed any infection control training.
- The registered manager was visible and approachable. Staff said the manager was friendly and approachable, and they felt confident to discuss any concerns they had with them. They told us the manager frequently supported the team when administrators were absent from work.
- During our inspection, the manager told us they intended to recruit a clinic manager to oversee the day to day running of clinics and improve the leadership of the service.

Vision and strategy

- **The service did not have a documented strategy or values; however, the manager had a vision for development of the service.**
- The service vision was to lead the field in private obstetric, gynaecological and general ultrasound diagnostic screening. The manager intended to expand locations, offering a franchise model, and to expand their services to offer In Vitro Fertilisation (IVF) diagnostics.
- The service did not have a documented strategy or values in place.

- Most staff we spoke with could not describe the vision of the provider. Staff commented they were happy to do their job and were not concerned with the service strategy.

Culture

- **Managers supported staff across the service, however they did not create a sense of common purpose.**
- Staff fed back they felt supported by the manager and their opinions were respected and valued. We observed positive interactions between staff and managers.
- During our inspection, we informed the manager there were areas of the service that required improvement. The registered manager responded positively to this feedback and put some actions in place, demonstrating an open culture of improvement.
- We saw that staff helped with all tasks, such as administrative and reception tasks, to ensure the patients had the best experience they could.
- Not all staff understood what the Duty of Candour (DoC) was, however all staff told us apologies would always be offered to patients and steps were taken to rectify any errors. Staff understood their responsibility to be open and transparent with patients.
- DoC was not cited in the service policies and procedures, so the expectations of staff applying DoC was unclear.
- Staff told us they rarely met with other staff. Staff did not feel a connection with the organisation, however, enjoyed working in the service

Governance

- The **service did not have a systematic approach to improving service quality and safeguarding high standards of care. There was a lack of overarching governance.**

  There were limited formal governance arrangements in place to promote the safety and quality of care. We found there was a reliance on a non-structured approach across the service. However, managers told us they were committed to improving governance within the service and at our follow up inspection on 08 May 2019, we observed actions had been taken. For example, the manager had sourced an audit tool to undertake image quality audits.

- There was no formal process in place for reviewing, updating and ratifying policies and procedures. For example, both the medical records policy and the safeguarding adults' policy had not been formally reviewed since 2010 and were not due for review until 2020. The medical records policy also referenced the Data Protection Act 1998 which had been superseded by the Data Protection Act 2018. There was also no reference to the General Data Protection Requirement (GDPR).
- In addition, the process for publishing policies was unclear and we did not see evidence that staff were made aware of changes when policies were updated. We raised these concerns with the manager following our inspection on 25 April 2019. At our follow up inspection, we saw evidence that managers had identified an external provider to review policies. However, we were not assured that that there was an effective plan with timescales for completion. Furthermore, we were not assured managers had considered the on-going process for reviewing policies and procedures or how they would ensure staff understanding and compliance.
- We found policies and procedures to support staff lacked detail; for example, the safeguarding policy had no local contact details included that were relevant to the service location.
- The service did not demonstrate they had an effective process in place for reviewing clinical protocols. We were not assured all clinical protocols were up to date or reflected current best practice. Scan protocols did not have review dates or references to national guidance. We also did not see evidence of an obstetric scan protocol. Guidance found in the scanning room regarding obstetric measurements (for example, femur length and head circumference) was printed in 2012. This folder also contained guidance from the British Medical Ultrasound Society (BMUS) issued in 2000 and 2003. Furthermore, we did not see evidence of staff being updated when protocols were reviewed. During

our follow up inspection on 08 May 2019, the BMUS guidance and measurement charts had been updated; however, we were not assured there was an effective plan to update the ultrasound protocols.

- Systems for monitoring staff training compliance were not always effective and we did not find evidence that processes were in place to competency assess staff to ensure they had the skills and abilities to fulfil their role. We saw no evidence of a training needs analysis to ensure staff were provided with role specific training. For example, administrative staff were not required to complete information governance training, despite them handling patient sensitive data.
- There was not an effective system for recording, handling, responding to, and learning from complaints. For example, there was limited evidence of complaints being investigated the policy did not outline the process for learning and sharing lessons learnt.
- There were limited processes in place for learning lessons from incidents, complaints and audits. Whilst the registered manager told us any learning would be directed to the individual, we were not assured learning was shared with other staff to improve quality and safety across the service.
- There were limited opportunities for staff to be updated on performance, complaints, incidents, policies, patient feedback and clinical issues. Staff told us they had not met all staff working within the service and had not attended any meetings. Sonographers working within the service did not know each other, limiting opportunities to build professional and supportive relationships.
- The service did not minute meetings that took place between staff. Therefore, we were unable to gain assurance that both quality and sustainability were given sufficient coverage within such meetings, and staff were engaged in improving quality and sustainability across the service.
- Mechanisms for reviewing and improving the quality of the service were limited. There was no audit schedule in place; for example, we did not see evidence of infection control audits or any quality and outcome audits. Whilst the service completed peer review audits, there was no system in place for documenting the audit and the outcomes of the audits. Furthermore, there was no evidence the findings were discussed with staff or service improvements being made. During the inspection it was unclear what the schedule for audits was and who was responsible for them.
- Staff underwent appropriate recruitment checks prior to employment to ensure they had the skills, competence and experience needed for their roles. We reviewed the personnel records for staff and found all required information was available, such as employment reference, disclosure and barring service (DBS) checks, full employment history, evidence of qualifications and professional registration.
- The service level agreements between the service and other external providers were managed by the registered manager.
- The service did not require individual practitioners to hold their own indemnity insurance. All staff working for the service were covered under the provider's insurance.

Managing risks, issues and performance

- **There were not effective systems in place for managing risks, and there was no evidence risks and their mitigating actions were discussed with the team.**
- There was no formalised approach to identify and manage risks within the service. For example, the service did not have a risk register or any action plans or risk assessments to improve the quality and safety of the service. Furthermore, we were not assured managers were aware of the risks within the service. For example, during our inspection, we identified infection control risks due to clinical rooms not having hand washing facilities and carpeted flooring. These risks were not recorded, and we did not find evidence risk assessments were carried out to mitigate any potential risks. We also identified occasions of lone working which had not been identified as a risk. There were no risk assessments in place to safeguard staff who frequently worked alone at the end of the clinics. At our follow-up inspection on 08 May 2019, the

manager advised us they had sourced an external company to write service risk assessments. However, the timescale for this was unclear. It was also not clear how future risks would be identified by the service.

- We asked staff and managers what the main risks were within the service; however, not all staff could confidently explain the main risks for the service and what, if any, mitigation had been put in place.
- The service did not have a business continuity plan in place to outline how the service would deal with situations that could disrupt the service. However, the registered manager could tell us how they would utilise satellite sites in the event one base was not operational.

- There was no formal process in place to demonstrate that the service used patient feedback, complaints and audit results to help identify any necessary improvements needed to ensure they provided a high-quality, effective service. For example, the service received feedback about the length of time patients waited in the service for their scan. The registered manager was aware this was a concern, however, had not put these concerns into an action plan to improve the service and experience for its patients.

Managing information

- **The service did not collect, analyse, manage, and use information well to support all its activities using secure electronic systems with security safeguards.**
- Whilst staff we spoke to were aware of the requirements of managing patients' personal information, the service policies and procedures did not reflect the most up to date legislation. For example, the medical records policy referenced the Data Protection Act 1998 which has been superseded by the Data Protection Act 2018.
- Information governance training was only mandatory for sonographers who were 17% complaint with this training. The registered managers or the administrative staff had not completed information governance training. However, during our follow up inspection on 08 May 2019, we saw evidence that online information governance training had been sourced for all staff to complete. Staff were aware of the requirements of managing a patient's personal information in accordance with relevant legislation and regulations.
- The service collected a limited amount of information to improve performance of the service. Before and during the inspection, we asked for information on numbers of scans, waiting times, cancellations and report turnaround times. This information was not readily available; therefore, we were not assured the service was using information effectively to improve outcomes.
- Staff had access to the information they required to undertake their roles. All staff had access to policies and procedures.

- The service used secure electronic systems with security safeguards to maintain confidential patient information. Ultrasound images for baby scans were saved onto a memory stick so the patient could choose an image in a private room. All images were deleted as soon as the image was printed.

Engagement

- **The service engaged generally well with patients, however engagement was not used systematically to improve the service. There was limited staff engagement.**
- Patient satisfaction surveys were sent automatically to patients to give feedback about their experience within a week of the scan appointment. The manager told us the feedback was monitored monthly using an online feedback platform. However, we did not see evidence that feedback was systematically used to drive service improvements.
- There was evidence on social media feedback sites that managers responded to patient feedback. Where a bad review was received, we did see evidence of further reviews thanking the service for dealing with their concern.
- Staff engagement was limited. Staff fed back they enjoyed working for the service, however did not have many opportunities for team working.

Learning, continuous improvement and innovation

Inadequate

Diagnostic imaging

- **The service did not demonstrate it had a systematic approach to learning from when things went wrong and continuously improving.** For example, image quality peer reviews completed were not documented, shared or used as a measure to improve quality and performance of the service. The service did not have an audit schedule in place or document the completion of any service and quality audits.
- We did not see any examples of innovation.
- The service demonstrated a commitment to improve during and following the inspection. The manager was open to feedback and provided us with assurance on some of the issues raised with them. For example, we raised concerns with staff training requirements and compliance. During our follow up inspection on 08 May 2019, we saw evidence that training had been sourced for staff. However, we were not assured that the service had an action plan in place to ensure continuous improvement would be made in a timely manner.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that allergy information is documented on the patient medical questionnaire before the ultrasound procedure is undertaken. HSCA RA Regulations 2014: Regulation 12 (1) (2) (a) (b) (g) (h) (i) Safe care and treatment.
- The provider must ensure that infection, prevention and control risk assessments are in place to effectively mitigate potential risks in all areas. HSCA RA Regulations 2014: Regulation 12 (1) (2) (a) (b) (g) (h) (i) Safe care and treatment.
- The provider must ensure that there is a documented procedure, that staff are aware of, to deal with emergencies and patient risk. Referral pathways must be in place to ensure staff appropriately respond to concerning ultrasound finings. HSCA RA Regulations 2014: Regulation 12 (1) (2) (a) (b) (g) (h) (i) Safe care and treatment.
- The provider must ensure that complaints' procedures are reviewed and there is an effective process to record, investigate and learn lessons from complaints. HSCA RA Regulations 2014: Regulation 16 (1) (2) Complaints.
- The provider must ensure that all policies and procedures provide staff with clear and timely guidance, are regularly reviewed and reflect national guidance, including scanning policies and procedures. HSCA RA Regulations 2014: Regulation 17 Good Governance (1)(2)(b).
- The provider must review their local governance arrangements to ensure the whole team are informed about performance, complaints, incidents, patient feedback, clinical issues, and audit results in a timely manner. HSCA RA Regulations 2014: Regulation 17 Good Governance (1)(2)(b).
- The provider must ensure there is an effective and documented system in place for managing and monitoring staff compliance with mandatory training, reviewing staff competency, and for implementing an effective clinical audit programme. HSCA RA Regulations 2014: Regulation 17 Good Governance (1)(2)(b).
- The provider must ensure risks to their service are regularly reviewed, and mitigating actions are discussed with the whole team, including lone working. HSCA RA Regulations 2014: Regulation 17 Good Governance (1)(2)(b).
- The provider must ensure there is an effective and documented process to monitor the quality of their scan images, which is representative of the service they provide. HSCA RA Regulations 2014: Regulation 17 Good Governance (1)(2)(b).
- The provider must ensure that all staff have received training specific to their roles and that all leads roles within the service are appropriately trained, including safeguarding and use of chaperones. HSCA RA Regulations 2014: Regulation 18 Staffing 18 (2)(a)(b).
- The provider must ensure staff appraisals and competency assessments are completed, reviewed, updated regularly and documented. HSCA RA Regulations 2014: Regulation 18 Staffing 18 (2)(a)(b).

Action the provider SHOULD take to improve

- The provider should consider implementing a mechanism to communicate with all staff.
- The provider should implement a system to regularly check the temperature of the fridge used to store blood samples and provide guidance to staff outlining actions to take if the temperature goes out of range.
- The provider should review their safeguarding procedures to ensure all staff understand how to escalate safeguarding concerns and know how they can receive further advice and support.
- The provider should review the clinic structure to reduce the time patients are waiting to go in for their scan appointment.

Outstanding practice and areas for improvement

- The provider should improve systems for monitoring service activity and implement a systematic approach for improving the service.
- The provider should consider providing training for staff on how to communicate and care for patients living with dementia, learning difficulties and mental ill health.
- The provider should review their incident reporting procedures to improve oversight and monitoring of incident investigations.
- The provider should ensure bodily fluid spill kits are in place across all sites and staff are trained how to use them.
- The provider should review delays in the running of clinics and implement strategies to reduce the time patients wait for their scan appointment.
- The provider should review the content of the service website to ensure that the content reflects the actual services offered.

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 16 HSCA (RA) Regulations 2014 Receiving and acting on complaints How the regulation was not being met: • The service did not have an effective and accessible system for identifying, receiving, recording, handling and responding to complaints. • There were delays in logging complaints. • It was unclear whether complaints were thoroughly investigated and resolved within acceptable timescales. • The service did not have an effective complaints policy in place. • There was no evidence of lessons being learnt and shared with staff.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance How the regulation was not being met: • Systems and processes were not established and operated effectively. • There was limited evidence that management had an understanding and oversight of governance within the service.

This section is primarily information for the provider

Requirement notices

- There was not an effective system for reviewing and ratifying policies and procedures to ensure they were up to date and in line with national guidance and best practice.
- There was not an effective system in place for managing and monitoring staff compliance with training and to ensure clinical staff were competent to undertake their roles.
- There was limited evidence of audit completion, such as infection control audits, hand hygiene audits and image quality audits.
- The service did not document meetings that took place between staff.
- The service did not have a system in place to assess, monitor and improve the quality and safety of the service.
- The service did not have a formalised process for identifying and mitigating risk. We were not assured the service identified all potential risks.
- The service did not have an effective system in place to act on feedback and outcomes from complaints, incidents or use information to continually evaluate and improve.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 18 HSCA (RA) Regulations 2014 Staffing How the regulation was not being met: • The service did not ensure that staff received appropriate training, professional development, supervision and appraisal as is necessary to enable them to carry out their duties. • The service did not provide mandatory training in key skills to all staff.

This section is primarily information for the provider

Requirement notices

- Staff were not all compliant with safeguarding training and some staff were not trained to the expected level required for their role.
- Clinical staff and managers were not complaint with mandatory training requirements.
- Staff taking blood samples had not completed refresher venepuncture training.
- Staff undertaking leader roles were not trained to support staff.
- Staff undertaking chaperone duties were not provided with training.

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 had not ensured that care and treatment was provided in a safe way for service users.** • Allergy information was not recorded on the patient medical questionnaire. • Not all areas of the service were safe to use for their intended purpose or have appropriate risk assessments in place to mitigate risks. • Hand washing facilities were not available in all clinical areas. These areas had not been risk assessed. • Carpeted flooring at Watford Clinic was not in line with infection, prevention and control best practice and had not been risk assessed. • Clinical fridges where blood samples were stored were not routinely monitored to ensure the temperature did not go out of range. • The service did not have a policy or documented procedure for dealing with emergencies or patient risk.

This section is primarily information for the provider

Requirement notices

- The service did not have documented referral pathways to local healthcare providers for patients where abnormalities were detected during the scan.
- There were no risk assessments or procedures in place to mitigate the risk of staff working alone or in isolation.
- Up to date protocols for ultrasound scan procedures provided by the service were either not in place or reflect national guidance.