Lakeside Medical Diagnostics

Quality Report

C/O Purfleet Care Centre
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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	Requires improvement
Are services safe?	Requires improvement
Are services effective?	
Are services caring?	Good
Are services responsive?	Good
Are services well-led?	Requires improvement

Overall summary

Lakeside Medical Diagnostics is operated by Lakeside Medical Diagnostics Limited. The service has one ultrasound scanning room, an office and a waiting area shared with patients who use other facilities located at the site.

The service has one registered location with additional services provided from three satellite clinics held at NHS community facilities based in Billericay and Waltham Cross.

The service provides diagnostic imaging through the use of ultrasound imaging to NHS patients aged 16 years and over. Modes of ultrasound scanning included but were not limited to; musculoskeletal, upper abdominal ultrasound, urinary tract renal ultrasound, scrotal, transvaginal and vascular ultrasound. We inspected this service using our comprehensive inspection methodology. We carried out an unannounced inspection on 3 December 2018.

Summary of findings

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.

The only service provided was diagnostic imaging.

Services we rate

Our rating of this service was **Requires improvement** overall.

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

- There was a lack of effective systems in place to oversee the governance process.
- There were no effective processes in place to oversee the servicing of ultrasound equipment.
- Equipment maintenance and service records were unorganised. Servicing records where illegible in places.
- We found inconsistencies in the consent process, seven out of the 18 medical care records reviewed did not have written consent.
- We could not gain assurance that risks within the service were regularly reviewed and managed owned by staff.

However, we found good practice in relation to:

- The dedicated clinical room used for the patient scanning was clean, tidy and contained the appropriate resources which were stored correctly.
- Appointments were scheduled to meet the needs and demands of the patients who required these services.
- Staff interactions with patients were supportive and professional.
- The service had direct access to electronic information held by community services, including GPs. This meant that hospital staff could access up-to-date information about patients, for example, details of their current medicine.

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 to help the service improve. We also issued the provider with one requirement notice that affected diagnostic and screening services. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Requires improvement 	Lakeside Medical Diagnostics is operated by Lakeside Medical Diagnostics Limited. The service provides diagnostic imaging services (ultrasound scans) to the local communities in and around the Essex area. The service is registered to provide diagnostic imaging (ultrasound scans) to patients aged 16 years and above. We rated this core service as requires improvement overall because; - There was a lack of effective systems in place to oversee the governance process. There were no effective processes in place to ensure that equipment was maintained and serviced in line with manufacturer recommendations. There was an inconsistent approach to ensuring that consent was in line with the consent policy. There were not effective processes in place to identify and monitor risk.

Summary of findings

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Diagnostic imaging.

Summary of this inspection

Background to Lakeside Medical Diagnostics

Lakeside Medical Diagnostics is operated by Lakeside Medical Diagnostics Limited. The service opened in 2012. It is a diagnostic service located in Purfleet, Essex. The service primarily serves the communities of South Essex through referral from approximately 25 local GP practices.

The hospital has had a registered manager in post since January 2012.

We carried out an unannounced inspection of the service on 3 December 2018. The service had previously been inspected in August 2013 where it was non-compliant with regulations in three areas. In March 2013, the service was compliant with all regulations.

Our inspection team

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

Information about Lakeside Medical Diagnostics

The service is provided from a primary care centre which has one clinical room and is registered to provide the following regulated activities:

- Diagnostic and screening procedures

During the inspection, we visited the service's location in Purfleet, Essex. We spoke with five staff including a registered sonographer, reception staff, and senior managers. We spoke with three patients. During our inspection, we reviewed 18 sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection. The service has been inspected twice before in August 2012 and March 2013.

This report is based on what we found during the unannounced inspection on the 3 December and includes a review of all available evidence during and following the inspections.

Activity (August 2017 to July 2018)

- In the reporting period August 2017 to July 2018 there were 12,160 NHS funded outpatient attendances; between the ages of 16 to 85 years of age.
- The service employed an operational manager, three administrative staff, one chaperone and four dual role administrative staff/ chaperones on a part time basis. The service had access to sonographers employed by NHS trusts that provided regular sessional work.

Track record on safety

- There were no never events
- There were no serious events
- There were no clinical incidents.
- There were four complaints, none were upheld.

Services accredited by a national body:

- The service currently had no accreditations by national bodies.

Services provided under service level agreement:

- Clinical and or non-clinical waste removal
- Grounds Maintenance
- Maintenance of medical equipment

Summary of this inspection

The five questions we ask about services and what we found

We always ask the following five questions of services.

Are services safe?

Requires improvement

We rated safe as **Requires improvement** because:

- The provider did not segregate clinical and non-clinical waste.
- The service did not carry out local audits for hand hygiene or environmental cleanliness.
- We were told that ultrasound equipment was serviced annually. Information provided on the day of inspection and post inspection was not legible, therefore we were not assured of this.

However, we also found the following examples of good practice:

- There was one dedicated clinical room used for the patient scanning which we viewed and found it to be clean, tidy and contained the appropriate resources which were stored correctly.
- The sonographer used the British Medical Ultrasound Society (BMU) and Society of Radiographers (SOR) 'pause and check' checklist which is recommended to be completed prior to an ultrasound scan.
- Staff demonstrated sound knowledge in the cleaning and decontamination of the ultrasound probe.

Are services effective?

We do not rate effective.

- We reviewed policies, procedures and guidelines, which had implementation and review dates.
- The policies referenced guidelines from professional organisations such as the National Institute for Health and Care Excellence (NICE) and the Department of Health (DoH).
- Staff showed us they could easily access policies via the service's electronic system
- The provider had a local audit plan in place. Local audits were completed monthly, quarterly and annually. Areas subject to audit included but were not limited to; reporting standards, adverse incidents, infection and prevention control, patient feedback and waiting times with clear action improvement plans in place.

However we found;

- Of the 18 medical care records reviewed seven did not have written consent which did not meet the consent policy requirements.

Summary of this inspection

Are services caring?

Good

We rated caring as **Good** because:

- We observed staff interactions with patients and found staff were supportive and professional.
- Patient's privacy and dignity were protected by the use of a privacy cover and curtains.
- The service received positive patient feedback with comments such as how kind, efficient and caring staff were.

Are services responsive?

Good

We rated responsiveness as **Good** because:

- The clinical room was suitable and appropriate to meet the needs of the patients.
- Patients could access the service in a timely manner. The service ensured there were appointments available to meet the service needs of the patients.
- Clinics were organised to ensure availability in all locations.
- Patients were sent a text to remind them of their appointment.

Are services well-led?

Requires improvement

We rated well-led as **Requires improvement** because:

- There was a lack of effective systems in place to oversee the governance process.
- There were no effective processes in place to oversee the servicing of ultrasound equipment.
- We could not gain assurance that risks within the service were regularly reviewed and owned by staff.
- The service did not carry out local audits for hand hygiene or environmental cleanliness.
- We found inconsistencies in the consent process, seven out of the 18 medical care records reviewed did not have written consent.
- There was no formal process in place to log or document when encrypted storage devices were in use.

However, we also found the following examples of good practice;

- Leaders were visible, approachable and supportive to staff.
- There was a positive culture amongst all staff. Staff enjoyed working for the service and would recommend it as a place to work.
- The service had a business continuity plan policy which identified risks and responses.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

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

Requires improvement

Diagnostic imaging

Safe	Requires improvement
Effective	
Caring	Good
Responsive	Good
Well-led	Requires improvement

Are diagnostic imaging services safe?

Requires improvement

Mandatory training

- **The service had processes in place to provide staff with training in key skills but did not ensure that everyone completed it.**
- Mandatory training compliance was overseen by the service's business manager.
- Subjects included but were not limited to; health and safety, dementia awareness, basic life support, information governance and infection prevention and control.
- Medical staff, including consultant radiographers and sonographers held substantive posts with NHS trusts and completed mandatory training with their primary employer. The business manager oversaw compliance with mandatory training to ensure all staff were up to date.
- Chaperone and administrative staff completed mandatory training through a variety of methods including e-Learning and face to face.
- Up to August 2018, mandatory training compliance was 88% for administration staff and between 81% and 95% for the clinical staff. Information submitted post inspection demonstrated most outstanding training had been booked.
- However, information submitted post inspection showed three out of the four sonographers had not attended mental capacity training (MCA), nor were there dates booked to attend this outstanding training.

Safeguarding

- **Staff understood how to protect patients from abuse and the service worked well with other agencies to do so.**
- Staff understood how to protect patients from abuse and were aware of their responsibility to safeguard vulnerable adults from abuse. There were clear internal processes to support staff to raise concerns.
- The safeguarding policy contained definitions of abuse, signs of potential abuse, the definition of female genital mutilation (FGM) and it raised the awareness of the government's PREVENT strategy. The aim of the strategy was to provide staff with the knowledge to enable them to be aware of the need to safeguard vulnerable people from being drawn into terrorism or exploited for extremist behaviour. The policy contained up to date contact details for the local authority and clear guidance on the process staff should follow if they suspect abuse or harm. We reviewed the safeguarding policy which referenced national guidance and was dated April 2018 and due for review in April 2019.
- The service had a named safeguarding lead who was trained to level three safeguarding adults and children. We spoke with the lead who was passionate about safeguarding and had previously acted as a

safeguarding champion in a previous role. They demonstrated sound knowledge with regards to the principles of safeguarding and identification of a vulnerable person.

- Safeguarding referral information was displayed in a prominent place with the administration area. This enabled staff to have access to information in a timely manner.
- There had been no reported safeguarding incidents in the reporting period July 2017 to August 2018.
- Staff confirmed that online safeguarding training provided information and guidance on child sexual exploitation and female genital mutilation.
- We reviewed safeguarding training compliance for staff and saw that 100% of staff had completed safeguarding adults, 100% had completed children level two, and 80% compliance of child safeguard training level three. Information submitted post inspection showed that outstanding training had been booked.
- Staff received training in PREVENT. This training is designed to help stop vulnerable people from being exploited and drawn into terrorism.
- The service did not have a chaperone policy, however the patient dignity and respect policy, implemented August 2018 incorporated and defined the role of the chaperone.
- The sonographer used the British Medical Ultrasound Society (BMU) and Society of Radiographers (SOR) 'pause and check' checklist which is recommended to be completed prior to an ultrasound scan.

Cleanliness, infection control and hygiene

- **The service had some processes in place to prevent and control the spread of infection.**
- During our inspection, we observed most staff had arms bare below the elbow. However, we observed clinical staff with nail vanish during clinical practice which was against clinical guidance.
- Hand washing posters were in appropriate areas demonstrating the World Health Organisation's '5 Moments for Hand Hygiene' (revised August 2009). We saw staff using the hand sanitising gel correctly, in line with the World Health Organisations 'five moments of hand hygiene' before touching a patient, before clean/aseptic procedures, after body fluid exposure/risk, after touching a patient, and after touching patient surroundings. These guidelines are for all staff working in healthcare environments and define the key moments when staff should be performing hand hygiene to reduce risk of cross contamination between patients.
- Staff told us that they did not carry out local audits for hand hygiene or environmental cleanliness. Therefore, we could not gain assurance that staff were adhering to best practice with regards to infection prevention and control.
- We asked staff what precautions were in place to manage patients with suspected communicable diseases, although there were no formal processes in place staff were able to describe to us how they would manage this.
- There was no segregation of hazardous and non-hazardous waste. All waste was placed in the clinical waste bins.
- All areas we inspected were clean and free from visible dirt. Cleaning was carried out by the service responsible for maintaining the building. Staff used a daily checklist to ensure that all relevant areas were clean and ready to provide episodes of patient care.

  Staff had completed training which included infection, prevention and control training as part of the electronic learning package. Infection control awareness compliance for all staff was 100%.
- Personal protective equipment (PPE) such as disposable gloves and aprons were readily available for staff to use.
- Examination couches, chairs and pillows had wipeable covers to enable effective cleaning. Disinfectant wipes were available at regular intervals throughout the service.
- In line with manufactures instructions staff demonstrated sound knowledge in the cleaning and decontamination of the ultrasound probe.

- We checked the disposable privacy curtains which were visibly clean and dated as last changed in August 2018. Staff confirmed the curtains were changed every six months or immediately replaced when soiled or dirty.
- The service had a service level agreement with a third party for the management and removal of clinical and non-clinical waste.

Environment and equipment

- **The service had suitable clinical premises but the office area was cramped and did not meet the needs of the staff. We were not assured that the service maintained equipment in line with manufactures guidance.**
- The service did not have an effective process in place to ensure that equipment was serviced and maintained in line with the manufacturer's guidance. We saw equipment maintenance and service records that were disorganised, not fully itemised, and not maintained. There was no completed inventory held for equipment.
- We were told that ultrasound equipment was serviced annually. Information provided on the day of inspection and post inspection was illegible, therefore we were not assured of this.
- The business manager told us whilst there was no contract in place for equipment servicing, the company were responsive to requests and attended call out and requests for support in a timely manner. One of the ultrasound machines had been serviced June 2018, however this was not a planned service, the machine had developed a fault, whilst the engineer attended to this they also serviced the machine. We could not however gain assurance that servicing and equipment maintenance was carried out in line with manufacturer's recommendations.
- Staff ensured that alternative ultrasound equipment was available in the event of static machine breakdown through the provision of portable ultrasound machines, located on site.
- We viewed the office area which appeared cramped and confined. Staff stated that the working environment was compact. We discussed this with the senior team who acknowledged this was an area that caused concerned and they were actively looking to relocate the administration office.
- Patients attending for ultrasound appointments shared the waiting area with patients attending for other appointments. The area was well lit, visibly clean with wipe clean chairs.
- The clinical room was secured by a lock and in an area of the centre that was away from the main reception and waiting area. Disposable curtains were around the couch area and used to protect the patient's dignity and privacy.
- We reviewed eight pieces of electrical equipment, monitors, printers, fax machines and cables all had been checked with attached electrical safety labels dated April 2017, which met the Health and Safety Executive (HSE) standard. The standard states that all portable appliance testing (PAT) of IT equipment should take place every 24 to 48 months.

Assessing and responding to patient risk

- **Staff completed and updated risk assessments for each patient.**
- The service had an exclusion criterion in place. This ensured that only patients who were safe to attend the service could do so.
- The service did not have resuscitation equipment in any of the clinical areas, although in some of the areas where clinics were held, there was access to defibrillators which were provided by a third party. The service had a process in place for the management of patients who suddenly became unwell during their procedure. In the event of a cardiac arrest, staff called 999 for an ambulance. Staff were trained in basic life support (BLS) and would put their training into use until the ambulance arrived. BLS compliance for employed staff was 100%, however two out of the three sonographers BLS training had expired. We highlighted our concern to the registered manager who spoke to the sonographers, they confirmed that they had updated their training, we asked for the certificate to be sent with any requested additional information. Information submitted post inspection

confirmed both had completed BLS training, one in September and one in November 2018. We viewed the resuscitation policy which had an implementation date February 2018 with the review date January 2019.

- The service had a qualified first aider. In addition, staff could access help from the GP team, located at the premises.
- We reviewed 18 sets of patient medical records and noted for patients who underwent a transvaginal ultrasound scan (TVS) a non-latex cover was used to cover the ultrasound probe. We were told this was a precautionary measure as not all patients knew if they were allergic to latex.
- The service had clear procedures in place to guide staff on what actions to take if any abnormal findings were found on an ultrasound scan.
- The service was aware of the British Medical Ultrasound Society and Society of Radiographers 'pause and check' checklist which is recommended to be completed prior to an ultrasound scan. This is a series of safety checks such as patient name, date of birth and the correct site to ensure the patient details are correct prior to the procedure.
- On the day of our inspection we saw sonographers consistently used the pause and check checklist prior to scanning taking place.

Staffing

- **The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and to provide the right care and treatment.**
- The service employed an operational manager, business manager, and seven-part time dual role administrative/chaperone staff. The service had access to sonographers employed by NHS trusts that provided regular sessional work.
- The service used an electronic rota to ensure the clinics had the appropriate staff with the right skills. All clinics had a sonographer and a chaperone.
- In addition to sonographers, the service had the support and input from three consultant radiologists who provided senior clinical review of the ultrasound scans and feedback on quality of reporting and accuracy.
- Information provided prior to the inspection indicated the service had no vacancies.
- We reviewed employee files, all files contained Disclosure and Barring (DBS) checks, references, training and appraisals.
- The service did not use agency staff. Staff told us working part time gave them flexibility and they were able to cover annual leave and absences from work due to staff being unwell.
- The service did not have episodes of lone working for staff. Clinic's had set minimum staffing levels of one sonographer and chaperone, in addition to administrative staff.

Records

- **Staff kept detailed records of patients' care and treatment.**
- All requests for ultrasound examinations came direct from the patient's GP. The clinician completing the scan composed a report of findings which was sent either by email, or fax to the referral requester.
- We reviewed 18 ultrasound reports for patients who had used the service in November 2018.
- All reports had the relevant patient information, referrer details and NHS numbers however, in two records, it did not state if the ultrasound request was routine (within three weeks) or urgent (within two weeks).
- We raised our concerns with the registered manager who advised this was an issue with the referring GPs but they were working with them to address this concern through the GP forums.
- At clinics located away from the main centre, ultrasound reports were typed saved to an encrypted storage device and sent to the referring GP via a secure NHS email address.
- There was no formal process in place to log or document when encrypted storage devices (USB

sticks) were in use. The registered manager told us that a visual check was performed each day to ensure all devices were accounted for. We saw that the devices were stored in a locked drawer at the service. However, loss of the device could potentially be a concern due to the confidential information held on the device.

- We reviewed the recently implemented records policy with a review date August 2020. The policy contained concise details on storage, retention times and disposal of records. However, the encrypted storage devices were not included in the policy.
- Medical records/ultrasound reports were kept for a minimum of eight years. The service had access to medical records storage facilities and we saw that all areas were secure, with restrictive access measures in place.

Medicines

- The location did not order, store or use controlled drugs.
- The location did not have any non-medical prescribers within the organisation and did not use any patient group directives (PGDs).

Incidents

- **The service had some processes in place to manage patient safety incidents.**
- Incident reporting was paper based with a form named 'Incident form/Significant event form'. The service's business manager advised that staff completed forms then submitted them to the administrative office for review and completion of investigations if required.
- Staff had access to a policy named 'serious incident management and reporting'. The document had been reviewed in April 2018. However, the incident reporting form contained within the policy was inconsistent with the example shown to inspectors during the inspection.
- We spoke with two members of staff who told us incidents very rarely happened. When asked, one member of staff was unaware of the incident reporting form in use.
- There were no never events reported for the service from August 2017 to July 2018. Never events are serious incidents that are entirely preventable as guidance, or safety recommendations providing strong systemic protective barriers, are available at a national level, and should have been implemented by all healthcare providers.
- There were no serious incidents reported for the service from August 2017 to July 2018. Serious incidents are events in health care where there is potential for learning or the consequences are so significant that they warrant using additional resources to mount a comprehensive response.
- There were no reported clinical incidents from August 2017 to July 2018.
- Due to no reported clinical incidents taking place in the 12 months prior to our inspection, we were unable to gain assurance that effective investigations or root cause analysis took place.
- The service reported no incidents meeting the requirements of duty of candour from August 2017 to July 2018. Duty of candour (DoC) is a regulatory duty under the Health and Social Care Act (Regulated Activities Regulations) 2014 which states 'As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must notify the relevant person that the incident has occurred, provide reasonable support to the relevant person in relation to the incident and offer an apology'. The duty of candour regulation only applies to incidents where severe or moderate harm to a patient has occurred.
- We spoke with two members of staff about the duty of candour. Neither staff members were able to tell us what the term duty of candour meant.
- The service's business manager maintained an incident log. We reviewed the incident log which detailed complaints received in the last 12 months, along with an incident where telephone lines failed and a patient could not locate the service.

Requires improvement

Diagnostic imaging

Are diagnostic imaging services effective?

We do not rate effective in diagnostic imaging.

Evidence-based care and treatment

- **The service provided care and treatment based on national guidance and evidence of its effectiveness**.
- We reviewed policies, procedures and guidelines information, which referenced guidance from professional organisations such as National Institute for Health and Care Excellence (NICE) and the Department of Health (DoH).
- Staff easily accessed policies via the service's electronic system.
- The provider had a local audit plan with audits identified. Local audits were completed monthly, quarterly and annually. Topics audited but were not limited too were reporting standards, adverse incidents, infection and prevention control, patient feedback and waiting times.

Nutrition and hydration

- **Staff gave patients enough food and drink to meet their needs and improve their health.**
- Due to the nature of service provided and transient time spent in clinic, the service did not routinely offer food. However, water, hot drinks and biscuits if required could be provided to patients.

Pain relief

- **Staff assessed and monitored patients regularly to see if they were in pain.**
- Staff told us that they would ask patients if they were comfortable during the procedure but no recognised pain assessments took place as the procedures were usually pain free.
- We saw staff checking patient comfort during scanning process to ensure they were pain free.

Patient outcomes

- **Managers monitored the effectiveness of care and treatment and used the findings to improve them.**
- The service monitored patients who did not attend (DNA). From April 2018 to July 2018, 4% of patients' DNA'd, below the providers threshold of less than 5%. Staff told us they would contact the patient to find out why they were unable to attend and offer the patient a further appointment. If the patient did not attend on the second appointment a letter would be sent to the patient and the service would inform the patients GP of the non-attendance.
- All sonographers underwent regular peer review audits. These retrospective audits reviewed the quality of the ultrasound scans produced and the quality of the reports produced by sonographers.
- Patients were given a satisfaction survey to complete after their treatment with questions related to the quality of the service, the clinic locations, staff attitudes, any appointment delays and whether they would recommend the service. The information was collated and presented at monthly meetings. This formed an integral part of the key performance indicators (KPIs) the provider had to present to the commissioners of the service monthly. Information submitted on the monthly patient feedback audits for May 2018 to July 2018 showed 83% of patients would recommend the service, however a further 7% were unlikely to recommend the service. The service was unable to follow this up as the forms were anonymised. On the day of the inspection we reviewed 10 patient satisfaction survey returns, all 10 recommended the service.

Competent staff

- **We were not assured that the service made sure staff were competent for their roles.**
- The business manager had an annual appraisal facilitated by a consultant within the service. All other chaperone and administrative staff received an annual induction with the business manager.
- We reviewed appraisal records which demonstrated 100% of staff had received an appraisal in the 12 months prior to our inspection.

Requires improvement

Diagnostic imaging

- Two out of the four sonographers were advanced practitioners and all of the sonographers were registered with a professional body the Society of Radiographers (SOR) or the Health and Care Professions Council (HCPC).
- Sonographers were employed on a sessional basis as they worked in the surrounding NHS trusts where training and continuous professional development took place. Information submitted by the service stated the service held copies of the training certificates for the sonographers used by the service which we saw in staff files.
- We were told validation of the sonographers took place informally but that there was no formal process in place to oversee the sonographers' validation. Revalidation is a process where medical practitioners, nurses and midwives practicing in the UK are subject to prove their skills are up-to-date and they remain fit to practise. It is intended to reassure patients, employers and other professionals, and to contribute to improving patient care and safety.
- Two members of staff told us how the senior management team had supported their professional development. One member of staff had secured a new role with promotion and another member of staff had secured funding from the service to continue with post graduate training.

Multidisciplinary working

- **Staff of different kinds worked together as a team to benefit patients.**
- We were told that all staff members on all levels worked well with each other to ensure patients had a positive experience at the service. Staff told us if there were any shortages of staff in any areas, other members of the team would help.
- The service had direct access to electronic information held by community services, including GPs. This meant that the service staff could access up-to-date information about patients, for example, details of their current medicine.
- External stakeholder feedback about staff from the service was positive.
- Reports were communicated to the GP via an electronic system, for GP's who did not have this in place reports were scanned and sent via a secure NHS email. Ultrasound images were also uploaded on to an electronic system which could be accessed by NHS healthcare professionals to identifying correct treatment decisions.

Seven-day services

- The centre was open six days a week, Monday to Saturday.
- To meet additional capacity, we were told the service would offer appointments on Sundays, if required. The service's director told us that Sunday clinics were very popular as they provide flexibility to patients.

Health promotion

- As services were held at primary care centres, patients had access to a wide variety of health promotion leaflets included but not limited to, diabetes, high blood pressure, heart disease and diet.

Consent and Mental Capacity Act

- **We were not assured that staff understood how and when to assess whether a patient had the capacity to make decisions about their care.**
- Information submitted post inspection showed three out of the four sonographers had not attended Mental Capacity Training (MCA,2005).
- The service had recently implemented a consent policy (August 2018). The policy referenced the Mental Capacity Act (MCA) 2005 and provided guidance for staff regarding processes for assessing capacity and obtaining consent in adults, however the policy did not reference the consent process for children. In the reporting period July 2017 to August 2018, there were 44 outpatient attendances of young people between the ages of 16 to 18 years of age.
- We were told that all sonographers worked at NHS trusts, where consent training was included.
- We observed an explanation and written consent taken from a patient undergoing a transvaginal ultrasound scan (TVS) which provided some assurance that staff understood the concept of the consent process.

Requires improvement

Diagnostic imaging

- However out of the 18 medical care records reviewed seven did not have written consent which did not meet the consent policy requirements.
- We raised our concerns with the registered manager who told us they would raise this with the clinical staff.

Are diagnostic imaging services caring?

Good

We rated caring as **good.**

Compassionate care

- **Staff cared for patients with compassion.**
- We observed the administrative team answering calls and queries from patients in a polite manner.
- We observed a number of episodes of patient care during our inspection. We noted how a patient's privacy and dignity were maintained, particularly when intimate ultrasound scans were required. Staff used a privacy sheet and curtains to maintain patient dignity and scans were carried out in rooms with doors locked.
- Staff ensured that chaperones were always available and that all patients could request examinations to be carried out by a member of staff who was the same sex.
- We saw that staff introduced themselves when greeting patients and all staff spoke with patients in a kind and considerate manner.
- A quality report undertaken by an external stakeholder 5 May 2018 found both clinical and administration staff to be polite and treated patients with respect. Administration staff took time to explain to patients the kind of preparation that was required prior to the ultrasound scan and the clinical staff took time to explain what the procedures were and ensured that patients were as comfortable and relaxed as possible.
- Patient feedback from satisfaction surveys were generally positive with comments including; 'I wouldn't change anything', 'lovely service' and 'perfect'.

Emotional support

- **Staff provided emotional support to patients to minimise their distress.**
- We spoke to three patients who found staff to be friendly, supportive, very reassuring and very kind'. One patient spoke of how respectful and efficient the service had been.
- One patient described how supportive the staff had been, explaining the process and procedure as the patient was undergoing a transvaginal scan (TVS) she had found this very helpful.

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.**
- We observed that staff answered patients' questions appropriately, and in a way, they could understand.

Are diagnostic imaging services responsive?

Good

We rated responsive as **good.**

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.**
- Facilities and premises were appropriate for the service that was delivered.
- Clinical commissioning groups (CCG's) and the senior management team were involved in the planning of the service. Services were delivered at primary healthcare facilities which meant services were provided to local people in their local setting negating the need to travel considerable distances for an ultrasound scan. We observed the appointment teams checking with the patient that they were able to attend the clinic.
- As the clinics were based in primary healthcare services car parking facilities at these locations were free for patients to use.

- The service was located on a local bus route for ease of patient access.
- The service offered a range of appointment times, days and locations to meet the needs of the patients who required the service.
- Female patients were offered the choice of a female sonographer, particularly for internal scans and male patients were offered the choice of a male sonographer if the scan involved male genitalia.

Meeting people's individual needs

- **The service took account of patients' individual needs.**
- Staff received online training in dementia awareness and learning disabilities. At the time of our inspection 92% of staff had completed this training.
- Telephone translation service information was displayed within administrative areas of the service. However, we spoke with one member of staff who did not know this service was available.
- Patients who were hard of hearing and required access to hearing loops would have appointments booked into satellite clinics that had the facility.
- Two of the clinics were based on the ground floor and two on the first floor with a lift, all locations were able to accommodate wheelchair access.
- The service had a clear exclusion criterion which included a comprehensive list of who they were unable to include non- ambulant, persons with complex needs, persons unable to give verbal consent, persons with learning disabilities, those under 16 years old, service users who require an image guided biopsy, non- NHS patients and patients requiring ophthalmology scanning.

Access and flow

- **People could access the service when they needed it.**
- Access to the service was monitored daily through key performance indicator (KPI) monitoring in conjunction with the local clinical commission group (CCG).
- Referrals were received from GP's by e-referral, email, choose and book and fax. We were told that referral by fax was discouraged and more practices used a secure NHS email address. For assurance, when results were faxed to GP Practices a confirm receipt would be requested.
- Patients awaiting ultrasound examination were classed as either routine or urgent, specified by the referring clinician. The service aimed to offer routine appointments within three weeks and urgent appointments within two weeks.
- To meet contractual requirements the service was expected to meet quality performance indicators around waiting times for routine scans of three weeks. The percentage of patients seen within two weeks of the initial referral met the 75% threshold. Data provided from April 2018 to July 2018 showed that between 79% and 80% of patients were seen within two weeks of the referral and 100% were seen within three weeks.
- Waiting times for urgent ultrasound scans were between one to two weeks. Data provided from April 2018 to July 2018 demonstrated that 100% of patients were seen within two weeks.
- From August 2017 to July 2018 the service cancelled one clinic. The access road to the clinic was closed due to a car accident and the sonographer was unable to attend. The manager told us that an additional clinic was booked for the following day to accommodate the patients who had been cancelled.
- Our review of 18 medical records showed that 11 patients had been seen within the contractual target timeframe according to the urgency of the request. Six patients were not seen within the recommended timeframe but within the NHS timeframe of six weeks and one patient record did not include date of referral. We were told this was due to patient commitments and choice.

Learning from complaints and concerns

- **The service treated concerns and complaints seriously, investigated them and learned lessons from the results, and shared these with all staff.**
- The service had received four complaints in the 12 months prior to our inspection.

Requires improvement

Diagnostic imaging

- There were no specific themes in complaints, however two had related to the failure of telephone lines within the service and one related to staff attitude. We saw that the service had responded in a timely manner, to these informal complaints offering an apology to patients and purchased a mobile phone to ensure patients and referring clinicians had a method of contact with the service.
- The service's website contained information on how a patient could raise any concerns in addition to a feedback box located in a visible area within the waiting room.
- The service had a complaints policy. The document contained information for staff on the handling of complaints, including response timeframes. The policy had been reviewed in April 2018.
- Complaints were discussed at monthly clinical governance meetings as a standard agenda item.
- Complaints were monitored through key performance indicators' (KPI's) monitoring in conjunction with the local clinical commission group (CCG).

Are diagnostic imaging services well-led?

Requires improvement

We rated well-led as **requires improvement.**

Leadership

- **We could not gain assurances that managers at all levels in the service had the right skills and abilities to run a service providing high-quality sustainable care.**
- This was a small service, the registered manager and nominated individual made up the leadership team supported by two senior consultants who undertook the roles of clinical lead and business manager.
- Although the team were passionate about the service provided, we found there was a lack of skills and knowledge to effectively lead the service as identified in the safe part of this report.
- Staff we spoke with told us that the leaders were visible, accessible, approachable and supportive.

Vision and strategy

- **The service had a vision for what it wanted to achieve and workable plans to turn it into action, which it developed with staff, patients, and local community groups.**
- The service had a clear vision to offer a value based service to meet the needs of the patients. The strategy for the service showed that it aimed to continue to grow and offer a comprehensive quality assured ultrasound scanning service to a wider range of patients.
- The provider had recently appointed a medical director to develop the service and introduce a 'one stop clinic'. A one stop clinic would provide patients with a same day service.
- The provider would like to expand the service to include domiciliary visits to the vulnerable and elderly in the local communities.
- The service wanted to explore the provision of late evening clinics but acknowledged staff work life balance must be considered.

Culture

- **Managers across the service promoted a positive culture that supported and valued staff, creating a sense of common purpose based on shared values.**
- All staff we spoke with told us they felt respected and valued by their managers and colleagues. Many of the staff had worked for the service for a number of years and were part of an established team. Staff told the inspectors that they were able to approach any members of the senior team for help and advice.
- Staff told us that they delivered high quality care and that they would recommend the service to their families and friends.

Governance

- **We were not assured that the service systematically improved service quality and safeguarded high standards of care by creating an environment for excellent clinical care to flourish.**

Requires improvement

Diagnostic imaging

- We were told that each member of staff had their own memory stick to use with the relevant templates with patient identifiable data on. These were locked away in a secure box and placed within a locked cupboard, they were visually checked at the end of each day. However, there was no formal process in place to log or document when encrypted storage devices were in use. This meant that in the event of loss, no audit trail was in place to determine the last known location for the encrypted storage device.
- We were told that clinical governance meetings took place monthly with a standardised agenda in place. Items included, but were not limited to; audit cycles, scanning protocol reviews, patient feedback, clinical peer review and guidance update from The Royal College of Radiologists.
- We reviewed previous meetings minutes however, these were limited in content. Whilst a broad range of staff attended clinical governance meetings, there was a lack of minuted discussion to provide assurance that relevant areas had been covered.

Managing risks, issues and performance

- **The service had limited systems and processes in place to identify risks, plan to eliminate or reduce them, and cope with both the expected and unexpected.**
- The service had introduced a risk register approximately 12 months prior to our inspection. Our review of the risk register showed that whilst most applicable risks had been identified, there were no regular review of risks nor were there any documented actions taken to mitigate risks the service may face.
- We raised our concerns with the service's business manager and director. They agreed that the documentation of risk was an area where the service could make improvements.
- The service had a business continuity plan policy with identified risks and responses. Risks included but were not limited to evacuation of the building, loss of computer systems, loss of power, gas supply and water supplies. The policy had an implementation and a review date April 2020.

Managing information

- **The service collected, analysed, managed and used information well to support all its activities, using secure electronic systems with security safeguards.**
- The service had checked systems and processes were in place for their compliance with the General Data Protection Regulation (GDPR) introduced from May 2018. The General Data Protection Regulation (GDPR) is a legal framework that sets guidelines for the collection and processing of personal information of individuals within the European Union (EU).
- To meet contractual requirements the service collated, analysed and used information to meet a number of quality performance indicators around waiting times for routine and urgent scans. patients who did not attend (DNA) and patient feedback.

Engagement

- **The service engaged well with patients, staff, the public and local organisations to plan and manage appropriate services, and collaborated with partner organisations effectively.**
- We were told quarterly team meetings were held., We reviewed previous meetings minutes however, there was a lack of minuted discussion to provide assurance that relevant areas had been covered.
- The service sent a satisfaction survey to GP's, however we were told that very few were returned.
- The service was passionate about patient engagement and achieved regular feedback through a variety of methods, local community services and a public website
- Patient satisfaction surveys were reviewed monthly the service also received feedback from a local patient participation group.
- We saw examples of where change had taken place as a direct result of patient feedback. clinic availability and opening hours had been altered to suit the needs of patients.

Learning, continuous improvement and innovation

- **The service was committed to improving services by learning from when things went well or wrong, promoting training, research and innovation.**

Requires improvement

Diagnostic imaging

- Commissioners of the service met with the provider quarterly to discuss the quality performance indicators where quality improvements were discussed.
- Two employees told us how the senior team had supported their professional development and the outcome of this. One employee had secured a new role with promotion whilst the other employee had been funded through some post graduate training.
- However due to no reported clinical incidents taking place in the 12 months prior to our inspection, we were unable to gain assurance that effective investigations or root cause analysis took place.

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:

- The provider must ensure that risks to patients are identified, assessed and monitored consistently.
- The provider must take prompt action to address a number of concerns identified during the inspection in relation to the governance of the service.
- The provider must ensure that all equipment maintenance and service records are fully itemised, organised and maintained.

Action the provider SHOULD take to improve

Action the provider SHOULD take to improve

- The provider should ensure that there is a consistent consent process.

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 17 HSCA (RA) Regulations 2014 Good governance Regulation 17 HSCA (RA) Regulations 2014 Good governance. 17 (1) Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part. 17 (2)(b) assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the regulated activity. 17 (2)(f) evaluate and improve their practice in respect **of** the processing of the information referred to in sub-paragraph (a) to (e).