Clinical Diagnostix Ltd

Quality Report

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

Overall summary

Clinical Diagnostix Ltd has been established for approximately 10 years. Services provided include; mobile echocardiography (echo), ambulatory electrocardiogram (ECG), ambulatory blood pressure (BP) monitoring and, exercise tolerance testing to NHS and private patients in the community or hospital settings. Echocardiography uses ultrasound to visualise the moving heart, great vessels and valves and can include doppler (a specialist instrument) to establish blood flow. The procedure lasts approximately 30 minutes is pain free and delivered in a clinic setting. Ambulatory ECG is used to determine rhythm abnormalities. Ambulatory BP monitoring is useful in establishing white coat hypertension and exercise tolerance testing demonstrates what happens when a patient's heart is put under stress. White coat hypertension is a syndrome whereby a patient's feeling of anxiety in a medical environment results in an abnormally high reading when their blood pressure is measured.

Summary of findings

The service sees adults and children from the age of 16 years although the number of 16 to 18-year olds is very low (five in the reporting period August 2017 to August 2018) .

We inspected this service using our comprehensive inspection methodology and diagnostic imaging framework. We carried out the announced part of the inspection on 2 October 2018.

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. We do not rate effective for diagnostic imaging services.

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

Services we rate

This was the first time we rated this service. We rated it as Good overall.

We found the following areas of good practice:

- Good induction processes were in place for new staff, 100% of staff had attended annual mandatory training updates.
- Staff had the appropriate level of safeguarding training and checks were in place to protect vulnerable persons.
- Reliable systems were in place to prevent and protect people from health care acquired infections.
- The environment and equipment used was appropriate to deliver the service.
- Staff could recognise when a patient had an urgent medical condition and systems were in place to refer to urgent medical services.
- There were adequate staff levels to deliver safe care to patients and meet current demand.
- Patient information was managed in a way that kept people protected from avoidable harmand records were stored securely.
- Staff could recognise and report incidents. An incident management policy was in place and incident reporting forms were carried by staff.
- The service adhered to evidence based guidance for echocardiogram, ambulatory blood pressure (BP) monitoring, ambulatory electrocardiograph (ECG) and exercise tolerance test.
- Ten percent of all echocardiogram reports and images per month were audited by an external auditor.
- Staff had the skills, knowledge and expertise to deliver an effective service.
- Staff liaised with other health care professionals involved in the care of the patient.
- Staff understood the principles of consent and the Mental Capacity Act.
- We observed staff treating patients with kindness and compassion, 100% of patients in the most recent patient survey said they were given all the privacy they needed during the test.
- Patients described being 'put at ease', 'made to feel relaxed' and one patient said they felt apprehensive but staff helped them to relax and reduced their anxiety.
- Patients and those close to them were given adequate information about the test, knew what to do next and when the test results would be available.
- The service was delivered in locations which met the needs of individuals and appointment times were flexible.
- All locations had good wheelchair access and interpreting services could be arranged with commissioners if required.
- Waiting lists were short and met key performance indicator standards, clinics ran on time.
- Report were sent to the referring clinician within two working days.

Summary of findings

- Leaders had the capability and capacity to manage the service. They could articulate the challenges faced but also, due to its compact size, respond quickly to patient and commissioner feedback.
- There was a culture of openness and honesty which was demonstrated during our inspection. Staff felt valued and supported.
- The directors held governance meetings regularly, service level agreements and contract meetings were held with commissioners which meant the service was reviewed regularly.
- The service had a clear business continuity plan in place which described the action that would be taken in the event of a major incident or business disruption.
- Information was managed securely and in line with relevant regulation.
- The provider actively sought feedback from patients via an annual patient survey. The last patient survey was overwhelmingly positive in all aspects.

However, we also found the following areas for improvement:

- The provider did not undertake hand hygiene audits.
- There was no service schedule for the ambulatory blood pressure machine.
- Four out of seven staff had not had a formal appraisal meeting with their line manager.
- The provider did not have a duty of candour policy, and duty of candour was not reflected in the incident or complaints policies.
- Staff meetings were not taking place.
- There was no formal risk register in place.

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 one requirement notice. Details are at the end of the report.

Amanda Stanford

Deputy Chief Inspector of Hospitals (Central)

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Good 	We rated this service as good overall because it was safe, caring, responsive and well led.

Summary of findings

Contents

Good

Clinical Diagnostix

Services we looked at
Diagnostic imaging

Summary of this inspection

Background to Clinical Diagnostix Ltd

Clinical Diagnostix Ltd is operated by Clinical Diagnostix Ltd an independent provider established approximately 10 years. The company has an office base on the outskirts of Derby. The service primarily covers the communities of the East Midlands but, does accept patient referrals from outside this area. The service sees adults and children over the age of 16 years, private and NHS patients.

The service has had a registered manager in post since 2010.

The service offers a number of cardiorespiratory diagnostic procedures including echocardiography, ambulatory ECG, exercise ECG and ambulatory BP.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and was overseen by Carolyn Jenkinson, Head of Hospital Inspection.

Information about Clinical Diagnostix Ltd

The company is led by three directors who are clinical physiologists, and there are four additional clinical physiologists. Although the company has an office base just outside Derby the service is largely managed remotely. The service is mobile using portable ultra-sound equipment, sees private patients usually in private hospital settings and NHS patients usually in GP practices. Currently the service operates from 12 locations.

During this inspection we visited the service being delivered from a local private hospital.

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures

We spoke with two clinical physiologists, two patients and one relative. We received 33 'tell us about your care' comment cards, which patients had completed prior to our 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. The service had been inspected once in December 2013, when it was found that the service was meeting all standards of quality and safety it was inspected against.

Activity (August 2017 to August 2018)

- In the reporting period August 2017 to August 2018 there were 3921echocardiograms perfomed.
- Track record on safety
- Zero never events, clinical incidents or serious injuries in the reporting period.
- No incidences of health care acquired infections.
- No complaints

Services accredited by a national body:

- British Society of Echocardiography accreditation December 2014

Services provided under service level agreement:

- Information Technology support
- Equipment maintenance
- External auditor
- Consultant Cardiologist

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?

Are services safe?

Good

We rated safe as good because:

- Good induction processes were in place for new staff, 100% of staff had attended annual mandatory training updates.
- Staff had the appropriate level of safeguarding training and checks were in place to protect vulnerable persons.
- Reliable systems were in use to prevent and protect people from health care acquired infections.
- The environment and equipment used was appropriate to deliver the service.
- Staff could recognise when a patient had an urgent medical condition and systems were in place to refer to urgent medical services.
- There were adequate staff levels to deliver safe care to patients and meet current demand.
- Patient information was managed in a way that kept people safe and records were stored securely.
- Staff could recognise and report incidents. An incident management policy was in place and incident reporting forms were carried by staff.

However, we found the following issues that the service provider needs to improve:

- The provider did not undertake hand hygiene audits.
- There was no service schedule for the ambulatory blood pressure machine.

Are services effective?

Are services effective?

Not sufficient evidence to rate

We do not rate effective:

- The service adhered to evidence based guidance for echocardiogram, ambulatory blood pressure (BP) monitoring, ambulatory electrocardiograph (ECG) and exercise tolerance test.
- 10% of all echocardiogram reports and images per month were audited by an external auditor.
- Staff had the skills, knowledge and expertise to deliver an effective service.
- Staff liaised with other health care professionals involved in the care of the patient.

Summary of this inspection

- Staff understood the principles of consent and the Mental Capacity Act.

However, we found the following issue which the service provider needed to improve:

- Four out of seven staff had not had a formal appraisal meeting with their line manager.

Are services caring?

Are services caring?

Good

We rated caring as good because:

- We observed staff treating patients with kindness and compassion, 100% of patients in the most recent patient survey said they were given all the privacy they needed during the test.
- Patients described being 'put at ease', 'made to feel relaxed' and one patient said they felt apprehensive but staff helped them to relax and reduced their anxiety.
- Patients and those close to them were given adequate information about the test, knew what to do next and when the test results would be available.

Are services responsive?

Are services responsive?

Good

We rated responsive as good because:

- The service was delivered in locations which met the needs of individuals and appointment times were flexible.
- All locations had good wheelchair access and interpreting services could be arranged with commissioners if required.
- Waiting lists were short and met key performance indicator standards, clinics ran on time.
- Report were sent to the referring clinician within two working days.

Are services well-led?

Requires improvement

We rated well-led as requires improvement because:

- The provider did not have a duty of candour policy, and duty of candour was not reflected in the incident or complaints policies.
- Staff meetings were not taking place.
- There was no formal risk register in place.

However, we found the following areas of good practice:

Summary of this inspection

- Leaders had the capability and capacity to manage the service. They could articulate the challenges faced but also, due to its compact size, respond quickly to patient and commissioner feedback.
- There was a culture of openness and honesty which was demonstrated during our inspection. Staff felt valued and supported.
- The directors held governance meetings regularly, service level agreements and contract meetings were held with commissioners, which meant the service was reviewed regularly.
- The service had a clear business continuity plan which described the action that would be taken in the event of a major incident or business disruption.
- Information was managed securely and in line with relevant regulation.
- The provider actively sought feedback from patients via an annual patient survey. The last patient survey was overwhelmingly positive in all aspects.

Good

Diagnostic imaging

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

Are diagnostic imaging services safe?

Good

We rated safe as good.

Mandatory training

- Staff delivering the service had received effective training in safety systems, processes and practice. The mandatory training record showed that all staff had attended mandatory training within the last twelve months. Mandatory training included relevant topics such as, life support, health and safety, infection control, information governance and duty of candour.
- On appointment staff completed a competency based, practical echo assessment checklist, which included use of the equipment, recording and reporting of results. When equipment was updated the manufacturer provided technical training, which at least two members of staff attended and then rolled out to other staff.

Safeguarding

- Systems were in place to safeguard people from avoidable abuse and neglect. One of the directors was the named lead for safeguarding concerns. A safeguarding policy was available to staff; however, at the time of inspection it did not include guidance on female genital mutilation or child sexual exploitation. We discussed this with the registered manager and the policy was subsequently updated. The policy did have referral pathways for the different locations that staff operated in and staff were able to demonstrate they knew how to recognise and respond to a safeguarding concern.
- All staff had attended level two safeguarding adults and children training within the last year and three members of staff had attended level three training. This meant the staff had the appropriate level of training as set out in the Safeguarding children and young people: roles and competencies for health care staff intercollegiate document 2014.
- It was routine procedure for staff to check three points of identification with patients to ensure the right patients was being examined and we witnessed this in the examinations we observed.
- Chaperones were available. There were two members of staff in attendance at most of the clinics and when only one member of staff was in attendance they could ask other staff at GP practices or hospitals to act as chaperones if necessary.
- Staff recruitment processes included disclosure and barring service (DBS) checks for all staff. DBS checks enable organisations to make safer recruitment decisions by identifying candidates who may be unsuitable for certain work especially that involving children or vulnerable adults.

Cleanliness, infection control and hygiene

- Reliable systems were in use to prevent and protect people from health care acquired infections. Staff demonstrated a good understanding of infection prevention and control measures. One of the directors was the infection prevention and control lead.

Echocardiography was carried out in rooms supplied by GP practices and private hospitals. Service level agreements were in place. These included cleaning requirements and during the inspection we saw a cleaning schedule was in place for the room being used.

- The equipment was cleaned according to the manufacturers guidance and the providers equipment cleaning and decontamination policy. The transducer (a hand held part of the ultrasound machine that is responsible for the production and detection of ultrasound waves) and connecting wires were cleaned with antibacterial cleanser at the start of each clinic session, in-between each patient and at the end of the clinic session. The examination couch was cleaned in-between each patient and fresh bed roll used to cover the couch, and we observed this during the inspection.
- Hand hygiene audits did not take place; however, staff were "bare below the elbows" to allow effective hand washing and alcohol hand sanitiser was available. We saw that clinical wash hand basins were compliant with the Department of Health's Health Building Note 00-09. We saw staff wash their hands and use hand gel appropriately, for example before and after patient contact. This was in line with the world health organisation's (WHO) "Five moments for hand hygiene".
- Staff told us that occasionally they were asked to examine patients on the ward who had an infectious disease and in this case, they would adhere to ward protocols in relation to the infection control and prevention measures to be taken.

Environment and equipment

- During our inspection we were assured that the environment and equipment used was appropriate for the service delivered and maintained to a standard which kept people safe.
- Electrical equipment conformed to the relevant safety standard and was safety tested annually.
- We saw the emergency resuscitation equipment was located close to the consulting room being used and was easily accessible. Staff were informed where emergency equipment could be located in GP surgeries and we saw this information clearly documented.
- Personal protective equipment was available to staff although they told us they rarely needed to use it.
- The provider stored hazardous substances appropriately and in accordance with the Control of

  Substances Hazardous to Health Regulations 2002 (COSHH). COSHH is the law that requires employers to control substances that are hazardous to health. We saw comprehensive records relating to COSHH risk assessment.
- No clinical waste resulted from the examination. However clinical and domestic waste bins were available and clearly labelled.
- We saw the service records for the cardiac ultrasound and ambulatory ECG equipment which showed they had been serviced annually. However, the provider was unable to supply a service record for the ambulatory blood pressure monitor, which meant we could not be assured of its accuracy. We raised this with the registered manager during inspection and arrangement were made for the equipment to be calibrated.
- The provider replaced the cardiac ultrasound equipment approximately every four years. This meant it was of a high specification and conformed to national and international safety standards. If the cardiac ultrasound machine broke down the maintenance contract included the loan of an alternative machine so the service was not disrupted.
- A checklist of equipment necessary to perform the echocardiograms was available for all staff and included reference material for the cardiac ultrasound.
- In the event of a technology failure the picture archiving and communication system (PAC system) used by the provider had 24/7 support. System updates and maintenance were planned and technicians could access the system remotely if necessary to identify and solve any problems.

Assessing and responding to patient risk

- Staff were able to describe to us how they recognised if a patient was unwell and the action they would take. Most patients attending for echocardiogram were medically fit and able to attend clinic for the examination. Staff described how one patient had arrived and was experiencing chest pain. An emergency ambulance was requested and medical staff working on the premises called to support the patient.
- We saw the onward referral protocol and pathways of care which detailed where the clinical physiologist should refer the patient depending on the results of the echocardiogram and the timescales. For example, patients could be referred to their GP, specialist secondary care or emergency medical care. Timescales were, routine (within two days), urgent (same day) or emergency (immediate). In the case of urgent referrals, the clinical physiologist contacted the referring clinician directly to discuss the urgent findings and agree on next steps for the patient.
- The clinical physiologists had access to a cardiologist for advice and a second opinion on the echocardiograph. The cardiologist could log into the PAC system within 24 hours to review and report on the results.
- Exercise tolerance tests were only carried out under the supervision of a cardiology consultant. The clinical physiologist constantly monitored the patient's heart during the test and would stop the test if it had any adverse effect on the patient. Emergency equipment and drugs were kept in the room during the test.

Staffing

- There was adequate staffing to deliver safe care to patients and meet current demand. All seven staff were clinical physiologists. One of the directors was responsible for planning staff to cover the clinics. Staff rotas were created manually and took in to account staff availability, holidays and study leave.
- Staff had access to a cardiologist for advice and support who was commissioned specifically to fulfil this role.
- Lone working was not an issue for the provider as staff always worked in premises where other staff were available if required.

Records

- Patient information was managed in a way that kept people protected from avoidable harm. The provider did not hold any patient records. All reports and images were electronic and stored on a secure web based PAC system.
- The NHS number was used as the unique identifier for community patients and the hospital number for hospital patients.
- Information from paper referral forms was transferred on to the electronic system. The paper forms were stored securely and destroyed after the patient had been seen and the results sent to the referrer.
- The PAC system was secure and password protected, referring clinicians were give a unique password so they could view the images. The registered manager told us they could not think of an occasion when the system had not been available to referring clinicians.
- Reports were sent to referrers within two days in a portable document format (PDF) by e mail or electronic fax.

Medicines

- Emergency medicines were available for patients undertaking the exercise tolerance test. These were supplied and checked by the hospital at which the test was carried out and administered if necessary by the hospital cardiologist.

Incidents

- Systems were in place for staff to raise concerns and report incidents. We reviewed the incident reporting protocol which clearly detailed the process staff should follow if an incident took place. There were no incidents in the reporting period August 2017 to August 2018.
- Incident reporting forms were available to staff in the documentation pack which was kept with the portable cardiac ultrasound equipment. One of the directors was responsible for investigating incidents and sharing any learning with staff or other healthcare site managers.

Good

Diagnostic imaging

- Staff we spoke with demonstrated an open and honest approach to discussing incidents and errors with patients. We noted duty of candour regulations were not evident in the incident policy or staff training.

Are diagnostic imaging services effective?

Not sufficient evidence to rate

We did not rate effective

Evidence-based care and treatment

- The service adhered to evidence based guidance for echocardiogram, ambulatory blood pressure (BP) monitoring, ambulatory electrocardiograph (ECG) and exercise tolerance test.
- Echocardiogram was performed conforming to the British Society of Echocardiography (BSE) protocols, Society for Cardiological Science and Technology for ambulatory ECG and exercise tolerance test and the European Society of Hypertension guidelines for ambulatory BP.
- We saw evidence and reference to the guidelines during our inspection including the BSE minimum dataset for echocardiogram. For example, each patient had their height and weight checked prior to the cardiac scan to improve the accuracy of measurements by relating heart chamber sizes to individual body size.

Pain relief

- Echocardiology is a painless procedure. Staff were aware that some of the positions patients were required to take for the examination could be uncomfortable. We observed staff checking that patients were comfortable during the test. Staff also told us they did not measure certain views of the heart in pregnant women during the latter months of pregnancy as it was too uncomfortable.
- Staff told us that if patients taking the exercise tolerance test experienced angina pain relieving medication was at hand and administered by the consultant. Angina is a chest pain linked to heart disease.

Patient outcomes

- Regular review of echocardiogram images and reports was taking place. Ten percente of images and reports were audited monthly by an independent external auditor who was accredited by the BSE and used the BSE guidelines as a benchmark. The monthly reports were reviewed by one of the directors and the results fed back to individual staff. Any serious discrepancies in the report would be shared with the referring clinician.

Competent staff

- We were assured that patients were receiving competent care from staff with the right skills and knowledge. All staff working for the service were registered with the Registration Council for Clinical Physiologists and were BSE accredited. Staff were revalidated for BSE accreditation every five years and we saw up to date certificates in staff files.
- New staff completed an induction check list which included the providers policies and procedures and a competency based practical echo assessment. Staff were only allowed to work unsupervised when they had successfully completed all the competencies.
- Training on new equipment was delivered by the manufacturer and updates to the information technology(IT) systems was delivered remotely by the IT technical team.
- Staff told us the provider supported them to develop their skills for example paying for them to attend relevant conferences such as the BSE annual conference and British Heart Valve Society events.
- All staff had undertaken intermediate life support training to enable them to deal with any medical emergencies and conflict management training to support them in managing patients with challenging behaviour.
- Four out of seven staff had attended a formal appraisal meeting in the last twelve months. It is recommended that all staff have an annual appraisal meeting with their manager to discuss their career status and continuing professional development needs. We discussed this with the manager and the outstanding appraisals were planned to take place by the end of the year.

Good

Diagnostic imaging

- The registered manager told us that if they suspended a member of staff they would inform the BSE routinely.

Multidisciplinary working

- The service only accepted patients for echocardiogram on receipt of a written referral from the referring clinician who may be a GP or hospital consultant. Staff liaised with referring clinicians if they had any queries on the referral form. We observed that staff had close working relationships with staff in the hospital where they were working.
- Reports were usually written on the day of the cardiac scan and sent to referring clinicians within two days. The report included recommendations on what the referring clinician should consider next for the patient.
- If other clinicians needed access to the report and images a password was provided so they could access the providers PAC system.

Consent and Mental Capacity Act

- During our inspection staff demonstrated an understanding of consent and decision-making requirements. Patients' understanding of the test and consent to proceed was checked at the beginning of each appointment.
- Staff attended annual mandatory training which included awareness of the Mental Capacity Act and the principles of patient consent.
- Staff sought verbal consent from each patient before they began the cardiac scan.

Are diagnostic imaging services caring?

Good

We rated caring as good

Compassionate care

- We observed patients being treated with kindness and sensitivity, staff introduced themselves and acted in a caring manner. Before the test began patients were given a brief description of what to expect and were allowed time to ask any questions. Two patients asked about other tests and appointments that were not connected to the cardiac scan but staff went to other hospital staff to try and resolve the queries for the patients. Patients told us the 'The human side was wonderful', 'Staff were fantastic and treated you with dignity and respect'.
- Patients privacy was maintained as much as possible (the examination required exposure of the upper body). The consultation room had privacy blinds at the window and privacy curtains around the examination couch. Disposable privacy sheets were used for the patient to cover themselves and patients were asked throughout the scan if they were comfortable. In the most recent patient survey 100% of patients responded positively to the question, 'Were you given all the privacy you needed during your test?'.
- Chaperones were available. There were two members of staff in attendance at most of the clinics and when only one member of staff was in attendance they could ask other staff at GP practices or hospitals to act as chaperones if necessary.

Emotional support

- Staff told us the referring clinician had usually explained the procedure to patients at the time of referral. There were no specific information leaflets about echocardiogram; however, a leaflet was available for patients undergoing chemotherapy explaining why cardiac scans were necessary to monitor the effects of chemotherapy drugs.
- During our inspection we observed staff informing patients what to do next, for example patients who had been referred by their GP were told to make an appointment in one weeks' time for the results of the test.
- One chemotherapy patient told us she had her scan in the morning and by late afternoon she had contact from her chemotherapy nurse with the results.
- Staff told us their patients rarely became distressed or emotional but if they did they would take them in to a quiet room and give reassurance and support. Patients said, 'They put me at my ease instantly', 'I was made to feel very relaxed', 'I was apprehensive at first but the staff were charming and made me feel relaxed'.

Understanding and involvement of patients and those close to them

Good

Diagnostic imaging

- All the patients we observed on the day of inspection understood how they would receive their test results and when to make appointments with referring clinicians. Staff gave clear verbal information to patients and checked their understanding. Patients told us they were given 'good explanations and information'.
- Patients could bring their friends, family members or carers into the consulting room, we observed a mother and daughter discussing test results and next appointments with one of the clinical physiologists.
- Patients did not receive a copy of the report sent to the referring clinician. Staff told us the reports were very technical and it would not be helpful for patients to have a copy before they saw their GP/consultant.

Are diagnostic imaging services responsive?

Good

We rated responsive as good

Service delivery to meet the needs of local people

- The waiting area and consulting room used on the day of inspection was patient friendly. The provider had a list of requirements it shared with hospitals and GP practices detailing what was required of patient areas which included, 'Suitable and comfortable waiting area for patients with toilet facilities and car parking.'
- The waiting area had adequate seating, hot and cold drinks, television and a variety of reading material and was easily accessible for wheelchair users or people with reduced mobility.
- The consulting room was spacious and private with seating for patients' relatives or friends if needed.
- Appointment letters included a phone number for patient to use if they had any concerns about the procedure or wanted to change their appointment. Information about the procedures could be found on the providers website.
- Most appointments were from 9am to 5pm. However, evening appointments could be arranged if patients could not attend during these hours.
- On the day of our inspection the first appointment did not attend. The patient was contacted by phone and unfortunately had forgotten about the appointment. The clinical physiologist offered the patient an appointment later the same day which they accepted.

Meeting people's individual needs

- The service supported patients with a disability or sensory loss as much as was practicable considering they worked remotely on premises belonging to other healthcare providers.
- Managers told us they were reliant on the referring clinician to inform them on the referral form whether a patient had any special requirements. Clinical physiologists contacted patients at home to discuss and clarify if any special arrangements were needed for the patient to attend the appointment.
- Interpreting services could be organised through the hospital or GP practice where the clinical physiologists were working. Staff told us these were quite easy to organise with some forward planning.
- On the day of our inspection we observed good access for wheelchair users or those with limited mobility. Managers told us all the locations they worked from had adequate disabled access. If necessary the cardiac scan could be done in a sitting position for patients who could not transfer from wheelchair to the examination couch.
- Whenever possible elderly patients were given appointments later in the day to give them more time to get ready and travel to the clinic. There was adequate time during the appointment for patients to ask questions or discuss any concerns.

Access and flow

- On the day of our inspection we observed that all appointments ran to time. Managers told us the only time appointments were delayed was due to seeing a patient with an urgent clinical need. One patient told us 'Appointments were spot on time, very quick and efficient'
- Once the provider received the referral the appointment was sent to the patient on the next working day.

Good

Diagnostic imaging

- Waiting list and report turnaround times were monitored as key performance indicators (KPI) in service level agreements and contracts. The waiting list for cardiac scans was three weeks. If it looked as if the waiting time was going to exceed three weeks, the provider arranged extra clinic sessions. The KPI for waiting list time was six weeks so the provider was well within target.
- Ten procedures were delayed in the reporting period due to equipment failure. This was one clinic session, an extra clinic was scheduled and patients were rebooked within two weeks.
- Patients could change their appointment easily if necessary, a phone number to the appointment booking system was included in the appointment letter.
- Generally, reports were written and sent to the referring clinician on the same day or within two working days which meant the provider was meeting the KPI for report turnaround times.

Learning from complaints and concerns

- The provider had a clear complaints policy. This supported staff in responding to oral or written complaints. It contained contact details of complaints advocacy services for patients who did not feel their complaint had been dealt with fairly. Details about how to complain were included in the patient appointment letter and staff carried complaints forms with them. One of the directors took responsibility for complaints management.
- There were no complaints in the reporting period. The provider gave an example of where they had responded to a concern raised by a patient in the routine patient survey, this resulted in wording in the appointment letter being amended.

Are diagnostic imaging services well-led?

Requires improvement

We rated well-led as requires improvement

Leadership

- The directors of the service were experienced and knowledgeable in the field of echocardiology and the challenges of providing a health service. This meant that staff respected them as professionals and managers. Staff told us the directors were approachable and understanding but aware of their clinical responsibilities.
- Directors had clear roles within the organisation and these were detailed in the director roles and responsibilities document. We spoke with two of the directors who could articulate the challenges to the service however, there was no strategy or succession planning in place. Managers told us that one of the advantages of being a small service was that change could be implemented quickly in response to patient or commissioner feedback.

Vision and strategy

- The providers values statement was 'our experience counts' which was a true reflection of the service and the staff. However, there was no vision or strategy to accompany this statement.

Culture

- Staff we spoke with were positive about working for Clinical Diagnostix. They said they felt supported and valued and had close working relationships with their colleagues. They told us the provider supported them in attending development opportunities by funding attendance at courses and conferences and associated expenses.
- Processes were in place to address staff performance that was not in line with professional principles or the providers policies and procedures. For example, managers described how they had forwarded information to the Registration Council for Clinical Physiologists (RCCP) when a member of staff had not completed their revalidation in line with registration requirements.
- During the inspection staff demonstrated a culture of openness and honesty and staff demonstrated to us they understood the principles of duty of candour. Mandatory training included duty of candour.

- The provider adopted the RCCP reporting concerns (whistleblowing) procedure which provided a helpline and qualified advisor for to guide whistle-blowers through the process.
- The provider considered the health and wellbeing of staff. Mandatory training included health and safety topics including; (RIDDOR) and Control of Substances Hazardous to Health (COSHH). Some consulting rooms had panic buttons installed and staff were provided with panic alarms. Personal safety and lone working was covered in the annual mandatory training course.

Governance

- Structures and processes were in place to support the delivery of a sustainable service. The directors held regular meetings which encompassed both clinical and operational issues. We saw the minutes of two meetings, topics discussed included; policies and procedures, information governance, new clinical guidance and staffing. Managers told us that information from the meetings was disseminated to staff through e-mail, but staff meetings did not take place.
- Service level agreements and contracts were reviewed regularly. We saw the agenda for a contract review meeting between Clinical Diagnostix and a commissioning group. This included reviewing the service specification, contract compliance and performance. This meant the services were constantly reviewed.
- Monitoring was in place. We saw the reports for report turnaround times and appointment times measured against the key performance indicators in contracts and service level agreements. All were well within target.
- Recruitment processes were in line with NHS best practice. We saw completed documentation which include proof of identification, references and professional certificates.
- Appropriate policies and procedures were available, but on review were mainly one-page documents. Some policies did not have a review date and some did not reference statutory or regulatory requirements. For example, the complaints management and incident management policies did not make reference to duty of candour nor was there a seperate duty of candour policy. The safeguarding policy did not make reference to female genital mutilation and child sexual exploitation.

Managing risks, issues and performance

- The provider did not have a risk register or process for identifying and manging risks to the service. Risks were not identified and therefore no mitigating actions in place to reduce the effects of the risk.
- A business continuity plan was in place detailing the action the provider would take in the event of a major incident and also covered business continuity in the event of adverse weather and information technology disruption.

Managing information

- The provider managed information securely and in line with relevant regulations. Policies and procedures were in place to support staff to keep information secure and information governance was covered in the annual mandatory training updates.
- The provider completed an on-line data security and protection toolkit each year. The toolkit must be completed by all organisations that have access to NHS patient data and systems. The provider reached the required minimum compliance level of two.
- The provider was registered with the Information Commissioner for the purposes of notification under the Data Protection Act 1998.
- The picture archiving and communication system was secure and password protected. Referring clinicians were give a unique password so they could view images if required.

Engagement

- The provider actively sought the views of patients, staff and commissioners to shape and improve the service. We were given several examples of where changes had been made to the service following feedback which included; changes to the wording on the appointment letter, clearer instructions for patients on how to access a clinic location and the purchase of additional equipment to improve patient turnaround times.

Good

Diagnostic imaging

- We saw an example of where positive patient feedback had been shared with staff.
- We saw the results of the most recent patient survey which was overwhelmingly positive. In answer to the question, 'Overall how did you find the service?' 84% of patients said excellent, 10% very good and 5% good.
- Managers had ongoing dialogue with staff and welcomed ideas or suggestions on how the service may be improved.

Learning, continuous improvement and innovation

- The provider had measures in place to continuously improve the service. Staff were encouraged to develop professionally by attending relevant learning events.

British Society of Echocardiography accreditation and membership of the Registration Council for Clinical Physiologists were requirements of working for the provider.

- Learning from audit and feedback was shared with staff and we saw examples of where changes had been implemented.
- The provider replaced equipment every four years to ensure they were using the most up to date equipment.
- Staff told us they met outside of work occasionally at social events and at Xmas received a gift for the provider in acknowledgement of their contributions to the service.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider MUST take to improve

- The provider must ensure that the Duty of Candour is embedded in relevant policies.

Action the provider SHOULD take to improve

- The provider should undertake hand hygiene audits at least once a year.
- The provider should make sure all equipment used to deliver the service is serviced regularly and that a record of the service is documented.
- The provider should facilitate a formal appraisal meeting for all members of staff.
- The provider should ensure that staff meetings take place regularly.
- The provider should implement systems for documenting and managing risks to the service.
- The provider should make sure the safeguarding policy is relevant to both adults and children and includes guidance on female genital mutilation and child sexual exploitation.

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 Duty of Candour was not embedded in policies and procedures. The registered manager must ensure that Duty of Candour requirements are reflected in appropriate policies.

This section is primarily information for the provider

Enforcement actions

Action we have told the provider to take

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