C V S Health Limited

CVS Health Limited (Trinity House)

Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Requires Improvement
Are services caring?	Good
Are services responsive to people's needs?	Requires Improvement
Are services well-led?	Inadequate

Summary of findings

Overall summary

As a result of this inspection we had serious concerns about the safety of patients at this location and took immediate action to limit risk. We imposed a suspension of the service for eight weeks so that the provider could improve governance and safety checks at the location before caring for patients again.

We rated it as inadequate because:

- Systems to review self-employed clinical staff training were not monitored effectively, for example the provider did not make sure clinical staff had completed advanced life support training. However, the service provided mandatory training in key skills to administrative staff and made sure they completed it.
- Staff did not fully understand how to protect patients from abuse and the service did not understand the importance of working with other agencies to do so. Staff had limited training on how to recognise and report abuse and they were unsure of how to apply it.
- The maintenance and use of facilities and equipment did not keep people safe. Staff were not trained to routinely check or use lifesaving equipment. Equipment servicing was out of date and clinical waste was not managed well.
- Patient risk assessments were limited, staff completed basic risk assessments and updated them. Staff identified and acted upon patients at risk of deterioration although there was no standard operating procedure for dealing with emergency situations.
- The service did not manage patient safety incidents in line with national guidance. Staff recognised incidents and near misses, but they did not report them appropriately. Managers failed to ensure that incident forms were available for staff and that actions from patient safety incidents were implemented and monitored.
- The service did not provide assurance that care and treatment was based on national guidance and evidence-based practice. They did not have regular policy review meetings and some policies were outdated.
- The service did not monitor the effectiveness of care and treatment. They did not use findings to make improvements and could not benchmark outcomes for patients against national averages.
- The service did not have complete oversight of the competence of sub-contracted staff specific to their roles. The manager appraised administrative staff annually but did not always capture the competency evidence of clinical staff's performance in a timely manner. The manager was unable to provide assurance that practising privileges were adequately monitored.
- Staff could not effectively support patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent, but they had not received the appropriate training on how to support patients who lacked capacity to make their own decisions or were experiencing mental health illness.
- Leaders did not always manage or understand the priorities and issues the service faced even though they had the skills and abilities to do so. Managers were not always visible in the service for patients and staff, which led to a lack of oversight on safety and governance.
- Leaders had not ensured the service had effective governance systems and processes to guarantee the service was managed safely and in compliance with the regulations. Not all staff were clear about their roles and accountabilities and they did not have regular opportunities to meet, discuss and learn from the performance of the service.
- Leaders did not effectively use systems to manage performance. Risks and issues were not always identified and escalated appropriately to reduce their impact. They had plans to cope with unexpected events but did not have effective policies to limit risks. Staff did not have opportunities to contribute to decision-making to help avoid financial pressures, compromising the quality of care.
- Leaders reviewed improvements and innovation but failed to share practice updates with staff. Staff lacked understanding of quality improvement methods.

Summary of findings

However:

- The provider managed infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.
- Staff kept records of private patients' care and treatment. Records were clear, up to date, stored securely and easily available to clinical staff providing care.
- Staff gave patients practical support and advice to lead healthier lives.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, and took account of their individual needs.
- Staff provided emotional support to patients to minimise their distress. They understood patients' personal, cultural and religious needs.
- The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.
- People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.
- People could give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.
- The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy.
- The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required via encrypted software.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic imaging	Inadequate 	We rated it as inadequate. See overall summary for more information.

Summary of findings

Contents

Summary of this inspection

Background to CVS Health Limited (Trinity House)

CVS Health Limited (Trinity House) has provided cardiac diagnostic and consultancy services since opening in 2011. The service is owned and managed by a team of partner consultant cardiologists offering a 'one stop' service to private patients who live in Kent and East Sussex. They are based in Eastbourne and services are delivered by qualified and experienced local NHS cardiologists and physiologists for the people of Sussex and Kent.

The provider offers a wide range of services which include, but are not restricted to, cardiac analysis, electrophysiological studies, coronary angioplasty, cardiac diagnostic testing, and angiograms.

They also provide interventional cardiac pacemaker treatments once a month. This invasive service is carried out off site at cardiac laboratories within two NHS trusts in the Kent and East Sussex area which we did not inspect.

The service is registered with the Care Quality Commission (CQC) to provide the following regulated activities:

- Diagnostic and screening procedures
- Surgical procedures
- Treatment of disease and disorder.

The registered manager has been in post for 10 years.

This is the first inspection at this location.

What people who use the service say

Patients found the service easy to access, and staff treated them with respect. The CQC had not received any complaints or concerns regarding this service.

The main service provided by the provider was diagnostic imaging. Surgical procedures were not conducted on-site.

How we carried out this inspection

During the inspection visit, the inspection team:

- Spoke with three members of staff including the receptionist, one physiologist and the registered manager
- Inspected two clinical rooms
- Spoke with four patients who had been referred to the service from the NHS
- Reviewed four digital patient records
- Observed reception staff speaking to patients
- Observed four episodes of patient care
- Looked at a range of policies, procedures and other documents relating to the running of the service.

You can find information about how we carry out our inspections on our website: https://www.cqc.org.uk/what-we-do/how-we-do-our-job/what-we-do-inspection.

Summary of this inspection

Areas for improvement

Action the service MUST take is necessary to comply with its legal obligations. Action a trust SHOULD take is because it was not doing something required by a regulation but it would be disproportionate to find a breach of the regulation overall, to prevent it failing to comply with legal requirements in future, or to improve services.

Action the service MUST take to improve:

We told the service that it must take action to bring services into line with The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 legal requirements. This action related to diagnostic imaging services.

- The service MUST ensure that staff providing patient care are trained in advanced life support so that staff can administer lifesaving medication in the event of an emergency. (Regulation 12: Safe care and treatment (c)).
- The service MUST ensure all equipment has service checks in line with manufacturer's guidance, so people are protected from mechanical breakdowns of that equipment. (Regulation 12: Safe care and treatment (d)).
- The service MUST ensure that emergency equipment is checked in accordance to national guidance, so people have timely access to emergency care and treatment if required. (Regulation 12: Safe care and treatment (e) (f)).
- The service MUST ensure that the incident reporting process is reviewed and implement a process in line with national guidance so that learning can be shared and acted upon. (Regulation 17: Good governance (b)).
- The service MUST ensure that it updates its adult safeguarding policy, so it reflects the Adult Safeguarding: Roles and Competencies for Health Care Staff (2018) national guidance including identifying a lead for safeguarding. (Regulation 13: Safeguarding service users from abuse and improper treatment 13 (1).
- The service MUST ensure that it maintains appropriate records, including Disclosure and Barring Service checks, of persons employed to carry on the regulated activity to protect people from potential abuse (Regulation 19: Fit and proper persons employed 3 (a) (b)).
- The service MUST ensure that it takes prompt action to address several significant concerns identified during the inspection relating to governance systems and process and risk management to ensure the quality and safety of service. (Regulation 17: Good governance 1&2 (a) (b).

Action the service SHOULD take to improve:

- The service SHOULD ensure that staff receive appropriate mental capacity act training in the provision of the Mental Capacity Act (2005).
- The service SHOULD create a policy for the management of any rapid deterioration of a patient and make sure staff understand and follow this.
- The service SHOULD complete audits on diagnostic images and reports to make sure images and reports are accurate and of good quality.
- The service SHOULD make sure all staff are fully trained to use the internal software system so they can access policies and information in a timely manner.
- The service SHOULD consider having regular multi-professional meetings that are inclusive, have a formal agenda and are recorded and reviewed.
- The service SHOULD ensure that leaders have regular risk meetings and that there is a clear agenda and that there is evidence of completed actions.
- The service SHOULD make sure it provides clear information on costs, fees and tariffs associated with their care and treatment.
- The service SHOULD clearly display the complaints procedure to support people in making a complaint.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic imaging	Inadequate	Requires Improvement	Good	Requires Improvement	Inadequate	Inadequate
Overall	Inadequate	Requires Improvement	Good	Requires Improvement	Inadequate	Inadequate

Inadequate

Diagnostic imaging

Safe	Inadequate
Effective	Requires Improvement
Caring	Good
Responsive	Requires Improvement
Well-led	Inadequate

Are Diagnostic imaging safe?

Inadequate

Mandatory training

Systems to review self-employed clinical staff training were not monitored effectively, for example the provider did not make sure clinical staff had completed advanced life support training. However, the service provided mandatory training in key skills to administrative staff and made sure they completed it.

Administration staff received mandatory training specific to their role. Training included fire safety, information governance, basic life support, duty of candour and chaperone training.

The registered manager monitored training most of the time and alerted staff via email when they needed to update their training.

The service did not provide training for clinical staff on site, as they relied upon staff to receive their training from their substantive NHS posts and submit their certificates once completed. The provider CQC statement of purpose (2021) state “As staff are self-employed but with NHS employment, we deem it good practice to monitor continued professional development, fire safety, health and safety and other training considered specific to the role. Training identified, if not provided by the NHS would be instigated by CVS Health with the co-operation of the individual concerned.”

The registered manager provided some evidence of training, but they had not ensured that staff delivering care had been trained in advanced life support. CVS Health limited (Trinity Trees) is a clinic specialising in cardiac conditions and most of the patients were older people meaning the risks of a cardiac emergency are higher. Section 1 of The Human Medicines Regulations 2012, states that staff should be able to demonstrate that they have received advanced life support training so they are allowed to give drugs to patients in cardiac arrest or they must be prescribed by a doctor and given under a patient group direction (PGD). The registered manager did not provide us with a copy of the PGD.

There was no evidence that medical staff had received any mandatory training as the registered manager was unable to access their records during our visit.

Reception staff were not trained in how to respond in an emergency.

Inadequate

Diagnostic imaging

Safeguarding

Staff did not fully understand how to protect patients from abuse and the service did not understand the importance of working with other agencies to do so. Staff had limited training on how to recognise and report abuse and they were unsure of how to apply it.

The provider had not ensured safeguarding policies and practices used in the service were fit for purpose and in line with national guidance. The service's Safeguarding Policy was not aligned to Adult Safeguarding: Roles and Competencies for Health Care Staff (2018) and used outdated inappropriate terminology. For example, the policy was entitled 'Vulnerable Adults Protection Policy' and national guidance states the most recent terminology is 'Adult Safeguarding' or 'Safeguarding Adults'. The service policy mentioned staff safety and wellbeing before it mentioned patients. This is not in line with the Care Act 2014, it did not contain the current key definitions, or all the types of abuse, harm or neglect and it did not have the contact details of the local authority or police.

There was no identified lead for safeguarding. National guidance says all boards should have access to safeguarding advice and expertise through dedicated designated or named professionals. The service had no safeguarding lead with expertise to provide quality assurance or take responsibility for overseeing safeguarding training, the review of safeguarding policies and safeguarding referrals.

Safeguarding training was provided at level 1 Adult safeguarding for the administration staff and records confirmed that staff received safeguarding training in 2019. Adult Safeguarding: Roles and Competencies for Health Care Staff August 2018, outlines the required competency levels for each level of training. Staff should have awareness of the potential indicators of abuse, harm and neglect and the ability to locate local policy and procedures so they can take the appropriate action and report concerns to the right people at the right time. Staff we spoke with did not have a clear understanding of how to identify adults and children at risk of significant harm, suffering, neglect or abuse. One staff member found it difficult to access the safeguarding policy and a another could not access the policy on the electronic system.

Subcontracted clinical staff were expected to complete safeguarding training within their NHS role. One clinical staff member was trained at level 2 Adult safeguarding but could not recall when they had last updated this. The registered manager advised us that he could not access consultants training records; therefore, there was no evidence that the consultants providing care for patients had recently received any kind of safeguarding training.

Staff did not have the skills, training or support necessary to recognise abuse or to respond to allegations of abuse. Staff did not know how to make a safeguarding referral or who to inform if they had any concerns.

The provider had failed to implement a safeguarding referral form so staff could not formally report safeguarding concerns. Staff did not have access to the contact details for the local authority safeguarding team.

Cleanliness, infection control and hygiene.

The provider managed infection risk well. Staff used equipment and control measures to protect patients, themselves and others from infection. They kept equipment and the premises visibly clean.

Clinical areas were clean and had suitable furnishings which appeared clean and well maintained. Cleaning records were kept in each clinical room and demonstrated all areas were cleaned regularly. Each clinical room had a sink, with soap and hand decontamination gel and safe hand washing posters were displayed.

Inadequate

Diagnostic imaging

Staff on duty the day of our inspection followed infection control principles which included the use of personal protective equipment (PPE). Masks and gloves were readily available for use in both clinical rooms. Staff cleaned equipment after patient contact using clinical decontamination wipes which were available for use in each clinical room.

Environment and equipment

The design, maintenance and use of facilities, premises and equipment did not keep people safe. Staff were not trained to routinely check or use lifesaving equipment. Equipment servicing was out of date and clinical waste was not managed well.

The service was on the first floor of a large historical building and accessed via stone stairs or for people with reduced mobility a small single person stair lift. The environment appeared clean and adequately maintained.

The provider failed to make sure that all equipment used by the service was safe, and properly maintained. The stair lift had not been recently serviced. The registered manager stated this was completed annually but could not provide any evidence of this. They stated they cancelled servicing last year due to Covid-19 although they continued to see patients.

Sharps bins had not been labelled and clinical waste was not routinely collected. The registered manager advised that they had an ad-hoc agreement with a third-party company to collect waste on request. This meant that clinical waste could be stored on site for months, with an increased risk of contamination.

The provider had not made sure that all medical and diagnostic equipment was serviced in line with the manufacturer's guidelines. Servicing had taken place for the treadmill. However, the registered manager advised us that some servicing had been cancelled last year due to Covid-19 even though patients were still seen. This meant patients were exposed to the risk of missed diagnosis or harm in the event of equipment failure.

There was no evidence of staff training on using medical diagnostic equipment. We requested training records after the inspection and these were not provided.

The provider had not made sure that emergency equipment was safe, properly maintained and appropriately checked. The medical emergency and resuscitation policy were not readily available to staff who were unaware of a policy which could not be produced on the day of inspection. The provider sent this after the inspection. The section on checking equipment was unclear, did not clearly define which staff were responsible for completing checks or how often. This was not in-line with national guidance issued by the Resuscitation Council.

Emergency equipment was not checked regularly to ensure it remained ready for immediate use. This could have catastrophic consequences. The clinic's defibrillator had not been checked since April 2021.

The checking of the emergency equipment and medication was delegated to a non-clinical member of staff and this had not been carried out since April 2020 The emergency "grab bag" did not contain a list of contents so staff could not be sure its contents were complete. Providers should complete annual risk assessments of resuscitation "grab bag" medication in accordance with the Human Medicines Regulations 2012 and this had not been completed during the last year. The registered manager told us that the grab bag had been instated two years ago on advice from an advanced life support advisor who was based in a hospital and could not provide evidence of this. We asked to see a risk assessment of the "grab bag" but this could not be produced.

Inadequate

Diagnostic imaging

There was no routine checking of the emergency call system in treatment rooms. When we tested the emergency call system, the receptionist was unaware of what the sound was, and how to react. This meant people may be exposed to the risk of harm as staff did not recognise the sound of the emergency buzzer and were slow to act.

The service had a fire safety policy which was in date and staff received annual fire safety training. The service completed annual fire safety checks on signs, fire alarms and fire extinguishers.

Assessing and responding to patient risk

Patient risk assessments were limited, staff completed basic risk assessments and updated them. Staff identified and acted upon patients at risk of deterioration although there was no standard operating procedure for dealing with emergency situations.

Most patients were referred from a local NHS integrated cardiac service where they had been risk assessed by a multidisciplinary team. Request forms were sent electronically to the location prior to the clinic date.

Staff shared key information to keep patients safe when handing over their care to others. Request forms included the patient's details, the requested procedure, a brief patient history, mobility and accessibility needs, body mass index (BMI) and main language.

Staff did not provide a full risk assessment when patients arrived in clinic and did not ask routine Covid-19 questions on arrival because the patient had been telephoned the evening before by the NHS provider to assess their Covid-19 status. Private patients were asked Covid-19 questions when booked and completed a brief questionnaire on arrival.

Staff completed basic risk assessments when the patient arrived in clinic prior to providing care by reviewing the referral letter. Staff made sure patients were clear about the examination they were supposed to have, Staff told us that there had been a couple of occasions when the wrong person went into the clinical room when a name was called and could have ended up with the wrong procedure.

Private patients were referred from third party private health providers and consultants were responsible for assessing and updating patient risk using a standardised assessment tool that was accessed electronically.

The provider had not made sure that staff were aware or trained to follow a policy for responding to an emergency, so patients were put at risk of not receiving the right lifesaving interventions in the event of an emergency. Staff often cared for patients alone. We observed staff react to one patient whose condition worsened and they required additional treatment. Although the staff member remained calm, and reviewed the patient, vital equipment was not available in the room and they did not call for help.

Staff were not aware of a service policy for dealing with deteriorating patients. The registered manager was unable to locate this on the system. After the inspection we were sent a copy of their medical emergency & resuscitation policy, which was not dated, did not contain details of staff training and mentioned a location that had been closed for a year. The local NHS trust had recently provided their own guidance called 'Physiologist/CVS staff Protocol for Community Cardiology Test Results where there is a possible EMERGENCY, URGENCY or UNCERTAINTY' for emergency situations when caring for patients referred by the NHS. However, this was not formally implemented, staff had not received training on how to use it and staff had difficulty locating a copy which was eventually produced from the bottom of a pile of papers in reception.

Inadequate

Diagnostic imaging

Staffing

The service sub-contracted staff with the right qualifications, skills, and experience to keep patients safe and provide the right care and treatment. Managers reviewed and adjusted staffing levels and skill mix but did not make sure that sub-contracted staff had a full induction.

This was a small service, which employed two part-time administration staff who job shared over a five day, 9am to 5pm working week.

The registered manager worked remotely and was only on site once a fortnight.

Clinical staff included three cardiac physiologists who held substantive posts in the NHS and worked within the clinic on a self-employed basis. The manager allocated their clinics in line with their availability.

The service had four cardiologist consultants who also worked part-time within the NHS. Consultants were employed under practising privileges and this was monitored by the board. The registered manager did not have oversight to those records because he could not access them.

The manager adjusted staffing levels weekly according to the needs of third-party commissioners.

Records

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

Private patient records were complete and staff delivering care could access these via a secure safe log in.

NHS patient records were stored off site, the referral forms were received and stored electronically, updates to patient care were completed and sent via email to the appropriate NHS clinician. Diagnostic imaging and outcomes of tests performed on site, were stored on digital cloud-based software and access was shared with teams working for the NHS and the relevant consultants caring for the patients on a need to know basis. Access was password protected.

Medicines

This service did not use medicines safely.

The service did not complete regular checks of emergency medication in line with the Human Medicines Regulations 2012. The clinic kept emergency medication in the emergency resuscitation bag, but this was checked by administrative staff infrequently. We found the bag contained one ampule of Amiodarone 30mg resuscitation medication which had expired in May 2021 and there was no replacement on site.

Incidents

The service did not manage patient safety incidents in line with national guidance. Staff recognised incidents and near misses, but they did not report them appropriately. Managers failed to ensure that incident forms were available for staff and that actions from patient safety incidents were implemented and monitored.

Inadequate

Diagnostic imaging

Leaders had not implemented an effective system for reporting incidents, investigating incidents and ensuring staff learn from incidents. Staff were unaware of the incident reporting procedure policy, which was not available during the inspection, but the registered manager did send a copy after the inspection. The policy appeared incomplete, it was not aligned to the Serious Incident Framework 2010 updated 2015 it did not mention adverse events and did not outline a clear serious incident management process but did refer to the Health and Safety Executive. The policy contained an incident referral form, but staff had no awareness of this, and it was not used for two recent events.

Service users may be exposed to the risk of harm as the service did not have incident management systems in place to prevent further occurrences of incidents and make sure that improvements are made as a result.

Staff had not received training on how to report incidents properly. Not all incidents were reported and there was no robust process for staff to submit incident reports. The manager confirmed the provider did not have a specific incident reporting policy in line with the patient safety incident response framework. We were made aware of two incidents where patients had become unwell at the location staff failed to report these, and the incident that occurred during our inspection. The registered manager was unaware of these and neither had been reported.

Managers used an electronic folder named “event reporting” to record incidents and this system generated a reference number. Staff were unaware of this process, they said they emailed the registered manager when incidents occurred, but we found this was not always done.

One serious incident was reported at the location in 2019. The manager submitted a statutory notification to the CQC. This was investigated, but there was no clear evidence of any learning or its dissemination.

Safety thermometer

The service did not use or monitor results to improve safety. Staff did not collect safety information.

Are Diagnostic imaging effective?

Requires Improvement

Evidence-based care and treatment

The service did not provide assurance that care and treatment was based on national guidance and evidence-based practice.

The service provided care and treatment based on national guidance from the British Cardiology Society (BCS), Royal College and National Institute for Health and Care Excellence.

The service did not have regular policy review meetings**.** Policies were reviewed off site by a recently retired consultant on an ad-hoc basis, which meant they may not be aligned to the most recent national guidance.

There was a lack of audit processes at the location, this meant it was difficult to show if patient tests were completed in line with National Institute for Health and Care Excellence (NICE) Diagnostic Assessment Programme.

Inadequate

Diagnostic imaging

The service had one environmental audit programme to measure the quality of the echocardiogram tests. An echocardiogram is an ultrasound test used to examine and measure the structure and functioning of the heart and to diagnose abnormalities and disease. Previous audits demonstrated a consistent quality of echo being achieved with good compliance. The auditing was normally completed by the cardiac technicians on a rotational basis. However, due to Covid-19 this audit had not been completed since 2019.

The service had written patient information and gave verbal advice that reflected best practice guidance from the British Cardiology Society.

Nutrition and Hydration

Staff offered water to patients on request. This was a small diagnostic clinic and patients were given 45-minute appointments so catering facilities were not required.

Patients were provided with an information leaflet on healthy eating from the British Cardiology Society (BCS).

Patient outcomes

The service did not monitor the effectiveness of care and treatment. They did not use findings to make improvements and could not benchmark outcomes for patients against national averages.

There was no other formal local audit activity completed by the service which meant that there was no formal assurance of care being delivered in line with BCS or NICE guidance. Managers could not provide any evidence of any audits after the inspection.

The service had no recent oversight of the quality of diagnostic images. Records provided after the inspection confirmed that auditing of diagnostic image results were reviewed monthly until March 2021 since then no audits could be produced. The last audit of nine records identified limited imaging quality in two results, adequate imaging for four results and good for three.

Outcomes for interventional procedures were not shared with staff. The manager told us that interventional procedure audits were completed at local NHS sites and were reported into the Cardiovascular Outcome Research (NICOR) audits, but the registered manager could not produce records of these.

Competent staff

The service did not have complete oversight of the competence of sub-contracted staff specific to their roles. The manager appraised administrative staff annually but did not always capture the competency evidence of clinical staff's performance in a timely manner. The manager was unable to provide assurance that practising privileges were adequately monitored.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. The manager kept records of training and annual appraisals but did not effectively monitor the renewal of professional accreditation. The service required all cardiac physiologists to have a British Society of Echocardiography (BSE) accreditation when working with the service that is updated every five years. However, staff had not been asked to provide evidence of the most recent certificate. This meant the provider may allow some staff accreditation to expire and this meant their practice may not be aligned to the most recent evidence-based guidance.

Inadequate

Diagnostic imaging

Clinical staff working alone with cardiac patients were not trained in advanced life support. They were trained in intermediate life support which meant they were not trained to administer emergency medication.

Managers did not always give new staff a full induction tailored to their role before they started work. The service had a job description for cardiac physiologists, but staff were not aware of their role or responsibilities in terms of daily check lists. This meant staff did not always take ownership for checking routine or emergency equipment or policy updates.

Service policies and training packages were available online and staff were all given a secure log in. However, the service had not created a training package on how to use the software system and we noted that staff found it difficult to navigate the software systems and find important information that supported their role.

The provider had a practising privileges policy although it did not state how often the board of governors reviewed these for consultants working at the location. We requested practising privileges records but the registered manager did not have access to these so the registered manager could not be assured all information required was kept and was current. The registered manager was not involved in the review of training for consultants and had no oversight of what mandatory training consultants had completed.

Records confirmed that the contracted reception staff had a yearly appraisal.

Managers did not make sure clinical staff attended team meetings and there were no meeting minutes available.

Multidisciplinary working

Doctors and cardiac physiologist healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.

The service was delivered by a team of cardiologist consultants and cardiac physiologists who completed diagnostic testing.

Clinical staff liaised daily with the local NHS integrated cardiac service to discuss patient care, gain a multi-professional perspective on any challenging situations and provide feedback on completed diagnostic tests.

Cardiac imaging software was used during the procedure and physiologists plotted the findings which were input via NHS cloud based diagnostic imaging software. These were sent back to the referring clinician at the NHS integrated cardiac service.

The service made sure treatment plans were reviewed with other healthcare professionals including a range of consultants. However, there was no audit trail to evidence of multidisciplinary reviews and staff did not have routine multi-professional meetings.

Seven-day services

The nature of the service meant seven-day services were not required.

This was a cardiac diagnostic imaging service that was open Monday to Friday 9am to 5pm. The interventional service was provided one Saturday a month at a local NHS trust.

Inadequate

Diagnostic imaging

Health promotion

Staff gave patients practical support and advice to lead healthier lives.

The service had relevant information promoting healthy lifestyles and support. A range of health promotion from the British Heart Foundation was made available to patients. For example, this included healthy eating, importance of regular exercise, and medication management.

Staff gave verbal health promotion advice during consultations with patients.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff could not effectively support patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. However, they had not received the appropriate training on how to support patients who lacked capacity to make their own decisions or were experiencing mental health illness.

Managers did not monitor the service to make sure staff followed the Mental Capacity Act and made changes to practice when necessary. The provider had a mental capacity act policy which was not in line with current national guidance and did not contain a formal process for assessing people's mental capacity.

Staff did not receive mental capacity training, this lack of understanding of capacity may mean patients were not able to understand the implications of their conditions and associated investigations and treatment and thereby give valid consent. The provider failed to make sure that the appropriate training in the provisions of the Mental Capacity Act (2005) was available "in house" and relied upon sub-contracted clinical staff to complete this training externally and submit evidence of this. The inter collegiate guidance (Adult Safeguarding: Roles and Competencies for Health Care Staff) states safeguarding training should include the provisions of the Mental Capacity Act (2005).

Staff gained consent from patients for their care and treatment in line with legislation and guidance prior to diagnostic tests. There was a process to ensure verbal consent before testing, patients were provided with information about the tests before their appointments. They were provided with enough time to ask any questions before the tests.

Consent was generally implied for most patients and records confirmed that written consent was only obtained for patients having an invasive procedure. Implied consent is an assumption of permission to do something that is inferred from an individual's actions rather than explicitly provided.

Are Diagnostic imaging caring?

Good

Compassionate care

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

Inadequate

Diagnostic imaging

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. Staff received chaperone training to help support patients who did not want to be assessed alone. The service had notices in reception advising people to ask if they required a chaperone.

Patients said staff treated them well and with kindness. Staff were polite to patients and treated them with compassion and we saw examples of this.

Patient feedback cards were available in the reception area. In the past year patients rarely left feedback, and this was not managed or encouraged since the Covid-19 pandemic.

Patient feedback on the provider's website was positive and gave examples of compassionate care. However, the feedback was not dated or verified.

Emotional support

Staff provided emotional support to patients to minimise their distress.

Staff supported patients to make advanced decisions about their care. Nervous patients were encouraged to bring a trusted friend or family member with them if needed.

Staff understood the emotional and social impact that a person's care, treatment or condition had on their wellbeing and on those close to them. Clinicians took time to make sure people fully understood their results and any concerns were talked through.

Understanding and involvement of patients and those close to them.

Patients were given time to ask questions during their consultation or after their tests. Staff provided clear explanations in way that was easy to understand and encouraged patients to ask questions.

Patients were given a full explanation at the end of the process and told that they would receive the completed report once their NHS clinician had reviewed the imaging reports. Clinic slots were 45 minutes to one hour which gave patients plenty of time to ask questions.

We did not see any evidence of fees displayed within the clinic or on the provider website. This is a breach of The Health and Social Care Act 2008 Regulation 9 Person Centred Care 3 (g) which states; providing relevant persons with the information they would reasonably need for the purposes, which includes costs fees and tariffs associated with their care and treatment.

Private patients were offered a copy of the digital imaging once their assessment had been completed.

Are Diagnostic imaging responsive?

Requires Improvement

Service delivery to meet the needs of local people

Inadequate

Diagnostic imaging

The service planned and provided care in a way that met the needs of local people and the communities served. It also worked with others in the wider system and local organisations to plan care.

The provider planned and provided services to meet the needs of the local population**.** The provider website gave details of all the services provided.

The service website contained several electronic information leaflets that outlined the available consultations and tests. These included treadmill exercise tests, cardiac holder analysis, and echocardiography.

The service provided local people with an alternative to NHS care. People could make a self-referral online. The service worked collaboratively with the local NHS to give local people choice about where they received their care. Working with the NHS meant people did not have long waits for investigations.

The provider supported local GPs with twenty-four-hour tape reporting. They provided patients with a medical device that recorded cardiac activity over a twenty-four-hour period, the equipment was returned to the provider who would report the findings to the GP.

The service also received referrals from third party commissioners such as private health insurers and an NHS cardiologist service.

Patients were sent written confirmation of the appointment electronically or via letter, the information included travel directions, contact number of the provider and the process for changing the appointment if required.

Meeting people's individual needs.

The service considered patients individual needs. The service took a proactive approach to assessing patients and making sure they received the right care at the right time. Staff gave us examples of patients who had been reviewed at home when they had voiced concerns about being able to attend the clinic.

The service's access was limited for bariatric patients, people with reduced mobility or those using a wheelchair. The NHS provider who commissioned the service risk assessed patients to make sure they were suitable to use the service and patients were sent pre appointment information about the accessibility of the service and were asked if they had any additional needs.

Patients who were diabetic or had specific needs were offered early appointment slots so that their blood sugar levels were not compromised because they needed to avoid food before the treatment. These patients were identified during the booking process and reviewed on an individual basis.

Managers made sure staff, patients, loved ones and carers could get help from interpreters or signers when needed. Telephone interpreting services were available to people whose first language was not English. Staff knew how to use the service.

The service offered a quick turnaround on most reports although there were no audits to confirm this.

There were no specific disabled toilets and the one toilet did not appear big enough to allow wheelchair access.

The service did not have a bariatric couch as space was limited, and they made patients and commissioners aware of this to avoid confusion.

There were no loop hearing systems for deaf people and no arrangements for people with sensory impairment.

Access and flow

People could access the service when they needed it and received the right care promptly. Waiting times from referral to treatment and arrangements to admit, treat and discharge patients were in line with national standards.

Managers monitored waiting times and made sure patients could access services when needed and received treatment within agreed timeframes. Records confirmed that 198 patients had been seen since January 2021. However, the service did not keep records of which patients were referred from the NHS and which have been referred privately.

People could access the service during normal office hours. NHS patients were seen within two weeks of their initial referral and records confirmed this. Self-funding or insured private patients could access the service usually within seven days and records confirmed this.

Cardiac imaging software was used during the procedure and physiologists plotted the findings which were input via NHS cloud based diagnostic imaging software. These were sent back to the referring clinician at the NHS service the same day.

The service said it offered a quick turnaround on most reports although there were no audits to confirm this.

Managers and staff worked to make sure patients did not stay longer than they needed to. Upon arrival patients checked in at reception and were asked to take a seat and wait to be called. They were asked their name and what procedure they were booked for. On the day of our visit the clinic ran on time.

Managers worked to keep the number of cancelled appointments to a minimum but did not provide records of audits for appointments cancelled during the reporting period July 2020 to June 2021.

Staff used a local verbally agreed process for following up on patients who did not attend (DNA) their appointments. Staff followed patients up with a phone call and a letter and if there was no response, they would notify the commissioner/referrer most of the time.

The service did not complete regular audits of patients who DNA appointments; therefore, there were missed opportunities to make sure cardiac patients understood the importance of having diagnostic testing.

Learning from complaints and concerns

People could give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff. The service included patients in the investigation of their complaint.

Inadequate

Diagnostic imaging

The service treated concerns and complaints seriously. There was a complaints policy and procedure which reflected best practice. This outlined how complaints would be acknowledged, responded to and investigated. It stated that complaints would be acknowledged within two working days and a detailed response provided within 20 days.

Staff welcomed feedback of concerns and offered an opportunity for a local resolution in the first instance.

The provider website had a tab for patient comments and a box that gave people the opportunity to feedback to the service. The contact details of the provider were also displayed clearly on the website and within the clinic.

There was no easy way for patients to obtain details on how to make a complaint. There were no complaints leaflets within the service or details on the provider's website.

During the reporting period July 2020 to June 2021 the CQC did not receive any complaints about the service. There was one formal complaint which was managed in line with the provider's policy.

Are Diagnostic imaging well-led?

Inadequate

Leadership

Leaders did not always manage or understand the priorities and issues the service faced even though they had the skills and abilities to do so. Managers were not always visible in the service for patients and staff which led to a lack of oversight.

The service organisational structure was led by a managing director who was also the medical director. They had the knowledge, skills and qualifications to oversee the service. The board was made up of four consultants including the managing director. The managing director had been working abroad for some time which meant that their oversight was limited**.** Evidence received after the inspection confirmed that the consultants held medical protection certificates which is a type of indemnity insurance for doctors.

The service had two clinical leads who worked part-time at CVS Health Limited (Trinity House) who were both senior cardiologists at NHS trusts.

The operations manager was also the CQC registered manager and had worked for the service for 10 years. The operations/registered manager worked remotely most of the time, and only visited the site once a fortnight and delegated daily tasks to the part-time administrators. Staff were happy with the leadership structure.

The leadership team met off site, although the registered manager was unclear about how often these meetings occurred, was not invited and did not have access to any formal minutes.

The fragmented approach to service leadership, meant systems and processes to safeguard patients, families, staff and sustainability were not well established. We found that governance and risk systems and processes were not monitored or reviewed effectively. This was evident when we found that equipment servicing checking had lapsed for a long period

of time and vital emergency medication was out of date leaving patients at risk of serious harm. The safeguarding and incident reporting policies and process were outdated, and the information did not keep people safe. The service did not have the physical presence of the service manager onsite to empower staff and manage the day to day running of the service and provision of the regulated activity.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy.

The provider had a vision for what it wanted to achieve. This was to expand the current service to provide an enhanced 'one stop' patient experience with collaboration of a local NHS trust to provide the invasive cardiac procedures. They planned to commence day case invasive testing by renting time and space at local NHS premises. Plans to set up a virtual consultancy service were discussed at a recent meeting and leaders were making set targets for a two-hour response for appointment enquiries.

Culture

Staff felt respected and supported, but not always valued. They were focused on the needs of patients receiving care.

Administrative staff managed the day to day running of the service and liaised with physiologists and consultants to make sure clinics ran smoothly. They were experienced, friendly and self-motivated, they escalated concerns to the registered manager when required.

The service manager wanted to promote a positive culture that created a common purpose with shared values. However, he was rarely on-site to actively engage with staff and manage the service. A staff member commented they felt valued and respected and had worked for the service for many years.

The service did not hold multidisciplinary staff meetings because clinical staff were subcontracted on a part-time basis and had to honour commitments in their other roles. This created a lack of inclusion for clinical staff who were reliant upon the administrative staff to update them of the day to day running of the service.

Staff showed a lack of ownership which meant some tasks got overlooked as there were not always clear lines of responsibility. An example was the lack of routine checking of emergency equipment because staff made assumptions about the responsibility for this.

Governance

Leaders had not ensured the service had effective governance systems and processes to guarantee the service was managed safely and in compliance with the regulations. Not all staff were clear about their roles and accountabilities and they did not have regular opportunities to meet, discuss and learn from the performance of the service.

Inadequate

Diagnostic imaging

An NHS community cardiologist service used CVS. However, there was no service level agreement with the NHS community service to provide echocardiograms. However, the service had a verbal agreement for daily liaison to make sure that appointment times were adhered to. This meant that commissioning could be withdrawn, putting the service's sustainability at risk.

Leaders had not ensured the service had effective governance systems and processes to guarantee the service was managed safely and in compliance with the regulations. There were no clinical or internal audits to monitor quality or safety and no formal process for identifying, mitigating and monitoring risks to patients, staff or visitors. There were no risk or governance meetings. The last annual general meeting was on the 22 May 2021, but the registered manager did not have the minutes of this meeting. Board meeting minutes produced after the inspection confirmed that there was no formal process for assessing policies or completing risk assessments. The minutes focused on generating business and discussing new pricing.

Leaders did not keep accurate data on patient access and flow; they were unable to provide a proper breakdown of which patients were referred from the NHS and which patients were referred privately. They did not keep records of people who did not attend and there were no systems of monitoring wait times. This information helps limit wait times and missed appointments and informs future service level agreements.

Governance arrangements did not support the early identification and management of any risks and poor performance. There was no formal procedure for managing and monitoring work the provider did on behalf of third parties including the NHS for whom they conducted echocardiograms. The registered manager was onsite approximately once a fortnight, but this could not be evidenced. We found multiple failures in governance that indicated a lack of ongoing supervision of the regulated activities. Board minutes confirmed that leaders had discussed the importance of maximising invasive work at the location but there was no mention of risk assessing this or creating a service level agreement with the local NHS.

There was no effective system for managing required background checks when recruiting staff or awarding practicing privileges. The service could not provide appropriate records of persons employed in the carrying on of the regulated activity. The service manager advised us that the administrative staff had been in post for over 10 years but had undergone employment checks and references at the point of recruitment. However, they could not provide evidence of schedule 3 recruitment checks, or practicing privileges records, because he did not have access to the completed files for the consultants.

The registered manager did not make sure that staff completed a Disclosure and Barring Service (DBS) check for the service. They relied upon clinical staff to produce DBS certificates from third party services which were over three months old. This was not in line with Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 19. Registration under the Health and Social Care Act 2008: Disclosure and Barring Service (DBS) checks (formerly criminal record (CRB) and barring checks states that "All health and social care providers registered with CQC, including dental and primary medical services, are responsible for checking the suitability of their staff".

A stakeholder meeting had taken place this year (2021). Minutes included a review of the local cardiology NHS requirements, a review of incidents and service risks, discussions on the next board meeting and plans to discuss premises rent with the landlord. The meeting was attended by the service/registered manager and a director of a third-party organisation.

Management of risk, issues and performance

Inadequate

Diagnostic imaging

Leaders did not effectively use systems to manage performance. Risks and issues were not always identified and escalated appropriately to reduce their impact. There were no effective systems to cope with unexpected events or to limit risks. Staff did not have opportunities to contribute to decision-making to help avoid financial pressures compromising the quality of care.

Managers were aware of the risks but failed to organise regular meetings to review and update the risk register. Stakeholder and board minutes reviewed current risks related to financial sustainability and the liability of the property lease for the building but there was no evidence of a formal business continuity plan. The registered manager could not provide us with an action plan to assure us that the service was fully monitoring the risks and looking at approaches to reduce these.

There was no established service level agreement with the NHS for the delivery of echocardiograms and referrals were provided via an honorary verbal contract. There was no quality assurance process with the NHS and outcomes were not audited so managers were not always aware if their clinicians' care and treatment was accurate or safe.

The service manager completed an annual premises risk assessment which included compliance to electrical and fire safety and the findings were reported to the board.

Information Management

The information systems were integrated and secure. Data or notifications were consistently submitted to external organisations as required via encrypted safe software.

The provider's systems and process to identify and manage and mitigate risks had been updated over the last 18 months. The digital software had the potential to provide leaders with all the information it needed to run an effective service. However, managers did not provide staff with proper training to use the system effectively. Staff could not access policies in a timely way and found it difficult to navigate the systems which meant they did not always find the information they needed to provide adequate care.

Information was managed in line with General Data Protection Regulations (GDPR). The provider had a policy for managing people's data and information which was in line with the regulations. People could make a self-referral online which also contained a consent tick box to assure patients of adherence to General Data Protection Regulations.

Patient sensitive data was transferred via secure passwords and secure password protected emails.

Leaders did not use information systems effectively. Information that was collected was not always used to monitor performance effectively. The software package had been installed during the last 18 months and all staff had secure protected password access but not all staff knew how to use the system properly to access information to help increase performance and productivity.

Engagement

Provider engaged with patients, staff, the public, local organisations to plan and manage services. They collaborated with partner organisations to help improve services for patients.

Inadequate

Diagnostic imaging

The service gave people the opportunity to engage on an individual basis. There were feedback leaflets and feedback cards available in the reception area and a feedback box was on display for people to post feedback. There was a tab on the provider website for people to ask questions.

There were no regular inclusive multidisciplinary staff meetings and updates to create and inclusive culture that would enhance patient care and increase safety.

The service did not have a formal system to gain staff feedback and relied upon staff to speak to the service manager on an ad-hoc basis.

Learning, continuous improvement and innovation

Leaders reviewed improvements and innovation but failed to share practice updates with staff. Staff lacked understanding of quality improvement methods.

Leaders discussed continuous improvement during board meetings which were held quarterly. However, the actions discussed at meetings were not always reviewed and updated. For example, leaders discussed the potential for research activity to become a Post Tachycardia Syndrome (PoTS) centre during the March meeting but this was not reviewed during the May meeting.