

CVS Health Limited

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?			
Are services caring?		Good	
Are services responsive?		Good	
Are services well-led?		Requires improvement	

Mental Health Act responsibilities and Mental Capacity Act and Deprivation of Liberty Safeguards

We include our assessment of the provider's compliance with the Mental Capacity Act and, where relevant, Mental Health Act in our overall inspection of the service.

We do not give a rating for Mental Capacity Act or Mental Health Act, however we do use our findings to determine the overall rating for the service.

Further information about findings in relation to the Mental Capacity Act and Mental Health Act can be found later in this report.

Summary of findings

Letter from the Chief Inspector of Hospitals

CVS Health Care (CVS) has provided cardiac diagnostic and consultancy service since opening in 2012. 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. The service offers a wide range of services which include, but are not restricted to, cardiac analysis, electrophysiological studies, coronary angioplasty, cardiac diagnostic testing, ablations, pacemakers, implantable cardioverter defibrillator and angiograms.

It also provides an interventional cardiac treatment once a month. This invasive service is delivered from the cardiac laboratories of two NHS trusts in the Kent and East Sussex area.

We inspected this service using our comprehensive inspection methodology. We carried out the unannounced visit to the service on November 12th, 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.

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

Our key findings were as follows:

- Staff had access to and completed regular mandatory training.
- The service had a safeguarding adults' policy which was understood by staff.
- Equipment was regularly serviced, cleaned and checked.
- Care was provided by professional, compassionate and caring staff.
- The patients we talked to and feedback we reviewed showed a consistent level of satisfaction.
- Services was planned and delivered in a way that met the needs of patients.
- Policies and procedures reflected best practice and national guidance.

We found areas of practice that require improvement in the service:

- Systems to monitor the standard and quality of care delivered by CVS were not established.
- We did not see governance systems or processes that protected patients from the risk of receiving poor care or treatment.
- There was a lack of systems to identify risk and mitigate risk in the service.

Following this inspection, we told the provider that it must take some actions to comply with the regulations and that it should make other improvements, to help the service improve. We also issued the provider with one requirement notice that affected CVS Health Limited. Details are at the end of the report.

Nigel Acheson

Deputy Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Diagnostic imaging

Rating Summary of each main service

Good



The provider had suitable premises and equipment was serviced in line with manufactures guidance. The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and abuse and to provide the right care and treatment. Records were clear, up-to-date and available to all staff providing care.

The service provided care and treatment based on national guidance. The service had a multidisciplinary approach to care and sought the advice from colleagues working in the NHS settings. Staff cared for patients with compassion. We saw staff talk to patients in a kind and dignified way. Staff promoted patients' dignity and treated them respectfully. Feedback from patients confirmed that staff treated them well and with kindness.

The service planned and provided the services in a way that met the needs of local people. People could access the service when they needed it. There was a vision and strategy which staff felt involved with and aligned to. Staff felt support and valued by the leadership team. There was a clear leadership structure and lines of accountability.

However,

The infection control policy did not incorporate any quality monitoring processes.

We found a fragmented approach to service leadership. Risk management systems required further development to protect patients from the risk of receiving poor care.

Governance processes required further development to ensure oversight of the quality of the service provided.

Summary of findings

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Good 

CVS Health Limited

Services we looked at

Diagnostic imaging;

Summary of this inspection

Background to CVS Health Limited

CVS Health Care was opened in 2009 and provides consultancy, diagnostic and interventional cardiac services. It is a private service delivered from two locations, with the main site in Ashford, Kent and a second site in Eastbourne, East Sussex. The service serves the communities of Kent and East Sussex and received the majority of referrals from GP's across both counties. No NHS work is undertaken by the provider.

The service offered a wide range of adult cardiac diagnostic services which included, but was not restricted to, cardiac analysis, electrophysiological studies, coronary angioplasty, cardiac diagnostic testing, ablations, pacemakers, implantable cardioverter defibrillator and angiograms.

The service was last inspected in 2013 under the previous CQC inspection methodology and met all five standards that it was measured against.

Our inspection team

The team that inspected the service comprised a CQC lead inspector, and a specialist advisor with expertise in cardiology. The inspection team was overseen by Catherine Campbell, Head of Hospital Inspection.

Why we carried out this inspection

Our unannounced inspection took place on November 12th, 2018. Before the inspection, the service provided us with a range of information, which was reviewed by our inspectors and this formed part of the preparation and planning stage of the inspection. We visited the service's

main clinic, located in Ashford, spoke with six members of staff including a service manager, registered manager, clinical lead, and administrative staff. We spoke with three patients who gave feedback on their experience of using the service. We looked at ten patient records.

Information about CVS Health Limited

The service is registered to provide the following regulated activities:

- Diagnostic and screening procedures
- Treatment of disease, disorder or injury
- Surgical Procedures.

During the inspection, we visited the Ashford site. We spoke with six staff including; cardiac technician, reception staff, medical staff, and senior managers. We spoke with four patients and one relative. During our inspection, we reviewed ten sets of patient records.

There were no special reviews or investigations of the service ongoing by the CQC at any time during the 12 months before this inspection.

Activity (September 2017 to September 2019)

- 116 exercise tolerance tests
- An average of five invasive cardiac procedures a month in an NHS setting.

Track record on safety

- No reported never events serious or clinical incidents and no duty of candour notifications
- No incidents of hospital acquired infections
- No complaints within the inspection time frame

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?

We rated safe as Good because:

- Staff understood how to protect patients from abuse because they were trained on how to recognise and report it.
- Staff kept themselves, equipment and the premises clean.
- The service had suitable premises and equipment and looked after them well.
- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and abuse and to provide the right care and treatment.
- Staff kept appropriate records of patients' care and treatment. Records were clear, up-to-date and available to all staff providing care.

However:

- The infection control policy did not incorporate any quality monitoring processes.

Good



Are services effective?

We do not rate effective:

- The service provided care and treatment based on national guidance.
- The quality of echocardiograms was audited in line with guidance from the British Society of Echocardiography.
- The service had a multidisciplinary approach to care and sought the advice from colleagues working in the NHS settings.

However,

- The service did not have an established audit programme to show patient outcomes.

Are services caring?

We rated caring as Good because:

- Staff cared for patients with compassion.
- Staff talked to patients in a kind and dignified way.
- Staff promoted patients' dignity and treated them respectfully.
- Feedback from patients confirmed that staff treated them well and with kindness.

Good



Summary of this inspection

- The service actively gathered patient feedback. Comment cards were readily available in the waiting room so patients could easily provide feedback about their experience of using the service.

Are services responsive?

We rated responsive as Good because:

- The service planned and provided the services in a way that met the needs of local people.
- People could access the service when they needed it. Waiting times from treatment were and arrangements to admit, treat and discharge patients were in line with good practice.
- The service took account of patients' individual needs.
- No complaints were made in the twelve months before the inspection, but the service had systems and process to treat concerns and complaints seriously, investigate them and learn lessons from the results.

Good



Are services well-led?

We rated well-led as Requires Improvement because:

- We found fragmented approach to service leadership which meant systems and process to safeguard patients, staff and the business were not well established.
- Risks management systems needed further development to protect patients from the risk of receiving poor care.
- Governance processes required further development to ensure oversight of the quality of the service provided.





However,

- There was a clear leadership structure and lines of accountability.
- There was a suitable vision and strategy which staff felt involved with and aligned to.

Requires improvement



Diagnostic imaging

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

Are diagnostic imaging services safe?

Good 

Mandatory training

- The service provided mandatory training in key skills to all staff and made sure the everyone completed it. The service had enough staff with the right qualifications, skills and training.
- Administration staff did a combination of on-line, and face-to-face training.
- Clinical staff obtained their training from their main employer. The CVS service manager reviewed skills and qualifications. Staff training certificates were reviewed and recorded on the CVS electronic database. The provider used the training database to provide oversight of individual training and compliance rates.
- All staff had completed mandatory training. We saw training compliance records were held electronically on a central database for easy oversight. Examples of the training provided included the following topics, fire health and safety, infection control, information governance, customer service, equality band diversity. The service had a set training compliance rate of 100%.

Safeguarding

- Staff understood how to protect patients from abuse because they were trained on how to recognise and report it.
- The service had a safeguarding policy which reflected national guidance. It was available on the provider's

shared drive. Staff were able to tell us how they would access the policy if required. Staff told us that they would alert the operations manager if a concern was identified.

- No safeguarding referrals had been made to CQC or the local authority in the twelve months prior to inspection.
- Administration staff received adults level one safeguarding training. The operations manager and nursing staff had received level two adults safeguarding training. One consultant had obtained level three adult safeguarding. This training was in line with current best practice guidance.
- Children were unable to access the service; therefore, this training was not required.

Cleanliness, infection control and hygiene

- Staff kept themselves, equipment and the premises clean. They used control measures to prevent the spread of infection. However, there was a lack of quality assurance mechanisms to monitor infection and cleanliness standards.
- All consultation rooms appeared clean and tidy on the day of inspection.
- Staff had access to an ample supply of personal protective equipment (PPE). PPE can be defined as clothing that protects people and health care workers from infections, gloves for example. We saw staff using PPE in line with national guidance when interacting with patients and we observed staff washing their hands in between patient contacts in line with the World Health Organisation (WHO) 'Five moments for hand hygiene'.
- We saw staff use disposable pillow cases, and use disposable paper sheets to cover treatment couches. We also saw staff clean the treatment couch before use.
- Patients told us they considered the environment as clean, and well maintained.

Diagnostic imaging

- The service completed an annual infection control risk assessment. We reviewed this and noted it did not have any outstanding concerns or risks.
- There was no provider assurance framework for the infection prevention and control. For example, there was no cleaning records, or hand hygiene audit records available.

Environment and equipment

- The service had suitable premises and equipment and looked after them well.
- A third party undertook environmental maintenance. We saw a range of environmental risk assessments which were used to identify and manage any risks. These did not indicate there were any concerns with the way the building was maintained.
- The service had fire extinguishers available. We saw records which showed these were routinely checked. The service completed an annual fire risk assessment. We saw this and found no outstanding areas of concern. The operations manager was the dedicated fire warden.
- The service chose to purchase all the equipment rather than use a system of loaning the equipment from the manufacturers. Staff told us that the electronic kit used for diagnostic testing was serviced annually and maintained by a recognised service team. There was a service level agreement with an external company who served the machines once a year. We saw records which confirmed this.
- Diagnostic equipment was checked by staff before use. We saw this on the day of the inspection but this was not always documented. The provider did not have a standard policy which outlined the frequency or process for checking diagnostic equipment.
- Emergency equipment was available in the clinic. We saw records which showed the emergency equipment was checked daily.
- We saw a suitable waste management policy and valid contract with a new clinical waste company. Clinical and domestic waste was separated and disposed of in line with best practice guidance.

Assessing and responding to patient risk

- Patients who used the service had risks assessed to ensure their needs could be met before they came to the service.
- Administration staff completed a registration form at the point of booking. This included information such as the

patients name and address, chaperone requirements, and type of check required. This information was then sent to the consultant for review and all referrals were accepted. However, there was no standardised, or formal acceptance criteria in use. This meant patients individual risks and care needs was potentially being assessed differently depending on which consultant reviewed the information.

- We saw each patient had a three-point check completed prior to their any diagnostic tests. Staff confirmed all patients had their name, address and date of birth checked before starting an investigation.
- The service responded swiftly to any concern identified. Staff escalated any concerns or abnormalities they identified to the referring consultant on the same day by phone and email. his response included urgent contact with the responsible consultant who reviewed the individual risk and indicated how soon the patients required a review
- The provide had a policy which clearly outlined the response to an emergency situation which was to call 999. If a patient deteriorated during a consultation the staff provided any necessary basic life support and awaited a response from the emergency service. CVS had a training database which showed all relevant staff had undertaken basic life support training.

Staffing

- The service had enough staff with the right qualifications, skills, training and experience to keep people safe from avoidable harm and abuse and to provide the right care and treatment.
- The service directly employed the administration staff. The clinical staff were contractors which meant they worked on an 'as and when' basis. The clinical team was made up of consultant cardiologists, cardiac technicians and cardiac nurses.
- The service did not use any bank or agency staff, preferring to cover any unexpected vacancies with the clinic's own staff team.
- Staff worked flexibly to ensure appropriate staffing was maintained.

Medical staffing

- The medical director of the service had a professional GMC registration. There were two clinical leads on each site.

Diagnostic imaging

- There was a total of seven consultants providing the service and working as a partnership.

Consultants were allocated their own clinics on specific days of the week. There was a flexible approach to leave cover and providing additional clinic cover.

Records

Records were clear, up-to-date and available to all staff providing care. They were stored securely and kept confidential. At the time of the inspection records were kept on paper. However, the provider was in the process of moving towards an electronic patient record systems. The provider was in the process of scanning and archiving old records at the time of the inspection. We saw records which showed this was undertaken in a secure manner.

- We reviewed ten sets of notes and found records were managed in a way that kept patients safe and staff always had access to up-to-date, accurate and comprehensive information on patients' care and treatment.
- The consultants' private secretaries typed all the consultation letters. There were completed within 24 hours of the consultation and sent by secure email to patients GP's. Urgent correspondence was treated as such, and completed and sent on the same day.

Medicines

- The service did not use any controlled drugs or other medicines.

Incidents

- The service had an incident reporting policy and procedure for staff to follow. However, it required further development to incorporate incidents occurring in the acute settings.
- The service had a paper reporting system on both sites. Paper forms were available at each office.
- Administration staff were aware of how to raise an incident and could tell us the process.
- There were no reported incidents in the twelve months before the inspection.
- We asked clinical staff how incidents occurring during the invasive procedure lists in the NHS settings were reported to the CVS. We were told that there was no

formal system, or established route to routinely take account of these. We discussed this with the provider during the inspection and have since received assurance our concerns would be addressed.

- We reviewed historic incident that occurred in an NHS setting. This was investigated, and the learning discussed amongst the team to prevent recurrence.

Are diagnostic imaging services effective?

We do not rate the effective domain.

Evidence-based care and treatment

- 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 had an audit programme to measure the quality of the Echocardiogram tests. An echocardiogram can be defined as an ultrasound test used to examine and measure the structure and functioning of the heart and to diagnose abnormalities and disease. Audits demonstrated a consistent quality of echo being achieved with good compliance. The auditing was undertaken by the cardiac technicians on a rotational basis. The results were routinely reviewed by the medical director.
- There was a process to escalate identified anomalies to the medical director who took responsibility to ensure discrepancies were addressed.
- The service reported carrying out 116 exercise tolerance tests between November 2017 and November 2018. Of the 116 tests completed, six were undertaken to ensure patients were safe to drive and could retain their driving licence. Due to the lack of audit processes it was difficult to show the other 110 tests undertaken were done in line with National Institute of Health and Care Excellence. An Exercise Tolerance Test (ETT) is used to determine how well your heart responds during times when it's working its hardest.
- We saw verbal and written patient information reflected best practice guidance from the British Cardiology Society (BCS).

Nutrition and hydration

Diagnostic imaging

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

Patient outcomes

- There was no other local audit activity undertaken in the service which meant there was no formal assurance of care being delivered in line with NICE and BCS guidance.
- Outcomes for the interventional procedures undertaken at the NHS sites was reported into the National Institute for Cardiovascular Outcome Research (NICOR) audits.

Competent staff

- Records showed all contracted administration staff had a yearly appraisal. All sub-contracted staff had an appraisal in their own permanent place of work.
- The provider kept a database of clinicians training records and annual appraisals to ensure they had oversight of their training needs.
- Staff had relevant pre-employment checks in place before starting work. We saw two personnel files which showed this.
- The provider ensured all cardiac technicians had a British Society of Echocardiography (BSE) qualification. This qualification was part of the key criteria for employment. We saw evidence this qualification was held by all technician staff.
- New staff were provided with a formal induction and support package which included service policies and procedures, fire safety handling complaints, and customer service.

Multidisciplinary working

- The service was delivered by a team of cardiologist consultants and cardiac technicians who undertook the diagnostic tests.
- Staff told us they utilised the multidisciplinary forum at their respective NHS trusts to seek a multi professional perspective on challenging cases. This ensured treatment plans were developed with other professionals incorporating specialist knowledge from a range of consultants. However, this was an informal arrangement and there was no audit trail to evidence these multidisciplinary reviews.

Seven-day services

- The service was provided Monday to Friday between 9 am and 7:30pm. The interventional service was provided on a Saturday morning at a local NHS trust in Kent and East Sussex.

Health promotion

- A wide range of health promotion from the British Heart Foundation was made available to patients. For example, this included healthy eating, importance of regular exercise, medication management.
- Health promotional information was also provided to patients on an individual basis during their consultation consultations.

Consent and Mental Capacity Act

- The service had a current consent policy which was in line with national guidance.
- Patients consent was gained prior to diagnostic tests. There was a process to ensure verbal consent before a test happened. Patients were provided with information about the tests before their appointments. They were provided with sufficient time to ask any questions before the tests.
- Consent was generally implied for the majority of patients and written consent for having an invasive procedure. Implied consent can be defined as an assumption of permission to do something that is inferred from an individual's actions rather than explicitly provided
- Mental capacity training was included in the safeguarding training module staff undertook
- Staff understood their role in identifying patients who did not have capacity to consent.
- Administration staff told us they would alert the service manager immediately if they felt there was a capacity related concern.

Are diagnostic imaging services caring?

Good 

We rated Caring as **good**.

Compassionate care

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

Diagnostic imaging

- Staff told us they provided chaperones for patients when requested. However, the staff had not received chaperon training.
- We saw a large amount of feedback from patients which was overwhelmingly positive. We saw feedback about the consultants and the administration staff which showed patients were happy with the compassionate care they received.
- Examples of the comments we saw included, “The doctor was very reassuring”, “the service provided was excellent in every way”, “all the staff were extremely polite and helpful” and “I have always found the service to be top quality”.
- A comment we received during the inspection said “excellent service, wonderful staff, extremely safe and hygienic environment, listened to and given the right care and treatment which was needed urgently”.
- Patients we talked to during the inspection also provided consistently positive feedback.

Emotional support

- Staff provided emotional support to patients to minimise their distress.
- We saw staff communicate with patients in a kind, compassionate and reassuring way.
- Nervous patients were encouraged to bring a trusted friend or family member for support.

Understanding and involvement of patients and those close to them

- Patients told us they felt involved in planning their care.
- The service enabled a family member or carer to remain with the patients for their appointments to provide morale support.
- Patients were given time to ask questions during their consultations or after their tests, and staff provided clear the required information in a way that was easy to understand.
- Staff provided clear explanations about the tests and encouraged patients to ask questions.
- Comment cards were available in the waiting room so patients could easily provide feedback about their experience of using the service. An example of the comments received included “Quick appointment, informative consultation, all excellent”

Are diagnostic imaging services responsive?

Good 

We rated Responsive as **good**.

Service delivery to meet the needs of local people

- The provider planned and provided services in a way that met the needs of local people.
- The service opening hours gave patients extended choice to access the service at a time that was convenient to them.
- The senior team had identified a local need for an improved ‘one stop’ approach to care delivery. As a result, there was a planned service expansion which incorporated more invasive procedures and diagnostic imaging.
- The service provided local people with an alternative to NHS care.

Meeting people’s individual needs

- The service took account of patients’ individual needs.
- The centre was compliant with the Disability Discrimination Act 1995. The service was provided on the ground floor of the building and had an allocated disabled parking space outside the front door. There was a suitable toilet facility with mobility supports, an emergency alarm and handwashing facilities at the right level for those using a wheelchair.
- A telephone interpreting services was available to those whose first language was not English. This was provided by a telephone interpreting service. Staff told us they have never had to use it, but they were confident they could access the service, if required.
- Patients who were diabetic, or had other specific care needs were offered early appointment slots or double appointment slots if their needs required more time and personal input from staff. These were identified during the booking process and reviewed on an individual basis by the clinical staff.
- The service reporting seeing very low numbers of patients with mental health problems and learning difficulties. The staff adjusted how the service was delivered to meet the individual needs of these patients

Diagnostic imaging

by offering appointments at the beginning or end of a list to reduce anxiety and welcomed a trusted individual to accompany the patient for their consultation or diagnostic tests.

- The service had bariatric couch which could hold a weight of 220 kg.
- The service took a proactive approach to ensure that patients had the right care at the right time. This was evident in how the staff took the service into the community to those who had difficulty attending CVS sites. We were provided with examples where a member of staff carried out home visits to ensure patients had their cardiac device checked.
- The provider also supported local GPs with twenty-four-hour tape reporting. A 'twenty-four-hour tape' is a medical device that measures the heart's activity, such as rate and rhythm over a twenty-four-hour period. CVS offered a two to three day turn around on the majority of reports.

Access and flow

- People could access the service when they needed it.
- All the referrals were from self-pay or insured patients. The service did not have a referral or acceptance criterion and accepted all referrals.
- Patients were seen within five to seven days of a referral being received by the service.
- Upon arrival to the service, patients checked in at the front desk and took a seat in the waiting room until called to the consultation room or test suite.
- Patients were corresponded with directly and sent written confirmation of the appointment which included travel directions and a contact number for patients to call if they required additional information or had to change the appointment.
- Staff told us if there was a surge in referrals the service would be able to meet that demand by providing additional capacity. Patient's waited on average between five and seven days for an appointment.
- Patients rarely Did Not Attend (DNA) their appointments. Whilst there was no formal DNA policy in the service we saw administration staff followed these up via telephone call and had a system of sending three formal reminder letters. If there was no response to the contact attempts, the patients would be discharged from CVS health. The referrer was also made aware of the nonattendance and lack of a response to the contact letters.

Learning from complaints and concerns

- The service treated concerns and complaints seriously. There was an in-date complaints policy which reflected best-practice. It outlined how complaints would be acknowledged, investigated and responded to. Staff could easily access the policy if unsure of how to manage a complaint.
- The manager and administration staff told us they welcomed comments and concerns and always offered an opportunity for local resolution in the first instance.
- Administration staff provided examples of how they managed a comment or concern. This included giving patients the service address to send their formal feedback and making the service manager aware immediately.
- There were no complaints made in the last twelve months before the inspection. All the feedback comments we were viewed were positive.
- However, there was no easy way for the patients to obtain details on how to make a complaint. For example, there were no specific complaints leaflets or information on how to complaint readily available. We discussed this with the provider during the inspection who provided assurance the service would address our concerns.

Are diagnostic imaging services well-led?

Requires improvement 

We rated Well led as requires improvement:

Leadership

- The service had a clear organisational structure with a medical director and two clinical leads, one for each site. There was also a service manager who worked across all sites to ensure continuity and oversaw the day to day running of the business. The medical director was also the CQC registered manager.
- The registered manager only worked from the Eastbourne site and had no presence at the Ashford site. This was a breach of the registered managers regulations and we raised this during the inspection. The service manager regularly worked cross site which meant there was visible leadership on both sites. Staff we talked to were very complimentary about the

Diagnostic imaging

leadership. They told us they felt very valued and respected and were sufficiently supported. All the staff we talked to had worked for the service for many years and felt this reflected how satisfied they were working for CVS health.

- We found a leadership team were responsive to the service and communicated well with each other. Staff told us they could email any of the leadership team and get a same day response. We saw this happen during our unannounced inspection.
- The administration team had bi-monthly staff meetings. Meeting minutes contained very little information on the discussions had and there was no standardised approach. For example, minutes showed a lack of discussion in relation to learning from incidents, service risks, or patients compliments or comments. This meant the service was not routinely discussing or learning from there areas.
- The minutes we viewed showed discussions regarding the General Data Protection Regulation (GDPR), utilities, equipment, billing and staffing.
- We found fragmented approach to service leadership which meant systems and process to safeguard patients, staff and the business were not well established. This related to our findings in terms of how risk, quality and governance systems and processes were developed and managed in the service. This included but was not restricted to the lack of an service referral and acceptance criterion, lack of policies and procedures relating to the checking of diagnostic equipment, no infection prevention and control quality monitoring, the risk register not accurately reflecting the risks in the service, incident reporting culture, lack of easy access to information on how to raise a complaint, and failing to ensure patients have access to fee information prior to entering the service.

Vision and strategy

- 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 with a specialist London NHS trust being used to provide the invasive cardiac procedures. However, the current governance systems are not sufficiently effective to enable this to be done safely without further development.

- The vision also included a change to how the service employed staff. For example, with the exception for the administration staff, all other staff were independent contractors. The new vision specified a change to incorporate an employed staffing model.
- Staff were aligned with and understood the service strategy which was to provide high quality service to patients at an affordable price to ensure the service was accessible and affordable to those who did not have private health insurance.

Culture

- The service manager promoted a positive culture that supported and valued staff creating a sense of common purpose based on shared values.
- From our interactions and observations of the staff, we found a cohesive, open and team oriented staff group. We saw a positive attitude being applied to all aspects of the work undertaken by the service.
- We saw the team communicated well with each other and with patients who attended for consultations and those who contacted the team via telephone.
- The senior team described the culture as "positive" and a "good culture of getting things done with a flexible workforce".

Governance

- The systems and process for monitoring the quality of service delivered required development. We found a lack of systems and process to measure quality and safeguard patients from receiving poor care.
- The system and culture towards incident reporting, and learning from such events was not well established. The senior team acknowledged this during our inspection and were keen to address our concerns.
- Patients were offered a chaperone service, however, staff had not received chaperone training.
- Meeting minutes did not have a standardised agenda to ensure key areas such as incidents, complaints and comments was routinely discussed at both sites. There was no formal way to communicate learning, key governance messages, or areas for development with staff who worked on the acute site.
- The service did not have an established audit programme to take account of the quality and risk in the service. There was a lack of oversight and assurance

Diagnostic imaging

frameworks to monitor the safety and quality of the service delivered at the NHS trust. We reviewed the service level agreement which did not have any reference to quality monitoring reporting systems.

- There was no audit trail to show how the service monitored the standard of cleanliness at the Ashford or Eastbourne sites. There was no oversight of the infection prevention and control standards for the interventional work undertaken off site.
- However, this was addressed with the provider during the inspection who was very receptive to the feedback. We received additional correspondence to demonstrate the actions that were planned to address the concerns.

Managing risks, issues and performance

- The system and process to identify, manage and mitigate risk required further development.
- We saw a corporate risk register which identified twenty-five risks categorised as low risks. The risk register had entries for each risk, and how it was identified. All the risks were identified through carrying out a risk assessment, and the date the risk was added and the severity of the risk was also recorded.
- However, the recorded risks did not accurately reflect the actual risks in the service. For example, staff told us the biggest risk to the service was staffing and clinical complications. The clinical complications risk was recorded on the register however, staffing was not.
- We also asked how risks for the interventional service delivered at the local NHS hospital was monitored and mitigated. For example, we talked about how incidents that occurred on the NHS site were reported to CVS and managed and the quality assurance process that patients received safe care and treatment. We were told that there was no formal assurance processes and any reported incidents for this work was not reported back to CVS.
- The service did not have a formal standardised acceptance criterion to assess patients risk and ensure the service could meet individual needs.
- There was no policy to guide staff on the frequency or formal recording of routine diagnostic equipment checks.
- The provider undertook a range of annual risk assessments which included a review of the facilities, electrical safety and fire compliance.

Managing information

- Information was managed in line with best practice guidance.
- The provider had updated the information management procedures which took account of the new General Data Protection Regulation (GDPR).
- Information governance was included in the mandatory training modules.
- All patient sensitive data was transferred via a secure password protected email system.
- The service was in the process of moving to an integrated IT software package which would allow access to all medical records from all sites.
- All the service policies and procedures were available on a shared drive for staff to access.
- We saw evidence that each patient was provided with an itemised bill this information once they entered the service. However, we found there was no easy for patients to access a consultation or test price list before entering the service. Price information was not available on the service website nor readily available at the clinic. This was a breach of the Health and SocialCareAct2008 (Regulated Activities)Regulations2014:Regulation 19.

Engagement

- A small but dispersed team provided care. This meant, staff engagement happened daily via email and telephone and was not formalised, other than in staff meetings.
- Staff told us there were plans for a more integrated approach to staff engagement and communication when the service expands.
- At the time of the inspection there was no public engagement strategy. However, patients were actively encouraged to provide feedback about their experience of using the service. Comments cards and pens were readily available in the waiting room for patients to provide feedback.

Learning, continuous improvement and innovation

- The service took a proactive approach to ensure that patients had the right care at the right time. This was evident in how the staff took the service into the community to those who had difficult attending CVS sites. This meant that patients were able access the service regardless of personal issues which limited their ability to visit the service.

Diagnostic imaging

- The service responded immediately to CQC feedback and acted to make the necessary improvements. The provider was in the process of developing an action plan to address the concerns we raised.

Outstanding practice and areas for improvement

Areas for improvement

Action the provider **MUST** take to improve

- The provider must ensure that risks to patients are identified, assessed and monitored consistently and used for trend and theme analysis.
- The provider must take prompt action to address a number of significant concerns identified during the inspection in relation to care quality, risk management, and governance systems and processes.
- The provider must develop the current risk register to incorporate all the risks to the service, steps taken to mitigate the risk, and develop an enhanced audit trail and timeframe for each risk need to be clearly documented.
- The provider must ensure there is oversight of compliance with infection control and safety practices across the service, in particular the invasive work undertaken NHS hospitals.
- The provider must develop systems and process to ensure oversight of all CVS work delivered at third party sites.
- The provider must develop a formal standardised referral and acceptance criteria to ensure all patients have their risks assessed in the same way prior to using the service.

- The provider must ensure patients have easy access to information regarding the cost of the service before entering the service.
- The registered manager must have a presence in both locations to be compliant with the terms and conditions of the registered managers conditions.

Action the provider **SHOULD** take to improve

- The provider should ensure a clinical audit programme is developed to monitor the quality of service and patient outcomes in line with national guidance and best practice guidelines.
- The provider should ensure that all incidents, including those occurring off site are captured, investigated, and learned from to prevent recurrence.
- The provide should ensure there is an audit trail to demonstrate learning from complaints and comments.
- The provider should ensure patients have easy access to information on how to raise a formal complaint.
- The provider should ensure staff undertaking chaperone duties receive formal training.
- The provider should develop formal multidisciplinary processes and keep evidence of such reviews.

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

Diagnostic and screening procedures
Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 5 (Registration) Regulations 2009 Registered manager condition

5 Registered manager condition

(1) Subject to paragraph (2), for the purposes of section 13(1) of the Act, the registration of a service provider in respect of a regulated activity must be subject to a registered manager condition where the service provider is—

(b) an individual who—

(ii) is not, or does not intend to be, in full-time day to day charge of the carrying on of the regulated activity.

Regulated activity

Diagnostic and screening procedures
Surgical procedures
Treatment of disease, disorder or injury

Regulation

Regulation 17 HSCA (RA) Regulations 2014 Good governance

17.—

1. Systems or processes must be established and operated effectively to ensure compliance with the requirements in this Part.
2. Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to—
 - A. assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity (including the quality of the experience of service users in receiving those services);
 - B. assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arise from the carrying on of the regulated activity;

This section is primarily information for the provider

Requirement notices

f. evaluate and improve their practice in respect of the processing of the information referred to in sub-paragraphs (a) to (e).

Regulated activity

Diagnostic and screening procedures

Surgical procedures

Treatment of disease, disorder or injury

Regulation

Regulation 19 CQC (Registration) Regulations 2009 Fees

19.—

Where a service user will be responsible for paying the costs of their care or treatment (either in full or partially), the registered person must provide a statement to the service user, or to a person acting on the service user's behalf—

The statement referred to in paragraph (1) must be—

- a. in writing; and
- b. as far as reasonably practicable, provided prior to the commencement of the services to which the statement relates.

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.