

Cambridge Heart Clinic

Quality Report

Addenbrooke's Hospital
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2016
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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?

Good 

Are services caring?

Good 

Are services responsive?

Good 

Are services well-led?

Requires improvement 

Summary of findings

Letter from the Chief Inspector of Hospitals

We carried out an announced inspection visit on 25 August 2016 and an unannounced inspection on 07 September 2016.

Overall the service was rated as good. We rated safe, effective, caring and responsive as good in both core services reviewed. However, we found that well-led required improvement because robust governance arrangements were not in place. We have issued the service with a requirement notice in this respect and told them to make improvements to the systems and processes they have in place. We will follow this up to ensure improvements have been made in due course.

Our key findings were as follows:

Are services safe at this service

- The service had a good track record for safety. There were no clinical incidents, non-clinical incidents or never events reported between April 2015 and March 2016.
- Appropriate infection control procedures were in place and the environment was clean and utilised well.
- Staff recognised how to respond to patient risk and there were arrangements to identify and care for deteriorating patients.
- Staff were aware of their responsibility to safeguard vulnerable adults from abuse. There were clear internal processes to support staff to raise concerns.
- Staffing levels were appropriate and planned in line with capacity. There had been no agency or bank usage in the past year.
- Staff and leaders were aware of their responsibilities in relation to duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- Patient records were well maintained, legible and up to date. We saw that there were stored securely and noted regular auditing took place.
- Appropriate medicine management procedures were in place. We found that medicines were stored and administered in line with legislation.
- We were informed that staff were up to date with their mandatory training, however we could not be provided with data which confirmed this.

Are services effective at this service

- The Cambridge Heart Clinichad a service level agreement (SLA) with Cambridge University Hospitals NHS Foundation Trust ('the trust') which detailed arrangements for CHC sharing policies and procedures developed by the trust. We saw that CHC monitored these policies to ensure that these were in date and updated to reflect best practice.
- The CHC did not participate in national audits. This was due to the unique set up of the service and low patient volume which meant national benchmarking could not be achieved. However, the service did undertake some local audit and measure patients' outcomes through patient feedback. There had been no negative outcomes recorded with all patients reporting an improvement in their condition following treatment with CHC.
- There had been no unplanned readmissions to the service within the past year.
- There were effective procedures in place to ensure medical staff were appraised, competent and revalidated. This was monitored through the Medical Advisory Committee (MAC) who on an annual basis ensured those consultants working under practicing privileges submitted evidence such as their annual appraisal and GMC registrations to demonstrate their fitness to practice. Full practicing privileges reviews were undertaken on a bi-annual basis.
- Consent was consistently well recorded and audited.

Summary of findings

- Staff were aware of the requirements of the Mental Capacity Act and Deprivation of Liberty Safeguards.
- We were informed that staff were up to date with competency checks, however we could not be provided with data which confirmed this.
- There was also a limited amount of clinical audit taking place across the service and this could be improved upon to demonstrate effective practice.

Are services caring at this service

- The service received consistently positive feedback from patients. We reviewed feedback from the 2015 feedback and found that overall, out of six individually test areas, patients' scored the service excellent.
- The satisfaction survey also demonstrated that 99.3% of patients would recommend the service.
- Patients we spoke with were complimentary about the service. One patient we spoke with stated it was "amazingly good" and another patient stated "I can't fault any aspect of my care – I have been here three times and it's always been fantastic."
- Patient's privacy and dignity was maintained and they were well respected at all times. We saw many positive interactions between staff and patients. For example, one patient had travel a long way to get to their outpatient appointment and was quite flustered when they arrived at the clinic. We saw staff comfort this patient, they made them a cup of tea and sat with them for a while in the waiting room.
- The use of chaperones was encouraged and additional requirements were discussed upon booking, prior to attendance at the clinic.

Are services responsive at this service

- Access to the service was seamless and without delay. Outpatient appointments were offered immediately upon referral and were usually attended within five weeks. We saw one case where a patient was referred, seen in the outpatient clinic and admitted for treatment in the same day.
- The clinic offered preferential access (as per the SLA agreement with the trust) to the catheterisation laboratory minimise waiting times.
- The clinic offered individual, patient focused care through the use of specialist nurses, chaperones and translation services where required.
- There was no cancellation of procedures due between April 2015 to March 2016.
- The individual needs of patients were being met with access to specialist dementia and learning difficulty nurses and chaperones. Specialist equipment was also available via the SLA agreement with the trust and the premises was accessible for those people living with physical disabilities.
- There was a robust complaints procedure in place. The CHC had one complaint for the reporting period of April 2015 to March 2016. We saw this was reviewed and discussed, with evidence of learning having taken place.

Are services well led at this service

- Governance systems required improving. We found the services governance framework made reference to out of date guidance and a reporting structure which was not accurate.
- In addition, the governance framework made reference to various reports and annual plans which should have been in place but were not.
- There was no agreed governance framework between CHC and the trust. Whilst processes were in place these were not documented and agreed by both parties which meant that intended outcomes could not be monitored.
- SLA monitoring was not robust. CHC did not receive or take appropriate assurance on the quality of staff training and competency.
- The policy ratification/approval process for CHC was not robust. For example, we found from the services governance framework that the clinical audit strategy should have been signed off by the MAC but instead it was signed off by the executive management team. In addition, there was no audit trail for the signing off of this document as it had not been presented to an executive management team meeting for approval.

Summary of findings

- However, the service had a clear vision and staff were aware of this.
- The leadership team was proactive and approachable. Staff told us that they felt comfortable in raising concerns and that they had confidence these would be taken forward.
- Staff felt there was an open and honest culture within the service.
- The service was working to improve services and was in the processes of redefining its strategy following announcements that the environment it worked within (cardiology services) were being redesigned and improved on locally.

We saw an area of outstanding practice:

- A patient was referred to the service by their GP and offered an outpatient appointment the same day. A treatment plan was agreed which meant the patient was also admitted the day of their referral and received treatment the following day.

However, there were also areas where improvements are required. Importantly, the provider MUST:

- Consider reviewing its clinical audit plan to include a wider range of audits to demonstrate patient outcomes and identify areas where practice could be improved.
- Consider reviewing its governance framework to ensure this accurately reflects the governance arrangements in place.
- Consider ensuring these arrangements are approved and agreed with the trust.
- Consider how it takes appropriate assurance that all aspects of the SLA with the trust are working effectively.
- Consider implementing an effective policy approval process.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Summary of findings

Our judgements about each of the main services

Service

Rating Summary of each main service

Medical care

Good



Overall we rated medical care services at the Cambridge Heart Clinicas good because: The service had a good track record for safety and Medical records were completed fully and accurately to a high standard. Medicines were stored according to trust policy and medical services had safe levels of staffing. All clinical and non-clinical areas we visited were visibly clean. The service had systems in place to check and maintain cleanliness. Patients had access to a choice of appointments with minimal waiting times for inpatient care and treatment.

The service had received consistently positive patient feedback relating to the care and treatment provided and we saw evidence of multidisciplinary team working. Staff reported that senior management were approachable and responsive to any concerns or queries raised. Staff described good working relationships between the NHS trust staff and the Cambridge Heart Clinicstaff.

However:

We could not gain assurances that patient safety was monitored in an effective way because results of key performance indicators were not monitored on a regular basis and patient outcomes were not effectively monitored due to a lack of participation in national audits and limited local audit activity. Governance arrangements were not robust. We found that governance documents did not reflect the processes taking place and that monitoring of the SLA was not effective.

Outpatients and diagnostic imaging

Good



Overall we rated outpatient services at the Cambridge Heart Clinicas good because:

The service had a good track record for safety. There were no clinical incidents, non-clinical incidents or never events reported between April 2015 and March 2016. Outpatient medical records were completed fully and accurately to a high standard. All clinical and non-clinical areas we visited were visibly clean. The service had systems in place to check and maintain cleanliness. Patients had access to a choice of appointments with minimal waiting times for

Summary of findings

outpatient care and treatment. Medicines were stored according to trust policy, with legal requirements surrounding the storage of medicines being met. Medical services had safe levels of staffing, care hours per patient were calculated in advance of patient admission. We saw evidence of multidisciplinary team working (MDT) and staff described good working relationships between the NHS trust staff and the Cambridge Heart Clinic staff.

However:

There was limited auditing taking place to monitor patient outcomes in outpatient services. We could not gain assurances that patient safety was monitored in an effective way because results of key performance indicators were not monitored on a regular basis. Governance arrangements were not robust. We found that governance documents did not reflect the processes taking place and that monitoring of the SLA was not effective.

Summary of findings

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Good 

Cambridge Heart Clinic

Services we looked at

Medical care; Outpatients and diagnostic imaging;

Summary of this inspection

Background to Cambridge Heart Clinic

The Cambridge Heart Clinic (CHC) is a private patient cardiology unit located within Addenbrooke's Hospital, designed to meet the needs of patients in the early detection and management of heart and cardiovascular disease. The Cambridge Heart Clinic is an innovative partnership between Cambridge University Hospitals NHS Foundation Trust (the trust) and a company called Regent's Park Heart Clinics Ltd (Regent's Park). Regent's Park is a specialist cardiovascular services company that has been delivering invasive cardiology services in partnership with the trust since 2006. The Cambridge Heart Clinic is the first in a series of specialist cardiology centres the company is developing across the UK. The partnership means that the Trust can re-invest surplus monies back into NHS patient care. The CHC opened in 2008. Since opening to the present day it provides cardiovascular services exclusively. This includes both outpatient investigations and invasive (catheterisation laboratory) procedures such as coronary angiography, pacemaker insertions and coronary angioplasty.

This service is available to private funded patients through GP referral only.

CHC is located on ward K2 at Addenbrooke's hospital, providing both inpatient and day case admissions for invasive procedures. The clinic has access to five inpatient and day case beds as well as three outpatient consulting rooms.

We have inspected CHC as part of our programme independent health inspections meaning it was a routine inspection. We looked at all services provided by the clinic. However, we did not inspect diagnostic services as part of the outpatient and diagnostic imaging core service because CHC did not provide these services.

The service is managed by Anil Ohri who is also the Chief Executive Officer of Regent's Park. Mr Ohri has been the registered manager of the service for six years.

Our inspection team

The team included 2 CQC inspectors and a nurse specialist advisor.

How we carried out this inspection

To get to the heart of patients' experiences of care, we always ask the following five questions of every service and provider:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well led?

The inspection was announced and took place on 25 August 2016. We also undertook an unannounced inspection on the 7th September 2016, to follow up on some additional information.

Before inspecting, we reviewed a range of information including information held by us and information provided by the service.

We talked with patients and staff and we observed how people were being cared for. We also reviewed patient records and spoke with members of staff from the trust in relation to the working arrangements between the two organisations.

We would like to thank all the staff, patients and stakeholders for sharing their balanced views and experiences of the quality of care and treatment at the Cambridge Heart Clinic.

Summary of this inspection

Information about Cambridge Heart Clinic

Between April 2015 and March 2016, CHC carried out a total of nine inpatient and day case episodes of care with six of these patients requiring an overnight stay in hospital.

There were 592 outpatient appointments between April 2015 and March 2016. 422 of these appointments were first appointments with 170 being follow ups.

All attendances at the clinic were privately funded. There was no NHS work carried out by this service.

This service was available to adults only.

There were six consultants working at CHC with practicing privileges.

CHC employed one nurse (0.3 WTE). This member of staff held an honorary contract with the trust.

Another 5.8 WTE nurses were available to CHC via the SLA in place with the trust.

Services such as cleaning, infection control, equipment maintenance and staff training were provided to CHC via a service level agreement (SLA) with the trust.

The Controlled Drug Accountable Officer (CDAO) for this service was the Head of Pharmacy Services employed by the trust via the SLA in place.

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?

- The service had a good track record for safety. There were no clinical incidents, non-clinical incidents or never events reported between April 2015 and March 2016.
- Appropriate infection control procedures were in place and the environment was clean and utilised well.
- Staff recognised how to respond to patient risk and there were arrangements to identify and care for deteriorating patients.
- Staff were aware of their responsibility to safeguard vulnerable adults from abuse. There were clear internal processes to support staff to raise concerns.
- Staffing levels were appropriate and planned in line with capacity. There had been no agency or bank usage in the past year.
- Staff and leaders were aware of their responsibilities in relation to duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- Patient records were well maintained, legible and up to date. We saw that there were stored securely and noted regular auditing took place.
- Appropriate medicine management procedures were in place. We found that medicines were stored and administered in line with legislation.
- We were informed that staff were up to date with their mandatory training, however we could not be provided with data which confirmed this.

Good



Are services effective?

- The Cambridge Heart Clinic had a service level agreement (SLA) with Cambridge University Hospitals NHS Foundation Trust ('the trust') which detailed arrangements for CHC sharing policies and procedures developed by the trust. We saw that CHC monitored these policies to ensure that these were in date and updated to reflect best practice.
- The CHC did not participate in national audits. This was due to the unique set up of the service and low patient volume which meant national benchmarking could not be achieved. However,

Good



Summary of this inspection

the service did undertake some local audit and measure patients' outcomes through patient feedback. There had been no negative outcomes recorded with all patients reporting an improvement in their condition following treatment with CHC.

- There had been no unplanned readmissions to the service within the past year.
- There were effective procedures in place to ensure medical staff were appraised, competent and revalidated. This was monitored through the Medical Advisory Committee (MAC) who on an annual basis ensured those consultants working under practicing privileges submitted evidence such as their annual appraisal and GMC registrations to demonstrate their fitness to practice. Full practicing privileges reviews were undertaken on a bi-annual basis.
- Consent was consistently well recorded and audited.
- Staff were aware of the requirements of the Mental Capacity Act and Deprivation of Liberty Safeguards.
- We were informed that staff were up to date with competency checks, however we could not be provided with data which confirmed this.
- There was also a limited amount of clinical audit taking place across the service and this could be improved upon to demonstrate effective practice,

Are services caring?

- The service received consistently positive feedback from patients. We reviewed feedback from the 2015 feedback and found that overall, out of six individually test areas, patients' scored the service excellent.
- The satisfaction survey also demonstrated that 99.3% of patients would recommend the service.
- Patients we spoke with were complimentary about the service. One patient we spoke with stated it was "amazingly good" and another patient stated "I can't fault any aspect of my care – I have been here three times and it's always been fantastic."
- Patient's privacy and dignity was maintained and they were well respected at all times. We saw many positive interactions between staff and patients. For example, one patient had travel a long way to get to their outpatient appointment and was quite flustered when they arrived at the clinic. We saw staff comfort this patient, they made them a cup of tea and sat with them for a while in the waiting room.
- The use of chaperones was encouraged and additional requirements were discussed upon booking, prior to attendance at the clinic.

Good



Summary of this inspection

Are services responsive?

- Access to the service was seamless and without delay. Outpatient appointments were offered immediately upon referral and were usually attended within five weeks. We saw one case where a patient was referred, seen in the outpatient clinic and admitted for treatment in the same day.
- The clinic offered preferential access (as per the SLA agreement with the trust) to the catheterisation laboratory minimise waiting times.
- The clinic offered individual, patient focused care through the use of specialist nurses, chaperones and translation services where required.
- There was no cancellation of procedures due between April 2015 to March 2016.
- The individual needs of patients were being met with access to specialist dementia and learning difficulty nurses and chaperones. Specialist equipment was also available via the SLA agreement with the trust and the premises was accessible for those people living with physical disabilities.
- There was a robust complaints procedure in place. The CHC had one complaint for the reporting period of April 2015 to March 2016. We saw this was reviewed and discussed, with evidence of learning having taken place.

Good



Are services well-led?

- Governance systems required improving. We found the services governance framework made reference to out of date guidance and a reporting structure which was not accurate.
- In addition, the governance framework made reference to various reports and annual plans which should have been in place but were not.
- There was no agreed governance framework between CHC and the trust. Whilst processes were in place these were not documented and agreed by both parties which meant that intended outcomes could not be monitored.
- SLA monitoring was not robust. CHC did not receive or take appropriate assurance on the quality of staff training and competency.
- The policy ratification/approval process for CHC was not robust. For example, we found from the services governance framework that the clinical audit strategy should have been signed of by the MAC but instead it was signed off by the

Requires improvement



Summary of this inspection

executive management team. In addition, there was no audit trail for the signing off of this document as it had not been presented to an executive management team meeting for approval.

- However, the service had a clear vision and staff were aware of this.
- The leadership team was proactive and approachable. Staff told us that they felt comfortable in raising concerns and that they had confidence these would be taken forward.
- Staff felt there was an open and honest culture within the service.
- The service was working to improve services and was in the processes of redefining its strategy following announcements that the environment it worked within (cardiology services) were being redesigned and improved on locally.

Detailed findings from this inspection

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Medical care	Good	Good	Good	Good	Requires improvement	Good
Outpatients and diagnostic imaging	Good	Not rated	Good	Good	Requires improvement	Good
Overall	Good	Good	Good	Good	Requires improvement	Good

Notes

1. We will rate effectiveness where we have sufficient, robust information which answer the KLOE's and reflect the prompts.

Medical care

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

Information about the service

The Cambridge Heart Clinic (CHC) is a partnership between Cambridge University Hospital NHS Foundation Trust (CUHFT) and Regent's Park Heart Clinics Ltd (RPHC). Regent's Park Heart Clinic Ltd is a cardiovascular services company that has been delivering invasive cardiology services in partnership with Addenbrooke's Hospital since 2006. The Cambridge Heart Clinic (CHC) opened in 2008 and provides cardiovascular services exclusively. Services offered include diagnostic angiography, pacemaker insertion, cardiac defibrillator implants and cardioversion.

The clinic is located on ward K2 at Addenbrooke's hospital, providing both inpatient and day case admissions for invasive procedures. The clinic has access to five inpatient and day case beds within the K2 ward area. The had access to hospital facilities between the hours of 7.30am to 8.00pm, Monday to Friday with access to the cardiac catheterisation laboratory on these days depending on planned patient activity within the clinic.

Nursing and medical staffing were provided via a single service level agreement (SLA) with The Cambridge University Hospital Foundation Trust (CUHFT). An SLA is a contract between a provider and a supplier, in this case The Cambridge University Hospital NHS Foundation Trust and The Cambridge Heart Clinic. The NHS trust provided clinical services including the provision of trained and competent staff, equipment and premises for Cambridge Heart Clinic use.

Between April 2015 and March 2016, the Cambridge Heart Clinic carried out a total of eleven inpatient and day case episodes of care. During the period of April 2015 to March 2016, the clinic carried out five pacemaker insertions and

six coronary angiography procedures. Children and young persons under the age of 18 years are not seen at this service. All patient care was funded privately or by medical insurance.

Nursing staff worked between the hours of 7.30am and 8.30pm, with processes in place to ensure overnight medical and nursing staff cover was provided, should inpatient care be required. Consultants were on site at all times during planned inpatient and day case procedures.

Throughout this report the expression "CHC" or "clinic" shall mean The Cambridge Heart Clinic and "the Trust" shall mean Cambridge University Hospitals NHS Foundation Trust.

Medical care

Summary of findings

Overall we rated medical care services at the Cambridge Heart Clinic as good because:

- The service had a good track record for safety. There were no clinical incidents, non-clinical incidents or never events reported between April 2015 and March 2016.
- Medical records were completed fully and accurately to a high standard. Risk assessments were completed on admission and updated as required during the patients hospital stay.
- All clinical and non-clinical areas we visited were visibly clean. The service had systems in place to check and maintain cleanliness.
- Patients had access to a choice of appointments with minimal waiting times for inpatient care and treatment.
- Medicines were stored according to trust policy, with legal requirements surrounding the storage of medicines being met.
- Medical services had safe levels of staffing, care hours per patient were calculated in advance of patient admission.
- Medical staff were regularly appraised with robust systems in place relating to revalidation and practising privileges.
- The service had received consistently positive patient feedback relating to the care and treatment provided.
- We saw evidence of multidisciplinary team working (MDT). In addition, MDT working was clearly documented in medical records.
- Staff reported that senior management were approachable and responsive to any concerns or queries raised. Staff described good working relationships between the NHS trust staff and the Cambridge Heart Clinic staff.

However:

- We could not gain assurances that patient safety was monitored in an effective way because results of key performance indicators were not monitored on a regular basis.

- Concerns were identified that patient outcomes were not effectively monitored due to a lack of participation in national audits and limited local audit activity.
- Governance arrangements were not robust. We found that governance documents did not reflect the processes taking place and that monitoring of the SLA was not effective.

Medical care

Are medical care services safe?

Good 

We rated safe as good because:

- The Cambridge Heart Clinic had no clinical or non-clinical incidents between April 2015 and March 2016.
- Staff were able to demonstrate good knowledge of incident reporting requirements and duty of candour.
- Audit data revealed compliance with hand hygiene practice and general cleanliness audits demonstrated a clean environment.
- Documentation within medical records was completed to a high standard with monthly audits carried out for quality assurance purposes. Patients were assessed for the risk of deterioration during routine observation taking. Venous thromboembolism (VTE) risk assessments had been completed.
- All medicines were stored securely. The checking of medicines took place on a daily basis.

However:

- We found medical equipment that had not been serviced regularly. In addition, some equipment was not labelled to indicate whether servicing had taken place.
- We could not gain assurances that patient safety was monitored in an effective way.

Incidents

- There were no clinical or non-clinical incidents reported between April 2016 and March 2016. This was due to a low level service provision. We were confident that staff would act and report an incident if one was to occur. This was because they worked for the trust and were able to provide examples of when they would report an incident.
- There were no never events reported between April 2015 and March 2016. Never events are serious incidents that are wholly preventable as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- We spoke with one member of senior staff who described the incident reporting process in detail.

Incidents relating to the CHC would be raised electronically on the trust information technology system. A senior member of staff told us that a new incident reporting system had recently been implemented and that all staff had received training in the use of the software.

- We spoke with the ward sister who worked for both the CHC and the trust. They reported that whilst no incidents had been reported in the period April 2015 to March 2016, all NHS reported incidents were fed back to CHC to ensure dissemination of information and a prevention in the reoccurrence of incidents should this be a risk.
- We spoke with two members of staff about to the duty of candour. The duty of candour is a regulatory duty that relates to openness and transparency and requires providers of health and social care services to notify patients (or other relevant persons) of certain 'notifiable safety incidents' and provide reasonable support to that person.
- They were both able to tell us what this phrase meant and the processes to follow should an incident occur, including incident reporting and timely apology to the patient. One senior staff member reported that to date, no situations had arisen where an apology or explanation of when things had gone wrong to a patient had been required. The duty of candour was included in trust mandatory training, ensuring all staff working in the clinic had received this training under the existing SLA in place.
- We asked another member of nursing staff about their knowledge surrounding the duty of candour. They replied "it is being upfront and honest with people, we should tell them what has gone wrong and say sorry". The member of staff continued to explain the need to report errors as incidents, should they occur, with timely escalation to a senior member of staff.
- The Cambridge Heart Clinic had a local protocol in place to ensure that all staff had adequate knowledge and skills to be able to report an incident. We reviewed this document and noted it was in date.

Safety thermometer or equivalent (how does the service monitor safety and use results)

- We reviewed five sets of electronic private inpatient care records. Venous thromboembolism (VTE) risk assessments had been carried out on all records. We

Medical care

were told that pressure ulcer risk assessments and falls assessments were not routinely carried out due to the transient nature and short stay of inpatients within the department.

- There were no reported cases of hospital acquired VTE or pulmonary embolism (PE) between April 2015 and March 2016.
- The CHC monitored patient safety using key performance indicators (KPI). For example, these included complication rates pre and post procedure and re-admission rates. However, we could not gain assurances that these were monitored on a regular basis because KPI results were not provided to us through the registered manager's dashboard where we were informed these were located. Therefore we were not assured this was an effective way of monitoring patient safety.

Cleanliness, infection control and hygiene

- The CHC had no episodes of methicillin-resistant Staphylococcus aureus (MRSA) or methicillin-sensitive staphylococcus aureus (MSSA) in the reporting period April 2015 to March 2016.
- There were no reported cases of Clostridium difficile (C diff) between April 2015 and March 2016.
- During our inspection all staff were bare below the elbow and were seen to wash their hands at regular intervals prior to and after patient contact.
- After our announced inspection, we requested the results of hand hygiene audits for the months of June 2016 to August 2016. Audit results revealed that 100% of staff we seen to be carrying out correct hand hygiene guidance. This audit included all grades of staff.
- All clinical and non-clinical areas were visibly clean and free from clutter. Active cleaning was taking place on the day of our inspection. These services were provided by the trust under the existing SLA.
- Cleaning rotas were clearly displayed in the dirty utility room including cleanliness standards, responsibilities and the required frequency of cleaning in specific areas. We noted that all clinical areas were rated in relation to the level of risk for infection by a score displayed on the wall in the relevant area.
- General cleanliness audits were carried out on a monthly basis by the trust and results were shared with CHC as per the SLA. We reviewed the results of audits

that were carried out in July 2016 and August 2016. Audit scores revealed both clinical and non-clinical areas were 99.56% compliant with cleanliness standards.

Environment and equipment

- Access to the clinic was secured by intercom to the main reception. Seating within the waiting area for private inpatients was well maintained and free from damage. All corridors, clinical and non-clinical areas were free from clutter.
- All areas were well lit and clearly signed as to what each area pertained to.
- Clinical waste bins were clearly identified and located throughout the department. Correctly coloured lining bags were in use to ensure segregation of hazardous and non-hazardous waste. Sharps containers were correctly labelled and all within safe 'fill' limits.
- The provision and maintenance of equipment for the CHC was provided under the SLA in place with the trust. The trust was responsible for the upkeep, maintenance and repair of all equipment that was available for use by the clinic. The clinic had access to the trust's maintenance team should this be required. We reviewed the SLA in place and noted it had concise details regarding the equipment available for clinic use including an inventory of items.
- Cambridge Heart Clinic staff had access to the use of two resuscitation trolleys. One was placed in the main corridor and one in the catheterisation laboratory. During our inspection we checked both trolleys for adult resuscitation equipment, medicines and consumables. We noted that both trolleys had been checked on a daily basis when the service was open to patients, with the exception of 20/06/2016. Both trolleys had the required equipment available for use during a collapse/cardiac arrest. Defibrillators were within their service date and clearly labelled to state when the next service was due. All resuscitation drugs were in date and stored securely.
- Resuscitation training, including the use of resuscitation equipment was provided by the trust as part of the existing SLA in place. However, figures of training compliance could not be provided to us by CHC.
- During our inspection we noted that the defibrillator from the resuscitation trolley in the main corridor was taken to retrieve a patient from an NHS cardiac ward within the main hospital. This piece of equipment was away from the ward for approximately 40 minutes. A

Medical care

second defibrillator was located in the catheterisation laboratory. We noted concerns, that should a defibrillator be required, during an ongoing surgical procedure when access was restricted to this area, this would not be available for use. We escalated our concerns regarding this to the senior management team of the CHC on the day of our inspection. We were given assurances that should this situation occur, staff had access to an additional defibrillator from another ward, in accordance with the NHS partner's trust transfer policy.

- Cambridge Heart Clinic patients had access to five single patient side rooms. Each room had access to en-suite facilities, including disabled shower access. Each en-suite contained an emergency buzzer cord extending to floor level and bedside alarm system enabling patients to summon help if required.
- We examined various pieces of medical equipment within clinical and non-clinical areas. We noted that three sets of patient weighing scales were past recommended service dates of June 2016. In addition, two blood glucose monitoring kits and one urinalysis machine had barcodes but no servicing date stickers were displayed. We could not gain assurances that these pieces of equipment had been maintained and serviced on a regular basis. Staff told us the hospital trust were responsible for the servicing and maintenance of this equipment via an SLA. We escalated our concerns to the clinic manager at the time of our inspection.
- As a result of our concerns regarding equipment checking and servicing, we requested that the CHC provided assurances that equipment in the department was subject to regular testing and servicing. Following our inspection, we were provided with data indicating that equipment used by CHC was serviced and maintained on a regular basis. This document also revealed that the three sets of weighing scales identified as past the servicing due date on our inspection, had been checked with updated records reflecting this.
- During our unannounced inspection, a member of senior staff told us that both blood glucose monitoring machines had been serviced and were awaiting stickers to highlight this process had been carried out. In addition, a set of weighing scales that was outside of its service date had been serviced when we returned on our unannounced inspection.

- Staff had access to trust manual handling equipment such as bariatric hoists, chairs, beds and commodes. Processes were in place to arrange delivery of this equipment prior to patient admission through the SLA with the trust.
- We checked two electrocardiogram machines (ECG) and found both pieces of equipment were visibly clean and within their service period.
- Hand sanitising gel, gloves and aprons were available in all clinical areas. Cleaning wipes were stored in each clinical area and side rooms.
- The dirty utility area was free from clutter and was visibly clean. This area was accessed via a key coded door to ensure safe storage of substances hazardous to health (COSHH). Commodes stored within this area were visibly clean and had been identified as clean using labels. The macerator and bed pan washer were free from visible dirt and were well maintained.
- The clean utility room was accessible by key coded door. All consumables within this area were well stocked and easily identifiable due to clear labelling system.

Medicines

- The trust's pharmacy team were responsible for the supply of medicines through the existing SLA in place. The CHC local protocol in place clearly referenced trust policies in relation to the administration, dispensing and prescribing of medicine. We reviewed this local protocol and noted it was in date.
- Clinic staff referred to the trust's policy named 'Intravenous sedation for healthcare procedures in adult patients'. We noted this policy was written by a consultant anaesthetist which was ratified and within date, with clear guidance surrounding sedation procedures.
- We checked two controlled drugs (CD) cabinets within the facilities used by the service. One was located adjacent to the nurses' station and the second in the catheterisation laboratory area (catheterisation laboratory). Checks of both cabinets revealed that both fentanyl and diamorphine levels were accurately recorded in both CD log books. We noted, however, that both midazolam and diazepam were not recorded in this book. Although this is not a legal requirement, the recording of these two medications as a controlled drug is considered as best practice to identify that medication is not missing or being misused. We discussed our concerns regarding the storage of

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midazolam and diazepam on the day of our announced inspection. Following concerns raised, clinic staff carried out a review of medicines storage in conjunction with pharmacy staff from the trust. It was found that the ward were operating in accordance with the NHS trust's policy and legal requirements.

- Controlled drugs were stored in accordance with the law in a double locked metal cabinet. Keys to controlled drugs were held by one member of staff only.
- We reviewed records of controlled drug checks. We found that controlled drugs checks had taken place on a daily basis without any gaps in the records.
- We checked twelve medications, and found all medicines were within their expiry dates. The storage cupboards were tidy and well organised.
- The medication fridge was locked, we reviewed the temperature record and found these had been recorded daily without gaps. The maximum and minimum temperatures had not been exceeded.

Records

- The CHC had a local protocol in place for medical records. We reviewed this document and noted it was in date. There were clear minimum set standards and procedures in place for the secure storage, creation and maintenance of medical records.
- We reviewed five sets of electronic inpatient records that related to previous inpatients at the CHC. All notes were completed concisely; each entry clearly identified which clinician had entered information.
- We reviewed five electronic inpatient prescription records, all prescribing clinicians and staff who administered medicines were clearly identified and entries were dated. Allergies were clearly documented on each record and where appropriate, antibiotics had been prescribed following trust guidelines for antibiotic prescribing. All medication had been given as prescribed without gaps or omissions.
- The clinic reported that in the three months prior to our inspection, all inpatients were seen with the relevant medical records. All CHC medical records were secured securely on site in the administration office which had restricted access by lock to unauthorised staff.
- Administrators for the clinic monitored the accuracy and completion of medical records for quality assurance purposes. Monthly audits were carried out to examine

20 aspects of patient records for completeness, legibility and content. We reviewed audit results for the month of January 2016 to August 2016 inclusive. Audit results showed compliance of 98% or above for all months.

Safeguarding

- We spoke with three members of staff who were all clear on the process of how to report a safeguarding concern.
- Safeguarding training was carried out by the clinic's NHS partner on a yearly basis under the SLA in place. Within this agreement staff had access to a named safeguarding lead at the trust. Training included awareness of female genital mutilation (FGM). Again, we could not be provided with training compliance data by CHC.
- In addition, the clinic had a named safeguarding lead whose primary role was a full time administrator with the Cambridge Heart Clinic. We were told that this member of staff had received both adults and safeguarding training which was due for renewal in 2019.
- The CHC staff also had access to a clinic safeguarding adults protocol. This protocol was in date.

Mandatory training

- All mandatory training was provided by the trust with the existing SLA in place. However, we could not be provided with training data which demonstrated compliance for those staff which worked for CHC.
- We were told by CHC that trust staff monitored mandatory training compliance. CHC took its assurance that this training was completed via a signed declaration for trust management.

Assessing and responding to patient risk

- The clinic used the modified early warning score (MEWS) to monitor and detect deterioration in patients. We reviewed five sets of inpatient records which revealed scores had been completed correctly. MEWS scores were calculated as part of standard observations. The frequency of observations taken depended on how stable the patient was and what procedure had been carried out.
- Resuscitation services were provided under the existing SLA in place with the trust who provided support from a

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resuscitation services team should the need arise. The SLA detailed that post resuscitation all patients would be transferred to the intensive care unit or critical care unit as an NHS inpatient.

- Venous thromboembolism (VTE) risk assessments were carried out in accordance with the clinic's NHS partner's service level agreement. VTE risk assessments were correctly documented in five sets of private patient electronic notes that we reviewed.
- The CHC had a clear policy in place regarding the referral process and inclusion criteria for inpatient coronary angiography and pacemaker insertion. We reviewed the operational policy and noted it was approved and in date.
- The clinic had systems in place with the trust and other local NHS trust's to arrange the emergency transfer of patients in the event of significant patient deterioration. On the day of our inspection we pathway tracked one patient who had been referred to another NHS trust requiring emergency transfer. This process was carried out in a timely manner and in line with policy and procedures.

Nursing staffing

- Nurse staffing for day case and overnight stays was provided by the existing SLA with the trust. Staff for the CHC were provided by permanent ward staff from the main hospital.
- Nurse staffing requirements were calculated in advance due to the planned nature of inpatient stays. Care hours per patient day (CHPPD) were calculated to ensure an adequate number of nursing staff per patient.
- No bank or agency staff were used between the months of April 2015 and March 2016.

Medical staffing

- Medical staff worked for CHC under practising privileges. At the time of our inspection six consultants were working under practicing privileges. Site management at the trust were informed of all overnight admissions to the CHC. This ensured that NHS medical staff were aware of the potential need to attend should this be required.
- All invasive procedures were carried out under the supervision of a named consultant who was required to stay onsite pre and post procedurally to enable timely

monitoring and review if required. Outside of this arrangement emergency medical cover was provided by the trust under the SLA and the consultant remained on call.

Major incident awareness and training

- All CHC staff completed an NHS trust hospital induction and received local orientation prior to the commencement of work. This induction included major incident training.
- The Cambridge Heart Clinic had a major incident and business continuity plan in place. We reviewed this document which was in date.

Are medical care services effective?

Good 

We effectiveness as good because:

- The CHC did not participate in national audits due to low patient volume; patient outcomes were discussed at medical advisory committee (MAC) meetings. The clinic carried out local audits and monitored patient feedback on a regular basis.
- Medical staff had received regular appraisals with up to date personal development plans in place.
- There had been no unplanned readmissions to the service within the last year.
- All training was provided by the trust and CHC monitored competency training to ensure staff were up to date with relevant training.
- Medical record reviews revealed multidisciplinary team (MDT) working, with access to specialist nurses via the SLA with the trust. We saw evidence of MDT during our inspection at a board round.
- Consent was sought prior to treatment and regularly audited for quality assurance purposes.

However:

- We could not gain assurances that patient outcomes were effectively monitored due to a lack of participation in national audits and limited local audit activity.
- We could also not be provided with assurance that staff had received training in the mental capacity Act (2005) and Deprivation of Liberty safeguards (2009).

Evidence-based care and treatment

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- All staff had access on online policies via the NHS partner's information technology systems.
- Policies and protocols used by the CHC were monitored by the registered manager to ensure all polices and protocols were up to date. We saw the electronic system used by the manager which revealed the 29 policies and protocol in use were all within the review date specified.
- Antibiotics were prescribed in accordance with the SLA and trust microbiology guidelines in place
- The use of prophylactic antibiotics was based on guidance from the clinic's NHS partner. We reviewed five sets of electronic private patient notes. Out of this sample, two patients required prophylactic intravenous (IV) antibiotics prior to the commencement of an invasive procedure. Both patients had received prophylactic IV antibiotics at the start of the procedure as per recommended guidance. The administration of antibiotics was clearly documented on patient prescription records.
- A senior member of staff reported antibiotic usage followed guidelines from the microbiology department at the service's NHS partner.
- Hot drinks and snacks were offered to patients in between meal times. Each private inpatient was offered a choice of main meals from a menu, including one hot meal per day.
- Menu choices included healthy lifestyle options and catered for cultural and religious requirements.
- The clinic had access to specialist nurses and dieticians via the SLA in place with the trust.
- Patients who were required to fast prior to procedures were given both verbal and written instructions before inpatient admission. We spoke with two members of staff who could clearly describe different fasting measures and times, dependent on the procedure that was to be carried out.
- We spoke with a previous inpatient from the clinic after our inspection. They reported they had received both verbal and written instructions in relation to fasting, prior to the planned procedure taking place.

Pain relief

- Patient pain assessments were undertaken routinely and formed part of assessment through use of the modified early warning score (MEWS).
- We reviewed one set of patient notes in relation to pain relief, which showed pain scoring had been completed accurately in accordance with MEWS scoring. The assessment included questions on the location, intensity and type of pain patients were experiencing.
- We spoke with one private inpatient after our inspection. They said "I had some pain during and after my pacemaker was put in, they frequently asked me if I was in pain and kept checking me at regular intervals and provided pain relief when I asked for it".

Nutrition and hydration

- On the day of our inspection, the clinic had one admitted private patient. We were unable to observe the care environment of this patient in relation to hydration needs as the patient's privacy and dignity was protected due to treatment being carried out. We were told, however, that all patients had access to water at their bedside.

Patient outcomes

- The clinic did not participate in national audits due to low activity volumes. We were told that any patient complications would be presented and discussed at MAC meetings which took place on six to nine monthly basis. We reviewed meeting minutes from September 2015 and June 2016 and noted no patient complications had been reported.
- Cambridge Heart Clinic had no unplanned readmissions or transfers within the period of April 2015 to March 2016.
- There were no cases of unplanned return to the operating theatre in the reporting period of April 2015 to March 2016.
- There had not been any unplanned readmissions to the service in the past year.
- Cambridge Heart Clinic did not participate in national audits however; coronary angiogram and pacemaker implantation audits were carried out on a quarterly basis. We were told that due to low activity volumes data was not comparable to national statistics. We reviewed these audits for all of 2015 and outcomes were positive.
- The CHC carried out internal audits however these related mainly to infection control, equipment and record keeping. We could not gain assurances that patient outcomes were audited or monitored in the absence of participation in national audits and lack of local audits carried out.

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Competent staff

- Nurse training and competency checks were provided by the existing SLA with the trust. However, we could not be provided with data from CHC which confirmed staff who worked for them had undertaken appropriate competency checks.
- CHC sought assurances that all staff involved in invasive procedures complied with necessary competency requirements via a signed declaration from the trust that it would monitor staff competency. The Cambridge Heart Clinic executive management team were responsible for the granting and renewal of practising privileges for consultants. The executive team consulted with the MAC during all phases of this process for each consultant. Practising privileges were reviewed on a two yearly basis. The clinic had a clear policy on practising privileges which was within its review date.
- The clinic provided annual appraisal data for consultants and cardiologists who worked at the CHC. This data revealed that all medical staff had an up to date personal development plan and were in receipt of the appropriate mandatory training. We noted that General Medical Council (GMC) registrations were in date and they had a current licence to practice. All staff had received an appraisal with records showing these had taken place on a yearly basis from 2008.
- Data provided by CHC stated that 100% of nursing and medical staff had received an appraisal within the last year.

Multidisciplinary working

- The clinic had access to their NHS partner's radiation protection and medical physics advisers through the existing SLA in place. If required, the clinic could contact the trust's hospital engineers, radiographers and other technical or maintenance personnel.
- Discussion between medical specialities took place on a regular basis at board rounds. Frequency of board rounds varied depending on patient activity within the department.
- During our inspection we observed a board round. A board round is where all patients are discussed. Observations of this board round revealed good communication from the lead consultant. Various grades of nursing, laboratory and radiology staff were present. Each patient's treatment plan, allergies and medical requirements were discussed in an efficient and

timely manner. We heard the consultant leading this board round discuss both NHS patients and the one CHC patient that was an emergency admission on the day of our inspection. However, this arrangement was not reflected in the service level agreement which meant we could not be assured in which capacity the consultant reviewing the CHC patient was working. For example, were they working in an NHS or private capacity at that point in time.

- We reviewed five sets of inpatient records which all showed input from multidisciplinary teams including physiologists, radiologists and radiographers.
- The trust's radiology and cardiac physiology department provided staffing cover for all cardiac catheter insertion procedures.

Seven-day services

- The Cambridge Heart Clinic did not offer access to services 24 hours per day, seven days a week. In the event of medical support being required for overnight care, the clinic had an SLA in place with the trust to provide medical cover.
- Resident medical officers (RMO's) were available via a bleep system 24 hours per day to provide medical cover for private inpatients. This cover was provided through an SLA with the clinic's NHS partner and included access to cardiologists.
- Staff were able to request out of hours support from physiotherapists, pharmacy and diagnostic imaging via an existing SLA in place with the clinic's partner.
- During the discharge process, verbal information was given to patients on how to contact the clinic outside of normal opening hours should they have any questions or concerns regarding their treatment.

Access to information

- Cambridge Heart Clinic patients were allocated an NHS trust identification number. This allowed the appropriate sharing of clinical information to enhance patient care via the trust's electronic patient record system. This aided information sharing should a patient be transferred to NHS care and was accessible by both NHS and CHC staff.
- Private patients were provided with a printed discharge summary detailing clinical conditions, treatment given, findings, procedures carried out and any medications prescribed. In addition, this summary was sent to the patient's GP electronically.

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- We reviewed five sets of private inpatient notes which revealed that follow up letters had been forward to the patient's GP post treatment or procedure.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The Cambridge Heart Clinic had a policy for consent to treatment or examination. This policy was within its review date. Staff had access to this policy on the internet.
- We reviewed five sets of patient notes, all of which had documented that patient consent was gained prior to care or treatment.
- Monthly audits were carried out to ensure consent was obtained prior to treatment. The audit process selected five sets of patient notes per month. We reviewed that audit results from January 2016 to August 2016 revealed consent had been documented in 100% of all care records. It is to be noted that this audit information pertained to both inpatient and outpatient medical records.
- We spoke with a ward manager regarding the Mental Capacity Act (2005) and Deprivation of Liberty Safeguards (2009). We were told that training for these subjects was eLearning based. The ward manager was able to explain the process of the Mental Capacity Act and Deprivation of Liberty Safeguards applications. Training compliance was overseen by the ward manager responsible for CHC staff who reported that all staff were up to date for both Mental Capacity Act (2005) and Deprivation of Liberty Safeguards (2009) training. However, data could not be provided by CHC to confirm this.
- We spoke with one newly qualified member of staff who was unclear what the term 'deprivation of liberty' meant.

Are medical care services caring?

Good 

We rated caring as good because:

- The CHC had received consistently positive feedback from patients.

- Patients we spoke with were complimentary about the service stating it was "amazingly good" and confirming they felt respected at all times.
- Patient's privacy and dignity was maintained.
- The use of chaperones was encouraged and additional requirements were discussed upon booking, prior to attendance at the clinic.
- Patient satisfaction survey results revealed that 99.3% of patients would recommend the service.
- The CHC had clear policies in place regarding discussion of treatment costs, which took place prior to procedures being carried out.

Compassionate care

- The clinic undertook a survey in relation to patient satisfaction on a rolling basis; the results were available on the clinic website. Due to the clinic seeing private patients only, friends and family test data, collected by NHS organisations was not available. The patient satisfaction survey for 2015 revealed that the clinic had a return rate of 22%, which is comparable with surveys conducted by other organisations. The survey consisted of six questions relating to specific aspects of the service and whether or not the patient would recommend the heart clinic to others. Results revealed that out of a maximum score of five points, nursing staff received 4.98 and consultants 4.97. Overall satisfaction for the clinic was rated at 4.74 out of five. Patients were asked if they would recommend the clinic to a friend or relative. Results showed that 99.3% of patients would recommend this service.
- We spoke with one private patient who had previously received inpatient care at the CHC. The patient stated: 'staff were amazingly good, I felt respected at all times. Nothing was too much trouble. I was pleasantly surprised by the whole experience'. Another private patient said "I couldn't sleep, it was 4am, the nurses came and chatted with me, they were so kind. The service is so personalised, they know me by name and they make you feel so good, through being so caring".
- During our inspection, we saw one private inpatient. We noted that patient privacy was maintained at all times with utilisation of the inner side room curtain. We heard staff asking to enter the room, awaiting a response from the patient prior to doing so.

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- We viewed four customer service satisfaction survey responses. One question was 'how well were you treated by our staff? All patients reported they had been treated 'very well'. This survey related to both inpatient and outpatient responses.
- One customer satisfaction survey card stated: "I have had problems with my heart; I was looked after so well and have nothing to complain about. I owe my life to all of the staff at the Cambridge Heart Clinic and Addenbrooke's Hospital".
- Patients were offered treatment in a timely manner. The clinic offered preferential access to the catheterisation laboratory to minimise waiting times.
- There was no cancellation of procedures due to non-clinical reasons between April 2015 to March 2016.
- The individual needs of patients were being met with access to specialist nurses, chaperones and accessible premises for those with physical disabilities.
- There had been no complaints relating to medical care services in the past year.
- Administration teams ensured a personalised service from the first point of contact by a patient.

Understanding and involvement of patients and those close to them

- Leaflets providing information from the British Heart Foundation and various treatments were placed in the private patient waiting area.
- We spoke with staff from the administration team with regards to inpatient stays. We were told that patients were able to speak with the same person when making contact with the clinic which aided the booking process and provided a personal service to patients.
- We were told that patients were asked whether they had any specific needs such as dietary requirement, translation services or additional needs due to disabilities when procedures were booked.
- Prior to admission, one patient we spoke with reported that they had received specific instructions about the need to fast prior to treatment. This information was given both verbally and in writing.
- We spoke with one patient who had received inpatient care at the clinic. They reported that that had received information on what treatment had been carried out and were given a copy of the discharge letter for their personal records.

Emotional support

- Access to chaplaincy services was provided by an SLA in place with the clinic's NHS partner.
- Counselling services were available to patients via the chaplaincy service, which was in place through the existing SLA agreement in place with the trust.

Are medical care services responsive?

Good 

Service planning and delivery to meet the needs of local people

- The Cambridge Heart Clinic provided cardiac procedures to self-funding or insured private patients only.
- Local NHS GP practices referred patients for private investigation and treatment where required.
- A senior staff member told us that if relatives or carers wanted to stay overnight, nearby to a patient, arrangements were in place either by allocating a spare bed within the private patient area or by arrangement with a local hostel. They said to date the need for this provision has not arisen.

Access and flow

- Due to being a private business, the clinic could offer flexibility and short waiting times for those requiring treatment. Patients were offered variety of appointments demonstrating flexibility including evening clinics.
- Patients accessing inpatient services at the clinic required a referral from a healthcare professional prior to treatment or examination taking place.
- Prior to admission, patients were seen in the outpatient clinic by a consultant, where a treatment plan was formulated with subsequent discussions on care.
- The clinic had access to diagnostic radiology services through the SLA in place with their NHS partner.
- The Cambridge Heart Clinic reported that there were no cancellation of procedures due to non-clinical reasons between the period of April 2015 and March 2016.

We rated responsive as good because:

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- The clinic had access to pre booked slots at the catheter laboratory to provide patients access to treatment in a timely manner. This ensured that waiting times were kept to an absolute minimum.
- We were told that once a referral had been made by a healthcare professional, patients could access the outpatient clinic within two to five working days. If inpatient care was required this would be arranged in a timely manner.
- On the day of our inspection, we tracked the pathway of care for one patient. The patient had been referred to the clinic by their GP and received an appointment with the clinic on the same day, resulting in an inpatient overnight stay the same day as referral. Invasive treatment was carried out the following morning. We saw that this patient had received care and treatment in an efficient and timely manner.
- Patients had access to information on how to compliment or complain in the waiting room. There was a supply of patient feedback cards and post box visibly placed on the reception desk. In addition, 'tell us what you think cards' were on clear display within this area.
- We requested to see a selection of recent patient feedback cards. None were available as they were routinely sent to the CHC head office. We requested copies of these cards after our announced inspection. Out of four feedback cards we viewed, none highlighted negative comments or concerns about the clinic.
- There were no complaints for the Cambridge Heart Clinic reported to The Care Quality Commission between April 2015 and March 2016.
- Clinic staff had access to information on how to deal with complaints; we saw the CHC complaints policy document was in date, with clear processes and guidance for staff on how to deal with complaints.
- The clinic reported no complaints during the period of April 2015 and March 2016 in relation to day case or inpatient care.

Meeting people's individual needs

- The clinic was accessible to those with physical disabilities.
- When booking an initial appointment, clinic staff asked patients if any additional help was required with regard to interpreters, chaperones or other help. Patients were invited to bring companions in to consultations. We saw clear signage in place to offer patients a chaperone should they wish.
- The clinic had access to chaplaincy and translation services via a service level agreement (SLA) with Cambridge University Hospital foundation trust.
- Staff were able to utilise specialist nurses via the SLA, including tissue viability, learning disability and dementia nurses. Information for staff was displayed within the staff room containing details of how to contact the dementia nurses.
- Staff had access to a policy regarding the use of chaperones if required for religious or cultural reasons. We viewed this policy and found it was in date and clearly stated the role of a chaperone. Information telling patients on how to request a chaperone was clearly displayed on the reception desk within the waiting area.

Learning from complaints and concerns

Are medical care services well-led?

Requires improvement 

This section of the medical report is identical to the well-led section in the outpatient report. This is intentional because leadership and management structures for both areas were the same.

We rated well-led as requires improvement because:

- The service's governance framework made reference to out of date guidance and a reporting structure which was not accurate.
- This governance framework did not reflect the practices taking place within the service.
- There was not a robust governance framework between CHC and the Trust. Whilst processes were in place such as the sharing of governance meetings; these were not documented which meant that intended outcomes could not be monitored.
- Some aspects of SLA monitoring could be improved so that CHC is assured its processes are working effectively. For example, in relation to receiving appropriate assurance on staff training and competency.

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However:

- The service had a clear vision and staff were aware of this.
- The leadership team was approachable. Staff told us that they felt comfortable in raising concerns and that they had confidence these would be taken forward.
- Staff felt there was an open and honest culture within the service.
- The service was working to improve services and was in the processes of redefining its strategy following announcements that the environment it worked within (cardiology services) were being redesigned and improved on locally.

Vision and strategy for this this core service

- The Cambridge Heart Clinic's vision was 'to provide unrivalled, consultant-led, high quality patient focused care using the most advanced equipment and experienced, well trained staff'. The clinic reported they aimed to achieve this vision through providing a patient focused, specialist led service. Specialist staff included cardiac nurses, consultant cardiologists, physiologists and radiographers.
- We spoke with two members of staff who had an understanding of Cambridge Heart Clinic's vision and gave examples of how this worked in practice which included attendance at specialist training events and working with worldwide cardiac specialists to bring the latest advances in treatment to the service.
- At the time of our inspection, the strategy for this service was being reviewed due to external developments and expansion within NHS and private cardiology services locally. All of the senior management team we spoke with were aware of the need to refocus the aims of this service and we noted from minutes dated June 2016 and July 2016 that the strategy was standing agenda item at operational team meetings.

Governance, risk management and quality measurement for this core service

- There was a framework in place which described the governance processes for the service, however we could not be assured its content was up to date and applicable. For example, on review of this governance framework dated September 2015, we noted that it made reference to out of date guidance and legislation such as the Care Standards Act 2000 and stated that the

registered manger was accountable to the chief executive officer. These were the same person; which meant there was a line of accountability which was not in place at the time of our inspection.

- In addition, the framework stated that CHC would produce an annual governance report and annual plans for continuous governance. We asked to be provided with these documents and were told that they had not been produced.
- We also noted the framework was not supported by a clear committee structure and key responsibilities and roles documented within it were not reflected within the arrangements shown or described to us during our inspection. For example, the clinical effectiveness and governance committee was not reported into the MAC. This meant we could not be assured the framework document accurately reflected the governance reporting processes for the service so that they could be monitored effectively so that appropriate assurance on the running of the service could be taken.
- CHC had an internal audit strategy in place. We reviewed this documented dated August 2015 and saw that an annual audit plan was to be developed. We noted that the registered manager's dashboard monitored this plan. However, the plan was limited and did not provide for sufficient learning and development opportunities.
- Furthermore, the audit strategy and its implementation had not been discussed at any of the senior management or governance committees in the past year. We were told that it was discussed at the clinical effectiveness and governance committee but found on review of minutes from the meetings dated 15 September 2015 and 14 June 2016 that no such discussion took place. This meant we could not be assured the CHC was learning from audits or improvements which could have improved its practice.
- There were monthly operational meetings which took place between CHC and the Trust. We reviewed minutes from June and July 2016 and noted that there was a dedicated agenda item to discuss the effectiveness of the SLA agreement. However, there was no detail in relation to the items that were discussed or assurances that were taken despite being told by senior managers that this was the forum in which CHC took assurance about shared services.
- In addition, members of the senior management team we spoke with told us that CHC linked into the trusts governance processes receiving minutes of governance

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meetings so that shared areas of learning and improvement could be identified. However this arrangement was not detailed within the SLA agreement so we could not be assured that the arrangement's intended outcomes were being met. Whilst the shared governance arrangements had been detailed in CHC's operational policy, this was not a robust legal framework for the sharing of these arrangements.

- We also noted that some areas of the SLA could be monitored more robustly to ensure that sufficient assurance was gained in relation to the running of the service. For example, we noted that assurance for staff competency and training was gained by the use of a signed declaration by a trust member of staff. The service did not receive training statistics which would allow it to ensure suitably trained and competent staff were caring for its patients.
- Also, during our inspection, pieces of equipment were found to be past their maintenance dates.
- We also noted that policies and procedures were not being signed off by the appropriate committees for example; the governance framework stated that the MAC was responsible for signing off the clinical audit strategy but we found this had been signed off by the Executive Management Team (EMT) in August 2015. In addition, we found that no EMT meeting was held in August 2015 and no reference to this strategy was made in either the April 2015 or October 2015 EMT meetings. This meant we could not be assured there were appropriate arrangements in place for the management and approval of policies which guide the running of the service.
- We had concerns about the quality of meeting minutes and their true reflections of meetings. This was because we were provided the meeting minutes of the clinical effectiveness and governance committee dated 15 September 2015 and 14 June 2016 and noted that parts of these minutes were identical. For example, the discussion reported to have taken place about the terms of reference for the committee was identical in both sets of minutes as was the documented conversation about clinical effectiveness. We also noted that in September 2015 the service reported to have had reviewed quarter 3 audit data when the quarter period had not yet been completed. These minutes also made reference to quarter 1 2016 data which was only available to be looked at during the June 2016 meeting.

- However, The CHC risk management policy was provided by the trust and the clinic had a local protocol in place which documented the utilisation of trust policies with regards to managing risk. This document had clear processes in place for the reporting of incidents and subsequent follow-up actions to ensure information was cascaded appropriately to relevant members of staff.
- The service had two specific risk registers in place, relating to the ward area and catheterisation laboratory. We reviewed both risk registers and noted that risks were scored and had clear review dates documented with action plans to reduce known risks. There were no high risks identified on either risk register.
- Robust processes in place for the monitoring of practicing privileges. This included annual competency reviews and full practicing reviews on a bi-annual basis. MAC meeting minutes from June 2016, confirmed this process as did the registered managers dashboard which confirmed all consultants working under practicing privileges were authorised.

Leadership and culture of service

- The service was led by an executive management team which was comprised of the chief executive officer (CEO), an area manager and also the clinical director for CHC. This team was also supported by a trust operational manager.
- We spoke to all of the senior leadership during our inspection and they demonstrated a cohesive understanding on the risks facing the service and the level of care it aimed to provide. They were all committed to the services vision and values. They were also supportive of one another and the staff who worked with them. Feedback from staff confirmed they were treated as equals.
- We spoke with three members of staff who all described senior managers as approachable. One member of staff said 'we see the senior managers in clinic at least once a week, they respond really quickly to any questions or concerns brought to their attention'. Another member of staff said 'there is no divide between Cambridge Heart Clinic staff and the NHS staff [working together in the area in which CHC operates]'.
- Two members of staff we asked told us that they felt the culture was open and honest. They felt that information would be acted upon and that they would receive feedback and be supported.

Medical care

Public and staff engagement

- Patients were able to leave feedback and comments via the clinic's website. In addition, feedback was requested from patients at the time of their visit to the clinic.

Innovation, improvement and sustainability

- The service was in the process of planning GP educational events, comprising of cardiology lectures. The aim of these was to generate clinic awareness and promotion of services. These were due to commence in September 2016.
- The clinic was planning the development of electrophysiology services, with a trial clinic performing simple ablation procedures (procedures to rectify heart rhythm problems) having already taken place. The clinic was working in conjunction with their NHS partner, with the possibility of providing a private patient list while NHS patients attended for ablation procedures.

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

Information about the service

The Cambridge Heart Clinic (CHC) is a partnership between The Cambridge University Hospital NHS Foundation Trust (CUHFT) and Regent's Park Heart Clinics Ltd (RPHC).

Regent's Park is a specialist cardiovascular services company that has been delivering invasive cardiology services in partnership with Addenbrooke's Hospital since 2006. The service is available to private patients only, through insurance or self-funding and provides outpatient cardiology services exclusively.

The CHC outpatient department is located on ward K2 at Addenbrooke's hospital and provides consultant led care. The clinic has access to consulting rooms and investigation rooms where various cardiac investigations are carried out. Investigative procedures and tests carried out at the clinic include electrocardiograms, blood pressure monitoring and echocardiograms. The clinic does not provide any diagnostic imaging facilities.

All medical and nursing staff are provided to the clinic via a service level agreement (SLA) with the trust. At the time of our inspection, the clinic had six consultants employed with practising privileges.

The CHC carried out a total of 592 outpatient appointments between April 2015 to March 2016. All patients were over 18 years of age.

Throughout this report the expression "CHC" or "clinic" shall mean The Cambridge Heart Clinic" and "the Trust" or "CUHFT" shall mean Cambridge University Hospitals NHS Foundation Trust.

Summary of findings

Overall we rated outpatient services at the Cambridge Heart Clinic as good because:

- The service had a good track record for safety. There were no clinical incidents, non-clinical incidents or never events reported between April 2015 and March 2016.
- Outpatient medical records were completed fully and accurately to a high standard.
- All clinical and non-clinical areas we visited were visibly clean. The service had systems in place to check and maintain cleanliness.
- Patients had access to a choice of appointments with minimal waiting times for outpatient care and treatment.
- Medicines were stored according to trust policy, with legal requirements surrounding the storage of medicines being met.
- Medical services had safe levels of staffing, care hours per patient were calculated in advance of patient admission.
- We saw evidence of multidisciplinary team working (MDT) and staff described good working relationships between the NHS trust staff and the Cambridge Heart Clinic staff.

However:

- There was limited auditing taking place to monitor patient outcomes in outpatient services.

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- We could not gain assurances that patient safety was monitored in an effective way because results of key performance indicators were not monitored on a regular basis.
- Governance arrangements were not robust. We found that governance documents did not reflect the processes taking place and that monitoring of the SLA was not effective.

Are outpatients and diagnostic imaging services safe?

Good 

We rated safe as good because:

- The Cambridge Heart Clinic had no clinical or non-clinical incidents between April 2015 and March 2016.
- Senior staff told us that all staff received training in incident reporting and the duty of candour. Staff were able to demonstrate good knowledge of these subjects.
- The clinic demonstrated good hand hygiene practice through audits. General cleanliness audits revealed that a clean environment was being maintained.
- Medical records were completed to a high standard with monthly audits carried out for quality assurance purposes.

However:

- We could not gain assurances that patient safety was monitored in an effective way because results of key performance indicators were not monitored on a regular basis.

Incidents

- The clinic had a local incident reporting policy in place, which was issued on 29th September 2014 and was due for review on 29th September 2017. Staff were instructed to follow the Regent's Park Heart Clinics 'Policy for the Management of Adverse Events and Near Misses', which was last reviewed in April 2016 and was due for review in March 2019. The policy included guidance on how to report incidents and how to investigate concerns.
- Incidents were reported through the trusts electronic reporting system. The ward manager told us that all staff had received training on the system. However, we were not provided with the necessary data to confirm this.
- The ward sister told us that incidents involving the clinic were reported to office administration staff and noted on the electronic incident record system. The CHC local protocol stated that the RPHC manager was responsible

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for conducting an investigation of any incidents and informing all relevant parties of feedback and results.

However, as there had been no reported incidents we could not test these arrangements worked effectively.

- The service reported no never events from April 2015 to March 2016. A never event is a serious incident that is wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.
- From April 2015 to March 2016 there were no serious incidents reported within outpatient services.
- There were no clinical or non-clinical incidents within outpatients and in the reporting period of April 2015 to March 2016. NHS reported incidents were fed back to CHC to ensure dissemination of information and a prevention in the reoccurrence of incidents should this be a risk
- From November 2014, all providers were required to comply with the duty of candour regulation 20 of the Health and Social care Act 2008 (Regulated Activities) Regulations 2014. The duty of candour is a regulatory duty that relates to openness and transparency. It requires providers of health and social care services to notify patients (or other relevant persons) of certain notifiable safety incidents' and provide reasonable support to that person. Staff understood their responsibilities with regard to the duty of candour legislation. Staff we spoke with could describe the principles of being open and honest with patients.

Safety thermometer or equivalent

- The CHC monitored patient safety using key performance indicators (KPI). For example, these included Did Not Attend (DNA) rates and waiting times. However, we could not gain assurances that these were monitored on a regular basis because KPI results were not provided to us through the registered manager's dashboard where we were informed these were located. Therefore we were not assured this was an effective way of monitoring patient safety.

Cleanliness, infection control and hygiene

- The clinic had cleaning services provided via the trust under the existing service level agreement (SLA) in place.

- Training on infection prevention and control was provided to staff working at CHC by the trust in accordance with the SLA in place.
- The clinic was visibly clean and uncluttered, protecting patients from risks of infection or falls.
- The entrance to the clinic and all side rooms had antibacterial gel dispensers at entrances and near patient bedsides. Appropriate signage regarding hand washing was visible at the entrance to the ward in line with World Health Organisation (WHO) guidance.
- We saw that rooms had appropriate facilities for the disposal of clinical waste and sharps. Staff signed a label on bins used for the disposal of sharp objects (sharps bins) which indicated the date they were constructed. This was in line with regulation 5 of the Health and Safety (Sharps Instruments in Healthcare) Regulations 2013, which requires staff to place secure containers and instructions for safe disposal of medical sharps close to the work area.
- Waste was appropriately segregated with separate colour coded arrangements for general waste, clinical waste and sharps (needles). Bins were clearly marked with foot pedal operation and were within safe fill limits.
- Personal protective equipment (PPE), including gloves and aprons, was available outside all private patient rooms and ward rooms. The catheterisation laboratory (catheterisation laboratory) had a range of specialist aprons for protection against radiation.
- We spoke with four patients who all said they had seen staff washing their hands and using hand gels.
- The hand hygiene audit data from June, July and August 2016 showed 100% compliance across the clinic.
- There was a separate dirty utility room available in the clinic for the disposal of clinical waste. This room was locked with a keypad entry system to prevent unauthorised access. The room was visibly clean and the floor was free from clutter. The room contained a macerator and bedpan washer which was well maintained. Cleaning information was displayed on the walls, including cleaning standards, frequency and work schedules. Commodes had 'I am clean' labels attached to indicate they were ready for patient use. Cleaning wipes were available in a dispenser on the wall.
- The CHC conducted a patient feedback satisfaction survey from October 2014 to September 2015. To the question, "How satisfied were you with the cleanliness of the Heart Clinic?" CHC scored 4.94 out of five.

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- The clinic conducted daily pre and post clinic environment audits and monthly environment and equipment audits. The purpose of these audits was to focus on cleanliness of the environment and equipment. The last monthly audits in May, June and July 2016, revealed 100% compliance with cleanliness.

Environment and equipment

- The trust were responsible for the provision, servicing and maintenance of equipment for the CHC under the existing SLA in place. The SLA detailed a concise list of equipment that was available for use by the CHC.
- Access to the clinic was provided via intercom to the main ward reception area. The main entrance to the clinic was open plan and well lit. Patients who arrived at reception were sign posted by reception staff to a specific private patient waiting area, located near to the consultation rooms. There was adequate seating in patient waiting areas.
- At the time of our inspection, the corridor was free of clutter and all exits were accessible.
- We observed that wards and consultation rooms were compliant with Health Building Note (HBN) 00-10 part A: Flooring, because they did not have any carpets in clinical areas and flooring was compliant where the floor joined to the walls. The HBN states: 'In clinical areas and associated corridors, there should be a continuous return between the floor and the wall. For example, covered skirtings' with a minimum height of 100mm for easy cleaning'. Whilst it was not necessary for the clinic to comply with this HBN it demonstrated best practice guidance was taken into account.
- Consulting rooms and equipment were visibly clean..
- Cambridge Heart Clinic outpatient staff had access to two resuscitation trolleys. One was placed in the main corridor and one in the catheterisation laboratory. We checked both trolleys for adult resuscitation equipment, medicines and consumables. Both trolleys had been checked on a daily basis when the service was open to patients, with the exception of 20/06/2016. The trolleys had the required equipment available for use during a collapse/cardiac arrest. Defibrillators were within their service date and labelled to state when the next service was due. All resuscitation drugs were in date and stored securely.

Medicines

- The trust's pharmacy team were responsible for the supply of medicines through the existing SLA in place. The CHC local protocol clearly referenced trust policies in relation to the administration, dispensing and prescribing of medicine. We reviewed this local protocol and noted it was next due for review in September 2017.
- We inspected medicines stored in the catheterisation laboratory and at the nurses' station, which were for use of inpatient and outpatient services. So What? Maybe amalgamate bullet 5 with this.
- Controlled drugs (CD's) were stored in double locked metal cupboards in the catheterisation laboratory and at the nurses station. One senior member of staff on shift held keys to controlled drugs at any one time.
- The stock levels for CD's matched records.
- We checked six medications in the catheterisation laboratory and all were within the expiry date.
- The tablets and injectable medicines storage at the nurses station was tidy and well organised. Six tablet medications and six injectable medicines were checked and all were within expiry dates
- The hospital had an onsite pharmacy that provided daily cover from 8am to 5pm. Nursing staff reported that the pharmacy team were available to offer support and advice to both staff and patients and dispensed outpatient prescriptions.
- The medication fridge was locked and staff monitored the temperature on a daily basis. This was to ensure the integrity of medicines that needed to be kept within a certain temperature range. Record checks revealed that checks had taken place on a daily basis without gaps.

Records

- We reviewed five sets of medical records pertaining to outpatients The five sets of records we saw showed patients were seen with valid referral letters
- The hospital used a paper based and electronic records system. The records we looked at were accurate, complete and legible, and up to date.
- We saw that records were stored appropriately within the outpatient department, in lockable cupboards.
- Patient records included risk assessments such as risk of falls or nutritional assessments. They were completed appropriately in all five records we looked at during our inspection. They included a GP referral letter, details of health insurance where applicable and details of any procedures or investigations carried out with relevant findings.

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- The four patients we spoke to told us that all their relevant records were available at their appointments to enable them to go ahead.

Safeguarding

- The Cambridge Heart Clinic had local protocols regarding safeguarding adults and children. Both protocols were issued in September 2014 and were due for review in September 2017.
- The protocols stated that the Cambridge Heart Clinic (“CHC”) adhered to all Cambridge University Hospitals NHS Foundation Trust (CUHFT) policies. The local protocol was read in conjunction with the relevant policies, including the Safeguarding Adults Policy, which was available on the Trust intranet.
- Staff working for CHC told us they had completed the CUHFT mandatory training. Mandatory training included safeguarding children and vulnerable adults. Training included awareness of female genital mutilation (FGM). However, we could not be provided with data on training compliance by CHC.
- Any safeguarding concerns were raised through a form on the trusts electronic software system, accessible by CHC staff.
- There had been no reported safeguarding incidents in the reporting period April 2015 to March 2016.
- CHC had a named safeguarding lead whose primary role was a full time administrator with the Clinic.
- We spoke with three members of staff who were all clear on the process of how to report a safeguarding concern.

Mandatory training

- All mandatory training was provided by the trust with the existing SLA in place. However, we could not be provided with training data which demonstrated compliance for those staff which worked for CHC.
- We were told by CHC that trust staff monitored mandatory training compliance. CHC took its assurance that this training was completed via a signed declaration from trust management.

Assessing and responding to patient risk

- There was a whiteboard in the catheterisation laboratory that displayed the World Health Organisation (WHO) checklist, which aims to provide safer care for patients undergoing minor procedures. The board

included the date, patient’s name, any allergies, International Normalised Ratio (INR), screening for infections and sharps. INR is a blood test used to monitor blood clotting in patients.

- The clinic conducted a monthly patient record keeping audit regarding quality and completeness of patient notes, which was conducted by the registered manager. The average cumulative monthly audit score from January 2016 to August 2016 was 98.9%. The audit focused on legibility of notes, comprehensiveness, and presence of appropriate signatures.
- Resuscitation services were provided under the existing SLA in place with the trust. A resuscitation services team was available should the need arise. The SLA detailed that post resuscitation, all patients would be transferred to the intensive care unit or critical care unit as an NHS inpatient.
- We spoke with two members of staff who were clear on the procedures should there be an emergency. This included calling the crash team (provided under the SLA) and arranging for a patient to be transferred to NHS Care.

Nursing staffing

- Nurse staffing for outpatients was provided by the existing SLA with the trust.
- Nurse staffing requirements were calculated in advance based on the planned nature and number of outpatient procedures. Care hours per patient day (CHPPD) were calculated to ensure an adequate number of nursing staff per patient.
- Staff for the clinic were provided by permanent ward staff from the main hospital. A senior member of staff informed us that staff were utilised from other nearby wards if bank or agency usage was required for CHC. Bank or agency staff would then be used to fill shifts in adjacent NHS wards.
- No bank or agency nursing staff were used in outpatient departments during the reporting period April 2015 to March 2016.

Medical staffing

- No medical bank or agency staff were used in outpatient departments during the reporting period April 2015 to March 2016.
- Medical staff worked for CHC under practising privileges. At the time of our inspection six consultants were working under practicing privileges.

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Major incident awareness and training

- All staff working for CHC had completed the CUHFT training through the existing SLA in place with the trust. Major incident training was included as part of the induction programme. However, supporting evidence could not be provided.

Are outpatients and diagnostic imaging services effective?

Not sufficient evidence to rate 

We effective as good because:

- The clinic carried out local audits and monitored patient feedback on a regular basis. Audits demonstrated the clinic was complying with its protocols and policies.
- Training was provided by the trust and the CHC was responsible for monitoring competency training to ensure staff were up to date with relevant training
- Patients told us consent was sought prior to treatment.
- Staff told us they had received training in the mental capacity Act (2005) and Deprivation of Liberty safeguards (2009).

However:

- There was limited clinical audit being undertaken to monitor the outcomes for patients attending clinics at this service.

Evidence-based care and treatment

- Staff in outpatients had access to CHC policies in site and online policies via the NHS partner's information technology systems.
- All staff had access to online policies via the CUHFT intranet. The CHC registered manager kept a log of all revisions to policies and the scheduled next review date. All policies and protocols were up to date at the time of our inspection.

Pain relief

- Patients could contact the outpatient department directly during normal operational hours if they had any issues, and speak to a nurse or their consultant if they were experiencing any pain after a procedure. If the clinic was not open, patients could contact their GP.

- Consultants could provide prescriptions for pain relief to patients in the outpatient department and they could collect medications from the onsite pharmacy.
- All four Patients we spoke with during our inspection had not required pain relief during their appointments.

Patient outcomes

- The CHC was responsible for ongoing audits, including daily pre and post clinic operational audits, weekly complaints audits, monthly equipment and environment.
- We could not gain assurances that patient outcomes were audited or monitored for outpatient services.
- The trust was responsible for ongoing monthly audits under the service level agreement for ward K2 of infection control, cleaning, fault logs, catheterisation laboratory risk register and ward risk register.

Competent staff

- Nursing staff had received regular appraisals. For the current year, January 2016 to December 2016, 100% of nursing staff had received an appraisal. The clinic reported that 100% of medical staff had received an appraisal, with the next review date due in July 2017.
- In order to maintain practising privileges, consultants were required to provide copies of their Medical Indemnity Insurance certificate, most recent appraisal and Professional Development Plan from CUHFT. Consultants were also required to provide evidence of completed mandatory training, GMC registration and current licence to practice.
- Revalidation of doctors was discussed at executive management meetings, which took place on a quarterly basis. Doctors provided evidence of revalidation at annual appraisals.
- All training for nursing staff was provided by the trust under the existing SLA.
- Nurse training and competency checks were provided by the existing SLA with the trust. However, we could not be provided with data from CHC which confirmed staff who worked for them had undertaken appropriate competency checks.
- CHC sought assurances that all staff involved in invasive procedures complied with necessary competency requirements via a signed declaration from the trust that it would monitor staff competency.

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Multidisciplinary working

- All patient records we looked at included a referral from a GP and a follow up report back to the patients GP with findings and any recommendations.

Seven-day services

- The clinic did not provide access to seven day services. It opened on average 20% of the working week between Monday and Friday. Clinics were arranged depending on patient demand and we run during the day or at evening. This was sufficient to see the patients accessing the clinic.

Access to information

- CUHFT used an electronic patient record system. Data on this system was accessible to NHS and CHC staff. CHC patients were allocated an NHS trust identification number, which was then trackable through the trusts record system. This allowed the appropriate sharing of clinical information.
- Private patients were provided with a printed discharge summary detailing treatment given, procedures carried out and any medications prescribed.
- A summary of any actions were sent to the patient's GP electronically.
- We reviewed five sets of private outpatient notes, which showed that follow up letters had been forward to the patient's GP after their visit to CHC.
- Patients told us that they were provided with details on how to contact the clinic outside of normal opening hours if they required any further support.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The CHC had a policy relating to consent and the Mental Capacity Act 2005 (MCA) and Deprivation of Liberty Safeguards 2009. The Policy for Consent to Examination or Treatment was issued on 8 August 2014 and was due for review on 29 September 2017.
- We spoke with a ward manager regarding the Mental Capacity Act (2005) and Deprivation of Liberty Safeguards (2009). We were told that training for these subjects was eLearning based. The ward manager was able to explain the process of the Mental Capacity Act and Deprivation of Liberty Safeguards applications. Training compliance was overseen by the ward manager responsible for CHC staff who reported that all staff were

up to date for both Mental Capacity Act (2005) and Deprivation of Liberty Safeguards (2009) training. We could not however be provided with data which confirmed this.

- There were clear directions for staff if they needed to make an application to deprive a patient of their liberty, which included who to send the application to. The policy also included information on when and how to access an independent mental capacity advocate (IMCA) if required.
- We spoke with the ward manager, who was aware of consent, Mental Capacity Act and Deprivation of Liberty Safeguards requirements.
- We spoke with two other members of staff about these requirements. One member of staff was able to describe the requirements in detail and demonstrated a good level of understanding of their responsibilities. However, the other member of staff could not describe the processes to us.
- The CHC had a standard adult consent form, a form for adults unable to give consent and a form to give consent to investigation or treatment by a patient who refuses to have a blood transfusion. We were provided with template copies of these forms prior to the inspection, which showed they were suitable and fit for purpose.
- The four patients we spoke with informed us that they were asked for their verbal and written consent before staff helped them, and before any procedures were undertaken.

Are outpatients and diagnostic imaging services caring?

We rated caring as good because:

- The CHC had received consistently positive feedback from patients through their patient satisfaction survey.
- Patients told us that their privacy and dignity was always maintained.
- Patients told us staff were polite, friendly and supportive.

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- The use of chaperones was encouraged and additional requirements were discussed upon booking and prior to attendance at the clinic. Patients were also offered translation services when required.

Compassionate care

- We observed staff to be polite and friendly towards patients and relatives.
- We spoke with seven patients who were unanimously complimentary of clinic staff and the hospital. They all stated they were treated with kindness and compassion.
- We observed staff interacting with patients in a professional and compassionate manner in clinics and in the waiting area. For example, one patient had travel a long way to get to their outpatient appointment and was quite flustered when they arrived at the clinic. We saw staff comfort this patient, they made them a cup of tea and sat with them for a while in the waiting room.
- Patients told us staff were kind, respectful and always introduced themselves; this was also observed in the clinic during the inspection.
- We observed the receptionists being kind, courteous and helpful when talking to patients on arriving at the clinic.
- Patients told us that their privacy and dignity was always maintained. Staff told us that CHC patients were always offered a private room when receiving treatment. Patient privacy was maintained whilst in side rooms by the use of an inner curtain. This was utilised when consultations, treatment or procedures were being carried out.
- Clinic rooms in the outpatients department displayed 'free/engaged' signs to prevent unnecessary access during consultations and treatment.
- Patients undergoing any examination would be asked if they required a chaperone. There were signs in the reception areas offering a chaperone if required.
- During our inspection, all seven patients we spoke with said they would recommend the clinic.
- One patient described their whole experience at the clinic as "organised, efficient and friendly." Another patient stated "I can't fault any aspect of my care – I have been here three times and it's always been fantastic."
- The CHC conducted a rolling review of responses to their patient satisfaction survey. The response rate for the October 2014 to September 2015 period was 22%. From the review, 99% of respondents said they would

recommend the clinic to a friend, which is comparable to the England average. To the question, "How well were you treated by our staff?" CHC scored 4.96 out of five for outpatient staff. From the period October 2015 to the date of our inspection, the CHC was scoring at 4.96 for the same question.

Understanding and involvement of patients and those close to them

- Patients we spoke with told us that their treatment was discussed and explained to them in detail and in a manner they were able to understand.
- Patients told us they were offered a choice of appointments to suit them.
- Consultants provided advice and information in relation to treatment and the next steps after their consultations.
- Patients were given the opportunity to be accompanied by a friend or relative during consultations.

Emotional support

- Access to counselling and chaplaincy services were provided through the SLA.
- Consultation rooms were private which meant people could discuss their emotional needs in confidence.
- All four patients we spoke with said that they were part of the decision making process regarding their treatment plan.

Are outpatients and diagnostic imaging services responsive?

Good 

We responsive as good because:

- Patients were offered outpatient appointments in a timely manner. The clinic offered preferential access to the catheterisation laboratory slots to minimise waiting times.
- The clinic offered individual, patient focused care through the use of specialist nurses, chaperones and translation services where required.
- The clinic had a robust complaints procedure.

Service planning and delivery to meet the needs of local people

Outpatients and diagnostic imaging

- The Cambridge Heart Clinic provided cardiac procedures to self-funding or insured private patients only.
- Local NHS GP practices referred patients for private investigation and treatment where required.

Access and flow

- Due to being a private business, the clinic could offer flexibility and short waiting times for those requiring treatment. Patients were offered a variety of appointments demonstrating flexibility including evening clinics if required.
- The administration team at the CHC were responsible for the booking of clinic appointments. Patients could book over the telephone and information regarding appointments was sent by post to confirm details.
- Patients accessing outpatient services at the clinic required a referral from a healthcare professional prior to treatment or examination taking place.
- The clinic had access to diagnostic radiology services through the SLA in place with their NHS partner.
- We were told that once a referral had been made by a healthcare professional, patients could access the outpatient clinic within two to five working days.
- All four patients we spoke to said they were satisfied with the waiting times for the clinic.

Meeting people's individual needs

- Clinic staff asked patients when booking an initial appointment if any additional help was required with regard to interpreters, chaperones or other help. Patients were invited to bring companions in to consultations.
- Information telling patients on how to request a chaperone was clearly displayed on the reception desk within the waiting area.
- The clinic had access to chaplaincy, a dementia nurse and translation services via a service level agreement (SLA) with the trust.
- Staff had access to a policy regarding the use of chaperones if required for religious or cultural reasons. We viewed this policy and found it was in date and clearly stated the role of a chaperone.
- Staff had access to translation services through the existing SLA in place with the trust. The clinic asked

upon booking whether any additional services would be required, for example a chaperone was offered at the time of booking. In addition, dementia and learning disability nurses were available via the trust.

- Patients told us that parking was available in the trust hospital car park.
- The reception desk was at a height accessible for wheelchair users to communicate effectively with the receptionists.

Learning from complaints and concerns

- CHC patients were given information in the waiting areas on how to compliment or complain about the service. There was a supply of patient feedback cards and post box visibly placed on the reception desk. In addition, 'tell us what you think cards' were on clear display within this area.
- There were no complaints for the Cambridge Heart Clinic reported to The Care Quality Commission between April 2015 and March 2016.
- Clinic staff had access to information on how to deal with complaints. We saw the CHC complaints policy document was approved in August 2014 and was due for review in September 2017. The policy also included guidance for staff on how to deal with complaints.
- The clinic received one direct complaint in the period of April 2015 to March 2016. The complaint was regarding a lack of information provided to a patient regarding the possible side effects of a new prescribed medication. We looked at medical advisory committee (MAC) meeting notes which detailed discussion about this specific complaint. Learning points and recommendations had been identified to prevent a recurrence. These included the need for clinicians to discuss and document conversations with patients, detailing side effects of medications prior to discharge. This complaint had been resolved at a local level, with the complainant receiving a complaint conclusion letter

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Are outpatients and diagnostic imaging services well-led?

Requires improvement 

This section of the outpatient and diagnostic imaging report is identical to the well-led section in the medical care report. This is intentional because leadership and management structures for both areas were the same.

We rated well-led as requires improvement because:

- The service's governance framework made reference to out of date guidance and a reporting structure which was not accurate.
- This governance framework did not reflect the practices taking place within the service.
- There was not a robust governance framework between CHC and the Trust. Whilst processes were in place such as the sharing of governance meetings; these were not documented which meant that intended outcomes could not be monitored.
- Some aspects of SLA monitoring could be improved so that CHC is assured its processes are working effectively. For example, in relation to receiving appropriate assurance on staff training and competency.

However:

- The service had a clear vision and staff were aware of this.
- The leadership team was approachable. Staff told us that they felt comfortable in raising concerns and that they had confidence these would be taken forward.
- Staff felt there was an open and honest culture within the service.
- The service was working to improve services and was in the processes of redefining its strategy following announcements that the environment it worked within (cardiology services) were being redesigned and improved on locally.

Vision and strategy for this this core service

- The Cambridge Heart Clinic's vision was 'to provide unrivalled, consultant-led, high quality patient focused care using the most advanced equipment and experienced, well trained staff'. The clinic reported they

aimed to achieve this vision through providing a patient focused, specialist led service. Specialist staff included cardiac nurses, consultant cardiologists, physiologists and radiographers.

- We spoke with two members of staff who had an understanding of Cambridge Heart Clinic's vision and gave examples of how this worked in practice which included attendance at specialist training events and working with worldwide cardiac specialists to bring the latest advances in treatment to the service.
- At the time of our inspection, the strategy for this service was being reviewed due to external developments and expansion within NHS and private cardiology services locally. All of the senior management team we spoke with were aware of the need to refocus the aims of this service and we noted from minutes dated June 2016 and July 2016 that the strategy was standing agenda item at operational team meetings.

Governance, risk management and quality measurement

- There was a framework in place which described the governance processes for the service, however we could not be assured its content was up to date and applicable. For example, on review of this governance framework dated September 2015, we noted that it made reference to out of date guidance and legislation such as the Care Standards Act 2000 and stated that the registered manager was accountable to the chief executive officer. These were the same person; which meant there was a line of accountability which was not in place at the time of our inspection.
- In addition, the framework stated that CHC would produce an annual governance report and annual plans for continuous governance. We asked to be provided with these documents and were told that they had not been produced.
- We also noted the framework was not supported by a clear committee structure and key responsibilities and roles documented within it were not reflected within the arrangements shown or described to us during our inspection. For example, the clinical effectiveness and governance committee was not reported into the MAC. This meant we could not be assured the framework document accurately reflected the governance reporting processes for the service so that they could be monitored effectively so that appropriate assurance on the running of the service could be taken.

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- CHC had an internal audit strategy in place. We reviewed this documented dated August 2015 and saw that an annual audit plan was to be developed. We noted that the registered manager's dashboard monitored this plan. However, the plan was limited and did not provide for sufficient learning and development opportunities.
- Furthermore, the audit strategy and its implementation had not been discussed at any of the senior management or governance committees in the past year. We were told that it was discussed at the clinical effectiveness and governance committee but found on review of minutes from the meetings dated 15 September 2015 and 14 June 2016 that no such discussion took place. This meant we could not be assured the CHC was learning from audits or improvements which could have improved its practice.
- There were monthly operational meetings which took place between CHC and the Trust. We reviewed minutes from June and July 2016 and noted that there was a dedicated agenda item to discuss the effectiveness of the SLA agreement. However, there was no detail in relation to the items that were discussed or assurances that were taken despite being told by senior managers that this was the forum in which CHC took assurance about shared services.
- In addition, members of the senior management team we spoke with told us that CHC linked into the trusts governance processes receiving minutes of governance meetings so that shared areas of learning and improvement could be identified. However this arrangement was not detailed within the SLA agreement so we could not be assured that the arrangement's intended outcomes were being met. Whilst the shared governance arrangements had been detailed in CHC's operational policy, this was not a robust legal framework for the sharing of these arrangements.
- We also noted that some areas of the SLA could be monitored more robustly to ensure that sufficient assurance was gained in relation to the running of the service. For example, we noted that assurance for staff competency and training was gained by the use of a signed declaration by a trust member of staff. The service did not receive training statistics which would allow it to ensure suitably trained and competent staff were caring for its patients.
- Also, during our inspection pieces of equipment (owned by the trust but utilised by CHC as part of the SLA) were found to be past their maintenance dates.
- We also noted that policies and procedures were not being signed off by the appropriate committees for example; the governance framework stated that the MAC was responsible for signing off the clinical audit strategy but we found this had been signed off by the Executive Management Team (EMT) in August 2015. In addition, we found that no EMT meeting was held in August 2015 and no reference to this strategy was made in either the April 2015 or October 2015 EMT meetings. This meant we could not be assured there were appropriate arrangements in place for the management and approval of policies which guide the running of the service.
- We had concerns about the quality of meeting minutes and their true reflections of meetings. This was because we were provided the meeting minutes of the clinical effectiveness and governance committee dated 15 September 2015 and 14 June 2016 and noted that parts of these minutes were identical. For example, the discussion reported to have taken place about the terms of reference for the committee was identical in both sets of minutes as was the documented conversation about clinical effectiveness. We also noted that in September 2015 the service reported to have had reviewed quarter 3 audit data when the quarter period had not yet been completed. These minutes also made reference to quarter 1 2016 data which was only available to be looked at during the June 2016 meeting.
- However, The CHC risk management policy was provided by the trust and the clinic had a local protocol in place which documented the utilisation of trust policies with regards to managing risk. This document had clear processes in place for the reporting of incidents and subsequent follow-up actions to ensure information was cascaded appropriately to relevant members of staff.
- The service had two specific risk registers in place, relating to the ward area and catheterisation laboratory. We reviewed both risk registers and noted that risks were scored and had clear review dates documented with action plans to reduce known risks. There were no high risks identified on either risk register.
- Robust processes in place for the monitoring of practicing privileges. This included annual competency reviews and full practicing reviews on a bi-annual basis.

Outpatients and diagnostic imaging

MAC meeting minutes from June 2016, confirmed this process as did the registered managers dashboard which confirmed all consultants working under practicing privileges were authorised.

Leadership and culture of service

- The service was led by an executive management team which was comprised of the chief executive officer (CEO), an area manager and also the clinical director for CHC. This team was also supported by a trust operational manager.
- We spoke to all of the senior leadership during our inspection and they demonstrated a cohesive understanding on the risks facing the service and the level of care it aimed to provide. They were all committed to the services vision and values. They were also supportive of one another and the staff who worked with them. Feedback from staff confirmed they were treated as equals.
- We spoke with three members of staff who all described senior managers as approachable. One member of staff said 'we see the senior managers in clinic at least once a week, they respond really quickly to any questions or concerns brought to their attention'. Another member of staff said 'there is no divide between Cambridge Heart Clinic staff and the NHS staff [working together in the area in which CHC operates]'.

- Two members of staff we asked told us that they felt the culture was open and honest. They felt that information would be acted upon and that they would receive feedback and be supported.

Public and staff engagement

- Patients were able to leave feedback and comments via the clinics website. In addition, feedback was requested from patients at the time of their visit to the clinic.

Innovation, improvement and sustainability

- The service was in the process of planning GP educational events, comprising of cardiology lectures. The aim of these was to generate clinic awareness and promotion of services. These were due to commence in September 2016.
- The clinic was planning the development of electrophysiology services, with a trial clinic performing simple ablation procedures (procedures to rectify heart rhythm problems) having already taken place. The clinic was working in conjunction with their NHS partner, with the possibility of providing a private patient list while NHS patients attended for ablation procedures.

Outstanding practice and areas for improvement

Outstanding practice

- A patient was referred to the service by their GP and offered an outpatient appointment the same day. A treatment plan was agreed which meant the patient was also admitted the day of their referral and received treatment the following day.

Areas for improvement

Action the provider **MUST** take to improve

- Consider reviewing its clinical audit plan to include a wider range of audits to demonstrate patient outcomes and identify areas where practice could be improved.
- Consider reviewing its governance framework to ensure this accurately reflects the governance arrangements in place.
- Consider ensuring these arrangements are appropriately agreed with the trust.
- Consider how it takes appropriate assurance that all aspects of the SLA with the trust are working effectively.
- Consider implementing an effective policy approval process.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Treatment of disease, disorder or injury	<p>Regulation 17 HSCA (RA) Regulations 2014 Good governance</p> <p>Regulation 17 (1) (2) (a) Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Which states:</p> <p>17 (1) Systems and Process must be established and operated effectively to ensure compliance with the requirements in this Part.</p> <p>(2) Without limiting paragraph (1), such systems or processes must enable the registered person, in particular, to –</p> <ol style="list-style-type: none">1. 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) <p>The service was failing to comply with this regulation because:</p> <p>The governance and assurance systems in place were not working effectively to enable the registered person to assess and monitor the quality of the services provided.</p>