

## iRhythm Technologies Limited

## iRhythm Technologies

**Inspection report** 

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

### **Ratings**

Overall rating for this location Good			
Are services safe?	Good		
Are services effective?	Good		
Are services caring?	Good		
Are services responsive to people's needs?	Good		
Are services well-led?	Outstanding	$\Diamond$	

### Summary of findings

### **Overall summary**

We have not rated this service before. We rated it as good because:

- The service had enough staff to care for patients and keep them safe. Staff had training in key skills, understood how to protect patients from abuse, and managed safety well. The service-controlled infection risk well. Staff assessed risks to patients, acted on them and kept good care records. The service managed safety incidents well and learned lessons from them.
- Staff provided good care. Managers monitored the effectiveness of the service and made sure staff were competent. Staff worked well together for the benefit of patients and had access to good information. Key services were available five days a week.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their
  individual needs, and helped them understand their conditions. They provided emotional support to patients,
  families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait for treatment.
- Leaders ran services well using reliable information systems and supported staff to develop their skills. Staff understood the service's vision and values, and how to apply them in their work. Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. Staff were clear about their roles and accountabilities. The service engaged well with patients and the community to plan and manage services and all staff were committed to improving services continually.

#### However:

• The service should ensure that recruitment documents are accessible and complete for all staff employed at the location.

## Summary of findings

### Our judgements about each of the main services

Rating Summary of each main service Service

**Community** health services for adults

Good

## Summary of findings

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### Summary of this inspection

### **Background to iRhythm Technologies**

IRhythm Technologies is an independent service based in Bagshot, Surrey. It supplies ambulatory electrocardiogram (ECG) monitoring products and services to a variety of healthcare services. ECG's are a clinical investigation that diagnoses heart arrhythmias and forms the basis of medical diagnosis for a range of conditions. The service supplies easy to use ECG monitors which are sent by post to hospitals or clinics where healthcare professionals are trained to fit the devices. Staff are available for help and support to all customers through patient support lines. ECG analysis of the monitor's data is completed by trained clinical physiologists who create reports that are shared with the patient's nominated medical professional who would typically be prescribing the ECG. The service runs from one location in the United Kingdom but also operates internationally in the United States of America (USA).

The service is registered to provide the following regulated activities:

• Diagnostic and screening processes

The service was registered with the Care Quality Commission in April 2020. This is the first time we have inspected this service. IRhythm technologies is an international organisation with five offices. Four of the offices are in the USA in San Francisco, Chicago, Houston and San Diego. The UK location has 46 members of staff. Staff work both remotely and face to face. The manufacture and clinical operations teams of the wider company are based at the USA.

### How we carried out this inspection

During this inspection we visited the main office of the service. We spoke with three staff members and four members of the leadership team. No patients were interviewed as part of the inspection as none were available to speak with.

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

### **Outstanding practice**

We found the following outstanding practice:

- The service had a comprehensive research and improvement programme associated with the ECG device.
- The staff development programme from induction through to their first year of service was structured, data driven, staff focused, and motivational for career development.

### **Areas for improvement**

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

### Action the service SHOULD take to improve:

5 iRhythm Technologies Inspection report

## Summary of this inspection

• The service should ensure that recruitment documents are accessible and complete for all staff employed at the location.

## Our findings

### Overview of ratings

Our ratings for this location are:

Community health services for adults
Overall

Safe	Effective	Caring	Responsive	Well-led	Overall
Good	Good	Good	Good	Outstanding	Good
Good	Good	Good	Good	<b>Outstanding</b>	Good

We have not rated this service before. We rated it as good.

### **Mandatory training**

### The service provided mandatory training in most key skills to all staff and made sure everyone completed it.

Good

Staff received and keep up to date with their mandatory training. The most recent training figures showed that staff completed on average 100% of their modules. Staff completed a mandatory training programme when they began their employment.

The mandatory training was comprehensive and met the needs of staff and patients. Staff completed mandatory training on subjects to support them in their roles. Staff had different roles depending on whether they interacted with patients and if their role was clinical or not. Staff also had access to training that covered the Mental Capacity Act, learning disabilities and dementia.

Managers monitored mandatory training and alerted staff when they needed to update their training. Managers accessed an electronic system which checked staff completion rates of mandatory training.

Managers could see the mandatory training status for each staff member and the status of each individual module. Managers individually reminded staff to complete upcoming mandatory training.

#### Safeguarding

Staff understood how to protect patients from abuse and the service worked well with other agencies to do so. Customer facing staff had training on how to recognise and report abuse and they knew how to apply it.



Staff received training specific for their role on how to recognise and report abuse. Staff completed level two training in safeguarding for adult and children. The most recent figures showed 100% of eligible staff had completed their adult safeguarding training and 100% of eligible staff had completed child safeguarding training. Safeguarding leads for the service supported staff and had enhanced safeguarding training at level three for adults and children.

Staff could recognise adults and children at risk of, or suffering, significant harm and worked with other agencies to protect them. Staff had a clear understanding of how to recognise and report abuse. Staff could access contact details of the local safeguarding teams and the hospital's safeguarding policy. However, managers and staff did not have examples of any safeguarding incidents in the last 12 months.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. The service had up to date policies for safeguarding children and vulnerable adults. Staff could explain how to raise a safeguarding incident using the department's reporting process and policy. Staff knew what actions they would take if they had concerns.

### Cleanliness, infection control and hygiene

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

Areas were clean and well-maintained. Managers and staff had access to hand sanitiser at all entrances and floors of the building. Offices were open, spacious and visibly clean. Managers conducted monthly health and safety risk assessment audits for all areas of the business. The most recent audit was May 2022 and found two areas for action which were related to lighting and staff orientation for suitable desk screen equipment (DSE). Managers had conducted relevant infection, prevention and control (IPC) risk assessments for the building. This included Covid 19, Patient Protective Equipment (PPE) and Control of Substances Hazardous to Health (COSHH). Managers completed individual risk assessments for fire safety and building maintenance. Managers used an electronic risk assessment tool which covered all risk assessments including actions that were needed and deadlines for when these needed to be met. Managers also conducted monthly health and safety meetings which covered incidents, near misses, building maintenance and first aid arrangements.

Staff followed infection control principles. Staff managed returned ECG monitors in a separate area where they removed monitors from their packaging with caution wearing suitable PPE for their hands. Managers had risk assessed the use of PPE and the suitability for different staff members depending on their role.

Managers screened staff for Covid 19 symptoms. Managers instructed staff to work remotely if they showed any symptoms. Managers had recently stopped lateral flow tests but showed awareness of the ongoing risks and a caring attitude towards their staff.

#### **Environment and equipment**

The design, maintenance and use of facilities, premises and equipment kept people safe. Staff were trained to use specialist equipment. Staff managed clinical waste well.

The design of the environment followed national guidance. The building was based on three floors. The first floor was for deliveries and processing. The second and third floors were office space and conference rooms. All areas of the building were open plan with private areas for conferences and staff to conduct their work.



Staff carried out daily safety checks of specialist equipment. Managers did not have clinical equipment that required calibration as all monitors were tested abroad before they arrived at the offices for dispatch to patients. Managers did complete some calibration for equipment associated with the office building which formed part of the health and safety management of the building.

Staff disposed of clinical waste safely. Staff had access to a sharps bin on the first floor if contaminates were found in the packaging when monitors were returned. Managers had awareness of the IPC risks of used patient equipment and we saw staff decontaminating the monitors before their data was processed.

### Assessing and responding to patient risk

## Staff completed and updated risk assessments for each patient and removed or minimised risks. Staff identified and quickly acted upon patients at risk of deterioration

Staff responded promptly to any sudden deterioration in a patient's health. Staff provided support to patient's remotely through a telephone advice line. Staff interviewed were able to describe how they would escalate risks. Staff expressed that an acute medical event would be escalated to the local hospital and through emergency services. Staff would also alert the named medical professional or clinic if a patient made contact with concerning symptoms using an urgent notification process. Staff gave us examples of where they had been needed to provide clinical support but told us this rarely happened. Each ECG device had a symptom button which could be pressed when the patient was experiencing symptoms. Staff could see this in the data when they analysed the monitor once it was returned and this provided a more complete picture for medical staff in the report that was created. Patients were provided with a diary which they were encouraged to fill out when they experienced symptoms which was also used in the analysis to provide further evidence of a potential diagnosis.

Staff shared key information to keep patients safe when handing over their care to others. Staff would create reports based on the results of the ECG monitors. The reports were extensive and personalised and allowed for staff to identify clearly areas of concerns and a potential diagnosis to explore. Staff worked within their remit while compiling these reports and there was a system to allow customers an opportunity to ask questions if they needed to.

### **Staffing**

The service had enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix.

The service had enough staff to keep patients safe. Managers felt they had enough staff to keep patients safe. Managers arranged rotas for the department in advance. Staff were positive about how the service staffing levels and there was enough staff with the right skill mix to cover the services that were provided.

Managers accurately calculated and reviewed the number of staff needed for each shift. Managers planned staffing needs for the service over a calendar year. Managers had set rules to ensure that the level of staffing was suitable and met the correct skill mix.

The service had low rates of bank and agency staff.

#### Records



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

Patient notes were comprehensive and clinical staff could access them easily. Staff created records following the arrival of the ECG monitors after patient use. Staff uploaded the data, and interpreted this, creating a custom report that was designed with specific sections that customers or medical professionals had requested to explore cardiac arrhythmia conditions. The report would also detail other information of concern that was discovered during the ECG monitor wear time. Staff completing the process had a quality assurance process overseen by managers and a separate quality assurance team that ensured the accuracy of records and staff performance was kept. This system used a numerical scale which managers used to provide constructive feedback and support to staff during their meetings and appraisals with a member of staff.

Records were stored securely. Staff created records using a secure system and the information was delivered to an appointed person in a secure way that was supported by policies that protected data security.

#### **Incidents**

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them appropriately. Managers investigated incidents and shared lessons learned with the affected members of staff. Managers ensured that actions from patient safety alerts were implemented and monitored.

Managers knew what incidents to report and how to report them. Staff understood the incident policy of the service. A quality assurance team reported incidents where a staff member incorrectly assessed an ECG monitor's data and informed their manager of what had occurred. The quality assurance process was actioned before any report was sent to the customer. Managers had an agreement with customers and medical professionals that if a significant observation was found, this would be reported to them at once. Managers also had an oversight of safety alerts that affected the ECG monitors, but these were rare and had not occurred in the last 12 months.

Managers raised concerns and reported incidents and near misses in line with the service's policy.

Managers of a quality assurance team has recorded 11 incidents in the last twelve months. Incidents were recorded as part of the service's quality assurance process and there was data to support this process. Incidents accounted for between 0.05%-0.2% of all scans performed in the last 12 months.

Staff received feedback from investigation of incidents to the service and Staff met to discuss the feedback and look at improvements to patient care. Where an incident was identified by the quality assurance team, managers conducted one to one coaching with the affected member of staff which looked at how it could be avoided and actions that may prevent a similar incident from happening in the future.

There was evidence that changes had been made as a result of feedback. Managers had oversight of the ongoing performance of a member of staff involved in an incident. Managers provided ongoing support and gave further input if the performance data of a staff member fell below a required level. This was part of the progression criteria that staff needed to meet to progress in their career to a higher clinical level.

### Are Community health services for adults effective?

We have not rated this service before. We rated it as good.

#### **Evidence-based care and treatment**

The service provided care and treatment based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance.

Staff followed up-to-date policies to plan and deliver high quality care according to best practice and national guidance. Managers had policies that followed relevant evidence-based practice. The policies were reviewed annually or more often when needed. The policies covered clinical risk and clinical operating policies. Managers provided accreditation for the ECG device they were using from the National Institute for Health and Care Excellence (NICE). This included specific guidance that was linked to the device. The device has also won an NHS Artificial Intelligence award in 2020 which had provided further funding to explore research opportunities associated with the technology of the device. Managers and leaders had identified through their product service review that the ECG device had been beneficial for picking up several medical conditions including Stroke, heart palpitations, transient ischemic attacks and collapse triggers. The service review found that the device was effective in aiding a diagnosis of a medical condition in 95% of scans from a sample size of 637 monitors.

Managers distributed scans to staff using a clinical competency framework. Managers also recruited external consultants to review scans at random for further quality assurance beyond their live and retrospective programmes. Managers conducted monthly clinical meetings and clinical governance meetings with staff from the service. Executive staff conducted quality councils every three months and an annual management review of quality were completed annually. Quality goals were checked using a Red, Amber, Green (RAG) system.

#### **Patient outcomes**

Staff monitored the effectiveness of care and treatment. They used the findings to make improvements and achieved good outcomes for patients. The service had been accredited under relevant clinical accreditation schemes.

Outcomes for patients were positive, consistent and met expectations, such as national standards. Managers assessed patient outcomes through data collection schemes. A separate quality assurance team had a scheme of both live and retrospective quality assurance for staff scanning interpretation performance and there was data compiled from these processes.

Managers and staff used the results to improve patients' outcomes. Managers met with staff regularly to discuss their performance as part of their development programme with the service when they joined. This included a review of any incidents that had been recorded and other data that was associated with performance indicators for the role. Where progress was proven, staff had the opportunity to conduct more complex scans and were supported with training to complete this.



Managers used information from the audits to improve care and treatment. Managers had access to quality assurance data that was compiled and acted as a continuous audit for several clinical parameters. Managers had analysed data using both numerical and visual charts to monitor the performance of the service.

Managers shared and made sure staff understood information from the audits. Managers would discuss data with staff both during meetings and one to one sessions for performance and development conversations.

### **Competent staff**

## The service made sure staff were competent for their roles. Managers appraised staff's work performance and held supervision meetings with them to provide support and development.

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Managers had a criteria which needed to be met before an interview was offered to staff and a minimum experience level in interpreting ECG scans was required. Managers had a development scheme for staff that focused on clinical development in their staff's own knowledge over a nine-month period. This was divided by grades which were continuously assessed. Each grade divided ECG scans in terms of difficulty. Staff achieved higher grades by producing positive outcomes in interpreting scans which rewarded staff for progression and an added skill set as they progressed.

Managers gave all new staff a full induction tailored to their role before they started work. Managers provided staff with a three-week induction period which included a clinical competency process before they started with the service.

Managers also supported new staff members with mandatory training and supervision requirements during this time.

Managers supported staff to develop through regular, constructive clinical supervision of their work. Staff expressed that their performance was reviewed on a regular basis using examples from their work. Managers expressed that they supported staff through constructive conversations.

Managers made sure staff attended team meetings or had access to full notes when they could not attend. Managers showed minutes of all meetings that were conducted with the service. Staff confirmed that they had access to meeting minutes when they needed them but were encouraged to attend when possible.

Managers identified poor staff performance promptly and supported staff to improve. Managers had a framework that supported staff if their performance was below the standard expected. Managers discussed incidents if they occurred or were picked up by the quality assurance team. Staff expressed that incidents were discussed in a supportive manner and staff confirmed they felt the process was effective and enhanced their confidence.

### **Multidisciplinary working**

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

Managers used agreed frameworks with referring medical professionals when interpreting data to ensure that patient safety was maintained. Managers and staff ensured that serious findings that affected patient safety were sent to the referring medical professional as soon as possible. The service held multi-disciplinary meetings with medical professional representatives as part of their product's service review programme. Managers had conducted programmes with their account holders and NHS accounts to outline the benefits of the ECG monitor through the collection of data and evidence-based practice to support the product's development in healthcare settings.



### Seven-day services

Key services were available five days a week to support timely patient care.

Staff were available Monday to Friday to give advice to patients over a telephone helpline. Staff also responded to email enquiries from patients if it was outside of the office hours.

### **Consent, Mental Capacity Act and Deprivation of Liberty Safeguards**

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. Staff had training associated with consent and the Mental Capacity Act 1984.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff we spoke with had a good knowledge of consent and acted within their remit of care for patients. Staff gained consent from patients for their care and treatment in line with legislation and guidance. Staff we spoke with had a good knowledge of consent and acted within their remit of care for patients. Managers expressed that the person who requested the use of the device and the recording had responsibility for obtaining informed consent. As a prescription from a licenced medical professional was required for this to be undertaken the service used this as confirmation consent had been obtained and provided the service with a suitable level of oversight that consent had been obtained correctly by the clinician initiating the treatment.

Staff understood how and when to assess whether a patient had the capacity to make decisions. Staff who spoke with patients directly had a good understanding of the complexities around a patient's capacity to make decisions. Staff received training in the Mental Capacity Act 1984 which formed part of their safeguarding training.



We have not rated this service before. We rated it as good.

#### **Compassionate care**

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

Patients said staff treated them well and with kindness. Managers provided results from their most recent patient survey which covered April 2021 to April 2022. The results found that 95% of patients surveyed found their cardiac monitor easy to use, 77% found the monitor comfortable to wear, 91% felt they could do their normal activities with the monitor on, and 90% of patients said they would wear the monitor again.

Staff understood and respected the needs of patients and how they may relate to care needs. Staff gave examples of support given to patients when they contacted the service helpline. For example, patients would call when their monitor



wasn't working correctly. This would normally be due to the monitor moving slightly and losing contact with the skin surface. Staff gave several examples where they offered practical advice to assist patients in resetting or adjusting the monitor manually. This could be difficult for some patients and where it was not possible to resolve the concern, arrangements were made with their local medical professional to help them.

### **Emotional support**

Staff provided emotional support to patients, families and carers to minimise their distress. They understood patients' personal needs.

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff gave examples where patients were in distress due to the ECG monitor not working correctly. For example, there were occasions where the monitor would show an error in its recording process which provoked anxiety among patients. Staff showed emotional support in these circumstances and offered support where possible. Staff also expressed examples where patients found the monitor uncomfortable, including skin irritation due to sensitive skin. Where needed staff would refer patients to a suitable medical professional so that the symptoms could be resolved.

### Understanding and involvement of patients and those close to them

Staff supported patients, families and carers to understand their condition and make decisions about their care and treatment.

Staff made sure patients and those close to them understood their care and treatment. Managers explained that a support line was available for patient to contact if they had any questions regarding the ECG monitor. There was also information leaflets and supportive information on their web site that provided frequently asked questions and guidance regarding the correct use of the monitor which were available.

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. Managers informed us that feedback forms were supplied with all ECG monitors that were dispatched to patients. Feedback could also be given through the provider's web site. Staff gave examples where they helped both patient family members and patient's carers when they encountered a problem with the device.

# Are Community health services for adults responsive? Good

We have not rated this service before. We rated it as good.

### Service delivery to meet the needs of local people

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

Facilities and premises were appropriate for the services being delivered. The service was not patient facing. Staff and managers expressed that they felt the location was suitable for the services that were being provided remotely.



The service had systems to help care for patients in need of additional support. Staff used patient information to provide support for a patient's care and treatment in a safe way and to reduce risks. If staff felt the service could not meet the patient's needs, staff referred them to an alternative health care provider who could better support the patient.

### Meeting people's individual needs

The service was inclusive and took account of patients' individual needs and preferences. Staff made reasonable adjustments to help patients access services. They coordinated care with other services and providers.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. Staff gave examples of helping patients who had difficulties due to disability or sensory loss. For example, patients with difficulties could express this to staff on a support line. Where able to, staff would assist with the issue. If this was not possible, alternative arrangements would be made to support patients.

Staff talked with patients, families and carers in a way they could understand. Staff had access to online or telephone language translation services.

The service had information leaflets available in languages spoken by the patients and local community. All information leaflets and feedback forms supplied met the accessible information standards (AIS).

### Access and flow

#### People could access the service when they needed it and received the right care promptly.

Managers expressed that there were no waiting times for the delivery of the cardiac monitors. Managers and staff aimed to dispatch the monitor within 24 hours of an order being received to ensure that the treatment begins promptly.

### Learning from complaints and concerns

It was easy for people to give feedback and raise concerns about care received. The service treated concerns and complaints seriously, investigated them and shared lessons learned with all staff.

Staff understood the policy on complaints and knew how to handle them. Patients, relatives and carers knew how to complain or raise concerns. Staff supplied feedback forms when dispatching the monitors informing patients how to raise concerns or give feedback. Patients could also provide feedback on the web site of the provider. Managers had not received any written complaints in the last 12 months.

Managers investigated complaints and identified themes. Managers monitored and logged all occasions where patients reported a problem with their monitor and treated these episodes as complaints. Themes included poor connection to the monitor, the monitor refusing to turn on, water breaching the device, skin irritation from the adhesive and data not being recorded by the monitor. Managers recorded these episodes through an electronic system that notified staff and managers that a patient had reported a problem.



Managers shared feedback from complaints with staff and learning was used to improve the service. Managers conducted clinical meetings with staff and used complaints data from the patients to inform and develop the product and service.

Are Community health services for adults well-led?

**Outstanding** 



We have not rated this service before. We rated it as outstanding.

### Leadership

Leaders had the skills and abilities to run the service. They understood and managed the priorities and issues the service faced. They were visible and approachable in the service for patients and staff. They supported staff to develop their skills and take on more senior roles.

The service location formed part of a larger international operation. Leaders were experienced in their field of ability and there were mechanisms to ensure this in the recruitment process. Leaders and managers were data driven in proving their performance and this directed them to their priorities and issues that required action. Staff felt that leaders were visible and available if they wanted to raise anything. Managers followed a structured process that allowed staff to develop their skills and to develop at a suitable pace that was clear and transparent with clear parameters and performance that staff needed to achieve that followed a data driven model of performance.

#### **Vision and Strategy**

The service had a vision for what it wanted to achieve and a strategy to turn it into action, developed with all relevant stakeholders. The vision and strategy were focused on sustainability of services. Leaders and staff understood and knew how to apply them and monitor progress.

Leaders of the service had a clear vision for the business and spoke about how they wanted to extend beyond the UK when the opportunity was considered suitable. Leaders showed an understanding of how the business would grow and their values were associated with patient centred care, research and the development of their staff. Managers checked business performance using a data driven approach with clear performance goals they wanted to achieve.

Managers felt that their expansions plans were dependent on the safety requirements of regulations in the new regions they would want to develop the profile of the ECG monitor. They acknowledged that the time periods and adaptions that would be required for this remained unclear despite initial research being conducted.

### Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work, and provided opportunities for career development. The service had an open culture where staff could raise concerns without fear.



Staff spoke positively about managers and other staff members working for the service. Staff expressed that managers were receptive and willing to receive feedback. Staff felt motivated in their role and spoke highly of the development structure the service used for their business. Staff expressed that their role enhanced their professional development and that the frequent feedback and structured one to one approach with managers was very helpful. Staff also praised added employee support that was provided to them which included wellbeing and occupational health support.

Managers had provided financial support during the pandemic period for staff as they recognised the difficulties that staff were facing. Staff also tried to meet often online to provide support for each other during the pandemic period, this included structured activities such as yoga classes. Staff had also created a culture group which was available remotely and staff were hoping for this to move to a face to face setting soon including plans for a summer social gathering.

#### Governance

Leaders operated effective governance processes, throughout the service and with partner organisations. Staff at all levels were clear about their roles and accountabilities and had regular opportunities to meet, discuss and learn from the performance of the service.

Leaders had established governance processes which were extended from their international operations. Managers held meetings on a Monday, Wednesday and Friday. Monday meetings were focused on performance, Wednesday meetings were focused on a clinical theme which normally would incorporate training and Friday meetings were an opportunity to follow up any other business as the week closed. Staff and managers held clinical meetings on a Tuesday, and this was fed into the clinical governance board which was conducted monthly.

Managers prioritised clinical governance with staff and there was a structured development programme for new starters that only allowed staff to complete more complex ECG analysis once they had achieved competence in easier clinical processes in ECG analysis. The analysis categories were divided up into six levels and at the completion of the final level, staff were eligible for a bonus or promotion. Managers outlined that the initial development process for staff would take just under one year if they followed the suggested timeframes for development using coaching sessions and providing a clinical service desk if staff encountered difficulties in identifying a specific arrhythmia. The clinical service desk team recorded and reviewed all interactions with staff for future learning with other staff members.

### Management of risk, issues and performance

Leaders and teams used systems to manage performance effectively. They identified and escalated relevant risks and issues and identified actions to reduce their impact. They had plans to cope with unexpected events.

Executive staff conducted quality councils every three months and an annual management review of quality was completed annually. Quality aims were monitored using a Red, Amber, Green (RAG) system. A master hazard analysis document acted as the service's risk register which analysed and captured hazardous situations and associated harms known with the ECG monitor. Risks found were also tiered using a RAG system which was calculated using a scale that looked at severity and probability.

Risk assessments were comprehensive and covered all areas of the business and the premises. This included environmental, business, and IPC. Staff were engaged with risk and felt that it contributed to the performance of the service. Managers informed staff during meetings of prominent risks they should be aware of.



### **Information Management**

The service collected reliable data and analysed it. Staff could find the data they needed, in easily accessible formats, to understand performance, make decisions and improvements. The information systems were integrated and secure.

Managers collected data for several areas of the service and evidence was given of comprehensive analysis which was used to drive performance and aid staff with their development.

Staff using computers in the office were password protected and staff switched off computers when not in use to ensure security of data. Customer data was held securely, and staff were aware of the requirements associated with general data protection regulation (GDPR) and patient confidentiality. Staff had facilities in the office for confidential waste.

### **Engagement**

### Leaders and staff actively and openly engaged with patients and staff to plan and manage services.

There was information available to patients to encourage them to communicate with the service. There were feedback forms sent with all monitors delivered by post. The service had a website which gave information on service, provided contact information and answers to frequently asked questions.

Leaders engaged often with staff using a series of meetings that covered performance, clinical and coaching areas. Staff expressed that they felt listened too and part of the service that was being provided. Staff praised leaders for their approach and their openness to feedback.

### Learning, continuous improvement and innovation

All staff were committed to continually learning and improving services. They had a good understanding of quality improvement methods and the skills to use them. Leaders encouraged innovation and participation in research.

Managers and staff were continuously learning and improving the service associated with their ECG monitor. The product had been awarded the NHS Artificial Intelligence Award for 2020 which had resulted in enhanced funding for the further development of the product. NICE had also accredited the device and there was specific guidance recommending it on their web site.

The product was currently under the research of three academic establishments in the UK and being researched by over 30 research studies in the USA. The research is looking at arrhythmias and how the device can enhance the diagnostic success rate of patients and oncology patients.

The product has been published in 31 international research studies and is referenced in the "Getting It Right First Time" NHS Improvement Stroke Speciality report (April 2022).

The product has also been referenced in other publications for offering a reduction in waiting times for patient treatment and faster diagnosis times for cardiac arrhythmias.

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.