Innovate Health Group Limited

# Innovate Diagnostics

**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 | Requires Improvement |
| Are services safe? | Requires Improvement |
| Are services effective? | Requires Improvement |
| Are services caring? | Good |
| Are services responsive to people's needs? | Good |
| Are services well-led? | Inadequate |

# Summary of findings

## Overall summary

We rated the service as requires improvement because:

- There was a lack of evidence of compliance with mandatory training, safeguarding training to the appropriate level for the service, infection prevention and control processes, and premises and equipment maintenance.
- There were no clear consistent protocols for managing deteriorating patients, insufficient evidence around life support training, and limited reporting or learning from incidents.
- The service followed evidence-based procedures, but not all policies were up to date and some clinical practices were not covered by the policies in use. Audits were not undertaken to show patients had good outcomes. There was no clear evidence to show staff were trained and competent.
- The service's processes for ensuring fit and proper person's were employed were not effective and not all clinical staff working within the service had evidence of records such as DBS checks and references.
- Managers had not implemented effective processes to ensure the service was delivered using reliable information, assurance and governance systems. Risk management processes were not used to identify or manage risk. There was no clear process used for updating and managing policies and some policies were not always followed in practice. There were minimal governance processes but records relating to these, including minutes of meetings, were not kept. There was little evidence of learning, continuous improvement and innovation.

However:

- The service had enough staff to care for patients and keep them safe.
- Patients would be protected from abuse or improper treatment as staff knew how to act in the event of suspected safeguarding concerns.
- 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 and made it easy for people to give feedback. People could access the service when they needed it and did not have to wait too long for their procedure.
- The service responded to the needs of patients and provided a service when it was required with few delays or cancellations.
- There was a vision and value for the service and the leadership were visible and approachable.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

# Summary of findings

## Our judgements about each of the main services

| Service | Rating | Summary of each main service |
|---|---|---|
| **Diagnostic and screening services** | Requires Improvement  | See overall summary at the beginning of this report. |

# Summary of findings

## Contents

# Summary of this inspection

## Background to Innovate Diagnostics

Innovate Diagnostics is an independent clinic providing cardio-respiratory diagnostic testing. Diagnostic packages include Transthoracic Echocardiogram, ambulatory and resting electrocardiogram (ECG) and ambulatory blood pressure monitoring. They accept patients from the NHS, the private sector, and self-referrals. Cardiac diagnostic services are performed and reported by cardiorespiratory physiologists and associate practitioners.

The service has been registered with CQC to carry out the regulated activity of Diagnostic and Screening procedures since 6 April 2022.

## How we carried out this inspection

We carried out an inspection of Innovate Diagnostics on 27 October 2023 using our comprehensive methodology. The service had not previously been inspected.

Our inspection was unannounced. During the inspection we interviewed the registered manager, a cardiac physiologist, the clinical lead and an administrator. We reviewed three patient records, spoke with three patients and observed diagnostic procedures and reviewed governance records.

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.

## 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 MUST take to improve**:

- The service must ensure it is assessing the risks to the health and safety of patients and mitigating those risks by having clear processes for acting in the event of a deteriorating patient or referring a patient in the event of abnormalities identified during procedures. Regulation 12 (2)(a)(b): Safe care and treatment.
- The service must ensure the premises and equipment used are safe and used in a safe way by ensuring there are regular recorded safety checks used to identify and manage risks, calibration and equipment safety. The service must ensure there is a process for acting on all safety alerts relating to equipment and clinical services (COSHH) Regulation 12(2)(d)(e): Safe care and treatment.
- The service must ensure the risk, prevention, detection and control of the spread of infections is assessed and safely managed. Regulation 12(2)(h): Safe care and treatment.
- The service must assess, monitor and improve the quality and safety of the service provided by ensuring there is effective and meaningful governance. The service must ensure there are governance processes operating to assure the service about quality and compliance with quality assurance. The service must ensure there is learning from any feedback, investigations, complaints or incidents. The service must maintain records of governance to demonstrate the service is assured it is providing a safe and quality service. Regulation 17(2)(a): Good governance.

# Summary of this inspection

- The service must assess, monitor and mitigate the risk to the service and improve the quality and safety of the services provided by assuring there is comprehensive risk assessment and management and improvements made when required. Regulation 17(2)(b): Good governance.
- The service must ensure it can provide evidence that staff are suitably qualified, fully trained and with all professional accreditation required to provide the regulated activity. This must include safeguarding training to the required level for the service. Regulation 18(2)(a): Staffing.
- The service must ensure all staff meet the fit and proper persons regulations and employment regulations including checks from the Disclosure and Barring Service. Regulation 19: Fit and proper persons employed.

**Action the service SHOULD take to improve:**

- To enable patients to make informed complaints about any aspect of the service, the service should make sure information on how to make a complaint is available.

# Our findings

## Overview of ratings

Our ratings for this location are:

| | Safe | Effective | Caring | Responsive | Well-led | Overall |
|---|---|---|---|---|---|---|
| **Diagnostic and screening services** | Requires Improvement | Requires Improvement | Good | Good | Inadequate | Requires Improvement |
| **Overall** | Requires Improvement | Requires Improvement | Good | Good | Inadequate | Requires Improvement |

Requires Improvement

# Diagnostic and screening services

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

## Is the service safe?

Requires Improvement

We rated safe as requires improvement.

### Mandatory training

**The service monitored staff training in key skills. However, managers were not able to provide evidence that all staff completed their mandatory training.**

There was limited evidence that staff received and kept up to date with their mandatory training. On the day of inspection, we saw evidence that the registered manager and an administrative staff member had their training completion recorded on a training log. This was mostly complete, except for practical training in basic life support. However, there was no record of physiologist training kept on the log and the manager told us they did not have evidence of up-to-date training . They reported they understood the physiologists completed the relevant training in their NHS roles, but had no evidence to demonstrate that. Following the inspection, we were provided with a log that included physiologist training. However, some gaps remained. For example, one physiologist had no record of basic or immediate life support training, no record of safeguarding training and no record of equality, diversity and human rights training.

Clinical staff did not consistently complete training on recognising and responding to patients with issues such as mental health needs or disabilities. All clinical staff had completed dementia training but there was no record of training around mental health awareness.

### Safeguarding

**Staff understood how to protect patients from abuse and had training on how to recognise and report abuse. However, staff in leadership roles did not have training at the recommended level and there were some gaps in training records.**

Some key staff did not always receive training specific for their role on how to recognise and report abuse. For example, the safeguarding lead for the service had a record of completing safeguarding vulnerable adults at level two rather than

level three. This was not in line with intercollegiate guidance: Adult Safeguarding: Roles and competencies for healthcare staff (August 2018). This states staff in leadership roles or potentially involved in the assessment of safeguarding needs should be trained at level three. In addition, one member of the clinical team had no record of safeguarding training.

Staff knew how to make a safeguarding referral and who to inform if they had concerns. There was clear guidance, including contact numbers of local safeguarding leads in the service's safeguarding policy.

Clinical staff worked on a self-employed basis within the service. Processes for checking they were fit for the role were inconsistent. For example, two clinical staff did not have a record of a Disclosure and Barring Service (DBS) check. The manager advised the check had been completed but the service had not retained the certification register number as evidence. In addition, while professional accreditation checks with the British Society of Echocardiographers were completed when physiologists started working at the service, these were not routinely monitored to ensure accreditation was maintained. Information about performance in previous roles was not sought prior to clinical staff starting work at the service.

Patients could request a chaperone during their investigation.

### Cleanliness, infection control and hygiene

**Staff did not consistently use equipment and control measures to protect patients, themselves and others from infection. However, equipment and the premises were visibly clean.**

Clinical areas were visibly clean and well-maintained. However, there were carpets and fabric chairs in use within clinical areas, which did not meet infection prevention and control guidance due to reduced cleaning effectiveness, and there was no risk assessment to recognise these risks and explain mitigating actions.

The service generally performed well for cleanliness in audits. A cleaning audit was completed daily by administrative staff to check the patient environment. Clinical staff were responsible for cleaning medical equipment and a cleaning contractor provided general environmental cleaning.

Staff were not following the service's policy around handwashing. The service policy required hand washing to be used instead of the use of hand gel. We observed clinical staff changing gloves in between patients and the use of hand gel. However, handwashing was not an observed practice.

Staff followed infection control principles including the use of personal protective equipment. Equipment was cleaned after patient contact.

### Environment and equipment

**The design, maintenance and use of facilities, premises and equipment did not give assurance that people were kept safe. Processes for managing clinical waste were unclear.**

There were limited processes for identifying and managing health and safety risks within the service. The service quality policy stated that a risk register was in use, but this was not the case. We observed specific risks that had not been identified or managed. This included a large mirror that was not fixed to the wall safely and posed a risk of falling. Although not in a patient area, an electrical socket was coming away from the wall in one of the rooms used by staff. There was no health and safety poster with information on health and safety responsibilities displayed within the service, as required by the Health and Safety Information for Employees Regulations, 1989.

Requires Improvement

# Diagnostic and screening services

Managers were unable to demonstrate they had suitably maintained equipment to ensure patients were safe. There was no evidence of maintenance or calibration documents for the 12 lead ECG machine or the weight machine. Quality control testing and daily checks of the ultrasound equipment were not routinely carried out in line with British Medical Ultrasound Society guidance. Not all equipment used within the service was within date and some had expired for use. There were ultrasound gels and clinical alcohol swabs that had expired.

There was no control of substances hazardous to health (COSHH) risk assessments or product safety sheets maintained. We found hazardous substances such as bleach stored in an unlocked cupboard in a clinical area.

The processes for the disposal of clinical waste were not clear and processes for dating and filling were not followed. We found a sharps bin filled with disposable razors for clinical use. The sharps bin was undated, unsigned and full. The processes for the safe removal and replacement of clinical waste equipment were not clear. However, following the inspection the manager told us they had arranged for the collection and replacement of sharps bins as required.

## Assessing and responding to patient risk

**Staff identified and quickly acted upon patients at risk of deterioration However, there was no clear referral protocol to ensure staff acted consistently. There was insufficient evidence to show clinical staff had received up to date basic or immediate life support training.**

Staff responded promptly to any sudden deterioration in a patient's health. However, there were unclear referral protocols in the event a patient became unwell and a risk of procedures not being followed. We reviewed the records of a patient who had an abnormal scan and saw in that case the physiologist had escalated concerns to the referring consultant immediately so the patient could access appropriate emergency treatment and care. However, the service did not have a clear referral protocol in the event of abnormalities, including when patients self-referred to the service. Following the inspection, the manager shared new procedures that had been developed. This included a procedure for urgent clinical findings identified on a transthoracic echocardiogram. The procedure included a clear pathway where physiologists were signposted to the referring clinician or emergency services depending on the nature of the concern.

There was no current record to show if staff caring for patients had basic or immediate life support training. If a patient was to deteriorate in circumstances not within the staff members training expertise, staff told us that in an emergency they would ring for an ambulance.

Staff completed an assessment for each patient on arrival, this involved asking about their clinical symptoms and medical history. Staff shared key information when handing over patients' care to others. For example, clinical staff provided reports on diagnostic testing and images to referring consultants. In the event of a patient self-referring, the patient would be referred back to their GP and a written report provided.

## Staffing

**The service had enough to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels to meet patient needs.**

The service had enough clinical staff to keep patients safe. The manager could usually arrange for additional staff if needed to meet the needs of patients. This was an appointment-only service provided on specific days of the week. Therefore, physiologists were allocated to shifts depending on patient need. All physiologists were self-employed, within the service on specific pre-booked days. Managers made sure all staff had a full induction and understood the service.

Requires Improvement

# Diagnostic and screening services

## 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 all staff could access them easily. We reviewed three patient records and saw booking forms were completed by the referrer. Diagnostic investigation reports were completed by the physiologists. Reports and diagnostic images were stored on a cloud-based system that could be accessed remotely by the referring clinician. Reports were therefore available to referring and treating clinicians without delay.

Records were stored securely. All were password protected with relevant safeguards to ensure secure sharing with clinicians involved in the patient's treatment and care.

## Medicines

**The service did not use or prescribe medicines.**

## Incidents

**Although there was no evidence to suggest they occurred often, the service did not show it recorded patient safety incidents to demonstrate they were investigated and learned from. It was not clear that staff recognised all incidents and near misses and reported them. Processes or evidence of investigating incidents and sharing lessons learned with the whole team and the wider service were limited. Managers did not ensure that actions from patient safety alerts were implemented and monitored.**

Processes for reporting all incidents and near misses were not clearly set out within the service. We were told there was an accident book for recording health and safety incidents. The accident book was not located at the time of the inspection, although we were told there had been no accidents recorded.

The service had a policy for reporting and recording serious incidents where notifications were required to be made to external organisations. There had been no incidents of this type.

Senior staff told us about incidents where things had gone wrong. This included an incident where a patient receiving an at home diagnostic test called a 24-hour phone line but had not been able to get through. We saw that this situation was recorded as part of a patient feedback review and senior staff told us they had followed this up. However, it was not recorded as an incident or shared with staff. In addition, records of any investigations were not maintained to demonstrate that the root cause of the incident had been identified and any subsequent action to make improvements had been taken.

Managers did not ensure actions from patient safety alerts were implemented and monitored. For example, managers and staff were not aware of a 2021 National Patient Safety Alert about the risk of infection with the use of reusable gel containers. The Alert recommended that only pre-filled disposable containers of ultrasound gel be used and that providers cease using large containers intended for decanting. However, it was common practice within the service to decant ultrasound gel into smaller containers.

Requires Improvement

# Diagnostic and screening services

## Is the service effective?

Requires Improvement

We rated effective as requires improvement.

### Evidence-based care and treatment

**The service provided procedures based on national guidance and evidence-based practice. Managers checked to make sure staff followed guidance. However, not all policies were up to date and some clinical practices not covered by the policies in use.**

The service had policies to plan and deliver high quality care according to best practice and national guidance. There was a suite of standard operating procedures that covered each investigation carried out within the service. Managers responsible for updating procedures took account of national guidance from organisations such as the British Society of Echocardiography and The National Institute for Health and Care Excellence (NICE). However, at the time of the inspection not all policies were up to date and some aspects of clinical processes and procedures were not covered by the policies in use. For example, escalation processes in the event of abnormalities or patient deterioration. Following the inspection, the manager sent us updated standard operating procedures that included onward referral processes in the event of urgent findings.

The clinical lead reviewed all diagnostic imaging reports to ensure staff followed the guidance within the standard operating procedures, and we were told a selection were reviewed as part of the medical advisory committee quarterly governance meetings.

### Patient outcomes

**Staff monitored the effectiveness of care and treatment. However, they were not able to fully demonstrate how they used audit and results to make improvements and achieve good outcomes for patients.**

There were processes to review the findings from investigations and check the quality of processes relating to images, measurements and reporting of findings. The clinical lead within the service reviewed all images and reports to identify quality issues. A selection of images and reports were also reviewed at governance meetings. However, the service did not produce quality assurance or improvement reports. Minutes of governance meetings were not maintained to demonstrate how effective this process was.

The service quality policy linked to a clinical audit of echocardiography requiring an audit of 10% of investigations. However, the manager was unable to provide evidence of an audit report or data that showed this 10% review of quality had been completed.

Staff recalled an audit taking place in 2022 but had not received feedback about this. Therefore, it was not possible for managers to demonstrate how audit information and results were used to improve care and treatment.

### Competent staff

**The clinical staff were self-employed and had the skills and knowledge to deliver the service effectively. However, processes for providing clear evidence of this and ongoing monitoring of staff skills and competence were not effective. There was no evidence of induction of new staff.**

Requires Improvement

# Diagnostic and screening services

The clinical staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Physiologists worked within NHS roles in addition to their self-employed role with the service. All were accredited with the British Society of Echocardiography (BSE). BSE accreditation required the submission of evidence of continuing professional development with a series of points allocated to different events and courses. However, records relating to continuous professional development were not held by the service. It was therefore not possible to assess how the service monitored ongoing professional development. The service training policy stated staff were encouraged to attend external training or conference attendance. However, there was no evidence of this.

Staff told us managers gave all new staff a full induction tailored to their role when they started working at the service. This included elements of health and safety as well as specific processes relating to their role. However, records relating to induction were not available.

Not all staff had received an appraisal in the last year. We saw an appraisal for 1 member of staff, but this did not include the self-employed clinical staff and there was no assurance process that these clinical staff had received an appraisal of their work elsewhere. Processes for reviewing performance were unclear in the absence of quality assurance data, supervision records or competency assessments. Clinical staff provided evidence of training and professional accreditation at the start of their agreement with the service, however, processes for ensuring ongoing competency were unclear.

## Multidisciplinary working

**Healthcare professionals worked together as a team to benefit patients. They supported each other to provide good care.**

Cardiac physiologists worked closely with the referring consultant in a way that reflected patients' individual needs and circumstances. Consultants had access to the cloud-based system to be able to review patients' reports and findings from investigations. Staff communicated directly with referring doctors to ensure patients received appropriate follow up and ongoing care.

## 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 understood how and when to assess whether a patient had the mental capacity to make decisions about their care. All cardiac physiologists had completed training in the Mental Capacity Act.

Staff gained consent from patients for their care and treatment in line with legislation and guidance or discussed ongoing care being provided with the referring doctor if the patient could not give informed consent. Patients were asked to complete an online consent form prior to their investigation. Cardiac Physiologists discussed the procedure with the patient to ensure they understood what they were consenting to.

Staff made sure patients consented to treatment based on all the information available.

[AG1]Note we can now rate

[JH2]Thank you

Requires Improvement

# Diagnostic and screening services

## Is the service caring?

Good

We rated caring as good.

### Compassionate care

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

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way. They ensured patients were comfortable during procedures and that their privacy and dignity were respected.

Patients said staff treated them well and with kindness. Those we spoke with told us staff were respectful and friendly. Written feedback was positive about the approach of staff.

Staff followed policy to keep patient care and treatment confidential. They were discrete and confidential conversations in clinical areas were not overheard.

Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs.

### Emotional support

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

Staff gave patients help, emotional support and advice when they needed it. Physiologists were experienced at supporting patients receiving investigations and understood the emotional impact of the experience. They provided information in ways that were clear and easy to understand.

Staff understood the emotional and social impact that a patient's care, treatment or condition had on their wellbeing and on those close to them.

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

**Staff supported patients, families and carers to understand their condition and make decisions about the process.**

Staff made sure patients and those close to them understood the process. They gave them information about when their results would be ready and which clinician they would be sent to. They answered questions about procedures and provided an explanation about what they were doing as they went along.

Staff talked with patients, families and carers in a way they could understand. Staff told us they could access support from interpreters or signers when they needed to and that any need for this would be identified at the point of booking. However, additional communication aids had not been needed to date.

Requires Improvement

# Diagnostic and screening services

Patients and their families could give feedback on the service and their treatment and staff supported them to do this. All patients were asked to complete a feedback form, and these were reviewed by managers. Most feedback forms were entirely positive, with some identifying areas where small improvements could be made.

## Is the service responsive?

Good

We rated responsive 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.**

Managers planned and provided services so they met the needs of the local population and other services referring patients for investigations. They offered scanning appointments from the location every Wednesday and Friday, on a pre-booked basis. Evening appointments were available for patients unable to access the service during the day due to work and other commitments.

Facilities and premises were appropriate for the services being delivered. There were two treatment rooms within the service, both with adjustable examination couches. The entrance to the service was at ground floor level and could accommodate a wheelchair if necessary.

The service had systems to help care for patients in need of additional support or specialist intervention. The manager told us they had not had requests for scans from patients with additional needs such as physical disabilities or learning disabilities. However, they told us they would allow extra time where necessary should the need arise. They asked that referrers inform them of additional needs at the point of referral so staff could contact the patient to ensure they could accommodate them. This was assessed on an individual basis.

### 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 contacted patients at the point of referral to identify if they had any needs or preferences that should be taken account of.

Staff understood and applied the policy on meeting the information and communication needs of patients with a disability or sensory loss. They told us they could access interpreters or signers as needed to support patients during an appointment.

Information leaflets were provided in English as this was determined by the service as the language required by most patients. However, we were told information could be translated or put into an accessible format should this be necessary.

Requires Improvement

# Diagnostic and screening services

## Access and flow

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

Managers monitored waiting times and made sure patients could access services when needed and received appointments within agreed timeframes. A key performance indicator was that all patients referred would receive an appointment within four weeks. Staff told us this was consistently achieved. However, there was no audit process to demonstrate this happened.

Referring consultants were aware of the appointment times available and were able to guide patients on when they were likely to be seen.

There was a key performance indicator for reporting, with a target of 72 hours from the test for the report to be available. At the time of inspection staff told us this had been achieved 100% of the time. However, they were unable to evidence this as quality assurance reports were not available. We were told no patients had to be re-referred for repeat testing due to quality issues. However, at the time of inspection managers were unable to provide evidence of monitoring this. Following inspection, the registered manager provided evidence of assurance monitoring logs that demonstrated all key performance indicators had been met.

## Learning from complaints and concerns

**It was easy for people to give feedback about care received and all patients were asked for feedback. The service had processes for dealing with complaints. However, it did not provide visible information for patients on how to complain. There had been no formal complaints to the service.**

There was a patient feedback process, and all patients were encouraged to complete a feedback questionnaire. We reviewed feedback responses and saw that most of these were positive about the service. Managers told us they acted on feedback. For example, they had changed the way they informed patients of directions to the service after feedback from a patient stating they had difficulty finding it.

Information on how to complain was not visible within the service so that patients, relatives and carers knew how to complain or raise concerns. There had been no formal complaints raised within the service.

[GA1]I've have changed this to a good rating as there's nothing of note to make it RI

[JH2]Ok, I'm happy with that.

# Is the service well-led?

Inadequate

We rated well led as inadequate.

## Leadership

**Leaders were visible and approachable in the service for patients and staff. However, although they had the skills and experience to run the service, they did not demonstrate how they had the assurance that the service was safe and delivering quality care and treatment.**

Requires Improvement

# Diagnostic and screening services

Staff we spoke with told us that service managers and leads were visible, approachable and supportive. The registered manager was a physiotherapist who ran their own physiotherapy clinic from another location. In addition, there was a retired cardiac surgeon as the non-executive clinical lead who provided advice and guidance on clinical practice as part of the Medical Advisory Committee. In addition, there was a lead associate cardio-respiratory physiologist who operated as the clinical manager. They provided day to day management and clinical leadership and oversaw interpretation and reporting of findings from diagnostic testing.

The leaders were skilled and experienced, but they did not demonstrate they were assured the service was safe and well managed.

## Vision and Strategy

**The service had a vision for what it wanted to achieve and a strategy to turn it into action. The vision and strategy were focused on sustainability of services and aligned to local plans within the wider health economy. Leaders and staff understood and knew how to apply them and monitor progress.**

The aim of the service was to provide easy to access private cardiac diagnostic services for a range of heart and lung conditions. The service had core values to innovate, provide excellence and ensure dignity and efficiency. Service leads had identified key objectives that included the provision of a weekly five-day diagnostic service in Northamptonshire and to offer a 'fast track' service where patients could access non-invasive cardiac diagnostic procedures within 72 hours of referral.

The service leads understood the wider health economy the service operated within and worked to align their provision with the needs of patients and referrers. They worked closely with referring clinicians to ensure the service was providing diagnostics and reporting that was relevant to the needs of patients and clinicians.

## Culture

**Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service had an open culture where patients, their families and staff could raise concerns without fear.**

Staff told us they were supported by managers and felt able to raise concerns should they need to. We observed staff focusing on the needs of patients, providing information and support as needed.

There were processes for patients to raise concerns, for example, they were encouraged to complete a feedback survey following each investigation. Patients we spoke with told us they felt able to raise concerns.

However, the service training policy referenced opportunities for staff to attend external training and conferences as part of their continuous professional development (CPD) but there were no records to demonstrate that this had happened.

## Governance

**Leaders did not operate effective governance processes. There were significant gaps in governance areas such as policy review and assurance processes.**

Governance systems were not operating to give assurance of a safe and well-run service. For example, policies were overdue a review and there was no system to manage them. Policies were not always followed or audited to check for compliance with policy. For example, the quality policy stated there was a risk register for the service, However, there

was no risk register or evidence of comprehensive risk assessments carried out. Although there was no evidence that patients were not safe or the processes were not effective, there was a lack of a referral protocol telling staff what action they should take in relation to onward referral in the event of the identification of an abnormality. As a result, clinical staff were not clear about the action they would take in this event.

Managers did not demonstrate the full oversight of clinical risk and decision making. Managers were unable to show they reviewed governance and quality assurance through meetings or discussion as minutes were not recorded. We were told governance committee meetings were held regularly, involving the registered manager, the senior cardiac physiologist and a retired cardiologist providing guidance and advice on clinical practice.

Managers told us the committee reviewed a selection of test results and reports to gain assurance of quality. However, evidence of this was not provided due to a lack of meeting records and at the time of inspection, quality assurance reports were not available.

Following the inspection, the registered manager provided us with performance logs that demonstrated achievements against key performance indicators (KPIs). The KPIs included consultant satisfaction, which was at 100%, the re-test rate, which was at zero, and reporting within 72 hours of the test which was at 100%.

The service quality policy referenced a clinical audit of echocardiography that involved an audit of 10% of investigations being carried out. However, the manager was unable to provide evidence of an audit report or data that showed this 10% review of quality had been completed. Staff recalled an audit taking place in 2022 but had not received feedback about this. There were informal arrangements for providing staff with feedback but managers were unable to demonstrate discussions about performance, learning or improvement.

Managers did not have systems to monitor the continuing professional development or ongoing accreditation of cardiac physiologists. Processes to ensure all staff were up to date with training were not being managed and there were gaps in mandatory training records. There were gaps in recruitment checks and ongoing assurances that clinical staff remained suitable and competent for their role.

Other governance issues included a lack of process for receiving and acting on safety alerts and management and control of substances hazardous to health (COSHH). There was a lack of quality assurance for testing of clinical equipment and not all items of clinical equipment were subject to maintenance contracts. In addition, there was no system for management assurance that all clinical staff had current medical indemnity insurance.

However, following the inspection the manager provided evidence to show that staff without indemnity insurance at the time of inspection now had cover.

### Management of risk, issues and performance

**The systems to manage risk, issues and performance were not operating effectively. There were limited processes to identify and manage risks and issues. Not all risks had identified actions to reduce their impact.**

There were not processes or systems to identify and manage risks. There was no risk register and risks associated with health and safety and infection control had not been identified and mitigating actions had not been taken.

### Information Management

**Staff could find the data they needed. The information systems were secure and integrated.**

Requires Improvement

# Diagnostic and screening services

The service used electronic computer systems for storing and transferring information about patients. We saw these were password protected. Staff had access to service documents through computer terminals. Patient information was stored in three different software applications, for referral, booking and reporting. The reporting system was cloud based and could be accessed by referring clinicians to be able to review the reports. There were appropriate safeguards to ensure only referring clinicians could access the record and there were appropriate consent processes in place for information sharing.

## Engagement

**Leaders and staff engaged with patients. They collaborated with referring clinicians to ensure services met the needs of referrers and patients. However, staff were not given feedback about the performance of the service as this was not being effectively produced or shared.**

The service manager mostly engaged with staff in email communications. The service actively sought views of patients using feedback questionnaires. However, it was not clear how concerns, although infrequent, were used to make improvements. Feedback processes to staff were informal and regular staff meetings were not held due to the practicalities of clinical staff working on a self-employed basis with limited crossover of days worked.

Staff we spoke with told us they did not always received feedback. For example, in relation to quality assurance and improvement processes.

## Learning, continuous improvement and innovation

**There was limited evidence of learning and improvement methodologies in use within the service.**

There was limited evidence of the use of learning to improve services and therefore of continuous improvement or innovation. Feedback processes were largely informal, and meetings were not recorded. Improvement processes such as clinical audit were referenced in the service's quality policy. However, managers did not provide evidence that quality improvement audits had been completed.

This section is primarily information for the provider

# Requirement notices

## Action we have told the provider to take

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

| Regulated activity | Regulation |
|---|---|
| Diagnostic and screening procedures | Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed<br>• The service did not evidence that all staff meet the fit and proper persons regulations and employment regulations including checks from the Disclosure and Barring Service. |

| Regulated activity | Regulation |
|---|---|
| Diagnostic and screening procedures | Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment<br>• The service did not have a clear procedure for assessing the risks to the health and safety of patients and mitigating those risks by having clear processes for acting in the event of a deteriorating patient or referring a patient in the event of abnormalities identified during procedures.<br>• The service did not ensure the premises and equipment used were safe and used in a safe way by ensuring there were regular recorded safety checks used to identify and manage risks, calibration and equipment safety. The service did not ensure there was a process for acting on all safety alerts relating to equipment and clinical services.<br>• The service did not ensure the risk, prevention, detection and control of the spread of infections was assessed and safely managed. |

| Regulated activity | Regulation |
|---|---|
| Diagnostic and screening procedures | Regulation 18 HSCA (RA) Regulations 2014 Staffing |

This section is primarily information for the provider

# Requirement notices

- The service could not evidence that staff were suitably qualified, fully trained and with all professional accreditation required to provide the regulated activity.

This section is primarily information for the provider

# Enforcement actions

## Action we have told the provider to take

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

| Regulated activity | Regulation |
| --- | --- |
| Diagnostic and screening procedures | Regulation 17 HSCA (RA) Regulations 2014 Good governance<br>• The service did not have effective processes to assess, monitor and improve the quality and safety of the service. Governance processes were not operating to assure the service about quality and compliance with quality assurance. Processes for learning from any feedback, investigations, complaints or incidents were unclear. Governance records were not maintained demonstrate the service was assured it was providing a safe and quality service.<br>• The service did not assess, monitor and mitigate the risk to the service and improve the quality and safety of the services provided by assuring there was comprehensive risk assessment and management and improvements made when required. |