Mediscan Diagnostic Services Ltd

Mediscan Diagnostic Services Limited

Inspection report

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

Ratings

Overall rating for this location	Inadequate
Are services safe?	Inadequate
Are services effective?	Inspected but not rated
Are services responsive to people's needs?	Insufficient evidence to rate
Are services well-led?	Inadequate

Summary of findings

Overall summary

Our rating of this location stayed the same. We rated it as inadequate because:

- Staff did not always understand how to protect patients from abuse. There was not a robust system and process in place for the appropriate and timely referral of safeguarding concerns.
- The service did not always control infection risk well and some policies were still not fully reflective of the service and it was unclear what monitoring processes had been implemented.
- The design, maintenance and use of equipment did not always keep people safe.
- There was limited assurance that there were robust systems and processes in place for the appropriate and timely referral, triage and escalation of patient care. There was limited evidence that the risk to patients and staff during care and treatment had been considered and mitigating actions identified.
- Records were not always stored securely and easily available to all staff providing care.
- The service did not always manage patient safety incidents well. Staff did not always recognise and report incidents and near misses. Managers did not always investigate incidents or shared lessons learned with the whole team and the wider service.
- There remained concerns about the competency and recruitment checks for agency staff.
- We had concerns raised with us from patients that it was not easy to contact the provider and raise complaints.
- Whilst steps had been taken to strengthen the leadership structure, leaders did not all have the skills and abilities to run the service. The service was receiving support from external agencies to fulfil leadership roles and there was not a robust process in place to ensure sustained long-term effective leadership capacity and capability to assess, monitor and improve the quality and safety of services provided.
- Leaders did not operate effective and governance processes, throughout the service and so staff at all levels could not be clear about their roles and accountabilities.
- Whilst some improvements had been made to systems and processes in relation to the management of risks, issues and performance. There was not a robust system and process in place to assess and monitor the improvements that had been implemented and risk management processes were not robust.

However:

- The service provided care and treatment based on national guidance and evidence-based practice. Improvements had been made to quality assurance processes and the service had implemented an audit schedule.
- The service made sure staff were competent for their roles. Improvements had been made to the appraisal process for staff and there were plans to hold supervision meetings with them to provide support and development.
- Consent documentation for intimate ultrasound examinations had been updated to meet with national guidance and the policy had been updated to reflect this.
- There was a process for people to give feedback and raise concerns about care received. The service investigated complaints and included patients. Improvements had been made to the process to evidence lessons learnt and share them with all staff.
- The service recognised that work to improve the culture in the organisation was required but had not progressed this since the last inspection. Leaders we spoke with felt valued and supported in their roles.
- Some improvements had been made to policies and monitoring processes.

Following our inspection, we took enforcement action under section 29 in which we issued two warning notices, due to risks identified with safe care and treatment and good governance.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Inadequate 	See the main summary for the overall

Summary of findings

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Summary of this inspection

Background to Mediscan Diagnostic Services Limited

Mediscan Diagnostic Services Limited is operated by Mediscan Diagnostics Services Ltd. The location has been registered to deliver diagnostic and screening procedure services since June 2013.

The location, which is also the provider's head office, the call and administrative and managerial centre from which the provider's national diagnostic imaging services are managed. The provider delivered a range of services including ultrasound scanning, audiology and physiotherapy.

The location does not host any clinics on site, the clinics are provided in GP surgeries, private clinic buildings, hospitals and a mobile endoscopy unit. The provider told us during this inspection that the activity they would focus on when re-opening would be ultrasound scanning, physiotherapy and audiology initially once the suspension was lifted.

The future plans for the service were unclear we were told that there would be four locations operating initially in Bradford, Nottingham, London and Kent but the number of clinics re-opening would depend on what contracts could be secured. There were future plans to introduce tele-radiology and MRI services.

We last inspected the service in August 2021 and it was rated as inadequate overall, we suspended the service which has prevented them from carrying out any regulated activity. There were breaches of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 identified at the last inspection:

- Regulation 5: Fit and Proper Persons: Directors
- Regulation 12: Safe care and treatment
- Regulation 13: Safeguarding service users from abuse and improper treatment.
- Regulation 15: Premises and equipment
- Regulation 17: Good governance
- Regulation 18: Staffing
- Regulation 19: Fit and Proper Persons

How we carried out this inspection

We carried out an unannounced focussed inspection of the diagnostic and screening core service on the 16 and 17 November 2021. During our inspection we visited the main location only because the service was currently suspended. We inspected to follow up concerns identified during the last inspection and to identify if the suspension could be lifted.

We looked at parts of the safe, effective, responsive and well led domains. We rated the service because we took enforcement action which included the use of our enforcement powers, where we issued two warning notices due to risks identified with safe care and treatment and good governance.

We reviewed specific documentation and interviewed key members of staff including a healthcare assistant, nursing staff, and the senior management team who were responsible for leadership and oversight of the service.

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

Summary of this inspection

Areas for improvement

Action the service MUST take to improve:

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

- The provider must assess the risks to the health and safety of service users in receiving the care or treatment and do all that is reasonably practicable to mitigate any such risks. (Regulation 12)
- The provider must ensure they operate an effective system to assess the risk of and prevent, detect and control the spread of infections. This must include but is not limited to ensuring effective infection control policies and procedures that are fully understood and adhered to by staff. (Regulation 12)
- The provider must ensure that the equipment used by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way. (Regulation 12)
- The provider must ensure that systems and processes are established and operated effectively to prevent the abuse of service users and to take action as soon as they are alerted to suspected, alleged, actual or the risk of abuse, this action should be in line with procedures agreed by local adult or children's boards. (Regulation 13)
- The provider must ensure that agency staff, receive such appropriate support, training, professional development and supervision as is necessary to enable them to carry out the duties they are employed to perform. (Regulation 18)
- The provider must ensure agency staff, records are maintained to provide evidence that they have undergone appropriate recruitment checks and that they continue to meet the professional standards which are a condition of their ability to practise or a requirement of their role. (Regulation 18)
- The provider must implement effective systems, processes and training for staff to assess, monitor and improve the quality and safety of the services provided in the carrying on of the regulated activity. (Regulation 17)
- The provider must implement effective systems, processes and training for staff to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk which arises from the carrying on of the regulated activity. This must include but is not limited to clear risk management systems and processes, including how risks are managed and mitigated and that staff managing risks have the skills knowledge and competence to do so. (Regulation 17)
- The provider must ensure that all policies and procedures are fit for purpose and reflective of the service provided. The provider must ensure that policies and procedures are monitored effectively and reviewed appropriately. (Regulation 17)
- The provider must maintain securely an accurate, complete and contemporaneous record in respect of each service user. (Regulation 17)
- The provider must ensure that personnel performing the functions of a director or similar have been through the appropriate recruitment and appraisal processes to ensure they have the qualifications, skills, competence and experience are relevant to their position or the work for which they are employed. (Regulation 5)

Action the service SHOULD take to improve:

- The provider should consider a review of the audit schedule to ensure it is reflective of the audits set out in all policies.
- The provider should ensure that there is a review and update of the statement of purpose to ensure it meets the requirements of the CQC and is reflective of the service they provided. (Regulation 12)
- The provider should consider progressing work to improve the concerns that the leadership team identified in relation to the culture of the organisation.

Summary of this inspection

- The provider should ensure a review of leadership, policies, processes and governance systems for physiotherapy and audiology services (regulation 17).

1.

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Inadequate	Inspected but not rated	Not inspected	Insufficient evidence to rate	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Not inspected	Insufficient evidence to rate	Inadequate	Inadequate

Inadequate

Diagnostic and screening services

Safe	Inadequate
Effective	Inspected but not rated
Responsive	Insufficient evidence to rate
Well-led	Inadequate

Are Diagnostic and screening services safe?

Inadequate

Our rating of safe stayed the same. We rated it as inadequate.

Safeguarding

Staff did not always understand how to protect patients from abuse. There was not a robust system and process in place for the appropriate and timely referral of safeguarding concerns.

We were given two different safeguarding policies dated November 2021 which contained different information. The flow chart in one policy instructed staff to contact a manager who assessed any safeguarding concerns. It was not clear which manager staff should contact or the role of the safeguarding lead in the referral process. Roles and responsibilities detailed in the policy differed from the flow chart and provided conflicting information about who should review and send safeguarding referrals.

Contact details for referrals within the policy did not align with publicly available safeguarding contacts in some local authority areas such as Oldham and Kent and Medway.

There was a risk of harm to patients if safeguarding referrals were not made in a timely manner.

There had been a new lead for safeguarding since our last inspection, the lead role was being provided by a consultant working for an external agency, who were supporting the provider to make improvements. It was not clear what contractual arrangements were in place which confirmed the period of time the external agency would provide this role.

Training compliance records had improved since our last inspection. Training compliance data matched the number of staff employed by the service and demonstrated that 100% of staff members employed by the service had completed safeguarding children and adults' level three training.

We were told that the safeguarding lead had delivered additional training to staff based on scenarios, but there was no evidence provided to demonstrate who had attended.

We saw in the meeting minutes for October 2021 that staff watched a safeguarding video and had discussions about the reporting of safeguarding concerns to external agencies. However, this was only attended by three out of the six clinical staff who worked for the service and there was no representation from the safeguarding lead.

Inadequate

Diagnostic and screening services

We were told that there was a monthly safeguarding audit planned which would look at the number of referrals raised and the locations where they were raised. We saw that the audit was referenced in the quality assurance audit schedule. We did not see evidence of completed audits as the provider was suspended at the time of our inspection.

Cleanliness, infection control and hygiene.

The service did not always control infection risk well. Whilst improvements had been made to infection prevention and control systems and processes, some policies were still not fully reflective of the service and it was unclear what monitoring processes had been implemented.

There had been a new lead for infection prevention and control since our last inspection, the lead role was being provided by a consultant working for an external agency. There was no robust agreement in place for the length of time they would be contracted by the service and there was limited evidence of succession planning for a new lead once the interim arrangement had ceased.

We were told that the infection prevention and control lead had delivered additional training to staff in infection prevention and control principles, but there was no documented evidence of this. However, mandatory infection prevention and control training clinical and non-clinical compliance data showed 100% of staff had been trained.

Daily environmental check forms had been introduced since our last inspection, these were in addition to the daily cleaning logs and spot check audits already in place. The checks covered all clinic areas and equipment and prompted staff to ensure they were clean. We were told that it was the health care assistant staff who would be responsible for completing the checks. There was no evidence of the monitoring processes which had been put in place for the completion of the checks and they were not included in the audit schedule. We did not see evidence of completed checklists as the service was suspended at the time of our inspection.

The decontamination policy which had been updated in October 2021 did not detail the process for the decontamination of transvaginal scanning probes or the recording and auditing processes in place. The audit schedule did not include any audits in relation to the decontamination of transvaginal probes or the quality assurance of ultrasound equipment which included cleaning.

The service had a single use instrument policy. However, it was unclear how this was relevant to the service as leaders confirmed that they did not use single use instruments.

However, we saw that additions had been made to infection prevention and control audit documentation which prompted areas of non-compliance to be added to the organisations risk register.

Environment and equipment

The design, maintenance and use of equipment did not always keep people safe. However, Staff were trained to use them.

We saw evidence that all 26 ultrasound scanning machines owned by the company had been serviced within the last 12 months and that annual servicing was in place.

At the last inspection we saw that the service had implemented a daily weekly and monthly quality assurance process for ultrasound equipment. The registered manager confirmed that the quality assurance of ultrasound equipment was not being undertaken whilst the service remained suspended.

There was no evidence of a clear plan for how equipment would be tested to ensure it was safe for use when the suspension ended. We observed a 'stress test' meeting which did not consider the process for ensuring that equipment was tested and safe to be brought back into use.

There was a risk that the quality of images would be compromised affecting the diagnosis and treatment for patients.

The policy for the quality assurance process stated audits would be undertaken quarterly by the lead sonographer. However, these were not included on the audit schedule for the service and at the time of our inspection the service no longer had a lead sonographer in post.

There were not robust contingency plans in place in case of equipment failure if machines in locations nationally failed. There was a risk of a delay to patients' diagnostic procedures and subsequent treatment if a failure did occur in a clinic which was not local to the head office such as London.

Assessing and Responding to Patient Risk

There was limited assurance that there were robust systems and processes in place for the appropriate and timely referral, triage and escalation of patient care. There was limited evidence that the risk to patients and staff during care and treatment had been considered and mitigating actions identified.

The triage process did not provide clarity about who would carry out the clinical triage for referrals or how these would be allocated. The registered manager gave conflicting accounts of who would be responsible for completing the clinical assessment, which included reference to himself as well as non-clinical and locum staff.

The lead sonographer job description stated that one of their responsibilities would be to triage referrals, however at the time of our inspection there was no lead sonographer in post and there were no clear recruitment plans for the role.

There was a risk that referrals could be missed or that they would not be appropriately triaged and prioritised resulting in potential delays to diagnosis and treatment for patients.

The process for image transfer had not been sufficiently addressed to prevent potential delays.

The process had not changed since our last inspection in August 2021 and it had not been further clarified in the records management or reporting policies.

There was a picture archiving and communication systems (PACS) flow chart for the electronic transfer of images, but this relied on the service having a PACS system in place. Leaders told us that the service planned to purchase a PACS system, but a contract had not been signed at the time of the inspection. We were provided a copy of a quote for a system which expired on 1 November 2021 and leaders confirmed that discussions with the company took place prior to the suspension.

There remained the risk that there could be a delay in the transfer of urgent images which could impact negatively on the diagnosis and treatment of patients.

There was no evidence of updated risk assessments to protect patients and staff and so we could not be assured that the risk assessment process had been improved.

We requested copies of the risk assessments in place for the service. Leaders were unable to provide evidence of these. The risk register did not contain evidence of risks identified from any risk assessments.

We were concerned that risks to patients and staff had not been identified or considered and appropriate action taken to mitigate any risks to their health, safety and welfare.

Records

Records were not always stored securely and easily available to all staff providing care.

At our last inspection we found concerns with the management of records. The records management/health records policy had been updated in September 2021 this still did not provide clarity about the process for the transfer and management of images or the management of transvaginal consent forms. The policy referenced regular record management audits, but these were not included in the audit schedule for the service.

The service had introduced an electronic consent form transvaginal scans which were completed with the patients at the time of booking, we were told that this process had been introduced to address the secure storage concerns we had at the last inspection. However, the document required decontamination information to be added during the scan and so would need to be printed in clinic locations.

There remained a lack of clarity about how the consent forms would be managed securely once they had been printed. Leaders told us staff would scan consent forms onto the computers at clinics and then email the forms to the head office and the originals would be shredded at the clinics. There was no clear process in for ensuring receipt of forms prior to them being shredded and so there was a risk that the audit trail of consent and decontamination would be lost. There was also a lack of clarity about what equipment staff would have access to scan and shred the forms in satellite locations which were not owned by the service.

Sonographer scan reports were checked by an administration staff member who was not a qualified sonographer. The service had introduced a checklist for the role. Whilst we saw that the majority of the checks were in relation to the administration aspects of the reports there were requirements to check clinical information. We were not assured that staff undertaking the process had the required knowledge and skills to do so.

Incidents

The service did not always manage patient safety incidents well. Staff did not always recognise and report incidents and near misses. Managers did not always investigate incidents or shared lessons learned with the whole team and the wider service.

There had been no changes to the way incidents were reported and recorded since our last inspection.

We were not assured that the service was operating effective systems and processes to report, investigate and share learning from incidents. Staff responsible for the investigation of incidents had not been provided with training in incident investigation methodologies to enable them to be competent in their role. They were unable to articulate investigation methodologies.

Inadequate

Diagnostic and screening services

We spoke with two senior staff members who gave contradictory accounts about the incident reporting process. There was a lack of distinction between incidents and complaints when speaking with staff and the complaints register referenced both complaints and incidents.

There was no oversight process in place for monitoring incidents and we did not see evidence in meeting minutes provided to us that incidents and associated learning would be discussed with staff at all levels.

There was a risk that incidents would not be reported and appropriately investigated, and that learning would not be identified and shared with staff to mitigate future risk to patients.

There was not a robust system and process in place to ensure that duty of candour was served in line with the regulation.

There was a lack of understanding of duty of candour and the process from the lead for incidents. The policies for duty of candour and being open did not provide staff with clarity about their roles and responsibilities in the process.

There was a risk that duty of candour would not be served in line with the requirements of the regulation and in a timely way to address any potential ongoing risks to patient care.

However, monthly incident audits had been added to the audit schedule for the service.

Are Diagnostic and screening services effective?

Inspected but not rated

We do not currently rate the effective domain for diagnostic imaging services.

Evidence Based Care and Treatment

The service provided care and treatment based on national guidance and evidence-based practice. Improvements had been made to quality assurance processes and the service had implemented an audit schedule.

We were told that policies and procedures were being made available for staff on the desktops of all laptops and that files were being created for all clinics which contained paper copies of policies. We saw evidence that index sheets had been created for satellite clinic files which covered a range of policies, procedures and checklists. We did not see evidence of electronic or paper access to policies for staff in satellite clinics during our inspection as the service was suspended.

The interim compliance manager told us at the time of the inspection that they had reviewed and updated 80% of the policies and procedures for the service to align them to the processes operated in the service. In most of the policies we reviewed we saw evidence of this.

The quality assurance policy had been updated since our last inspection and had been aligned to the internal processes within the provider.

The quality assurance audit schedule had been introduced and we saw that it included a range of audits such as infection prevention and control, health and safety, administration, reporting, complaints and the clinical audits. We did not see any evidence of audit results as the service was suspended at the time of our inspection.

However, we saw included in job descriptions that the lead sonographer for the service was responsible for the clinical audits of sonographer and the quality assurance process. At the time of our inspection the service did not have a lead sonographer in post, and it was unclear who would be responsible for this role in their absence.

There was no guidance for staff undertaking the clinical audit to support them in their role such as purpose, benefits and learning.

Policies for conducting ultrasound procedures did not provide a standardised approach to the different types of scans and so there was not a standardised approach to how staff scanned patients. Discrepancy meetings identified issues such as measurements taken during scans and directed staff to the British Medical Ultrasound Society (BMUS) guidelines. Discrepancies such as these could have been minimised if there was a standardised approach.

Some policies described audits which were not referenced in the newly implemented quality assurance audit schedule.

There were no policies or audits relating directly to audiology and physiotherapy services which we were told the service planned to re-start.

Competent staff

The service made sure staff were competent for their roles. Improvements had been made to the appraisal process for staff and there were plans to hold supervision meetings with them to provide support and development. However, there remained concerns about the competency checks for agency staff.

The recruitment policy had been updated to ensure that an unconditional offer of employment was not issued prior to receiving confirmation of registration, competencies, references and DBS checks.

The service had updated the electronic training system which was now reflective of the staff who worked for the service, which at the time of our inspection was 17 in total. We observed mandatory training data which demonstrated that the overall training compliance for the service was 99.49%. With modules ranging from 88.24% to 100% compliance. Mandatory training covered key modules such as adult basic life support, accident and incident reporting, health and safety and infection control. It was planned for mandatory training completion to be monitored by the HR department.

The service had updated the appraisal documentation to have more of a focus on objective setting. We were told that staffs personal development plans would be re-visited when services were resumed with the support of the human resource manager. We were told that individual training needs would be identified and addressed by individuals line managers. It was planned that actions from personal development plans would be overseen by the human resource manager and assistant.

The service had implemented a training and development policy which described the competency requirements for staff. The policy had competency assessment checklists included for different staff roles covering a range of staff employed by the service such as administration staff, health care assistants, sonographers and business development managers. However, it did not include other staff roles such as physiotherapists and audiology staff.

Inadequate

Diagnostic and screening services

The service had implemented an oversight document since our last inspection to track the registration of staff who were registered with professional bodies this included sonographer staff, the pharmacist and the registered manager who was a radiologist. We reviewed the document provided and saw that one sonographer who worked for the service that was not on the Register of Clinical Technologists in line with their contract of employment.

However, there had been no improvement to the systems and processes surrounding the recruitment, induction, competency checks and supervision for agency staff. The updated recruitment policy did not include the checks required when recruiting agency staff. The HR lead told us this was an area to be looked at but stated the use of agency staff would be a last resort. During discussions with the registered manager we were told that they would use agency staff to address staffing shortfalls. There was a risk that staff would be used by the service without the appropriate recruitment and competence checks, induction and supervision in place.

The staffing policy stated that the service should use the list of approved agency staff, the human resource department confirmed that there was no approved list in place.

Sonographer competency assessments responsibility sat with the lead sonographer for the service and this was evidenced in the job description provided. However, at the time of our inspection the service did not have a lead sonographer in post and so it was unclear who would be responsible for these in their absence of one.

There was limited evidence that the registered manager for the service had received an annual appraisal. We saw that appraisal dates were documented for January and February 2020.

Consent

Consent documentation for intimate ultrasound examinations had been updated to meet with national guidance and the policy had been updated to reflect this. However, it was unclear if staff were aware of the new process.

The consent policy for transvaginal scans had been updated since our last inspection and detailed that consent would be obtained over the phone by administration staff at the point of booking appointments. We were told that this process had been introduced to reduce paper and address concerns from previous inspections about the security of consent records.

We saw that the consent process had been discussed with staff during a meeting in October 2021. However, the attendance list confirmed that not all staff had attended the meeting and we were given different accounts of the consent process for transvaginal scans and so it was unclear if staff were aware of the new process. There was no evidence of what training administration staff had received to support them in obtaining consent for intimate scans.

Are Diagnostic and screening services responsive?

Insufficient evidence to rate

Our rating of responsive did not change as we did not look at enough key lines of enquiry to re-rate the domain.

Complaints

Inadequate

Diagnostic and screening services

There was a process for people to give feedback and raise concerns about care received. The service investigated complaints and included patients. Improvements had been made to the process to evidence of lessons learnt and share them with all staff. However, we had concerns raised with us from patients that it was not easy to contact the provider and raise complaints.

The complaints policy had been updated to capture reviews of the service on online review sites and there was a process to contact the person who had left the feedback to initiate a complaint.

The complaints lead stated that they planned to record and monitor both informal and formal complaints.

Formal complaints were allocated timescales for a response there was an acknowledgement after three days and 28 days to complete the investigation and provide the outcome response. It was planned for monthly complaints audits of the complaints register to be completed.

The complaints summary log had been updated to better capture lessons learnt as a result of complaints.

We were unable to see evidence of new completed complaints investigations or lessons learnt as the provider was suspended at the time of our inspection.

We received concerns from patients about the ability to make contact with the service to raise concerns.

Are Diagnostic and screening services well-led?

Inadequate

Our rating of well-led stayed the same. We rated it as inadequate.

Leadership

Whilst steps had been taken to strengthen the leadership structure, leaders did not all have the skills and abilities to run the service. The service was receiving support from external agencies to fulfil leadership roles and there was not a robust process in place to ensure sustained long-term effective leadership capacity and capability to assess, monitor and improve the quality and safety of services provided.

The leadership structure had been updated since our last inspection to include a compliance and quality manager who would report directly to the deputy CEO and CEO for the service. The role had been introduced to address the weaknesses in the clinical and regulatory compliance identified during previous inspections. At the time of our inspection the role was being fulfilled on a temporary arrangement.

Leaders confirmed that there was previously a lack of understanding about the requirements of the regulator and compliance. The service had sought support from an external agency who specialised in compliance and the Health and Social Care Act 2008.

There were staff who were not directly employed by the service in interim roles. This included the human resource manager, safeguarding and infection prevention and control lead and the compliance and quality manager. There was not robust evidence in place to demonstrate the contractual agreements in place for these roles and so there was limited assurance that these leaders would remain in place for the required period of time to embed the new processes.

At the time of our inspection the human resource manager confirmed that they had not yet agreed the terms of the contract.

There was a lack of clarity about the amount of days and hours these interim staff would be based at the service.

There were no clear plans in place for the upskilling of current staff into the infection prevention and control, safeguarding, human resource and health care assistant lead roles.

The provider had not organised any additional training in the investigation of incidents to support the manager with responsibility over incident investigations, in their role.

Managers had not received additional training to support them in appraising staff performance and there was no clear plan for this to take place.

The recruitment policy stated that recruiting managers would have equal opportunities training. This had not yet been delivered and there were no formalised plans for this. The human resource manager told us it would be delivered in 2022, however it was recognised that recruitment would be required before then.

The safeguarding lead for the service could not articulate the supervision in place to support them in their role and they were not present at the organisation on all operating days.

There were management roles in place which were not reflected in the organisational chart such as the contracts manager and the complaints and incidents manager and the lines of accountability were not reflective of what leaders told us.

The organisational structure did not include additional services that the service planned to provide such as physiotherapy and audiology and so it was unclear what the leadership arrangements for these services was.

The job description for the contract manager talked about the post holder requiring “a strong understanding of CQC regulations along with other overarching governing bodies relevant to the health and social care industry” and “experience of developing and overseeing an extensive health and social care ‘compliance’ based organisational framework”. However, the interim post holder for this role did not have any background or prior experience in health and social care.

There was a risk that the changes and embedding of systems and processes to assess, monitor and improve the quality and safety of services was reliant on staff who were not directly employed for the organisation and that without contractual agreements in place the required improvements might not be embedded or sustained.

We were told that leaders would require management training but there was no plan of how and when they would receive this.

Inadequate

Diagnostic and screening services

There was a lack of clarity about the scale and plan for the service or an understanding of the challenges the service faced. Leaders confirmed that the service would initially start with four satellite clinics in Bradford, Nottingham, London and Kent, but advised dependant on the contracts they secured they may open more clinics. However, at the time of our inspection there were three sonographers who worked for the service who were not located geographically close to any of the clinics. There was no clear staffing plan for meeting the needs of the service.

We observed a stress test which was undertaken by leaders it did not consider issues with equipment, staffing and facilities due to remote locations and did not provide evidence that leaders were aware of the challenges to the service.

Personnel files had been created for the board members and directors since our last inspection. However, we observed that the fit and proper persons requirements had not been fully evidenced in the files of the four people who were on the board or were directors. Gaps in the checks included qualifications, references, recruitment processes and DBS.

However, DBS checks had been updated since our last inspection. Evidence of the DBS certificates were no longer kept in personnel files. The process was overseen and signed off by the human resource manager. There was a DBS risk assessment form that was used if any concerns flagged on a DBS received. We observed that the risk assessments were comprehensive and required be sign off by the recruiting manager and a director of the company.

The service had introduced a DBS oversight sheet which documented issue dates and renewal dates for all employed staff excluding board members and indicated which staff had signed up to the update service.

We were told that detailed application forms and interview scoring sheets had been developed and that interviews would be support by the human resource manager initially. We did not see evidence of these.

Since our last inspection the service had implemented a fit and proper persons declaration form, we saw that these had been completed by the four staff who were required to complete them.

Culture

The service recognised that work to improve the culture in the organisation was required but had not progressed since the last inspection. Leaders we spoke with felt valued and supported in their roles.

Leaders told us that there was an aim to improve the diversity of the organisation. We were told that this was an area of improvement required at the last inspection but had not progressed and there were no clear plans about how this would be actioned. We were told that the work would be led by the human resource manager and a member of the board.

The updated recruitment policy stated that recruiting managers would undergo equal opportunities training. At the time of our inspection managers had not yet received the training and it was recognised that the service would need to undertake recruitment to support the re-start of services.

The Whistleblowing policy had been updated since our last inspection. The policy prompted staff to look at the board at head office to identify the person who was the Freedom to Speak up Guardian. At the time of our inspection we saw that this role was being provided by one of the consultants from an external agency. It was not clear how staff who worked in

remote locations such as London would know who the Freedom to Speak up Guardian was. The policy stated that whistleblowing concerns would be investigated by the operations and complaints managers. It was not clear how this would be independently managed particularly if a concern was in relation to either of these roles and it was unclear how the Freedom to Speak up Guardian was involved in the process.

The Freedom to Speak up Guardian confirmed they had not received the official training and was not linked into the national guardian office.

Leaders we spoke with felt valued and supported in their roles.

There was limited evidence of learning from incidents.

Governance

Leaders did not operate effective and governance processes, throughout the service and so staff at all levels could not be clear about their roles and accountabilities. However, some improvements had been made to policies and monitoring processes.

There was still not a robust governance structure in place that ensured an effective flow of communication to staff at all levels and effective oversight of remote locations.

Leaders were unclear about the flow of information from staff level to the board and back. We were not provided with evidence that there were standard agenda items discussed at board, staff meetings and weekly manager meetings. Staff meeting minutes provided as evidence did not cover standing agenda items that were covered on the governance meetings such as incidents, performance and risk.

Leaders were unclear about what would be discussed at board level and confirmed that they had not had an official board meeting.

There was no clear structure or plans in place to manage the service nationally. The service planned to obtain contracts and run clinical services from satellite locations nationally such as GP surgeries which would be managed from one location. However, there was no governance structure which outlined how services would be managed at a local and regional level. The operations manager and the lead for healthcare assistants were unaware of how they would manage the service if it was spread nationally as intended, and there were no clear plans in place for this.

There was a risk that important information and communication would not be shared with staff at all levels, so that learning, areas of improvement or concern could be identified, discussed and shared. There was a risk that there would not be clear oversight of risk and performance across satellite locations.

There were audits referenced in policies which were not reflected or differed from those identified in the audit schedule.

The service had updated their statement of purpose since our last inspection to reflect changes to regulated activities. We highlighted to the provider that the statement of purpose was not in line with the requirements of the CQC and did not fully reflect the service. We identified the areas of improvement required during the inspection.

There was no clear process in place for the ongoing update of policies and how staff would be informed of any changes. This included the update of paper files located in satellite clinics.

However, leaders recognised that policies had not been fit for purpose previously and adherence to them had been poor. At the time of our inspection we were told that 80% of the policies had been reviewed and updated. We saw improvements in most of policies we reviewed.

Human resource policies and processes had been improved to provide better oversight of recruitment checks, appraisals, training and professional registration. However, the audit frequencies described did not match those in the audit schedule. We were unable to review evidence of completed processes as the service was suspended at the time of our inspection.

The service had implemented new service level agreements which would form part of the process when securing premises to operate out of such a GP surgeries. These provided an agreement of roles and responsibilities in relation to environment, equipment and health and safety.

Managing Risks issues and performance

Whilst some improvements had been made to systems and processes in relation to the management of risks, issues and performance. There was not a robust system and process in place to assess and monitor the improvements that had been implemented and risk management processes were not robust.

The service had developed a quality improvement plan to address the regulatory breaches identified at the last three inspections. The plan dated 15 November 2021, had been signed off as complete even though there had been no embedding or testing of systems and processes, due to the service being suspended.

We were told that as part of the embedding process the action plan would be reviewed. However, there was no formalised process in place for its review and there was a lack of clarity about who would be involved in the oversight.

During our inspection we found continued breaches of Regulation 12 and 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, which had not been addressed.

There was a risk that the implementation of the improvement plan would not be monitored to ensure it was effective and embedded or to enable the identification of risks and concerns.

The service had not implemented a robust risk management process. We requested risk assessments that had been completed by the service following our last inspection in August 2021, they were not provided.

The service had implemented a risk register since our last inspection. We were provided with a copy of the register on day one which contained no risks. We were told that this was because audits had not yet been undertaken. However, on day two of the inspection there had been four risks added. There were anomalies in the risks on the register such as missing dates.

There was limited evidence of mitigating actions for the risks identified and no evidence that the risks had been through an approval process. It was not clear what risk levels were allocated to each risk and who was at risk. There were no dates to indicate when risks should be reviewed. Risks were rated by colour, but it was not clear what the rating meant. One risk was rated as green but from the information recorded actions had not yet been completed.

Inadequate

Diagnostic and screening services

There was no clear formalised process for the approval and review of risks identified by the service. The registered manager told us that this would be weekly between them and the compliance manager however, this was not reflected in the governance structure.

Leaders told us that risks would be added to the risk register as a result of compliance issues with audits, but there was no consideration of risks being identified outside of the audit process such as through incidents, risk assessments and general risks to the service.

The leadership team and board members were unable to articulate the risks to the service other than the impact on the business due to the suspension. Risks described were not reflected on the risk register. It was not clear how risks would be shared with staff at all levels.

There was a risk that the service would not identify and mitigate risks to patients, staff and the service putting people at the risk of harm.

We were told that there were plans to incorporate external audits in the monitoring processes, but these had not been agreed.

The leadership team had developed a strategy for the service which we observed at the time of the inspection. We saw that the strategy was a financial plan for the growth of the company and there was nothing included about quality and sustainability.

There was no strategic workforce plan in place despite the service having dramatically reduced the workforce during the suspension of the service.

We were told that there would be KPIs in place for each role in the organisation which would feed into the provider wide KPI's these had not yet been developed. It was not clear what these would be and how they would be monitored.

However, the service had implemented an audit schedule to monitor a range of activities across the service and check adherence to policies.

Leaders acknowledgement that processes were new and needed to be embedded.

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 Surgical procedures Treatment of disease, disorder or injury	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment .

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 13 HSCA (RA) Regulations 2014 Safeguarding service users from abuse and improper treatment .

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 18 HSCA (RA) Regulations 2014 Staffing .

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 5 HSCA (RA) Regulations 2014 Fit and proper persons: directors .

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	S29 Warning Notice
Surgical procedures	.
Treatment of disease, disorder or injury	