Mediscan Diagnostic Services Ltd

Mediscan Diagnostic Services Limited

Inspection report

Tameside Business Park, B2-36 The Forum
Windmill Drive, Denton
Manchester
M34 3QS
Tel: 01618201118

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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 a lack of clarity about the training staff had received about how to recognise and report abuse and they did not always know how to apply it.
- The service did not always control infection risk well. The infection prevention and control policies were not fully reflective of the service or provide clarity to staff about how to use control measures to protect themselves and patients.
- The policy for waste management was not fully reflective of the service and there was missing information.
- 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.
- Records were not always stored securely and easily available to all staff providing care.
- The service did not have robust systems in place to safely prescribe, administer, record and store medicines.
- 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.
- Although some improvements had been made to quality assurance processes, we found some out of date documentation, there remained limited evidence that managers had processes in place to make sure staff followed guidance and there was limited evidence of audits undertaken.
- Managers did not always appraise staff's work performance or hold supervision meetings with them to provide support and development. Whilst some improvements had been made to staff training, records were not always accurate or up to date and so we could not be assured that they provided appropriate oversight of staff training.
- There was limited evidence of lessons learnt and shared with all staff in relation to complaints.
- Whilst steps had been taken to strengthen the leadership structure, leaders did not all have the skills and abilities to run the service. They did not always understand and manage the priorities and issues the service faced. They did not always support staff to develop their skills and take on more senior roles.
- Staff did not always feel respected, supported, and valued. The service did not always have an open culture where patients, their families and staff could raise concerns without fear.
- Leaders did not operate effective and governance processes, throughout the service. Policies and procedures were not reflective of the services provided and so staff at all levels could not be clear about their roles and accountabilities.
- Leaders did not always use systems to manage performance effectively. They did not have effective risk management processes in place to identify and escalate relevant risks and issues or identified actions to reduce their impact.

However:

- There had been improvements made to cleaning checklists and ultrasound equipment cleaning processes.
- The design and maintenance of premises and equipment kept people safe.
- The service provided care and treatment based on national guidance and evidence-based practice.
- Consent documentation for intimate ultrasound examinations had been updated to meet with national guidance and staff were aware of the process.

Following our inspection, we took enforcement action which included the use of our urgent enforcement powers under Section 31 of the Health and Social Care Act 2008. We extended the suspension up until the 25 November 2021 due to risks identified with safeguarding, assessing and responding to risk, medicines, incidents, recruitment processes leadership and governance and risk management systems.

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 above for our overall summary of the service.

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, is 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, endoscopy procedures including sigmoidoscopy, colonoscopy and gastroscopy, audiology and physiotherapy, however we were told during this inspection that activity outside of ultrasound scanning would not be re-started immediately once the suspension was lifted. 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.

We last inspected the service in June 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 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

How we carried out this inspection

We carried out an unannounced focussed inspection of the diagnostic and screening core service on the 17 and 18 August 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 urgent enforcement powers, where we extended the suspension up until the 25 November 2021 due to risks identified with safeguarding, assessing and responding to risk, medicines, incidents, recruitment processes leadership and governance and risk management systems.

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

We were told that the endoscopy, physiotherapy and audiology services had been ceased and there were no immediate plans to re-start them if the suspension was lifted.

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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 ensure that care and treatment is provided in a safe way for service users. 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 that systems and processes operate effectively to assess the risk of, and prevent, detect and control the spread of, infections, including those that are health care associated (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. They must ensure that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way. (Regulation 12)
- The provider must ensure the proper and safe management of medicines. Staff responsible for the management and administration of medication must be suitably trained and competent and this should be kept under review. Staff must follow policies and procedures about managing medicines. Policies and procedures must be fit for purpose and in line with current national legislation. (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 all premises and equipment used by the service provider are clean, suitable for the purpose for which they are being used, properly used, and properly maintained. The provider must in relation to such premises and equipment, maintain records and standards of hygiene appropriate for the purposes for which they are being used. (Regulation 15)
- The provider must ensure that all staff, including agency staff, receive such appropriate support, training, professional development, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform. (Regulation 18)
- The provider must ensure that where staff, including agency staff, are health care professionals or other professionals registered with a health care or social care regulator, records are maintained to provide evidence 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 ensure that recruitment procedures are established and operated effectively to ensure that persons employed have undergone the appropriate checks for both employees and directors. Information set out in schedule 3 of the regulations must be confirmed before they are employed. (Regulation 19)
- 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 (including the quality of the experience of service users in receiving those services). (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. (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. The provider must ensure staff understand and know how to access the provider's policies and procedures. (Regulation 17)

Summary of this inspection

- The provider must maintain securely records that are necessary to be kept in relation to persons employed in the carrying on of the regulated activity and the management of the regulated activity. (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 ensure that it is easy for patients to raise complaints about their care and that they are responded to within the timescales set out in the policy. (Regulation 16)
- The service should ensure that lessons learnt from complaints are identified and shared with staff. (Regulation 16)

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 a lack of clarity about the training staff had received about how to recognise and report abuse and they did not always know how to apply it.

Since the last inspection the service had appointed a new safeguarding lead who worked part time. The new safeguarding lead had not received a higher level of safeguarding training to support them in their role and at the time of our inspection there was no supervision or support mechanisms in place for their role.

We were not assured that there was a robust system and process in place for the appropriate and timely referral of safeguarding concerns. The safeguarding policy had been updated in August 2021. It stated that all referrals should be sent to the safeguarding lead for triage who would then send them to the local authority if necessary, urgent cases were to be directed to the emergency services. The safeguarding lead did not work full time hours, and so would not always be available when the service was operating.

The registered manager told us that the lead sonographer and an administration lead for safeguarding would take the referral responsibility in the absence of the safeguarding lead. This was not referenced in the updated policy and so we are not assured that safeguarding referrals would be dealt with in a timely manner or that staff were aware of their roles and responsibilities. Following our inspection, the policy was updated in September 2021 which identified responsible staff members in the absence of the safeguarding lead.

We were not assured that staff have received the appropriate safeguarding training that was required for their role. We spoke with five sonographer staff and four Health Care Assistants (HCA), one HCA could not provide an example of a safeguarding concern and one sonographer was unaware what Female Genital Mutilation (FGM) was. Two sonographer staff stated they were only trained up to level 2.

We could not be assured that training records provided were accurate and up to date. Records for safeguarding level 3 training compliance for adults was 95% and children was 92% these were based on 78 staff requiring training. However, at the time of the inspection the staff list provided demonstrated that there were 41 staff working for the provider who were not all clinical.

The safeguarding lead had developed scenario training which prompted staff to identify the type of abuse, but the training did not cover the required action by staff. We were told that the scenario training session had been delivered to staff. The service was unable to provide a list of attendees as these were not recorded at the time. The safeguarding lead wrote a list of attendees from memory. The list only included one sonographer and so did not provide assurances that clinical staff had received additional training.

Two staff members we spoke with told us they had received face to face safeguarding training which was the same as the electronic training that they had already completed and did not provide additional information.

The new induction template stated that staff should be trained to level 1 and 2 safeguarding training and does not reference the requirement to have completed level 3 training.

Cleanliness, infection control and hygiene.

The service did not always control infection risk well. The infection prevention and control policies were not fully reflective of the service or provide clarity to staff about how to use control measures to protect themselves and patients. However, there had been improvements made to cleaning checklists and ultrasound equipment cleaning processes.

There was a new infection prevention and control lead appointed at the end of July 2021 who was a registered nurse. The did not work full time hours and it was not clear how many days a week they would work for the service.

Infection prevention and control policies had been updated since our last inspection. Decontamination, COVID-19 and personal protective equipment had been separated from the overall infection control policy.

There was a lack of clarity for staff on the correct infection prevention and control policies were not fully reflective of the service. For example, the infection control policy which was updated in June 2021 contained information which was not relevant to the service provided such as the processes for taking blood samples, urine samples, semen samples and undertaking smear tests. It also talked about responsibilities of personnel who were not relevant to the service.

The decontamination policy gave specific cleaning instructions for equipment which was not relevant to the service such as baby scales, near patient pathology testing machines, cervical diaphragms and caps and electrocardiogram machines. It did not specifically reference all equipment used by the service to inform staff of the relevant cleaning processes.

The updated personal protective equipment policy had been created in June 2021. It was generic and referenced practices which were not undertaken by the service. It did not provide specific detail about the personal protective equipment requirements for all staff.

The coronavirus policy implemented in June 2021 identified that staff should wear masks in all clinical areas and that staff received bi- weekly lateral flow tests. The service was suspended at the time of our inspection and so we did not see evidence of staff testing or adherence to wearing masks during the inspection.

The cleaning contract with an external company provided daily cleaning for the Mediscan owned clinic locations remained unsigned by the company, and so it was not clear that it was in place.

There was a lack of clarity about how infection prevention and control audits would be undertaken across all locations where the service provided activity. It was identified that this would sit with the infection prevention and control lead however, they were unclear about how this would be operationalised. We were told that in the future staff would be trained to undertake the audits however there was no clarity about when the training would take place and which staff would be included.

There was conflicting information about whether the infection prevention and control lead had visited the clinic sites to assess the cleanliness of premises. The registered manager stated that this had not yet taken place, however the lead stated that they had visited the Oldham clinic. When we asked for documented evidence of the visits and any identified actions, we were told there was no written record of this. Due to the concerns we identified in the Oldham location we could not be assured that any visits had taken place.

We were told that 'I am clean' stickers had been implemented. We did not see evidence of these in use at the time of our inspection.

However, there were new cleaning logs that had been created which identified specific roles and responsibilities for staff cleaning and the areas that required cleaning. These were not yet in use at the time of our inspection as the service was suspended.

Ultrasound machine cleaning had been included as part of the daily quality assurance process. There was a checklist that had been created to support this. The process was not being used at the time of our inspection as the service was suspended but there were plans to start this when the suspension was lifted. However, there was no evidence of monitoring processes in place for oversight of adherence to the checklists.

Environment and equipment

The design and maintenance of premises and equipment kept people safe. However, the policy for waste management was not fully reflective of the service and had missing information.

There were 28 ultrasound machines in the company we were provided with two contracts which demonstrated there were maintenance contracts in place for the machines. We sampled three machines and were provided with evidence that services had taken place. The service had created an 'ultrasound scanner service report which identified service dates and due dates, this was overseen by the lead for equipment.

Since our last inspection electrical safety testing had taken place again for electrical equipment in the clinics owned by the service.

Equipment records for the endoscopy service were not available. We were told that there were no immediate plans to re-start this service and that the unit had been dismantled.

Since the last inspection the service implemented a checklist for the daily, weekly and monthly quality assurance of ultrasound equipment in line with British Medical Ultrasound Society (BMUS) guidance. Training about the process had

been delivered to staff and two of the sonographers we spoke with could describe the process. However, upon review of the attendance list we saw that this only covered four current staff out of the 12 sonographers who remained employed by the service. We could not be assured of the accuracy of the training records provided as the list contained names of staff that were not on staff list provided by the service which covered 10 June to 17 August 2021.

Equipment maintenance had been added to the clinical governance standard agenda to provide oversight. However, there had not been a clinical governance meeting since our last inspection due to the suspension and so we did not see evidence about the information that would be shared.

However, the waste management protocol had been updated and was not fully reflective of the processes undertaken by the service. The protocol stated that staff will receive annual training in the control of substances hazardous to health this was not listed in the annual mandatory training modules provided by the service and there were missing details of contractors within this section of the policy.

Waste management documentation did not evidence that contracts were in place.

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. However, staff understood how to act on patients at risk of deterioration.

There were not robust systems and processes in place for the appropriate and timely triage and follow up of ultrasound patients in line with the services policies. There had not been an updated policy for the referral/triage process since our last inspection. The referral process in the referral/appointment monitoring policy stated that referrals undergo a 'clinical triage by consultant clinician'. However, the registered manager told us that they did not follow their process and they trusted that GPs had the skills and knowledge to request the correct scan and that sonographer staff should pick up any referral issues at the time of the scan.

The service could not provide evidence that referrals had been or will be clinically triaged, and it was confirmed that the triage process was not formally documented. This did not meet with the Policy for Justification of Ultrasound Examinations. The service later provided a new triage document to record the process. We did not see evidence that this was in use as the service was suspended at the time of our inspection. Following our inspection, the service provided an updated policy relating to the referral and triage process.

We were not assured that there was a robust system in place for the timely transfer of images particularly for urgent findings. The process in place for downloading images onto the system involved one staff member downloading the images from the equipment in clinics across the country using a hard drive. We were told that they travel to local sites every three days and sites further away such as London every two weeks, to collect the images. The registered manager told us that if urgent findings were identified they sent the images immediately to the hospital. This meant there was a potential delay in images being sent if they were requested immediately for urgent findings outside of the local area. This process was not detailed in the NOUS Discharge and Reporting Guidelines or the Records Management/ Health Records Policy.

Inadequate

Diagnostic and screening services

We received information of concern, that the service used an automated system from a third-party provider for the triage of referrals and there were concerns with the accuracy of the system. Following our inspection, the provider submitted a letter from their information technology support team who stated they did not use an automated system to triage patients and did not hold any patient data outside of the UK.

We received concerns about large numbers of patients who had been lost to follow up. The local commissioners had undertaken a review of the list and highlighted that there were 3674 lost referrals in the system, for which they have had to contact GPs to re-refer patients. These were in relation to patients within the Greater Manchester area. There was a risk that patients may or have been exposed to the risk of harm as a result of not receiving the required diagnostic procedures in a timely way. This could lead to delays in treatment for patients.

We were told that the provider did not treat children under 18, breast scans, known cancer scans or undertake pregnancy scans. However, there was no clear exclusion criteria in place we were told it was based on commissioning contract requirements. The website for the service advertised a range of pregnancy scans which included early re-assurance scans, gender scanning and pregnancy dating. It was not clear what training staff had received in relation to these scans and there were no policies or procedures in place which covered these.

Sixteen staff had attended training in June 2021 since our last inspection, for basic life support and the use of the defibrillators. We saw attendance lists which confirmed that 12 sonographers and four healthcare assistants had attended this training. However, three of the staff members on the attendance list were not on the providers employed staffing information for June 2021. We also saw there were inconsistencies in the overall training records that we reviewed. The mandatory training compliance documentation provided during the inspection stated 'archived' next to the module 'adult basic life support'. The total staff required for this training was identified as 100, which did not correlate with the providers current staff list which identified 41 in total.

At the time of our inspection the policy for deteriorating patients was under review.

However, we were told defibrillators had been installed at the Ashton clinic since our last inspection. Daily defibrillator checklists had been implemented for these. We did not see that defibrillator checks had been undertaken as the service was suspended at the time of our inspection.

Staff we spoke with could describe the process for the escalation of deteriorating patients.

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. At this inspection we were provided with the records management/health records policy, the approval date was May 2021 and so had not been updated since the last inspection.

There were conflicting accounts about how completed consent forms were managed. At our last inspection we found that staff took them home each night and then returned them to the office weekly, although we found forms covering a year stored in one of the locations. At this inspection some staff told us they returned the forms to the office at the end

of each shift, others told us they took photographs of the forms on personal devices and emailed them to the office and staff working in locations across the country stated they took the forms home each night then posted them back to the office weekly. The records management/health records policy did not provide clarity about the process for managing paper records.

Images were collected from clinics across the country by a member of staff who downloaded them onto a hard drive device. It was unclear what level of security was in place on the device. We were told that a hard drive device had never been lost but there was a risk that the device with the images could be mis-placed.

We received information of concern, that the service used an automated system from a third-party provider for the triage of referrals. There were concerns about the security of patient information held in this system.

The policy referenced regular record management audits and annual external record audits. We were told that records audits took place but there was no evidence of completed audits and they were not referenced in the clinical audit policy.

The policy for reporting images stated that reports were reviewed by the lead sonographer, however during our inspection staff told us that this was overseen by a non-clinical member of staff.

Medicines

The service did not have robust systems in place to safely prescribe, administer, record and store medicines.

Medicines were only used by the endoscopy service. At this inspection we were told that when the suspension was lifted there were no immediate plans to re-start the endoscopy service.

Since the last inspection the service had employed a pharmacist on a permanent contract however there were no set days for them to work and we were told the hours were on an ad-hoc basis. The pharmacist had identified concerns in the processes the service currently had in place. This included the, need to have medication disposal contracts in place, receipt and disposal documentation for controlled drugs and medicine incident reporting. There were no timescales for the implementation of the improvements as the pharmacist was new in post and there was a lack of clarity about when the service would re-start.

The medicines policy had not been updated since our last inspection and so was still not fully reflective of the service provided. We were told that there were no changes required to the policy but that they needed to implement some of the processes referenced.

There was no evidence that monitoring processes for medicines had been implemented since the last inspection and the clinical audit programme did not reference medication audits. The pharmacist told us they planned to implement audits for the prescribing of medicines in line with formulary, there had been no progress made with the work at the time of our inspection and the ideas were in development. There was no reference to plans for any safe and secure storage of medicines or controlled drug audits.

Incidents

Inadequate

Diagnostic and screening services

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.

We were not assured that there was a robust system and process in place for the appropriate reporting, investigating and learning from incidents. There was no evidence that staff in charge of this process had received appropriate training to support them in their role. The newly implemented significant events policy did not reflect the NHS serious incident framework or provide clarity about the management of lower level incidents. The lead for incidents did not know that duty of candour was (the process for being open and honest with patients when things go wrong). Following our inspection, the provider implemented a serious untoward incident policy.

There were two policies in place for duty of candour we were given one dated January 2021 and one dated August 2021. The policy dated August 2021 did not provide clarity about the roles and responsibilities of staff in relation to duty of candour as per the previous policy. Therefore, this provided conflicting information for staff to follow. The policy stated that staff would receive training in duty of candour however we saw that this was not a mandatory training requirement and so not all staff had completed it.

We requested evidence of incident investigations that had been completed and these were not provided. There was no evidence that a look back exercise had taken place to ensure previous incidents had been appropriately investigated and managed and that any learning had been identified.

There was no clarity about any changes to governance arrangements in place for the oversight of incidents and learning. We saw that 'significant events' had been added to the clinical governance meeting agenda template but there was no evidence or clarity about how or where all incidents would be monitored, and learning identified and shared.

Staff we spoke with were unclear about how to raise incidents and could not provide examples of learning from incidents other than through discrepancy meetings.

Incident audits were referenced in the significant events policy, this was not referenced in the clinical audit policy and so we could not be assured this monitoring process was in place.

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. Although some improvements had been made to quality assurance processes, we found some out of date documentation, there remained limited evidence that managers had processes in place to make sure staff followed guidance and there was limited evidence of audits undertaken.

Sonographer staff had 5% of their imaging reports audited for quality in line with the requirements of the Society of Radiographers. There were dedicated senior sonographer staff who carried out a review of the records. Discrepancy meetings were held quarterly, however there had been meetings in May and June 2021. We reviewed the discrepancy meeting agenda for June 2021 and saw that 20 cases were discussed which looked at technique and improvements in scanning.

Since our last inspection the service had implemented a daily quality assurance checklist to be completed by sonographers using the ultrasound machines, the process followed BMUS guidelines. The process included cleaning and operation checks of the machines which were required daily, weekly and monthly. There were checklists for staff to complete but these were not yet in use as the service was suspended at the time of our inspection.

Training had been provided to staff in relation to the new process. However upon review of the attendance list we saw that this only covered four sonographer staff out of the 12 sonographers currently employed by the service and so we could not be assured that all sonographer staff in the service had received training for the new process.

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 did not see evidence of electronic access to policies for staff in satellite clinics during our inspection as the service was suspended. However, we saw evidence of a paper file in the Oldham location and we found a copy of the decontamination policy which did not match the policy held in the main location. There was a risk that paper copies contained in files in remote clinics may become outdated and that staff would not have the most up to date version.

The quality assurance policy had exceeded its review date of July 2021. We saw that it referenced other organisations, talked about quality assurances processes which were not in line with the providers operations and did not provide clarity to staff about how quality assurance processes functioned and were monitored. This did not provide evidence that the service had implemented effective oversight of staff adherence to policies and the quality of the service. Following our inspection, the service had updated the quality assurance policy.

There was a clinical audit policy in place which identified the audits undertaken by the service these covered sonographer reports, infection prevention and control audits, control of substances hazardous to health, administration staff audits and performance audits. However, we found a number of audits referenced in policies such as the disposable of single use instrument policy, the incident policy and the records management/health records policy which had not been identified in the clinical audit policy, and so it was not clear if monitoring processes were in place.

We were told conflicting information about external audits. We were told that there was an external audit I which was undertaken by a doctor in another hospital who did this work remotely, however another member of staff told us there were currently no external audits in place but there were plans to introduce them. There was no evidence provided of external audits and external audits were not included in the clinical audit policy.

Coronavirus information leaflets provided out of date information for patients and referred to vaccines not being developed or available, they also referenced information not relevant to the service such as coronavirus on food products.

Competent staff

Inadequate

Diagnostic and screening services

Managers did not always appraise staff's work performance or hold supervision meetings with them to provide support and development. Whilst some improvements had been made to staff training, records were not always accurate or up to date and so we could not be assured that they provided appropriate oversight of staff training.

We were told that since the suspension the service no longer employed physiotherapy, audiology or endoscopy staff. The current staff list provided showed there were 41 staff in total employed by the service. Staffing consisted of 12 sonographers, eight healthcare assistants, three business development managers, five managers, eleven administration staff, one nurse and one pharmacist.

We were not assured that the necessary improvements had been made to the appraisal process or that all staff had received an appraisal. We requested appraisal compliance rates, but these were not supplied. We were given eight copies of completed appraisal documents for staff who were in administration, managerial roles and one sonographer. We saw there was limited evidence of objective setting and performance discussions.

We were told that clinical staff now received regular one to one meetings, but there was no documented evidence of this.

There was no evidence provided which showed managers had received training in providing appraisals since our last inspection.

Two staff members we spoke with told us they had not had an appraisal or a personal development plan.

A new induction checklist had been created which provided a more detailed induction programme. However, there was no clear monitoring process in place for its completion. We saw evidence that a new staff member had mandatory training signed off as completed however, their training record indicated that they had not completed any safeguarding training.

The new induction template stated that staff should be trained to level 1 and 2 safeguarding training but did not reference the requirement for clinical staff to have completed level 3 training.

There had been training days arranged for staff to attend since the last inspection examples of these were safeguarding, communication, intimate examinations and reporting document reading. Staff attendance lists were provided as evidence that staff had been trained however, attendance lists did not cover all staff who worked for the service, there were duplicated names on some lists and there were attendees listed who were not on employed staff lists provided by the service. We were not assured that records provided by the service gave them an accurate oversight of which staff had been trained.

We were not assured about the accuracy of mandatory training compliance rates provided. Compliance records for mandatory training demonstrated high compliance with rates ranging from 100% to 92%. However, records indicated total staff numbers of between 30 and 100 staff this was not reflective of the current list provided by the service which indicated that there were 41 staff in total employed at the time of our inspection.

However, we sampled five sonographer staff files and saw that competency assessments had been completed.

Consent

Inadequate

Diagnostic and screening services

Consent documentation for intimate ultrasound examinations had been updated to meet with national guidance and staff were aware of the process. However, the consent policy had not been updated since our last inspection and did not reflect the changes.

The transvaginal scan consent forms had been updated to include the recording of further details such as cleaning products, transducer serial numbers and clinical indication for the procedure. Staff were aware of consent procedures.

However, we did not see evidence that the consent policy for the service had been updated since our last inspection where we identified it referenced another organisation. The policy shown to us was dated January 2018.However, we did not see evidence that the consent policy for the service had been updated since our last inspection where we identified it referenced another organisation. The policy shown to us was dated January 2018.

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.

Learning from complaints and concerns

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

The complaints policy provided clear information about how to complain and the timescales for investigation. We were told that leaflets were available in all clinics about how to complain. We did not see evidence of this during our inspection due to the service being suspended. We were told that there was planned training for all staff with regards to the new policy.

The service had appointed a new lead for complaints. The lead had not received any training in managing complaints at the time of our inspection. The service gave us a copy of an email with a quote and proposal for the training, but there was no evidence that the training had been booked.

Complaints had been reviewed since the new manager had been in post and they were recorded in a summary log which outlined actions taken and response dates. The log demonstrated that there had been 15 complaints received by the service between 10 March and 5 July 2021. The records indicated that eleven of the records had been responded to within the 28-day response timeframe.

We saw from the complaint's summary log that the majority of complaints were categorised as staff attitudes and behaviours and poor communication. Each case had documented that the staff involved had been spoken to and that lessons learnt would be discussed at the next 'CQC meeting'. However, there was no evidence of what the lessons learnt were or any actions taken to make improvements. The 'CQC meetings' referenced were not part of the governance structure for the service and from the minutes we reviewed these were not attended by all staff and so it was not clear how lessons learnt from complaints would be shared with staff at all levels.

Inadequate

Diagnostic and screening services

We received concerns from patients about the ability to make contact with the service to raise concerns. Concerns raised with us related to attitudes and behaviours of staff, poor communication and delayed appointments.

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. They did not always understand and manage the priorities and issues the service faced. They did not always support staff to develop their skills and take on more senior roles.

Steps had been taken to strengthen the leadership team and a new structure had been recently devised. The new structure consisted of a board, a deputy chief executive officer and a senior management team consisting of an IT, finance, human resource, operations and quality/planning manager. We were told that this was to improve oversight of key areas of the service and make portfolios of work more manageable. However, given the concerns we identified during the recent inspections the clinical and regulatory compliance weaknesses had not been addressed within the new structure and there was no clinical staff member included within the new senior leadership team.

The deputy chief executive officer was a new role and we were told that it was planned for the role to be appointed to someone with a business background to focus on the business element of the service. Recruitment for this post had not yet been undertaken.

There was no evidence that managers had been provided with the relevant tools and training to support them to undertake their roles. For example, the complaints manager and the safeguarding lead had not been provided with any additional training.

The service had recruited a nurse to oversee safeguarding and infection prevention and control, however they worked for another organisation two days a week and it was not clear from their contract how many hours they would work for the service. It was not clear how they would manage a large portfolio of work across a wide geographical area working part time hours.

There had been a Pharmacist appointed for the oversight of medicines, the role did not have set hours of work and it was unclear about the requirements for this role as we were told that the endoscopy service where medicines were used had ceased and there were no immediate plans to re-start it following the suspension.

We were not assured that the required improvements had been made to the recruitment process to ensure that staff recruited to the service had the relevant checks in line with the provider's policy and that effective systems had been implemented for the process. Two staff members had been recruited in the last month, their personnel files did not contain completed Disclosure and Barring Service (DBS) checks prior to their start date. One DBS check was dated September 2020 and requested by the NHS trust they worked for, and the DBS certificate contained in the other staff members file was dated 2016. When we asked about the DBS certificate, we were later given a copy of a check of the update service which had been completed on the day of our inspection.

The two personnel files contained no evidence that staff competencies had been checked prior to recruitment and no references had been received prior to their commencement in post. There was no evidence of a recruitment processes being followed for one of the staff members. This places service users at risk of harm if they are treated by staff who have not undergone the relevant safety, skills and competency checks.

We reviewed the five personnel files that were available during the inspection, there were no references present or evidence of staff competency checks in all the files that we looked at.

The service had not implemented a robust process for the oversight of DBS checks. We were given a spreadsheet that the human resource assistant had created for CQC during the inspection but this did not cover all staff, it did not include clinical staff and indicated that there were staff who had not had a DBS check since 2016 or at all. Two staff members in managerial posts had, had DBS checks undertaken following our last visit.

Actions relating to recruitment processes and DBS checks remained amber or red on the action plan sent to us on 17 August 2021.

We requested the file for the company secretary, the service did not hold a personnel file for this staff member and there was no evidence that recruitment checks had taken place. We were provided with copies of documentation for the staff member, but this did not evidence that the recruitment processes had been followed. We were unable to clarify the role that this staff member undertook we were told they were the 'secretary.' On companies house they were recorded as the 'secretary' however, on documentation provided during the inspection said their role was 'deputy CEO'. There was a lack of assurance that fit and proper persons procedures had been correctly followed in line with Regulation 5 Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

We were told that a contract had been signed with an external company to assist in the management of HR processes and to provide better oversight and prevent gaps in files and recruitment processes occurring in the future. We reviewed the contract at the time of the inspection which was dated July 2020 and did not give us assurance that this would prevent the concerns in the future. However, following our inspection, we were told that the contract had been incorrectly dated and we were given an updated version of the contract dated July 2021.

We reviewed five appraisals and did not see evidence of objective setting or development plans to support staff to progress. Leaders delivering appraisals had not received any training to support them in providing meaningful appraisals for staff. We received concerns that staff progressed based on popularity.

The service had a whistleblowing policy which was not up to date, it stated a 'freedom to speak up guardian would be in place from 2017' and there was no reference in the policy to who this was. The policy did not provide clarity about how staff should raise concerns, there were omissions in where clinical staff should raise concerns and it referenced roles that the service did not have in place. We had concerns raised with us that staff were unable to raise concerns without fear of retribution from the leadership team. Concerns described behaviours of some leaders as "bullying" and "threatening".

Culture

Staff did not always feel respected, supported, and valued. The service did not always have an open culture where patients, their families and staff could raise concerns without fear.

We received mixed views about the culture within the organisation some staff described a positive and supportive culture. However, there were concerns about fear of retribution when raising concerns and there were descriptions of some staff being “defensive” and “resistant”.

We had some concerns raised with us about the leadership of the service with regards to attitudes and behaviours, their transparency and willingness to learn and improve.

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

There was limited evidence of learning from complaints and incidents.

We were told that the service planned to run strategy culture and leadership sessions with all staff. There was no documented evidence of these plans and they were still in the development stages.

We were told that the service wanted to become more diverse and was looking to recruit a more diverse workforce for the future.

Governance

Leaders did not operate effective and governance processes, throughout the service. Policies and procedures were not reflective of the services provided and so staff at all levels could not be clear about their roles and accountabilities.

We were not assured that there were robust governance systems and processes in place to mitigate the risks identified above. There were a number of repeated breaches found on this inspection which included but are not limited to Infection Prevention and Control (IPC), the triage process, the management of records, appraisals, safeguarding processes and recruitment checks.

We were given duplicate documents, different versions of the same documents and conflicting information throughout the inspection process. This did not demonstrate robust governance processes and clarity of information.

The service had implemented a number of new policies and updated others. Some policies overlapped and provided conflicting information for staff and a lack of clarity about their roles and responsibilities.

During the inspection staff gave us different versions of the same policy and so it was not clear which policies staff should follow. For example, the policy for duty of candour was duplicated and staff gave us both versions of the policy one was dated January 2021 and the other was dated August 2021. During our visit to the Oldham clinic we saw that the decontamination policy with a review date of July 2021 did not include the decontamination of transvaginal probes, however we were provided with a copy of the same policy at the Denton location which had the same review date of July 2021 that did include the decontamination of transvaginal probes.

Policies were still not fully reflective of the service being provided for example the infection prevention and control policy described processes for collecting blood and dealing with blood samples, semen and smear tests. It also stated that drugs are available following exposure to infection from a HIV patient. The decontamination policy referenced equipment not used by the service such as baby scales, electrocardiogram (ECG) machines, spirometry machines and peak flow meters.

The Clinical Audit Policy provided limited detail about clinical and non-clinical audits, it did not cover all the audits referenced in individual policies and did not provide assurance that there would be effective monitoring of all aspects of the service being provided.

The quality assurance policy was last updated in February 2020 and had a review date of July 2021, this had exceeded its review date and not been updated since the findings of our last inspections, where we identified it was not reflective of the service. Following our inspection, the service had updated the quality assurance policy.

Policies relating to the use of medicines had not been updated since our last inspection. There were no medicine audits that had been implemented since our last inspection. The pharmacist told us the audit planned for the service was to look at prescribing discrepancies, this was not evidenced in any documentation or in the clinical audit policy. There were no audits planned to look at the safe and secure storage and handling of medicines to include controlled drugs.

Policy signature sheets which had been introduced to demonstrate staff had read updated policies were blank.

There was limited oversight of training staff had received during the suspension period. Records in relation to staff training did not fully reflect the staff lists provided by the service. We were told that additional safeguarding training had been provided for staff, but an attendance list was not taken.

There was no evidence that changes had been made to the appraisal process or the oversight of appraisals. Appraisal reporting did not form part of the newly updated clinical governance agenda and there was no evidence that leaders had received training to facilitate appraisals.

There had been two 'CQC' meetings to review the concerns identified during the previous inspections, these took place on the 9 and 10 August 2021 and an action plan was formulated as a result. We received the action plan on 17 August 2021, it demonstrated that most actions remained amber or red and therefore did not give us assurance that a safe service would be operated when the current suspension period ended.

The registered manager for the service told us they did not feel that the service would be ready to see patients for a month or two following the current suspension end date of 25 August 2021.

The board member with a background in business turnaround identified that the service was only at the start of its improvement journey and encouraged a CQC visit in four months so that we could see implemented changes.

We were told that in line with the new leadership structure there were planned changes to meeting structures to include weekly management team meetings for emerging issues. This was currently in the development stages.

There was a planned monthly board meeting and a new board had been created. The board structure and agenda were still in the development stages at the time of our inspection and we were told by a board member that a board meeting had not yet been held.

There had been no clinical governance or staff meetings since the suspension in June 2021.

Changes had been made to the clinical governance meeting agenda to include equipment, significant events and medicines. It was not clear how this would feed into the staff meeting agendas or if they had been updated as this was not provided during the inspection and no meetings had taken place. We could not evidence any improvements to the quality of meeting records as these had not taken place during the suspension.

The service had planned a schedule of board, clinical governance and staff meetings for the next twelve months.

Managing Risks issues and performance

Leaders did not always use systems to manage performance effectively. They did not have effective risk management processes in place to identify and escalate relevant risks and issues or identified actions to reduce their impact.

We were not assured that effective risk management processes had been implemented since our last inspection or that there was good oversight of risk for the service. There was still no risk management system in place. The processes for the assessment of risk remained the same as the last inspection and there was no evidence of actions that had been implemented to mitigate risks to the service or patients.

We saw completed risk assessments which did not contain actions or had actions which were not assigned to a responsible person. We also noted that risk assessments referenced areas not applicable to the service such as canteens and lifts.

Staff and leaders were unaware of the risks to the service other than the financial risk, due to the suspension.

The newly formed board had not met at the time of our inspection. A board member had confirmed that they were unaware of the risks for the service.

We were told there were plans to implement role specific key performance indicators for staff so that they could measure individual performance. However, at the time of our inspection these had not yet been developed and it was not clear how these would fit into the provider wide key performance indicators.

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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 15 HSCA (RA) Regulations 2014 Premises and equipment

Regulated activity	Regulation
Diagnostic and screening procedures Surgical procedures Treatment of disease, disorder or injury	Regulation 19 HSCA (RA) Regulations 2014 Fit and proper persons employed

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 Surgical procedures Treatment of disease, disorder or injury	S31 Urgent suspension of a regulated activity