

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 well-led?

Inadequate



Summary of findings

Overall summary

Our rating of this service went down. We rated it as inadequate because:

- The service did not always control infection risk well. The infection control policy did not provide clear guidance for staff to follow in how to use equipment and control measures to protect patients. They did not always keep equipment and the premises visibly clean and monitoring processes were not robust.
- The design, maintenance and use of facilities, premises and equipment did not always keep people safe and there was limited evidence that staff had received appropriate training in the use of equipment. The service did not have robust systems in place for the oversight of equipment maintenance and we found equipment that posed a risk to patients' safety.
- There was not a robust process in place for the oversight of staff resuscitation training and the policies in place for staff to follow in respect of deteriorating patients were not fully reflective of the service provided. Staff used early warning scores for patient observations on the endoscopy unit, however our review of records identified mixed adherence to the completion of these.
- The service did not have robust systems and processes in place to safely prescribe, administer, record and store medicines.
- There was limited access to policies and procedures for staff and managers did not always check to make sure staff followed guidance, there were limited evidence of audits undertaken by the provider.
- The service did not always make sure that staff were competent for their roles there was limited evidence of staff competencies and required training compliance was low. Managers did not always appraise staff's work performance or hold supervision meetings with them to provide support and development.
- Patients were not always supported to make informed decisions about their care and treatment. Consent documentation did not always meet with national guidance and there was a lack of clarity about the consent process.
- Leaders did not operate effective 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,

- Staff could describe how to identify and quickly act upon patients at risk of deterioration or those with unexpected findings.
- The service provided care and treatment based on evidence-based practice.
- Staff had regular opportunities to meet, discuss the service and learn.

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 imposed conditions on the provider which prevented them from carrying out any invasive diagnostic procedures and told them that they must make improvements in relation to infection prevention and control, equipment maintenance, medicines management, staff competencies, leadership and governance and risk management systems.

Summary of findings

Our judgements about each of the main services

Service

**Diagnostic
and screening
services**

Rating

Inadequate



Summary of each main service

See the main summary above for the 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 delivers a range of services including ultrasound scanning, endoscopy procedures including sigmoidoscopy, colonoscopy and gastroscopy, audiology and physiotherapy which are regulated by CQC. 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 October 2018 and rated it as Good overall with good in each domain, there were no breaches of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 identified at the last inspection.

How we carried out this inspection

We carried out an unannounced focused inspection of the diagnostic and screening core service on the 6 to 7 and the 14 April 2021. During our inspection we visited the main location, and a sample of five satellite clinics based in Ashton Under-Lyne, Middleton, Heywood, Cheetham Hill and the mobile endoscopy unit in Bradford; because we received information that gave us concerns about the safety and quality of the services.

We looked at parts of the safe, effective and well led domains. We rated the service because we took enforcement action which included the use of our urgent enforcement powers, where we placed conditions on the locations registration in relation to infection prevention and control, equipment maintenance, medicines management, staff competencies, leadership and governance and risk management systems.

We observed care and treatment and reviewed specific documentation in ten endoscopy patient records. We reviewed medication administration records for 12 patients who had received endoscopy procedures. We interviewed key members of staff including a healthcare assistant, sonographer, nursing, medical staff and the senior management team who were responsible for leadership and oversight of the service. We spoke with 17 members of staff in total.

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

Areas for improvement

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

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

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:

Summary of this inspection

- 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 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 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)
- 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)

Action the service SHOULD take to improve:

We told the service that it should take action because it was not doing something required by a regulation, but it would be disproportionate to find a breach of the regulation overall.

- The service should ensure that the information included in the consent forms is reflective of all of the risks involved in the procedure and are written in line with national guidance. (Regulation 11)
- The service should ensure that consent is completed by the appropriate staff in line with the consent policy and implement effective monitoring processes to ensure adherence with the policy. (Regulation 11)
- The service should ensure that there is a robust system in place to ensure that there are consistent and regular checks of all resuscitation equipment and to ensure that they are safe to use prior to a clinic list. (Regulation 12)

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	Not inspected	Inadequate	Inadequate
Overall	Inadequate	Inspected but not rated	Not inspected	Not inspected	Inadequate	Inadequate

Diagnostic and screening services

Inadequate 

Safe	Inadequate 
Effective	Inspected but not rated 
Well-led	Inadequate 

Are Diagnostic and screening services safe?

Inadequate 

Our rating of safe went down. We rated it as inadequate because:

Cleanliness, infection control and hygiene

- **The service did not always control infection risk well. The infection control policy did not provide clear guidance for staff to follow in how to use equipment and control measures to protect patients. They did not always keep equipment and the premises visibly clean and monitoring processes were not robust.**
- The Infection Control and Decontamination with Handwashing policy did not provide clarity about personal protective equipment requirements for all staff in relation to COVID 19. The policy covered the equipment available for sonographer staff but it was not specific about the requirements and did not include other staff groups which the service employed such as healthcare assistants, nursing, physiotherapy and medical staff and did not specify the additional precautions for higher risk procedures such as endoscopy.
- Personal protective equipment identified in the Endoscopy Standard Operational Procedures did not provide clarity to staff about the level of protective masks they should be wearing for the different procedures and levels of risk. The document stated that staff should wear 'face mask and eye protection'. Accordingly, we were not assured that staff would know what type of personal protective equipment they should be wearing, which could lead to the transmission of COVID-19.
- We observed staff providing ultrasound scans at the Ashton clinic wore aprons and masks. We did not see that staff changed personal protective equipment between patients, the Infection Control and Decontamination with Handwashing policy stated that gloves and aprons should be changed after patient contact. During our observations we saw that staff did not wear gloves and the policy did not provide clarity about whether they were required to.
- Handwashing facilities in the clinical rooms in the Ashton clinic and on the mobile endoscopy unit in Bradford were not reflective of the handwashing facilities described in the Infection Control and Decontamination with Handwashing policy. They did not have elbow operated taps and wall mounted soap dispensers. Service users will or may be exposed to the risk of harm if infection prevention and control practices are not guided by infection prevention and control policies and procedures that are fit for purpose and are reflective of national guidance.
- There was limited documented evidence to show that cleaning had taken place. At the Ashton clinic there was a cleaning schedule on the wall for March 2021 which had been completed 1 to 9 March 2021 the remainder of the month was blank, there was no schedule for April 2021. Equipment cleaning and the cleaning of surfaces between patients was the responsibility of clinical staff, in all of the ultrasound clinics we visited there was no documented evidence that clinical staff had undertaken the appropriate cleaning of equipment. This meant that service leaders did not have oversight of staff adherence to cleaning procedures or assurance that the appropriate cleaning had taken place.

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- The cleaning schedule for the mobile endoscopy unit did not provide evidence that staff undertook appropriate cleaning of all areas. There were gaps in cleaning records including examples where staff had not cleaned general zones including floors. The cleaning schedule did not clearly identify the specific areas which required cleaning for each room and so it was unclear if cleaning had been completed.
- Staff were provided with household antibacterial wipes, clinical wipes and cleaning sprays for the cleaning of equipment and surfaces in between patients. Leaders told us that the household wipes were to be used for the cleaning of patient beds and surfaces and the clinical wipes and sprays were for the cleaning of equipment. Staff we spoke with were unclear about which products they should use. There was no clear guidance for staff about which products should be used for which areas and this was not reflected in the Infection Control and Decontamination with Handwashing policy. Service users may or will be exposed to the risk of harm by way of infection, if proper cleaning materials are not used to disinfect equipment and surfaces.
- During our inspection we observed that the environment in the Ashton clinic was visibly unclean. The walls in the clinical rooms were stained around the handwashing basin and above the clinical waste bin, there was thick dark dust on surfaces, equipment and on wires and the paint on the walls was heavily chipped.
- On the mobile endoscopy unit, we found the chrome metalwork on the patient beds in the procedure and recovery rooms to be heavily corroded, this posed an infection risk to patients.
- However, we found that the satellite clinics we visited that were hosted in GP surgeries, where the room and environmental cleaning services were provided, were visibly clean.
- We requested immediate assurance that the areas of concern that we found in the Ashton clinic were cleaned, and we received photographic evidence of this on 7 April 2021. However, there was limited assurance about actions to prevent similar recurrences in future.
- Following our inspection, the service has provided photographic evidence that the walls in the clinic room and toilet of the Ashton-Under-Lyne clinic had been re-painted.
- During our clinic visits on 6 and 7 April 2021, we spoke with nine staff in the main locations and satellite clinics who told us they could access infection control guidance via a web system. However, we observed that not all staff were unable to demonstrate this to us.
- The Infection Control and Decontamination with Handwashing policy did not fully reflect the monitoring processes in place for the service. It identified that the lead role for the auditing of the clinics sat with the 'clinical manager' and that 'matrons' undertook three monthly peer reviews of the audits. The service did not employ 'matrons' and infection control audits were undertaken by non-clinical staff. The Infection Control Lead for the service was the operations manager who was non-clinical, they told us they undertook the audits of the clinics based in the North and that the marketing team led the audits of the satellite clinics based in the South. Managers could not evidence how non-clinical staff had received the training required to undertake a clinical audit of infection control. Service users will or may be exposed to the risk of harm if infection prevention and control practices are not guided by infection prevention and control policies and procedures that are fit for purpose and are reflective of national guidance.
- During the transitional monitoring approach call held on 18 February 2021 the Registered Manager told us that infection prevention control audits for satellite locations based in GP surgeries had been suspended due to COVID-19 and the inability to access GP surgeries, due to the limits on visitors. During the inspection, we saw that clinic audits had been completed and discussed in the December 2020 and February 2021 Clinical Governance meetings.
- We reviewed the audit results discussed and observed that they did not cover all the clinics where services were provided. Some forms had missing information including the clinic location and the auditor's details. Accordingly, we could not be assured that the audits were being completed for all satellite clinics or were being completed correctly.
- Hand hygiene and clinic visit audits for December 2020 and February 2021 showed that clinics were fully compliant with the audits and there was 'no action required' each month. The audit template used to assess infection prevention and control did not provide clear guidance for staff for how to comprehensively assess cleanliness and infection prevention and control risks in clinical areas.
- Staff gave mixed responses about the frequency of the audit visits some said they were every two months others stated they were six monthly. Staff told us they did not receive feedback following the audits.

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- The infection control audit results of the clinic environment did not reflect the infection prevention control concerns that were found during the inspection at the Ashton-Under-Lyne clinic. An example of this was the audit completed on 2 March 2021 at the Ashton- Under-Lyne clinic, answered 'yes' to the consultation/examination rooms being 'clean, in good decorative condition and free from clutter and inappropriate items' and 'yes' to the areas 'walls, floor, ceiling, furniture, fixtures and fittings e.g. flooring, light fittings, chairs, desk, couches, curtains, blinds, handwashing facilities are in a good condition, clean and free from stains'. However in these rooms we found issues which included the paint on the walls to be heavily chipped, stained walls around the handwashing basin and above the clinical waste bin, the top of the examination couch to be loose and thick dark dust on surfaces, equipment and on wires and plugs. Senior managers told us that they did not always carry out a close inspection of the environment due to patients being in the room at the time of the audit. Accordingly, we could not be assured that the audits were serving their purpose to pick up on infection, prevention and control issues identified, thereby exposing service users to potential harm.
- Endoscopes were decontaminated on the endoscopy unit in a dedicated decontamination room. There was a bar code scanner so that individual scopes could be traced back to patients if appropriate. We saw traceability records for patients with the barcodes, the patients name, diagnostic procedure and date of procedure. There was a flexible endoscope decontamination timeline as part of the organisational policy and there were posters on the wall in the decontamination room with flow charts for decontamination. There was a dedicated member of staff who undertook the decontamination process who had received the required training.
- We were not assured that the service had the appropriate oversight of infection prevention and control policies, measures and audit and therefore there is a risk to service users.

Environment and equipment

- **The design, maintenance and use of facilities, premises and equipment did not always keep people safe and there was limited evidence that staff had received appropriate training in the use of equipment. The service did not have robust systems in place for the oversight of equipment maintenance and we found equipment that posed a risk to patient safety.**
- Services were provided in the providers clinic buildings, GP surgeries and in a mobile endoscopy unit.
- The clinic owned by the service which was based in Ashton under Lyne provided a waiting area with wipeable seating and two examination rooms. Hand washing facilities were provided in the examination rooms; however, it did not meet with the requirements of the facilities set out in the infection prevention and control policy for the service. The decoration in clinical rooms showed signs of wear and there were some chairs for patients and staff that were damaged.
- The facilities in GP surgeries were provided by the host surgery this included use of waiting areas and clinic rooms, in these satellite clinics the service used their own ultrasound machine and laptops, all the other equipment in these rooms was owned and managed by the host service.
- The endoscopy unit was a purpose built mobile unit which was located in the grounds of a GP surgery, the service had access to a waiting area and consultation rooms within the surgery for the consultation and consent process. The mobile unit for procedures was compact, with a small waiting area at the entrance. The mobile unit provided a changing room which was also the recovery room; a toilet; and a treatment room and decontamination area for the decontamination of flexible endoscopes. There was an emergency evacuation door near the unit entrance, with an evacuation chair available. However, the unit was accessed by steps and was not suitable for patients with mobility needs. The hand washing facilities in the procedure room did not meet the requirements set out in the infection prevention and control policy for the service.
- The service was not accredited by the Joint Advisory Group on Gastrointestinal Endoscopy (JAG), however the leadership team told us that they were working towards this.
- During our inspection of the Ashton Under Lyne clinic, we found unsafe equipment, equipment which had exceeded its re-test date and electrical equipment which had not been safety tested. We observed a patient examination couch was

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not safe to use, as the top of the couch was detached from the frame, and there was no indication that the two patient couches had been safety tested. There was a patient hoist which had exceeded the safety retest date, it had last been tested in September 2014 and had a label to indicate it was due to be re-tested in September 2016. As a result, service users were at risk of harm should the equipment fail.

- At the Ashton clinic there were two pieces of electrical equipment which had exceeded their electrical re-test dates, these were a portable air-conditioning unit which should have been re-tested in August 2016 and heater which indicated it required re-testing in 2009. There were four other pieces of electrical equipment which did not contain labels to indicate they had been safety tested.
- The manager with responsibility for the oversight of electrical testing, confirmed that electrical equipment should be safety tested annually but advised this had not been done since 2019. The service was unable to provide evidence that electrical equipment had been tested in 2019. Service users may or will be exposed to the risk of harm, if a service does not ensure electrical equipment is tested or have procedures to ensure they are routinely tested.
- The service had 27 ultrasound machines in total. There was a maintenance contract in place for medical equipment servicing.
- The asset register was held and overseen by the company who held the contract. Managers could not provide evidence of an effective system for ensuring their oversight of equipment maintenance and had not maintained accurate records of when all equipment was last checked or due to be checked.
- Eleven of the ultrasound scanning machines had been recently purchased and we were provided with a copy of the five-year warranty for this equipment, however the warranty stated servicing was not included. The manager with responsibility over equipment maintenance stated the company they purchased the equipment from had included servicing in the warranty via a verbal agreement, but there was no documentation to support this.
- In the clinics we visited, we found that most of the ultrasound scanning machines had been recently serviced and were within their re-test date. There was one machine which did not contain a label to indicate when it was last serviced, staff told us that the piece of equipment was new.
- We saw that staff were decanting ultrasound scanning gel from a large bottle at the Middleton clinic, the bottle they were using did not have an expiry date on it and staff were unaware of what this was, there was a risk that staff were using out of date gel.
- During our visit to the mobile endoscopy unit we looked at the medical and electrical equipment including diagnostic equipment for the procedures and a diathermy unit. There were service dates on the equipment, and they had been recently serviced and were within their re-test dates. However, we found that the two patient beds had corrosion on the chrome metal work, senior leaders were not made aware of the damage to the beds prior to visiting the unit.
- Staff in the satellite clinics we visited, were aware of how to raise a concern with equipment. Staff told us that the manager with responsibility of equipment maintenance was responsive in organising replacement machines and equipment maintenance as necessary.
- Resuscitation equipment was not provided by the service in the private clinics and satellite clinics in GP surgeries. We saw that the private clinics had first aid kits available for staff to use.
- During our checks of the first aid kit in the Ashton Under Lyne clinic, we found out of date items including Lewis pads that expired in January 2020, hand sanitiser that had expired in November 2020, low adherent dressing pads which expired in March 2021 and a cool pack for a cold compress that expired in July 2020. Staff told us that there was not a process in place for the checking the items in the first aid kit.
- The mobile endoscopy unit had two resuscitation trolleys, one in the procedure room and one in the recovery room. Both trolleys were padlocked at the time of our visit, we were told that this was the case when the unit was not in use. There was suction available and an automated external defibrillator on top of the trolley in the recovery area. The trolleys contained a range of sundries and emergency medicines which may be required in the event of an emergency. We sampled items within the two trolleys which were found to be intact and in date.
- There was a weekly checklist for the resuscitation trolley which included the expiry dates of everything on the trolley. We did not see evidence that there were separate checklists for each trolley. At the time of our inspection there was one checklist on the trolley in the recovery area which was dated 1 March 2021. We asked if we could see checklists for

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other dates, we were given checklists which demonstrated that the weekly checks had taken place from 26 January to the 1 March 2021. There was no evidence that the checks had taken place following this and we were aware that the service was seeing patients up until the end of a contract on 31 March 2021. The registered manager told us that it was the responsibility of the endoscopy nurse to check the trolleys at the start of each day, there was no evidence that daily checks had taken place.

- We were told that the clinical lead for the endoscopy service audited the completion of the resuscitation trolley checks. The clinical lead did not reference such audit when explaining the audits, they were responsible for and we did not see documented evidence of such audit being reviewed in the endoscopy clinical governance meeting minutes provided for 2020 and 2021.
- The service had eight endoscopy scopes; these were not on the site at the time of the inspection and had been taken for safe storage as the unit was not currently undertaking procedures. There was a decontamination room for the scopes at the end of the unit. This contained two stainless steel sinks and two washers for the scopes. There was a bar code scanner so that individual scopes could be traced back to patients if appropriate.
- We saw water testing records for water contaminants, and these had been completed by the manufacturer of the equipment for washing the scopes. We saw that there were cycle printouts for the washer which showed that the washer was working effectively.
- There was evidence of training for an individual for the decontamination of scopes.
- Sonographer training competency assessments included the use of the ultrasound equipment. The service was able to provide evidence of three completed sonographer staff competencies in total out of the 89 staff members they had on the system, assessments demonstrated that equipment training had been completed for these staff members. However, it was not clear how many staff had been trained in the use of equipment as the service was unable to provide evidence of staff competencies for the remaining staff.
- The review of endoscopy nurse competencies demonstrated that equipment training was not included. It was unclear what training endoscopy staff had received in the use of equipment on the unit.
- Clinical waste bins were not available in the Ashton Under Lyne clinic, however we saw that these were available in the other clinics we visited including the mobile endoscopy unit.
- There were sharps bins available on the mobile endoscopy unit that had not been overly filled.

Assessing and responding to patient risk

- **Staff could describe how to identify and quickly act upon patients at risk of deterioration or those with unexpected findings. However, there was not a robust process in place for the oversight of staff resuscitation training and the policies in place for staff to follow in respect of deteriorating patients were not fully reflective of the service provided. Staff used early warning scores for patient observations on the endoscopy unit, however our review of records identified mixed adherence to the completion of these.**
- The policy in place for staff to follow with regards to deteriorating patients was not fully reflective of the service and did not specify the processes to follow for the different staff groups and areas of the service, such as sonographer staff in private clinics, those in GP surgeries and the endoscopy staff in the mobile endoscopy unit.
- The Management of the Deteriorating Patient Escalation policy stated “Capture clinical data on mobile devices e.g. iPod Touches, in real-time at the point of care”, “Analyses and charts the observational data which can be accessed via the hospital intranet (on PCs), tablet, PCs and other mobile devices” and “Patients will have their observations and a NEWS score recorded prior to transfer from one clinical area to another and clearly recorded on the observation Medium and the Transfer Form. Once the patient has arrived on the new ward the observations will be recorded again on the form NEWS Medium”. Patient records for the endoscopy unit were paper based and we saw that patient observations were recorded as ‘MEWs’ scores, additionally the unit did not have access to wards or an “observation medium”.

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- The senior leadership team told us that staff followed an emergency procedure for patient's health who was deteriorating which included calling 999 for medical emergencies or accessing the GPs in clinics held within GP surgeries. There was no documented evidence of this in the deteriorating patient and escalation policy.
- Staff gave conflicting accounts of what to do in the event of a medical emergency one member of staff showed us an incident form they would complete, some stated they would dial 999 and others stated they would use the GP internal emergency number. Staff were unable to access policies for managing medical emergencies in the clinics we visited.
- Staff received training in basic life support, this included staff working on the endoscopy unit. We saw that training compliance for sonographer staff for adult basic life support was 80%. We reviewed the training records for three endoscopists and nine nurses who worked on the endoscopy unit we saw that the three endoscopists had up to date training. However, three out of the nine nurses had records which indicated their training had expired one had expired in May 2019, one in October 2019 and one in January 2020.
- There was not a robust process in place for the monitoring of staff's compliance with mandatory training such as basic life support. Staff competencies were held in different places dependent on their staff group. Sonographer training compliance was recorded on an electronic system which was overseen by the human resource manager, nursing, medical and physiotherapy staff training was not recorded as part of this system. The senior leadership team were unable to easily access competencies for these staff. The leadership team confirmed that mandatory training compliance was not reported and overseen as part of the clinical governance meetings.
- The service performed ultrasound scans for non-urgent NHS patients who were referred to the service mainly from GPs. We were told that the service did not provide scans for pregnant women or children. There was an agreed inclusion and exclusion criteria which had been agreed with the commissioners of the service. GP's were required to complete a request form which included patient details, clinical symptoms and whether the patient had a disability. The clinical staff had to complete the justification question based on the information provided. The pathway protocol stated that all referrals required triage by a clinical lead.
- There were care pathway protocols in place for staff to follow in the event of unexpected or urgent findings on an ultrasound scan. Staff were aware of the process and explained that they could put a flag on the electronic record which enabled the GP to prioritise the review of the record. Patients requiring urgent referral to the hospital for unexpected findings could have the images shared electronically with the hospital.
- The endoscopy service had an exclusion criteria, there was a lack of clarity about what this was, we were told that this included patients who were pregnant, those with a learning difficulty or those with mobility issues. These patients were referred to the hospital service. We reviewed the exclusion criteria on the leaflet provided by the service and saw that it did not cover the exclusions above but did cover the exclusion of acute symptoms which would require a two week pathway referral such as *"Rectal bleeding and change in bowel habit >40, rectal bleeding, no change in bowel habit >60, change in bowel habit >60, iron deficient anaemia of <HB11 in men or <HB10 in post-menopausal women, rectal mass, abdominal mass"*.
- Patients completed health questionnaires prior to their endoscopy procedure which covered past medical history, allergies and medication. Nursing assessments were completed prior to the procedure which looked at mobility, allergies and possible risk factors.
- Patients who had diabetes were prioritised for their endoscopy procedure and the service tried to give them the first appointments of the day. Women who had previously had gynaecological surgery were usually allocated a slot before the lunch break or at the end of the list as these patients' procedures could take longer.
- Patient attending for procedures were tested for COVID-19 using lateral flow tests 30 minutes prior to their procedure. We saw evidence that these had been completed in the records we reviewed.
- The service used World Health Organisation (WHO) safety checklist as part of each patient's procedure, this was to ensure that specific safety checks had been undertaken and equipment and samples were accounted for prior to and following the procedure. Our review of the World Health Organisation safety checklist noted that there were some pieces of equipment which was not covered such as the diathermy which should be communicated with all staff.

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- We looked at the completed World Health Organisation (WHO) safety checklists for ten patients. We found four which had not been fully completed this included missing information for specimens which had been removed during the procedures and the sign-out section being incomplete. The service did not audit the completion of the World Health Organisation (WHO) safety checklists. There was a risk that the important safety checks had not been completed and so could pose a risk of harm to patients.
- The service was using an early warning scoring system for patient observations during endoscopy procedures. The procedure documentation prompted staff to record observations and calculate early warning scores in the perioperative phase of the procedure. The recovery documentation prompted the documentation of observations of oxygen, pulse and pain score but not the calculation of early warning scores. The deteriorating patient and escalation policy did not provide clear guidance for staff to follow in the escalation of early warning scores.
- We reviewed ten patient records and saw that for four of the patients early warning scores had not been calculated and documented. We saw that the observations were documented but the score was not calculated, this was a concern because the score highlights to staff if the patient is deteriorating or at risk of deteriorating and prompts them to take action in escalating the patient for review.
- The service did not undertake audits of documentation and so could not be assured that observations and early warning scores were being documented appropriately or improvements made when required.
- Following the procedure patients were provided with information and contact numbers, in case they had any problems or complications. There was a number for working hours and one for out of hours. Calls to the numbers were triaged by administration staff who would contact the consultant if needed. We were told that the consultant who had performed the procedure would be contacted and that there were no concerns with access to the consultants to obtain advice and support for patients.
- Patients received endoscopy follow up via a telephone consultation. The service tried to ensure that the consultant who had performed the procedure undertook the follow up call.
- There was a follow up process in place for patients who did not attend their appointments, there were three contacts prior to patients being discharged back to the care of the GP. The follow up process was detailed in the care pathway protocol.

Medicines

- **The service did not have robust systems and processes in place to safely prescribe, administer, record and store medicines.**
- Medicines were used and stored by the endoscopy service only.
- The Medicines Policy did not reflect the way that medicines were managed by the service. The Medicines policy referenced 'trust', 'wards' and 'the practice' throughout the document which did not match the services provided. The medicines policy did not clearly identify staff roles and responsibilities in relation to the supply, ordering, storage, dispensing, preparation, administration, disposal, recording and monitoring of medication.
- The controlled drugs policy was not reflective of how the service managed controlled drugs. It referenced staff that the service did not have, such as 'Chief Pharmacist' a 'Controlled Drug Accountable Officer' and 'Pharmacy teams'. The registered manager confirmed that the service did not have these members of staff. As a result, it was not clear who would be responsible for actions assigned to those persons.
- We were told that the clinical lead for the endoscopy service, who was a locum consultant held responsibility for the oversight and management of controlled drugs. This was not reflected in any policies or documentation. Patients may or will be exposed to the risk of harm if it is not clear in policies, which members of staff are responsible for certain actions.
- There was a non-clinical medicine lead for the service, however they were not aware that there was a controlled drug standard operating procedure.

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- Senior leaders were unable to evidence monitoring processes and audit results in relation to the management of medicines, including controlled drugs in line with the processes detailed in the provider's Medicine and Controlled Drug policies. Endoscopy Clinical Governance meetings for February 2020 and January 2021 did not evidence that discussions were held in relation to the management of medicines.
- Managers described practices related to the ordering and disposal of controlled drugs which were not in line with the provider's controlled drugs policy. For example, the processes for ordering controlled as stock and for named patients was not in line with the controlled drugs policy. We were told that controlled drugs were disposed of by an external company however this was not reflected in the controlled drugs policy.
- It was stated that medicines were prescribed and ordered for named patients, however the service had obtained stock, controlled drugs whilst they had a contract with a local NHS hospital due to the increased demand and number of patients being seen. Even though the contract had ceased at the time of our inspection the service was still holding stock, controlled drugs.
- Managers have not ensured that the service has appropriate licenses required in relation to holding stock, controlled drugs. We requested evidence of Home Office Licenses on 12 April 2021. As of 19 April 2020, managers had not provided CQC with evidence of licenses or appropriate exemptions.
- The controlled drugs cupboard was located on the outside wall of the mobile endoscopy unit and did not meet with the required standards for the storage of controlled drugs. This Increased the risk of unauthorised access to controlled drugs.
- However, during our inspection we found that the cupboard was locked and there was a book for signing the medicines out which had been completed. We were told that there were regular audits of the controlled drug book, however we did not see any evidence of this. Leaders confirmed the audits undertaken by the service did not cover controlled drugs.
- Reversal agents for sedation were held as stock on the unit.
- Medicines were prescribed from a pre-printed sheet in the endoscopy documentation records and the dose was handwritten by the endoscopist.
- We reviewed 12 medication administration records for patients. We found that out of the twelve records nine had missing information, these were mostly the signature of the prescriber, but we also found that the strength of the dose given was not always documented for example whether it was milligrams or micrograms. It was therefore unclear who had prescribed the medication and what dose patients had received. The service did not undertake audits of the completion of documentation or medication administration records.

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 evidence-based practice. However, we found that there was limited access to policies and procedures for staff and managers did not always check to make sure staff followed guidance, there were limited evidence of audits undertaken by the provider.**
- The endoscopy service provided patients with health questionnaires to complete prior to their procedure which took account of their past medical history, current medications, allergy status and family medical history. Our review of patient records confirmed that these were fully complete for all of the records we looked at.
- 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.

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- There were monthly discrepancy meetings which sonographer staff attended, these looked at learning opportunities identified as part of the audits. We reviewed the meeting information from 14 February 2021. We saw that the meeting covered a review of ten case studies, these provided details of the concerns identified and highlighted learning points for staff. The actions covered were to read policies, scan carefully and update knowledge on guidelines. Staff were positive about the process and found these useful.
- Staff stated that they kept up to date with guidance and best practice through their professional body and through the company.
- Our review of policies and procedures saw that they referenced evidence based care and practice and national and professional standards. The service had a quality assurance policy, which detailed the clinical quality committee standard agenda this included a "review of patient safety alerts, NPSA, MHRA, CAS alerts, NICE guidance, PALS issues and national reports". The policy also outlined that staff clinical meetings would look at protocols, pathways and performance. Our review of staff meeting minutes saw that there was limited information included in relation to a review of protocols, pathways and performance and so it was unclear what information was discussed with staff in relation to these.
- Whilst we saw evidence that policies and procedures referenced national and professional guidance, we saw that they were not always fully reflective of how the service delivered care and treatment. We found that the ultrasound procedure had exceeded its review date which was November 2020, the policy also referenced 'guidelines for professional ultrasound practice revision 3 2018' Following a review of the national guidelines we saw there was an update in December 2019 which is referenced as 'revision 4'.
- The service had an Endoscopy Standard Operating Procedure which covered all aspects of the service including staff training, referrals, procedure processes such as the maximum size of polyp that could be removed on the unit and monitoring processes for the procedure. We saw that the policy referenced a range of national guidance and best practice documents. However, the policy was not fully reflective of how the service operated and monitoring processes referenced in the policy were not in line with what leaders had told us were in place.
- We saw that National Institute of Health and Care Excellence (NICE), Central Alerting System (CAS) alerts and policy updates were standing agenda items on the monthly clinical governance meeting minutes. We looked at the minutes covering December 2020 to February 2021 and saw that there had been "no updates" recorded for these items and so there was limited information recorded about what they had looked at in regard to standards updates.
- The endoscopy service was working towards achieving Joint Advisory Group (JAG) accreditation at the time of the inspection and as such was reviewing policies, procedures, pathways and systems and processes to align to the JAG standards. We saw that this was discussed as part of the endoscopy clinical governance committee meeting minutes recorded for February 2020 and January 2021. The service had invested in a new reporting system so that they could submit the required data to JAG.
- Staff were unable to demonstrate that they had access to policies and procedures for the service. We were told that they were available on a web-based system, but staff could not demonstrate an ability to access these. Staff we spoke with who were on induction stated that policies were emailed to them when they started with the service, but when we asked, they could not evidence this. There was a risk that staff were unable to access important policies and procedures to ensure that they undertook their role in accordance with the required standards.
- The service did not have a formal standard audit programme for the service. It was stated that their main audits were based on the requirements of the different commissioning groups to whom they provided services and so would be different in different areas. The services core audits were the clinic audit visits, hand hygiene, compliments and complaints and sonographer audits. We saw a sample of completed clinic audit visits and hand hygiene audits, and the discrepancy meeting minutes which sampled case studies from sonographer audits, we did not see evidence of complements and complaints audits. There was no evidence of action plans or areas for improvement identified and discussed as a result of the audit results.

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- There were annual sonographer audits which were undertaken by the lead sonographer for the company who covered all staff across the service and regions. These audits were an assessment of sonographer staff competence. We were told that staff were invited to the Ashton clinic for the observations. We requested evidence of the annual competency audits which could not be provided.
- The endoscopy service stated they carried out audits of comfort scores, three monthly consultant audits, decontamination audit 2020, KPI audits for consultant's performance, infection prevention and control audits and complaints. We saw that these were referenced as part of the endoscopy clinical governance meetings, however the service did not provide evidence of the audit results during our inspection.
- During our review of endoscopy patient records we found incomplete documentation in pathway and specimen documentation and there was no evidence of the information that patients received following their procedure which detailed what had happened. We found incomplete phlebitis pathway documentation for two out of the ten patients and three patients with incomplete specimen documentation. There was a risk that staff were not following the appropriate pathways. There were no monitoring processes in place for the completion of documentation and so there was a risk that issues with staff adherence to pathways and protocols would not be identified.
- Our review of patient records we found no evidence that the patients were given a copy of the endoscopy report following their procedure, and there were no endoscopy reports provided as part of our request for patient records. The only exception was a hand-written record of the procedure that had taken place, but this did not provide sufficient information for patient communication.

Competent staff

- **The service did not always make sure that staff were competent for their roles there was limited evidence of staff competencies and required training compliance was low. Managers did not always appraise staff's work performance or hold supervision meetings with them to provide support and development.**
- Managers told us that they did not discuss mandatory training or appraisals compliance in clinical governance meetings. The overall average compliance rate for mandatory training was 68%.
- Staff appraisal information showed that 54 out of 89 members of staff, had not had an appraisal in the last 12 months. Records demonstrated of these there were two members of staff who joined the company in 2017, one who joined in 2016 and three who joined in 2015 who had not had an appraisal recorded.
- We were told by the human resource manager that the process for checking staff had up to date professional registration was part of the appraisal process. As a result, we were not assured that there was a consistent approach across the different locations and satellites; neither were we assured that each location and satellite took the same approach to dealing with supervision, appraisals and mandatory training. Service users may or will be exposed to the risk of harm if the service does not have oversight over mandatory training to ensure it is being completed, or supervision and appraisals to ensure staff are receiving the training and support they need along with ensuring up to date professional registration.
- There was no oversight of training competencies for all staff. On 7 April we requested to see staff competencies for sonographers, physiotherapy and locum nursing staff. The Human Resource manager was unable to provide evidence of these. The sample of sonographer competency assessments that were provided were dated 2015/2016. There was no evidence of the annual assessments that were referenced in the quality assurance policy and those described by the registered manager.
- The human resource manager did not have oversight of endoscopy staff competencies and advised that endoscopy nursing staff did not complete competency assessments as they were employed as locum staff and deemed competent from their permanent roles.
- When we visited the endoscopy unit on 14 April 2021, we were provided with the competency assessments for six members of nursing staff. Staffing information for the endoscopy unit demonstrated there were eight nurses who worked on the unit. Two of the competency booklets contained the logo of a different company and all referenced

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another company in the information, it was not clear if the assessments were reflective of the role nurses undertook on the unit. Our review of personnel files for the nursing staff contained gaps in mandatory training, evidence of DBS checks and references from previous employers. We were not assured that staff providing endoscopy services had the necessary competencies or were being regularly assessed to ensure they were up to date with training developments.

- Documentation sent by the provider on Friday 16 April 2021, showed there were three consultants providing endoscopy services. We requested copies of the three personnel files, and we received two. We reviewed these personnel files, they did not contain any references from previous employers, there were no current contract of employment; the most recent contract was dated November 2018 and specified it was for one year only. There were gaps in mandatory training and no evidence of up to date appraisals.

Consent

- **Patients were not always supported to make informed decisions about their care and treatment. Consent documentation did not always meet with national guidance and there was a lack of clarity about the consent process.**
- There was a lack of clarity about the consent process. The process described by staff did not meet with the consent policy. We were told that the consultant would always undertake consent, however the consent documentation stated that this would be completed by the lead nurse.
- The consent policy referenced another organisation throughout and so it was not clear if it reflected the process for the service. The policy stated that the nurse could undertake the consent process if they had been trained and signed off as competent by the consultant. Leaders were unable to provide evidence of these competencies and confirmed that there was no training for consent for nursing staff on the unit, and staff were deemed competent due to their substantive roles in other organisations. The clinical lead for the endoscopy service confirmed that it was a consultant's responsibility to take consent from patients.
- Our review of ten endoscopy patient records found that two consent forms had been signed by nurses with no evidence of a consultant signature and one form contained no health professional signature which was not in line with the policy for the service. There were no concerns identified with the completion of the remaining seven consent forms.
- The information included in the consent forms for the service were not fully reflective of all of the risks involved in the procedure and were not written in line with national guidance. For example, in the typed consent for colonoscopy it didn't include risk of death, risk of perforation and bleeding in numerical form, such as 1:1000.
- However, the service did follow a two stage consent process in line with national guidance when completed.

Are Diagnostic and screening services well-led?

Inadequate 

Our rating of well-led went down. We rated it as inadequate because:

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. However, Staff had regular opportunities to meet, discuss and learn from the service.**

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- There were monthly clinical governance meetings held for the service. The meeting did not cover a review of all of the services provided such as endoscopy and physiotherapy as these were not included. We reviewed the minutes dated 14 December 2020, 15 January and 18 February 2021 which showed limited documented evidence of discussions of key agenda items.
- There were separate clinical governance meetings held for the endoscopy service and there was no evidence to show that these fed into the main clinical governance meetings for the provider and leaders confirmed this did not happen. The meetings were not held regularly, and our review of the meeting minutes showed that there had only been two meetings since February 2020. The meeting agendas were not standardised across the two meetings and so there was not a consistent review across both services, for example national guidance and safety alerts were not standing agenda items on the endoscopy clinical governance meetings.
- The clinical governance meeting minutes for December 2020 and February 2021 noted that hand hygiene and infection prevention control audits were received and discussed each month, however records showed '*no action required*' each month. This did not correspond to the infection prevention control concerns that were found during the inspection at the Ashton-Under-Lyne clinic. As a result, we could not be assured that there was appropriate oversight of the service, as key issues were not be discussed in proper detail at these governance meetings.
- The key performance indicator report monitored local quality requirements for each Clinical Commissioning Group for the ultrasound service. The service did not monitor key performance indicators at 'provider-wide' level. There was limited evidence that these had been discussed and considered as part of the clinical governance meeting minutes we reviewed.
- There was not a robust system in place for the oversight of mandatory training and appraisal compliance. We saw poor compliance with mandatory training and appraisal requirements. We identified that there were three sonographer staff had worked in the organisation for six years and not had one annual appraisal.
- We were told by the human resource manager that the process for checking staff had up to date professional registration was part of the appraisal process. We saw that appraisal data held for staff demonstrated a low compliance with 54 out of 89 members of staff having had an appraisal in the last 12 months, there was no process in place for monitoring compliance with professional registrations outside of the appraisal process.
- As a result, we were not assured that there was a consistent approach across the different locations and satellites; neither were we assured that each location and satellite took the same approach to dealing with supervision, appraisals and mandatory training. Service users may or will be exposed to the risk of harm if a service does not have oversight over mandatory training to ensure it is being completed, or supervision and appraisals to ensure staff are receiving the training and support they need along with up to date professional registration.
- Policies and procedures were not fully reflective of the service provided. We reviewed a range of policies and procedures and found that they had been taken from other organisations but had not been fully adapted to reflect the service and so it was not clear what staff roles and responsibilities were in relation to the procedures.
- For example the policy for Infection Control and Decontamination with Handwashing, Controlled Drugs, Medicines and Management of a Deteriorating Patient Escalation policy referenced 'wards', staff and practices which were not applicable to the service, for example: The Management of the Deteriorating Patient Escalation policy stated '*Capture clinical data on mobile devices e.g. iPod Touches, in real-time at the point of care*', '*Analyses and charts the observational data which can be accessed via the hospital intranet (on PCs), tablet PCs and other mobile devices*' and '*Patients will have their observations and a NEWS score recorded prior to transfer from one clinical area to another and clearly recorded on the observation Medium and the Transfer Form. Once the patient has arrived on the new ward the observations will be recorded again on the form NEWS Medium*'; Patient records for the endoscopy unit were paper based and we saw that patient observations were recorded as 'MEWs' scores, additionally the unit did not have access to wards.
- The Controlled Drugs Policy stated that the '*implementation and monitoring of this policy and associated Controlled Drug Standard Operating Procedures will be via the Medicines Management/ Pharmacy teams*' the Registered Manager confirmed that the provider does not employ Pharmacy staff.

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- There was limited assurance that recruitment processes were being followed. There was a recruitment policy in place for the service, which detailed the required recruitment checks. However, the policy did not cover the overseas recruitment programme or the requirements for agency staff.
- Our review of the recruitment files for the endoscopy service there was an inconsistent approach to the information held which was not reflective of the requirements set out in the recruitment policy. For example, we reviewed personnel files, for the consultant endoscopists and found they did not contain any references from previous employers, there were no current contract of employment; the most recent contract was dated November 2018 and specified it was for one year only. There were gaps in mandatory training and no evidence of up to date appraisals. We were not assured that the provider had systems and processes in place to ensure that staff met the requirements of the relevant professional body throughout their employment. We were not assured that staff providing endoscopy services had the necessary competencies or were being regularly assessed to ensure they were up to date with training developments.
- There was not a robust system in place for the monitoring and oversight of equipment maintenance. The service had a contract in place with an external company for the maintenance of clinical equipment. Asset registers for all equipment was held by the external company, the manager with responsibility for equipment had no oversight of the asset register and so was unaware of the servicing was carried out within the required dates. There was no forum where equipment maintenance was discussed with the senior leadership team. We found electrical equipment which had not received safety testing or was outside of its re-test date during our inspection. There was a risk to staff and patients if equipment was not safe to use.
- Ultrasound staff told us they attended quarterly team meetings at the main headquarters where they said they discussed incidents, complaints and changes to working practices. Staff stated that they did not receive minutes following the meetings.
- We requested meeting minutes covering the last three months and were provided with those from February 2021. We saw that they included patient satisfaction information, reporting key performance indicator compliance, personal protective equipment reminders and a discussion about the content of reports. However, it was not clear from the minutes what was discussed in relation to patient satisfaction information and there was no evidence that incidents had been discussed or were a standard agenda item. The information included in the minutes did not provide clarity about the content of the discussions for staff who may not have been present during the meeting and there was no record of which staff members had not attended.

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.**
- The key performance indicator report monitored local quality requirements for each Clinical Commissioning Group. The service did not monitor key performance indicators at 'provider-wide' level. The key performance indicator report did not provide evidence that managers had oversight at provider level of compliance with staff supervision, and appraisal rates.
- The service had not taken action to address data quality issues in mandatory training, it was acknowledged that the system did not give compliance rates for 'required' mandatory training but provided it across all training some of which was deemed 'not required' for individuals roles. The leadership team could not use the data to identify compliance issues with the training that was identified as 'required' and therefore did not have clear oversight of staff's overall compliance rates.
- The monitoring processes in place were not effective in identifying areas of risk, concern or poor performance that we identified during the inspection. For example, the audits for infection prevention and control had not been effective in

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identifying non-compliance with the policy and environmental issues that we observed, oversight of mandatory training and appraisals had not identified areas of non-compliance; including the average mandatory training rate of 68% and that 54 out of 89 members of staff had not had an appraisal in the last 12 months with three staff members who had not received an appraisal since joining the service in 2015

- There was no oversight of audits or monitoring in relation to the endoscopy unit in the providers clinical governance meetings. The endoscopy clinical governance meeting minutes for February 2020 and January 2021 did not provide evidence of the clinical audit results or a review of all of the audits undertaken described by the service leads.
- The risk register did not provide detail of key risks, and, or the mitigation and controls established to safely manage organisational risk. Managers told us the risk register was reviewed annually, however there was no evidence to support this.
- Managers had not undertaken appropriate risk assessments of the endoscopy unit. The risk assessment provided dated 20 September 2020 did not clearly identify the risks to staff and patients associated with endoscopy procedures and COVID 19. Where some risks were identified there was no evidence of mitigating actions in place.

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	S31 Urgent variation of a condition