Cobalt Health

The Institute of Translational Medicine

Inspection report

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

Ratings

Overall rating for this location	Requires Improvement
Are services safe?	Requires Improvement
Are services effective?	Inspected but not rated
Are services caring?	Good
Are services responsive to people's needs?	Good
Are services well-led?	Requires Improvement

Summary of findings

Overall summary

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

- The service did not always have enough staff with the right skills and experience on shift to care for patients and keep them safe. Staff did not consistently assess risks to patients.
- Some safety standards, including oversight and practice, were lacking, including for fire prevention, safeguarding, and magnetic field safety.
- The provider was not assured of the effectiveness of care and did not assess standards against national best practice guidance.
- Leadership was inconsistent and staff were unclear about their roles and responsibilities. There was a lack of coordination in the unit and governance, risk management, and performance processes did not provide assurance of effectiveness.
- The provider did not facilitate access to local rules and other critical safety information for all staff responsible for scanning.

However:

- Staff had training in key skills, but it was not evident they always used them appropriately. The service controlled infection risk well. The service managed safety incidents well and learned lessons from them.
- Staff treated patients with compassion and kindness, respected their privacy and dignity, took account of their individual needs, and helped them understand their conditions. They provided emotional support to patients, families and carers.
- The service planned care to meet the needs of local people, took account of patients' individual needs, and made it easy for people to give feedback.
- Staff felt respected, supported and valued. They were focused on the needs of patients receiving care.

Summary of findings

Our judgements about each of the main services

Service	Rating	Summary of each main service
Diagnostic and screening services	Requires Improvement 	We rated this service requires improvement. Please see the main summary for details.

Summary of findings

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Summary of this inspection

Background to The Institute of Translational Medicine

The Institute of Translational Medicine, also known as ITM Imaging Centre, is operated by Cobalt Health as charitable organisation. It is an independent health provider delivering magnetic resonance imaging (MRI) scans for an NHS acute trust. It is in a separate pre-fabricated building on the site of a hospital.

The service provides MRI scans to adult patients from 8am to 8pm, seven days a week. The booking team at the NHS trust book MRI Scans for patients at the centre.

The centre is registered to provide the following regulated activities:

- Diagnostic and screening procedures

The head of MRI is the registered manager (RM) and has been in post since July 2021. . The RM is based substantively at another site and fulfils multiple roles for the provider whilst they recruit permanently to a local manager role.

The unit is part of a wider research network, which is outside of our scope of regulation. Research scans and provision were therefore excluded from our inspection.

We last inspected this service in January 2019 and rated it good in each domain and good overall. We did not issue any requirement notices.

In the previous 12 months the team carried out 5325 MRI scans.

How we carried out this inspection

We carried out an unannounced inspection of the unit on 8 June 2022, led by a CQC inspector with support from a radiography specialist advisor.

To reach our ratings we spoke with a range of clinical and non-clinical staff, reviewed audits and other evidence provided by the service, spoke with patients, observed care, and reviewed patient records. We spoke with four members of staff from the provider, two staff from the host NHS trust, and three patients.

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:

Summary of this inspection

- The service must ensure all scanning staff always have access to local rules. (Regulation 12).
- The service must ensure staff complete and document risk assessments in advance of administering contrast. (Regulation 12).
- The service must ensure new fire safety protocols are fully implemented and embedded into the operation of the unit. (Regulation 12).
- The service must conduct effective audit, governance, and risk management systems. These must incorporate effective daily clinical management. (Regulation 17).
- The service must ensure each shift has a named responsible person for scanning, in line with Medicines and Healthcare products Regulatory Agency (MHRA) standards. (Regulation 17).
- The service must ensure they have consistent, visible and effective leadership in the unit. (Regulation 17).

Action the service SHOULD take to improve:

Diagnostic imaging

- The service should ensure staff have a consistent understanding of local safeguarding escalation and referrals protocols and processes. (Regulation 13).
- The service should ensure patients are kept informed of delays to scans. (Regulation 9).
- The service should ensure the provider is kept up-to-date with scan delays. (Regulation 17).
- The service should ensure agency staff have adequate access to electronic systems. (Regulation 12).
- The service should ensure they have effective systems to monitor the quality and consistency of staff practices and standards of work. (Regulation 17).

Our findings

Overview of ratings

Our ratings for this location are:

	Safe	Effective	Caring	Responsive	Well-led	Overall
Diagnostic and screening services	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Inspected but not rated	Good	Good	Requires Improvement	Requires Improvement

Requires Improvement

Diagnostic and screening services

Safe	Requires Improvement
Effective	Inspected but not rated
Caring	Good
Responsive	Good
Well-led	Requires Improvement

Are Diagnostic and screening services safe?

Requires Improvement

Mandatory training

The service provided mandatory training in key skills to all staff. However, not all staff were up-to-date with their mandatory training.

The mandatory training was comprehensive and met the needs of patients and staff. All staff undertook a programme that covered essential clinical and non-clinical areas such as fire safety, manual handling, and infection prevention and control.

Managers monitored mandatory training and alerted staff when they needed to update their training. The imaging manager ensured employed staff had protected time to complete training.

Staff undertook mandatory training using a dual system with the host NHS trust. This meant they completed training required by both the provider and the hospital. At the time of our inspection, completion of the provider training was 75% and completion of the NHS training was 88%. The low completion rates reflected the complexity in organising training for staff on shared contracts and temporary working arrangements.

Safeguarding

Staff understood how to protect patients from abuse and had training on how to recognise abuse and they knew how to apply it. However, not all staff understood how to report abuse and the service's safeguarding escalation processes were inconsistent.

Staff received training specific for their role on how to recognise and report abuse. All staff completed safeguarding adults and children level two training and were up-to date at the time of our inspection. There were no staff on site with training to level three in line with the intercollegiate document although staff from the NHS trust were readily available for support if staff needed them. The trust safeguarding team had staff with training up to level five if needed. There was no evidence the provider monitored the availability of safeguarding staff, or their presence in the unit, for consistency.

The provider's safeguarding policy reflected a dual reporting system with the NHS trust. The included explicit references to protected characteristics and provided staff with signposting to relevant legislation and support services.

Requires Improvement

Diagnostic and screening services

Staff knew how to identify adults and children at risk of, or suffering, significant harm. However, staff on shift did not understand the role of other agencies in safeguarding and were unclear on the differences between the provider's safeguarding lead and the NHS trust's safeguarding team. While the provider had a safeguarding lead, processes at this site referred only to the host hospital's team.

Staff did not always know how to make a safeguarding referral or who to inform if they had concerns. Three members of staff on duty on the day of our inspection gave a different process to follow, including one individual who said they would defer to a colleague. The provider had an up- to -date policy for safeguarding escalation, which included contact details for the first point of contact, the out-of-hours duty team and the NHS trust's lead nurse for safeguarding. Staff did not know if this policy was available in the unit; we obtained it afterwards from the provider. The policy reflected good practice and provided a clear pathway for staff to follow but this was not understood by staff we spoke with.

Cleanliness, infection control and hygiene

The service controlled infection risk variably and audits demonstrated inconsistent infection, prevention and control practices.

Clinical areas were clean and had suitable furnishings which were clean and well-maintained. The service performed variably for cleanliness. The provider audited the environment but only once each year which meant they may not be aware of environmental infection, prevention and control in a timely way and take action to address them. The most recent audit took place in 2021 and found 94% compliance, against a target of 85%. The audit found several areas for improvement and the senior team were working with the NHS trust's cleaning team to address them although there was not a timeline for completion.

The registered manager carried out six monthly infection prevention and control (IPC) audits. In the previous year the unit achieved 93% compliance with expected standards. This was an overall figure and included 100% compliance with hand hygiene standards of practice and reflected a need for more consistent practice in the use of personal protective equipment (PPE).

Staff changed PPE between patients, and we saw consistent use of handwashing and antibacterial hand gel. All staff were bare below the elbow in line with provider standards.

Environment and equipment

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

The design of the environment followed national guidance. The service was compliant with national building guidance for this type of service.

Staff cleaned equipment after patient contact and labelled equipment accordingly. Cleaning records were displayed in the unit although there were frequent gaps in completion, including of the resuscitation trolley and treatment preparation area. Provider audits indicated persistent problems with the standard of cleaning carried out by hospital staff, including a failure to clean visibly dirty areas. It was not evident the provider had addressed these issues. Resuscitation equipment was accessible in the controlled area. This included airway support equipment, rescue and emergency medicines, and an automatic external defibrillator (AED).

The service had enough suitable equipment to help them to safely care for patients. The provider owned and managed all equipment except for the resuscitation trolley and anaphylaxis equipment.

Requires Improvement

Diagnostic and screening services

Staff carried out daily safety checks of specialist equipment. MRI staff used protocols programmed into the MRI machine to prevent errors. The team completed a daily and weekly quality assurance record review of coils used, humidity levels, and the function of the quench system. The quench system protects patients and equipment in the event of a systems failure.

Staff managed equipment maintenance using a planned programme in line with manufacturer guidance.

Staff disposed of clinical waste safely in line with national guidance. The registered manager audited waste disposal management in September 2021 and found 100% compliance with expected standards.

The host NHS trust was responsible for the management, supply, and storage of cleaning chemicals subject to the Control of Substances Hazardous to Health (COSHH) Regulations. All staff undertook training in local safety and the provider maintained safety product sheets in the unit.

The unit had an MRI safe equipment list, which staff understood and was readily available to visitors. This was the list of items safe to be in the magnetic field area.

The service was compliant with national guidance in relation to sharps waste. The registered manager audited sharps management and cannulation insertion practices every six months. In the last 12 months staff achieved 97% compliance with expected standards. This was below the provider's target of 100% and the audit identified areas for improvement although there was no evidence of monitored improvement.

Staff carried out daily safety checks of the imaging environment in line with equipment manufacturer guidance.

During our inspection, the service was non-compliant with fire safety standards. The main escape route from the scanning area was partially obstructed with equipment, which would impede a fast evacuation. The fire extinguisher for the scanning room was blocked with equipment, which would slow access to it. While the unit had a visitor logbook so staff could track people in the event of an evacuation, it was incomplete and did not account for the range of health professionals visiting the unit. The team were unfamiliar with evacuation coordination procedures and did not know if a fire warden was on duty on the site.

After our inspection, the provider took action to address these concerns and provided us with evidence of improved systems of working, including a new electronic log system for visitors. The team was working with the trust's fire officer to carry out a fire drill to assess staff knowledge. Staff had mandatory training in fire safety, but it was not evident they could apply this knowledge in practice.

Fire systems such as alarms and lighting were well maintained, and the provider kept comprehensive records of testing.

The environment complied with national controlled area signage guidance in respect of where the area began and ended. However, there were no signs in place in relation to MHRA guidance about fringe fields. Fringe fields relate to the peripheral magnetic field around the MRI scanner and signage helps staff and visitors to identify the areas with the strongest magnetic field in place. After our inspection, the provider installed fringe field signage that met MHRA guidance.

Assessing and responding to patient risk

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

Requires Improvement

Diagnostic and screening services

Staff completed risk assessments for each patient, using a recognised tool, before each patient was prepared for scanning. There was a safety mechanism that meant if a scan presented a safety risk to the patient, staff would stop the process and liaise with the referrer for more information.

Staff did not always operate the service in line with national best practice guidance. For example, the service had magnetic resonance imaging (MRI) local rules in place in line with Society of Radiographers and Medicines and Healthcare products Regulatory Agency (MHRA) guidance. However, neither of the radiographers on duty could access them. The service did not have a local hard copy of the rules and neither radiographer could access the electronic version. There was some printed guidance from the Royal College of Radiographers readily available in relation to the use of contrast, although standards of contrast management did not reflect best practice.

Local rules were generic for all services the provider delivered. The senior team had drafted local rules specific to this site and the MRI safety committee was in the process of ratifying them.

The imaging assistant checked a patient's identity using the national three-point standard. We observed good standards of practice during our inspection. For example, the imaging assistant acted when a patient's relative tried to speak on their behalf and interrupted safety and security questions. This was good practice and reflected a safe method of working.

Staff used an urgent findings escalation pathway to refer patients to radiologists or the emergency department of the host site hospital.

On the day of our inspection, there were a number of risks to safety. There was no named member of staff in charge of the unit, no designated first aider, and no fire marshal. There were no staff on duty with immediate life support training (ILS) although all staff had first aid training. We spoke with senior staff about this who said there were clear allocated roles daily, However, this did not always happen in practice.

All staff were up-to-date with basic life support training. Employed radiographers and one imaging assistant had immediate life support (ILS) training although there was not always someone on shift with this training. The unit was based on the site of an acute NHS trust and was covered by the on-call resuscitation team as part of a service level agreement.

Staff knew about and dealt with any specific risk issues, such as pacemakers or metal implants. Staff carried out a safety checklist before each procedure and discussed anything which may cause potential scanning issues with patients. However, they carried out this risk assessment inside the controlled access area. This meant patients with risks might not be identified before harm occurs. After our inspection, the provider said staff used a two-part safety screening check, the first of which should be carried out before the patient enters the controlled access area. From our observations, this did not happen consistently.

Staff shared key information to keep patients safe when handing over their care to others. This included when discussing scan results with referrers and when transferring patients to other hospitals or services.

Care planning at the start of each shift was not well managed. The team did not use daily safety huddles or planning meetings on a case-by-case basis without coordination in advance. This meant staff did not always understand their roles and responsibilities.

Requires Improvement

Diagnostic and screening services

Staffing

The service did not have enough staff with the right qualifications, skills, training and experience to keep patients safe from avoidable harm and to provide the right care and treatment. Managers regularly reviewed and adjusted staffing levels and skill mix but staffing pressures meant this was inconsistent. They gave all agency staff a full induction.

The service did not have enough scanning and support staff to keep patients safe. A team of six staff, reflecting 5.4 whole time equivalent (WTE) posts, were assigned to the unit at the time of our inspection. This included three radiographers and three radiographic/imaging assistants.

The service's established staffing levels were two radiographers and one radiographic assistant. While the service maintained this in line with their policy, it was not evident this was enough.

There was a vacancy for a full-time unit MRI research superintendent radiographer, who would adopt the unit manager role, and a part time radiographer. However, pressures on staffing meant the provider relied on agency radiographers to continue to deliver care. A radiographer from the provider was not always on site when the unit was in operation. A contract with the NHS trust meant a radiographer from the hospital was always in the unit when it was open. The provider was working to address these issues and noted recent challenges relating to staff absence had compounded staffing issues.

On the day of our inspection, staff were scheduled to work for 13 hours with only a planned 30-minute break each. There was no contingency in the event of a problem and some patients were scanned over one hour late. Staff were unable to take their breaks as there was no relief cover available and they stated they had no choice but to work without a break.

The senior team described significant difficulties in recruitment. Both the provider and NHS trust each supplied one senior radiographer every day and an imaging assistant from the provider supported the service daily. Staff covered operational hours of 7.30am to 8.30pm as part of an established shared staffing model with the trust. This was part of an agreed contract. Radiologists and medical physics experts worked for the trust and visited the unit as needed to support scanning. Trust radiographers worked to joint processes with the provider and were fully qualified and managed by the hospital's diagnostics department.

All staff, including agency staff, had a full induction before they started work in the unit. The service had low sickness rates amongst staff with an average of just over 1%.

Records

Minimal records were kept in the unit as radiologists in the NHS trust were responsible for reporting patient's scan results.

The NHS trust held patient records and scan results and under the service level agreement was responsible for document management. This meant the service did not keep extensive records, only the risk assessments completed before a patient was scanned. While this was enough for the requirements of the regulated activity there was limited evidence the provider maintained enough information to audit standards of care.

Agency radiographers could not access the provider's or trust's records. This meant the agency radiographer on shift had to prepare patients without access to their referral or wait for help from a colleague.

Requires Improvement

Diagnostic and screening services

Staff in the unit documented risk assessments and made referrals based on urgent findings. Trust radiologists were responsible for reporting. The trust was responsible for all onward referrals.

Medicines

The service used systems and processes to safely prescribe, administer, record and store medicines. However, not all staff followed safe procedures in relation to the management of contrast dyes.

Staff followed systems and processes to administer medicines safely. Staff used patient group directions (PGDs) to administer contrast when conducting scans. PGDs enable certain staff to administer specific medicines within pre-defined criteria for specific categories of patients. The provider held up-to-date medicines training renewal documentation for all staff, including agency staff.

Radiologists in the host hospital prescribed medicines and arranged for handover to the imaging assistant in the unit. This process involved receipt and recording only, and the trust managed it directly. Staff from both organisations maintained a consistent standard of tracking and documentation, which ensured medicines were handled safely.

Staff stored contrast safely in a locked cupboard and tracked use with a contrast logbook. They monitored and recorded temperature daily and all contrast in the cupboard was in date.

Staff completed medicines records accurately and kept them up-to-date. They recorded contrast details clearly in patient records.

Staff learned from medicines safety alerts and the provider communicated these to staff on an on-going basis. Medicines incidents were rare and related to reactions to contrast. Staff recorded two in the previous 12 months, neither of which resulted in patient harm.

During our inspection, staff did not follow safe procedures in relation to the management of contrast. Some MRI scans involve having an injection of contrast dye to make certain tissues and blood vessels show up more clearly and in greater detail on the scans. We observed a radiographer drawing up contrast at the scanner control desk. This was not good practice and presented risks of contamination. While two members of staff checked contrasts before administering them, in one instance the radiographer did not carry out a risk assessment with the patient beforehand. This had the potential to cause harm to the patient.

Incidents

The service managed patient safety incidents well. Staff recognised incidents and near misses and reported them.

Staff knew what incidents to report and how to report them although there were inconsistencies in these processes. For example, on the day of our inspection two members of staff said they would report an incident to the provider and another member of staff described a different process. Incidents were duplicated between the provider and the NHS trust, which enabled both organisations to keep track of trends and themes.

The service reported two patient safety incidents in the previous 12 months. Both incidents required the attendance of the resuscitation team.

Requires Improvement

Diagnostic and screening services

The provider documented learning from each incident. Following one incident, the resuscitation team provided learning that staff needed to use more anaphylaxis in the event of a contrast reaction, which reflected a need for more consistent guidance for staff working to both provider and trust standards. After this incident, the trust increased the number of anaphylaxis trays provided to the unit, which we saw was in place during our inspection. The NHS trust was responsible for the supply of resuscitation equipment, medicines, and consumables.

Staff understood the duty of candour. They were open and transparent and gave patients and families a full explanation if things went wrong. The provider's incident management policy established the threshold to guide staff when to use the duty of candour. The unit had not had any incidents where the duty applied.

The provider had an incident management policy intended to ensure staff received feedback from the investigation of incidents, both internal and external to the service. However, on the day of our inspection none of the staff on duty could recall any incidents or subsequent learning.

Are Diagnostic and screening services effective?

Inspected but not rated

Evidence-based care and treatment

The service provided most care and treatment based on national guidance and evidence-based practice. Managers did not consistently follow national guidance.

The provider acknowledged the role of national guidance from the National Institute of Health and Care Excellence (NICE) but there was no system in place to monitor and implement standards of practice or policies. The service did not take part in benchmarking audits, , which was a condition of the contract with the NHS trust. The NHS trust conducted its own audits and used these to make care decisions for patients. The unit held national accreditation and had access to appropriate data to maintain this.

We saw staff did not routinely follow MHRA guidance in relation to enhanced screening for patients prescribed contrast who had kidney failure. Patients typically require more detailed pre-assessment due to the risk of nephrotoxicity from the contrast agent. Nephrotoxicity refers to a rapid deterioration in kidney function caused by medicines or chemicals.

Staff in this unit worked to a service level agreement with the host NHS trust who were also responsible for setting key performance indicators (KPIs). The provider did not routinely audit the KPIs and the clinical governance team were in the process of planning a new audit programme.

The provider worked closely with the trust to develop joint policies and standard operating procedures. This initiative aimed to standardise practice where trust staff had found differences when working in this unit on behalf of the provider. For example, the two organisations had developed joint processes for the use of contrast agents in patients at risk of nephrogenic systemic fibrosis (NSF) to help guide evidence-based practice.

The provider used an equality, diversity, and human rights policy to ensure staff delivered services within the Equality Act. The senior team assessed all policies and standard operating procedures with an equality impact approach that ensured patients and staff were not discriminated against in the delivery of services.

Radiologists, medical physics experts, and radiographers uploaded protocols to the MRI scanner in advance of a scan and the provider audited 10% of radiologist referrals for quality on a continuous basis. The audit found consistently good practice. The service did not undertake audits of local practice against national guidance as the NHS trust managed this.

Pain relief

Pain relief was not in the scope of the service. Staff could not prescribe pain relief. They scanned patients on an outpatient basis only and the referring hospital was responsible for pain relief.

Patient outcomes

Staff did not consistently monitor the effectiveness of care and treatment. The service had been accredited under relevant clinical accreditation schemes.

The service did not participate in national clinical audits.

The service audited MRI recall rates quarterly. Between April 2021 and April 2022, the recall rate was 0.5%, which reflected high standards of practice and 28 individual recalls. The service tracked recalls as a quality effectiveness tool and most were due to a need for additional scans based on initial findings.

The service had not audited the quality of radiographer scanning images since 2020. This meant the provider did not have assurance of effective scanning. However, the trust checked the quality of scans regularly and provided ad-hoc feedback if needed as part of an agreed approach.

Staff uploaded scans to the picture archiving and communication system (PACS) immediately and hospital radiologists carried out reporting. PACS is a secure electronic system used to store and transmit digital images from scans.

Staff used a 'red alert' system on PACS to escalate unexpected findings urgently to the referring team.

The service held Imaging Service Accreditation Scheme (ISAS) accreditation and the senior team was in the process of revalidating practices under the Quality Standards for Imaging (QSI) revalidation standard.

Competent staff

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

Staff were experienced, qualified and had the right skills and knowledge to meet the needs of patients. Managers gave all new staff a full induction tailored to their role before they started work.

Managers supported staff to develop through yearly, constructive appraisals of their work. Out of six unit staff, four were up-to-date with appraisals and the registered manager had scheduled the remaining for completion imminently. Appraisals demonstrated a positive focus on training, learning, and development.

Managers identified any training needs their staff had and gave them the time and opportunity to develop their skills and knowledge. The MRI team had trained colleagues from the host hospital to safely carry out scans in line with national guidance. This helped to improve scanning capacity and fill gaps in staffing. However, our evidence demonstrates inconsistent practice and no senior oversight of poor performance.

Requires Improvement

Diagnostic and screening services

Staff had the opportunity to discuss training needs with their line manager and were supported to develop their skills and knowledge. Staff maintained up-to-date training on the safe use of equipment in line with their professional registration and manufacturer guidance.

Managers made sure staff received any specialist training for their role. Radiographers maintained registration with the Health and Care Professions Council (HCPC).

Multidisciplinary working

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

Staff held ad-hoc multidisciplinary meetings to discuss patients and improve their care. This occurred on an ad-hoc basis when staff planned care for patients with complex needs and when multiple professionals or agencies were responsible for a patient's care.

Radiologists and medical physics experts were based on the host hospital site and provided support to radiographers for complex or unusual scans. Consultants and registrars from the trust accompanied radiographers in the control room to help speed up diagnosis and treatment decisions. During our inspection we observed very good standards of communication between multidisciplinary staff.

Radiographers used the PACS system to refer patients to multidisciplinary teams.

Seven-day services

Scans were available to support timely patient care seven days per week.

The provider had a service level agreement with the host hospital to provide scans every day of the week. Arrangements were made to conduct urgent scans.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

Staff supported patients to make informed decisions about their care and treatment. They followed national guidance to gain patients' consent. They knew how to support patients who lacked capacity to make their own decisions or were experiencing mental ill health.

Staff understood how and when to assess whether a patient had the capacity to make decisions about their care. Referring officers provided information to support staff delivering care with patients experiencing mental health issues. A radiologist and MRI superintendent were always on duty in the host hospital and supported the imaging team to manage mental health needs. The provider relied on the trust's standards of monitoring for this system.

Staff gained consent from patients for their care and treatment in line with legislation and guidance. Consent was included in the MRI pre-scan safety checklist and in our observations, staff were thorough in their discussions with patients. For example, where patients had risk factors or medical devices which may cause scanning issues, such as a pacemaker, staff took time to explain risks so that patients had a full picture before providing consent.

Staff received and kept up to date with training in the Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS). This formed part of mandatory training. It was very rare for a patient with a DoLS authorisation to be cared for in the department and the trust would carry out such scans instead. Staff maintained up to date awareness of legislation as good practice.

Requires Improvement

Diagnostic and screening services

Are Diagnostic and screening services caring?

Good

Compassionate care

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

Staff were discreet and responsive when caring for patients. Staff took time to interact with patients and those close to them in a respectful and considerate way.

Patients said staff treated them well and with kindness. Patient feedback was consistently positive. In the feedback survey one patient recently noted, “Everything was excellent, all the team were friendly and caring.” Another patient noted they had feared the scan process and staff had made them feel comfortable.

Staff followed policy to keep patient care and treatment confidential. We observed staff act with discretion and protect people’s personal information. The service asked patients if they felt staff had handled their data confidentially. In all responses in the previous 12 months patients confirmed this. In the same survey patients noted staff had delivered care with privacy and dignity.

Staff understood and respected the individual needs of each patient and showed understanding and a non-judgmental attitude when caring for or discussing patients with mental health needs.

Staff understood and respected the personal, cultural, social and religious needs of patients and how they may relate to care needs. Patients told us they felt respected by staff. One person said, “Everyone I’ve talked to was so approachable and caring.”

Emotional support

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

Staff gave patients and those close to them help, emotional support and advice when they needed it. Staff adhered to provider guidance when supporting carers or comforters to attend scans with patients.

Staff supported patients who became distressed in an open environment and helped them maintain their privacy and dignity. The team used private, quiet spaces to carry out difficult conversations and made these available to patients and relatives on demand.

Patients noted in the feedback survey they appreciated the kindness and friendliness of staff. One patient noted they appreciated that all staff smiled at them, which they said made a positive impression on them.

Staff were trained to support patients who experienced anxiety and claustrophobia and the provider had an evidence-based standard operating procedure. The magnetic resonance imaging (MRI) scanner was equipped with a sound system and patients could request specific music. It also had a digital system that enabled patients to watch multimedia programmes to help reduce claustrophobia anxiety. Staff provided earplugs to patients on request.

Requires Improvement

Diagnostic and screening services

Understanding and involvement of patients and those close to them

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

Staff made sure patients and those close to them understood their care and treatment. We observed the MRI service and found staff were interactive in their approach and fully involved patients in the process. Patients said they were happy with the service.

Staff talked with patients, families and carers in a way they could understand.

During our inspection, we observed staff from multiple disciplines worked well together in the best interests of a patient with complex clinical needs. They made the patient as comfortable as possible and maintained communication with them to explain what was happening and why.

The service sought patient feedback using a questionnaire, which patients completed on an electronic tablet before leaving the unit. However, the tablet had been out of service for several months and only three patients had completed the questionnaire since January 2022. All three patients provided positive feedback.

Patients noted in previous feedback surveys that they appreciated the flexibility of staff. For example, patients who had arrived late said staff still accommodated their scan.

Are Diagnostic and screening services responsive?

Good

Service delivery to meet the needs of local people

The service planned and provided care to meet the needs of people referred from the trust.

Managers planned and organised services, so they met the changing needs of the referring hospital. The senior team worked with local NHS services to support their waiting lists by providing additional capacity.

Clinical facilities and premises were suitable for the services being delivered. They included a private changing space and lockers for personal belongings. However, the waiting room was small and not equipped to accommodate the number of patients waiting along with those accompanying them. Some people had to stand for lengthy periods and there were no water facilities. While staff had access to a kitchenette area, they said they did not proactively offer patients drinks due to time pressures. Staff we spoke with after the inspection said they would usually offer patients the chance to wait in an adjacent coffee shop and call them when the scanner was ready. The unit was fully accessible by wheelchair.

Managers monitored and took action to minimise missed appointments. Managers ensured that patients who did not attend (DNA) appointments were contacted to check their wellbeing and offer an alternative appointment. The service contacted all patients within 48 hours of a referral to ensure they planned to attend and had information about the unit location. In April 2021, the service audited a sample of 139 referrals to check how many patients were reached in advance of their appointment. The audit found 25% of patients could not be contacted. In response the team worked with referring medical practitioners to ensure patient contact details were up-to-date.

Requires Improvement

Diagnostic and screening services

Meeting people's individual needs

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

All patients were under the care of the host NHS hospital and this service provided one aspect of their care pathway. The referring medical practitioner alerted unit staff if a patient was living with mental health problems, learning disabilities, or dementia, and staff in the unit adapted care accordingly. Staff undertook training to help them adapt care and communication to meet patient needs and we observed the imaging assistant skilfully communicate with a patient experiencing challenges. The referring medical practitioner indicated if a patient required a translator the service arranged this in advance. The team had access to a telephone language service on demand.

Staff supported patients living with dementia and learning disabilities by using 'This is me' documents and patient passports.

Staff understood the policy on meeting the information and communication needs of patients with a disability or sensory loss.

The service had assessed patient information against the requirements of the accessible information standard to ensure material was available for patients with specific communication needs.

The provider had established a policy to guide staff in providing scans for transgender patients in line with international best practice guidance, including the World Professional Association for Transgender Health. This work helped staff to tailor care to individual needs.

Staff used the capabilities of scanning equipment to support patients and reduce anxiety. The scanning room had mood lighting and the magnetic resonance imaging (MRI) scanner had speakers that meant patients could listen to music.

Access and flow

People could access the service when they needed it although the service did not effectively manage delays once patients were in the clinic.

The service provided scans to NHS patients from the host site hospital. The service required all patients to have a referral that indicated a clinical need for a scan and did not accept self-referring patients. Trust radiologists pre-assessed the scanning requirements for each patient and the MRI scanner was pre-programmed with the information. Radiologists followed national guidance for two-week wait cancer referrals and other urgent requests. The service met 100% of such referral times.

The service offered patients a choice of appointment seven days a week. We saw staff worked flexibly to accept short-notice, urgent referrals from the trust.

During our inspection the clinical list was running over one hour late. Staff did not proactively keep waiting patients up to date.

Staff contacted each patient in advance of an appointment to make sure they met the criteria for a scan. For example, the unit could not accommodate patients with mobility needs that required a hoist.

Requires Improvement

Diagnostic and screening services

The service provided scans continuously and did not have a waiting list. Staff accepted short-notice referrals from the host site.

Managers worked to keep the number of cancelled appointments to a minimum and there had been no cancellations for non-clinical reasons in the previous 12 months.

The service did not monitor delays to scheduled scans on the day, such as differences between a scheduled scan and the actual scan time. On the day of our inspection scans were running over one hour late by mid-afternoon. Staff did not proactively update patients with this information, and we observed people become frustrated with the wait, particularly those who had travelled considerable distance to attend the unit.

Learning from complaints and concerns

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

Patients, relatives and carers knew how to complain or raise concerns. The service clearly displayed information about how to raise a concern in patient areas.

Staff understood the policy on complaints and knew how to manage them. The provider had a standard complaints policy that applied to all services. There had been no formal complaints in the previous 12 months.

The service documented requests for improvement from patients although it was not always evident staff acted on these. For example, several patients noted it was not clear how they would obtain their scan results after leaving the unit but there was no indication practice had changed.

The provider subscribed to the Independent Sector Complaints Adjudication Service (ISCAS), which provided patients with an escalation process in the event they were unhappy with how the provider resolved a complaint.

Are Diagnostic and screening services well-led?

Requires Improvement

Leadership

Leaders had the skills and abilities to run the service but were not regularly present on site. We were not assured they understood and managed the priorities and issues the service faced.

The unit had a registered manager who was also the provider's MRI lead and was based at a different location. The post for a dedicated on-site manager had been vacant for some time. A seconded manager had led the unit from September 2021 to April 2022 Staff said the registered manager was easily contactable and other senior staff always provided support on request but there was limited continuity or presence of leadership on site.

Two senior radiographers were always present in the unit when it was in operation. However, the provider did not allocate a named lead out of the radiographers on the rota. Staff told us they knew who to contact in the NHS trust if they needed support during a shift.

Requires Improvement

Diagnostic and screening services

On the day of our inspection, there was no named person in charge of the unit and no named responsible person for scanning. This meant coordination of the service was inconsistent and staff were working to different processes and standards.

Vision and Strategy

The service had a vision for what it wanted to achieve and a strategy to turn it into action.

The provider had a vision that included a set of values and a mission statement focused on developing innovative treatment for patients. The head of magnetic resonance imaging (MRI) had worked with the team to establish a departmental vision that was aligned with the host trust. It was not evident local staff had contributed to this although it was based on the needs of patients. A draft strategic plan was awaiting ratification and reflected the demands on the sector including recruitment challenges and capacity. The draft strategy incorporated the joint nature of care in this unit with the host NHS trust.

The provider monitored staff awareness and understanding of their vision in the staff survey. Results were consistently poor and in both 2019 and 2021 30% of staff did not know if the organisation had a clear vision. Of the staff who did know about the provider's vision, 48% either disagreed with it or did not feel part of it. The provider had an action plan to address this although it was focused on increasing meetings and contact between senior staff and local staff. After our inspection the provider told us these figures related to overall staffing levels and that awareness of the vision and strategy amongst staff in this unit was significantly better than the overall figure.

Culture

Staff felt respected, supported and valued. They were focused on the needs of patients receiving care. The service promoted equality and diversity in daily work. Staff said the service had an open culture where patients, their families and staff could raise concerns without fear although survey results contradicted this to some extent.

Staff we spoke with were positive about the provider and said they felt respected and looked after. There were limited opportunities for progression at this location and staff said the provider supported them to progress with moves to other sites.

Staff had access to a comprehensive range of support in the event they needed to escalate a concern, including through an anonymous whistleblowing policy.

The provider had undertaken a staff survey in 2021. The results were mixed and while many staff reported a positive, rewarding working environment, there were several areas for significant improvement. These centred around better involvement of staff and engagement from the senior team at provider level. The provider prepared an action plan that included more frequent meetings and visits from senior managers. It was not evident from our inspection that the provider had successfully implemented these improvements. We saw evidence of some of the issues highlighted in the staff survey during our inspection, including a lack of senior presence that resulted in an uncoordinated approach to list management and worsening scan delays during the day.

While most staff were up-to-date with training and this was appropriate to the care setting, this had not resulted in consistent practice and application of knowledge. For example, on the day of our inspection staff had not acted to reduce a clear fire safety risk and were unable to clearly describe local safeguarding procedures.

Requires Improvement

Diagnostic and screening services

Governance

Leaders did not operate effective governance processes. Staff were not clear about their roles and accountabilities and did not have regular opportunities to meet, discuss and learn from the performance of the service.

The clinical governance framework was well established and reflected the nature of the service and the needs of its patients. A clinical governance group and quality management and audit committee supported the senior management team and board with governance processes. A research governance group ensured research activity was separated from regulated activities and provided opportunities for learning in broader practice.

The senior provider team held weekly meetings and staff were able to join even if they were not at work at that time. The meetings included NHS trust staff working on the day of the meeting but not agency radiographers. This meant they had limited impact on communications and sharing of governance issues.

A new governance lead recently joined the organisation and was preparing improvements to audit processes and governance communication with the wider team

Governance processes were operated jointly with the NHS trust. The trust's MRI superintendent worked with the provider to align standard operating procedures and policies. For example, incidents and complaints were recorded jointly on both organisational systems and the senior team from each coordinated their response.

The board of trustees maintained oversight of the service and liaised with the charity commission as needed to ensure governance processes were appropriate.

We spoke with NHS trust staff as part of our inspection. They described the provider's clinical governance system as "excellent" and said they were confident in local safety and operations.

Management of risk, issues and performance

Leaders and teams did not effectively manage risks and performance. They did not always identify and escalate relevant risks and issues or identify actions to reduce their impact.

The provider monitored risks using a series of risk registers assigned to different teams, such as the senior management team, information governance committee, or the board. Each risk had a control measure in place and there was evidence of reduced risks through appropriate improvements. For example, the provider had reduced a risk of the loss of scan images by implementing improved technology.

While risk management was embedded in committee and governance processes, we were not assured there were effective processes in place to manage the unit safely. For example, the trust's imaging and medical physics group carried out a quality and safety assessment in May 2022. While this found areas of good practice in relation to MRI operation, the assessment highlighted four safety concerns with local safety systems. This included improper or inaccurate use of equipment labelling in the MRI controlled area and the absence of information displayed about the supervisor and named safety staff. The provider acted on all the safety concerns, but they highlighted a gap in the consistency of local oversight. These actions had not resulted in consistently improved safety and risk management as we found standards lacking in safety practices.

The service did not routinely follow national best practice guidance where this was not required by legislation. For example, we asked the senior team why staff had not consistently followed MHRA guidance during our inspection. They told us the provider did not always follow guidance if it was not mandated by law. Although this meant we were not assured care was always delivered appropriately, there was evidence staff followed MHRA guidance in other areas, such as in documentation surrounding scanning pregnant patients.

The service held International Standard accreditation for environmental management for the implementation of quality management systems.

The team had access to 24/7 IT support in the event of systems failure and the unit had an emergency power generator.

Information Management

The information systems were integrated and secure.

All staff were required to complete information governance and general data protection regulations (GDPR) training and all staff were up-to-date with this. Staff used their training to work within the provider's data protection policies and ensure they avoided risks associated with data breaches.

Staff worked within the guidance of the provider's confidentiality code of practice. This ensured they protected patient identifiable data and acted with integrity when handling personal information. The data protection officer, senior information risk owner, and Caldicott Guardian provided advice and guidance to staff on demand.

Most information systems related to regulated care were shared with the NHS trust to enable staff to transmit and access patient records essential to the service. This included agency staff. The systems were encrypted and managed jointly by the IT teams of both organisations using clear data sharing agreements. The provider retained access to scans and records in the event of a future investigation or complaint.

Engagement

Leaders and staff did not actively and openly engage with patients and staff to plan and manage services. They collaborated with partner organisations to help improve services for patients.

On the day of our inspection, staff were mostly unsure about communications from the provider and said there was no daily planning or equivalent of a huddle for the day ahead. However, after our inspection, other staff said they felt communication from the provider was very good and consistent. For example, they said the provider sent out a daily report to each unit they operated so that staff had access to updates in policies and important information about the service. We were unable to establish why the team on shift on the day of our inspection did not know about the daily report nor why the senior leadership team thought everyone received it.

The provider did not consistently engage with patients. For example, an electronic tablet usually used to gather feedback through a questionnaire had been out of service for several months. While the service had implemented an alternative, patients had not used it and the service therefore had limited up-to-date understanding of patient engagement and experience.

The provider sought feedback from referring radiologists using a periodic survey. The most recent results from January 2022 showed high levels of satisfaction and 96% of respondents said the service was good or very good. The clinical governance team monitored results to identify opportunities for improvement, such as changes to the informational governance and management processes.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

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

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 12 HSCA (RA) Regulations 2014 Safe care and treatment • Not all scanning staff had access to local rules for MRI. • Staff did not consistently carry out risk assessments prior to administering contrast. • Fire safety was not well managed.

Regulated activity	Regulation
Diagnostic and screening procedures	Regulation 17 HSCA (RA) Regulations 2014 Good governance • Audit, governance, and risk management systems were ineffective. • There was a lack of adherence to MHRA guidance, including the absence of a named responsible person for scanning on each shift • There was not a consistent leadership presence in the unit.